

GENETICALLY MODIFIED PLANTS ARE NOT “INVENTIONS” AND ARE, THEREFORE, NOT PATENTABLE

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I. INTRODUCTION

Few, if any, cases have ever come before either the Supreme Court of Canada or the United States Supreme Court that possessed the potential to effect a change upon both the practice of agriculture and the field of intellectual property as did the *Schmeiser v. Monsanto*² case. Mr. Percy Schmeiser was sued by Monsanto in 1998 for planting and possessing canola seeds that contained a transgene that was, and is, protected by Canadian Patent Number 1,313,830.³ The Trial Division held that Mr. Schmeiser either “knew or should have known” that the canola plants were glyphosate resistant and found him guilty of patent infringement.⁴ Mr. Schmeiser appealed to the Canadian Federal Court of Appeals, arguing that he did not infringe the patent, and that the canola plants on his fields could not be protected by a patent.⁵ The Federal Court of Appeals found for Monsanto.⁶ Mr. Schmeiser then appealed to the Supreme Court of Canada, arguing the same points of law that he argued before the Federal Court of Appeals.⁷

On its face, the *Schmeiser v. Monsanto* case appears to be a mere patent infringement case. However, upon closer inspection, it becomes clear that the case actually challenged the long-standing concept that plants, plant cells, and transgenes contained in those plant cells may be protected by a patent.⁸ The *Schmeiser* Court explicitly stated that Monsanto did not claim a genetically manipulated plant in Canadian Patent Number 1,313,830.⁹ However, the Court ultimately found that Mr. Percy Schmeiser infringed the patent when he had pos-

2. *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶¶ 1-3.

3. *Id.*

4. *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶ 120.

5. *See Schmeiser v. Monsanto Can., Inc.*, [2002] F.C.A. 309, ¶¶ 29-46, 59.

6. *See id.* at ¶ 89.

7. *See generally Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶¶ 1-3.

8. *Id.*

9. *See id.* at ¶ 17.

session of the glyphosate-resistant plants and seeds on his land.¹⁰ Although the Court explicitly stated that Mr. Schmeiser had “used” the invention, it found that Monsanto was not entitled to collect damages from Mr. Schmeiser as Mr. Schmeiser gained no profit because he did not use Roundup on the fields of infringing canola.¹¹ In summary, the *Schmeiser* Court held the following: first, that Monsanto is entitled to extend a patent for a transgene, and a cell containing that transgene to include both a plant and a seed containing the transgene;¹² second, that merely possessing a plant which contains the transgene constitutes infringement of the patent rights of the patentee;¹³ and third, that if Roundup is not used on the plant, then the patentee is not entitled to damages.¹⁴

The *Schmeiser* Court has thrown the law of patents as it relates to patents for transgenes into complete disarray. Consider a plant or a seed, either of which contains the transgene that is protected by Canadian Patent Number 1,313,830. After *Schmeiser*, every farmer in Canada who has such a seed or plant on his farm is exposed to the risk of being sued by Monsanto, even though Monsanto cannot obtain a valid patent that contains a claim to either a plant or a seed.¹⁵ However, if the farmer has not used Roundup on the plants in his fields, then damages cannot be awarded to Monsanto; this is true even if the farmer knew that the plant or seed contained the patented transgene.¹⁶ Now that the *Schmeiser* Court has spoken, either the Parliament of Canada or the Supreme Court of Canada must visit the issues surrounding the patenting of transgenes and of the cells containing the transgenes to repair the damage done by the *Schmeiser* Court.

The courts must employ three key concepts when deciding the issue of the validity of patents for transgenes, cells containing the transgene, and living species containing the transgene: first, whether the subject matter at issue in a particular case is patented; second, whether the subject matter claimed in the patent is an invention; and third, whether the alleged infringer actually used the claimed subject matter.¹⁷ Although these three concepts are apparently separate and distinct, an understanding of each is obtained only when one understands the meaning of the term “invention” within the area of patents for transgenes.

Had Mr. Percy Schmeiser prevailed on the issue of the patentability of plant cells, then plants, seeds, plant cells, and even a transgene inserted into the

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10. *See id.* at ¶¶ 69-72.
 11. *See id.* at ¶¶ 75, 105.
 12. *See id.* at ¶¶ 40-71.
 13. *See id.* at ¶¶ 69-71.
 14. *See id.* at ¶¶ 98-105.
 15. *See id.* at ¶16.
 16. *See id.* at ¶101.
 17. *See id.*

plant cells would not have been protected by a patent in Canada.¹⁸ It is well established that under the patent laws of the United States, plants, plant seeds, and plant cells are patentable subject matter.¹⁹ This article will show that plants, seeds, plant cells, and the transgene in the plant cell may not be protected in either Canada or the United States even though a patent has been issued for these types of subject matter. The analysis and results presented in this Article are independent of the holding of the Supreme Court of Canada in *Schmeiser v. Monsanto*. A natural extension of the arguments presented in this work is as follows: if the seeds, which contain the transgene, cannot be patented then in the absence of a contract the farmer will be able to save seeds from one crop cycle for planting in subsequent crop cycles without fear of infringing the patent rights of the patentee. This simple result has the potential of altering the manner by which agricultural practices are carried out in Canada, and possibly the United States.

The prevailing concept in the area of intellectual property rights in genetically manipulated organisms is that genetically modified plants, plant cells, and transgenes contained in those cells are subject to protection by a patent in the United States.²⁰ In the course of the analysis, it will be shown that if the patent covers the transgene when that transgene is in a plant standing in the field of the farmer, then the effect of the patent is to claim the entire plant independent of whether plants are patentable subject matter under Canadian law. It will be argued that as presently designed, the patent laws of the United States and Canada prohibit the issuance of a patent for most, if not all, genetically modified plants, plant cells, and transgenes contained in those cells as well as all other genetically modified organisms.²¹ The conditions are also examined under which a patent that has issued for a genetically modified organism might be valid.

The *Schmeiser* case is the proper setting for the arguments contained in this work. Therefore, this article will briefly discuss the case, including a short analysis of the position of both Mr. Schmeiser and Monsanto, as those positions pertain to the hypothesis of this work. In Part III, a derivation of the proper rules is presented, which should be applied both when a patent is issued for genetically manipulated plants and when a farmer is alleged to have infringed the patent rights of a seed manufacturer in such plants.

18. See *id.* at ¶¶ 40-71. (The Supreme Court of Canada merely stated that those plants were indeed protected).

19. See *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 124 (2001).

20. See *id.* at 127.

21. This position is valid even in view of the *J.E.M. Ag. Supply* case.

II. BACKGROUND

*The Federal Courts below interpreted the claims as applying to the alpha, the beginning, and the billions of omegas which would be the differentiated cells in a plant. * * * Our contention is this: if it can mean any cell, then what you have done is indirectly claimed protection for a plant because to say that you haven't claimed a plant when you've claimed every cell within it is akin to saying that you haven't claimed Canada when you've claimed every province, every territory and every speck of dust within it. If that's what the claims mean, if they can apply to any cell, wherever found, however made, then, our contention is that that is a claim to unpatentable subject matter.²²*

In Canadian Letter Patent No. 1,313,830, Monsanto claimed neither a glyphosate-resistant plant nor a glyphosate-resistant seed.²³ However, Monsanto used the patent to a “glyphosate-resistant plant cell” and a “glyphosate-resistant oil seed rape cell” to reach into the fields of Mr. Schmeiser and assert control over his crop of canola.²⁴ Monsanto advanced the position that the exclusive intangible personal property rights conferred by Canadian Patent Number 1,313,830 allowed it to assert control over the entire plant and seed even though neither was specifically claimed in the application for patent.²⁵ Because the *Schmeiser* Court agreed with Monsanto on this issue,²⁶ the existing foundation of patent law and of constitutional law has been fundamentally altered.

Consider a claim for a “cancer-sensitive human cell.” This is not a claim to a human being, but under the logic used by Monsanto, the claim could be used to assert control over an entire human being comprised of “cancer-sensitive human cells.” Even Justice Binnie of the Supreme Court of Canada, who desires that all non-natural human-made compositions of matter should be patentable,²⁷ should have a hard time accepting this outcome.²⁸ However, if Monsanto is allowed to use the claim to a “glyphosate-resistant oil seed rape cell” to control the

22. Interview with Terry Zakreski, Solicitor, Saskatoon, Sask., Can. (Jan. 19, 2004).

23. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

24. See Appellants' Factum at 12, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (arguing Monsanto gained control over Schmeiser's canola seeds and plants).

25. See *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶ 1.

26. See *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶ 97.

27. See *Harvard Coll. v. Canada (Comm'r of Patents)*, [2002] S.C.C. 76, ¶ 8.

28. See *id.* at ¶¶ 54, 71 (Justice Binnie stated that the issue of whether a human being constitutes a composition of matter does not arise under the Patent Act. “If further reinforcement is required, ss. 7 and 15 of the Canadian Charter of Rights and Freedoms would clearly prohibit an individual from being reduced to a chattel of another individual.” Justice Binnie apparently accepts that an exception should be made to the rule under which all life forms would be subject; for instance, when a valid patent could issue for a human being from the zygote stage to the fully-mature human body.)

fully-mature plants in the fields of the farmers,²⁹ then presumably there is nothing to prevent either Monsanto, or any other company that specializes in biotechnology, from claiming genetically manipulated human cells and exerting control over a human body comprised of those cells and all generations of humans that ensue from that original human.

In the more general sense, the *Schmeiser v. Monsanto* case was about the balancing of rights: the rights of Mr. Schmeiser to farm as he had always farmed, to save seed from one crop cycle for planting in a subsequent crop cycle and the rights of Monsanto Canada, Inc. to engage in the business of supplying farmers with seeds and herbicides.³⁰ The Court was asked to decide how far the rights of Monsanto extended into the fields of Mr. Schmeiser, if at all.³¹ In particular, the *Schmeiser v. Monsanto* case was about the meaning of the word “invention” within the context of the Patent Act.³² The Court avoided the task of defining the term “invention” within the meaning of the Patent Act. However, if it had defined the meaning of the word “invention,” the Supreme Court of Canada could have clarified whether the patent rights of Monsanto cover the plants on the fields of Mr. Schmeiser.

A. The Patent In Issue

Mr. Schmeiser was sued by Monsanto for infringing Canadian Patent No. 1,313,830.³³ Canadian Patent No. 1,313,830 is nearly identical to and derives its

29. Cf. Appellants' Factum at 12, ¶48, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (stating a claim that “Monsanto’s monopoly rights over a” glyphosate-resistant oil seed rape cell amounted to Monsanto’s control over a farmer’s fields).

30. See *id.* at ¶¶ 1-7 (explaining the facts and issues in the case).

31. See Interview with Terry Zakreski, Solicitor, Saskatoon, Sask., Can. (Jan. 19, 2004).

32. See *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34. In this Article, I use the phrase Patent Act to refer to both the Patent Act of the United States, specifically Title 35 of the United States Code, and to the Patent Act of Canada, specifically Patent Act, R.S.C. ch. P-4 (1985) (Can.). The Patent Act, R.S.C. ch. P-4 (1985) (Can.), was based upon the U.S. Patent Act of 1793. See *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76, ¶ 3 (Binnie, J., dissenting). For the most part, the Patent Act of the United States and the Patent Act of Canada are parallel and in harmony; however, subtle differences exist in the meaning of the term “invention,” which is used to determine whether claimed subject matter is patentable, and in the meaning of the term “use,” which is used to determine whether the patent rights of the patentee have been infringed. Unless a particular statute is specifically identified, I shall use the phrase Patent Act to refer to both the Patent Act of the United States and the Patent Act of Canada.

33. *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶ 1; see also Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 MINN. INTELL. PROP. REV. 1 (2002).

priority date from U.S. Patent No. 4,940,835.³⁴ The Monsanto Company, U.S.A., is the assignee of both patents, and Monsanto Canada, Inc. is the licensee of the rights in Canadian Patent No. 1,313,830 in Canada.³⁵ Despite its overly-ambitious title, neither a plant nor a seed are claimed in the Canadian version of the patent.³⁶

The nature of both patents is easily derived from the abstract of the patents.³⁷ The language in the Abstract may be translated into layman's terms as follows: the subject matter of the patent is a gene that allows a plant to survive an application of glyphosate herbicide. It is worthwhile, at this point, to indicate that the "glyphosate-resistant plants" so trumpeted in the title of the patents are those that are regenerated from an isolated plant cell into which a transgene has been inserted. That is, the "glyphosate-resistant plants" were not generated as a direct result of the application of modern genetic manipulation techniques. The claims in Canadian Patent No. 1,313,830 are for a transgene, a tool, and a method for inserting that transgene into an isolated plant cell, and an isolated plant cell containing the transgene.³⁸

B. Mr. Schmeiser Meets Monsanto Canada, Inc.

In 1996, Monsanto released Roundup Ready canola in Canada for commercial sale.³⁹ In 1997, Mr. Schmeiser found some of that Roundup Ready canola growing in the ditches alongside some of his fields.⁴⁰ In 1998 Monsanto sued Mr. Schmeiser for having obtained brown-bag Roundup Ready canola and for patent infringement for having planted that seed.⁴¹ Having failed to find any proof that Mr. Schmeiser "obtained" brown-bag Roundup Ready canola, Monsanto dropped the allegation of having acquired "brown-bag" canola seed.⁴² In essence, Monsanto sued Mr. Schmeiser for patent infringement because Mr. Schmeiser had planted canola on his fields that presumably contained a gene that conferred glyphosate resistance upon the canola. By 2004, Monsanto was still

34. *Compare* Can. Patent No. 1,313,830, at [30] (filed Aug. 6, 1986) with U.S. Patent No. 4,940,835, at [22] (filed July 7, 1986).

35. U.S. Patent No. 4,940,835, at [73] (filed July 7, 1986); Can. Patent No. 1,313,830, at [73] (filed Aug. 6, 1986).

36. *See* Abstract to Can. Patent No. 1,313,830, at [3-5] (filed Aug. 6, 1986) (stating that the invention is comprised of a gene and not a plant or cell).

37. Abstract to U.S. Patent No. 4,940,835, at [57] (filed July 17, 1986); Abstract to Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

38. Summary of the Invention, Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

39. Interview with Percy Schmeiser, Farmer, Bruno, Sask., Can. (Jan. 19, 2004).

40. *Id.*

41. *Id.*

42. *Id.*

alleging that Mr. Schmeiser knowingly planted Roundup Ready canola on his fields with the intent of producing a Roundup Ready crop of seeds.⁴³

1. *Mr. Schmeiser Did Not "Obtain" Roundup Ready Canola Seeds*

Although Monsanto originally claimed that Mr. Schmeiser bought and planted "brown-bag" canola seed, that allegation was quickly dropped in favor of pursuing only the theory that possession of canola constituted infringement of the patent rights of Monsanto.⁴⁴ From the very beginning of the case, Monsanto tried to claim that Mr. Schmeiser must have obtained the transgenic canola through nefarious actions.⁴⁵ Consider, for example, the statements made by Mr. Roger Hughes, counsel for Monsanto, at the opening of the oral arguments:

This case, we submit, is a rather simple case of an infringement of a patent by the knowing use of the patented claimed material, in this case, nine fields, 1,038 acres of 95 to 98% pure Roundup Ready canola straight rows which were sold for \$140,000, a commercial price for that crop.⁴⁶

A further example is found in the following exchange between Mr. Hughes and the Court:

MR. HUGHES: My submission is, because he wanted to segregate his crop down to Roundup Ready canola and use for his seed which is exactly what he did, and that's what I'm going through in this book. It's exact – it was a deliberate plan to do just that.

MR. JUSTICE BASTARACHE: What was the use of that if he wasn't going to use Roundup?

MR. HUGHES: Because he wasn't going to use Roundup, in my submission, the evidence will show that the only herbicide that the evidence shows he bought was Roundup and that we don't have the evidence of Mr. Schmeiser but we have the evidence of his hired-hand talking to the local ga[s] station and saying he was using it.

MR. JUSTICE BASTARACHE: I think we're gonna have to go with the facts as they were found by the Courts below.

MR. HUGHES: The facts were that he says Schmeiser says – Schmeiser says he didn't use it. The point is that he used this –

43. *Id.*

44. Interview with Terry Zakreski, Solicitor, in Saskatoon, Sask., Can. (Jan. 20, 2004).

45. Interview with Percy Schmeiser, Farmer, in Bruno, Sask., Can. (Jan. 19, 2004).

46. Transcription of Cassettes at 30, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C.

MR. JUSTICE LeBEL: Mr. Hughes, there is no finding that he used it.

MR. HUGHES: And there is no finding that he didn't, My Lord. There's no finding that he didn't, and the finding is neutral. I'm answering the Chief Justice's question, why would he do this, and in my submission, so that he could get a Roundup Ready crop.⁴⁷

Mr. Hughes, counsel for Respondent Monsanto, repeatedly attempted to persuade the Court to consider the evidence and make a finding of fact that Mr. Schmeiser obtained Roundup Ready canola in order to produce a Roundup Ready canola seed crop for commercial sale.⁴⁸ Evidently, Mr. Justice Bastarache understood the tactic. Consider the following dialogue between the Justices and Mr. Hughes:

MR. HUGHES: With respect, no, Justice Binnie. There is no evidence that this spreads ... [advantitiously]. I've just read from the findings of the Court that it does not spread by wind or bees or trucks or any of these other matters in which it was suggested it spread.

MR. JUSTICE BINNIE: Well, when I read, the Court is saying that it's not established that his crop at the level of Roundup Ready to know that he had could be explained by these factors, so not that these other factors don't operate.

MR. HUGHES: And there's no evidence that this material was spreading to any extent ... there is no evidence whatsoever that this material spreads ... [advantitiously], there is absolutely no evidence put in here about the so-called ... [advantitious] spreading.⁴⁹

Mr. Hughes then goes on to respond to a question by Justice Iacobucci as follows:

MR. HUGHES: With respect, Justice Iacobucci, this is the only farmer who has this kind of quantity and spreading, the evidence is, this is the only farmer around who ever had this kind of quantity. This is not evidence of uncontrolled ... [advantitious] spreading this is the only person who ever came up.

MR. JUSTICE BASTARACHE: But is your argument that we know he planted the seed that he knew had this Roundup factor but are you saying that he bought seed, Roundup seed, and used it and that it wasn't only the seed that he got from the crops on his own fields? If that's what you're saying, you're asking us to make new findings of fact.

MR. HUGHES: I'm not asking you to make any finding of fact at all. I'm asking you to just note that the trial judge says that all the suppositions made by Mr.

47. *Id.* at 39.

48. *Id.* at 41.

49. *Id.* at 40.

Schmeiser don't explain what happened. What we do have is Mr. Schmeiser, in 1997, having in his possession by the fall of 1997, a quantity of material that is Roundup Ready seed and he knew it.⁵⁰

Shortly after Mr. Hughes stated that he was not asking the Court to make any finding of fact, he proceeded to read six pages of trial evidence into the record.⁵¹ Mr. Hughes was trying to do nothing else other than to convince the Court to make a finding of fact that Mr. Schmeiser "obtained" Roundup Ready seed in 1997 for planting and that he knew that he had saved Roundup Ready seed for planting in the spring of 1998.⁵² In fact, in the Amended Complaint, Monsanto effectively admitted that Mr. Schmeiser did *not* "obtain" brown-bag Roundup Ready canola.⁵³

Mr. Schmeiser did not "obtain" Roundup Ready canola seed either in the fall of 1997 or the spring of 1998 for planting at any time, particularly during the 1998 crop cycle.⁵⁴ Even Mr. Schmeiser was uncertain regarding how the canola came to be upon his lands.⁵⁵ He contends that his fields were contaminated by Roundup Ready canola in 1997 by natural forces.⁵⁶ The argument of Monsanto that genetic contamination could not or did not occur is disingenuous at best.⁵⁷

During the hearing before the Supreme Court of Canada, Mr. Hughes argued that there is no evidence of out-crossing of genetically modified plants nor was there any evidence of adventitious spread of genetically modified plants in the environment.⁵⁸ Indeed, evidence suggests that exactly the opposite is true and that Monsanto was fully aware that the position articulated by Mr. Hughes before the Supreme Court of Canada was in direct contradiction with the truth.⁵⁹ Inno-vest, a financial services firm that performs investor risk assessments, gave Mon-

50. *Id.* at 41.

51. *Id.* at 44-50.

52. *Id.*

53. In the Amended Statement of Claim, Respondent Monsanto specifically alleged in claim 13 that: "[t]he Defendants in 1998 have planted glyphosate resistant seeds at least some of which were harvested from the 1997 crop described herein, to grow a crop of canola for harvest in 1998 having a gene or cell as described herein."

54. See Memorandum of Fact & Law of the Respondent at 1, *Schmeiser v. Monsanto, Can., Inc.*, [2004] S.C.C. 34.

55. See Amended Statement of Claim, at claim 13, *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256.

56. See Interview with Percy Schmeiser, Farmer, in Bruno, Sask., Can. (Jan. 19, 2004).

57. See Philip J. Dale & Judith A. Irwin, *The Release of Transgenic Plants from Containment, and the Move Towards Their Widespread Use in Agriculture*, 85 *EUPHYTICA* 425 (1995) (discussing risk assessment and transgene movement into natural populations).

58. See Transcription of Cassettes at 39-40, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

59. See *id.* at 40.

santo the lowest possible environmental risk rating resulting from: (1) an above average risk exposure and market failure; (2) the fact that genetically modified organisms in general, and genetically modified plants in particular, have not been demonstrated to provide nutritional benefits to the end consumer; (3) a number of environmental and health concerns exist; and (4) environmental “contamination is inevitable.”⁶⁰ The analysis of the risk to investors of Monsanto was based upon the SEC 10K report filed by Monsanto.⁶¹ Specifically, Innovest reported:

Environmentally, Monsanto warns investors in its 10K about substantial losses that could result from unintended contamination of food crops by its GE seeds. Given the tendency of pollen and seeds to spread in nature, contamination is inevitable. As a result, the company is lobbying for regulations that allow some GE contamination of non-GE food products.⁶²

Logic and reason indicate that Mr. Schmeiser could not have intended to plant seed that was glyphosate-resistant in 1998. Mr. Schmeiser used some seed stored for the winter in “an old Ford truck” along with a substantial quantity of bin-run seed for planting in the spring of 1998.⁶³ The only reason to intentionally plant glyphosate-resistant canola is to facilitate weed control by the use of Roundup herbicide. If Mr. Schmeiser had sprayed his fields in the summer of 1998, he would have killed a substantial portion of his crop; that is, he would have killed the portion that grew from “bin-run” seed. The facts of the case and simple analysis lead to the conclusion that Mr. Schmeiser did not intend to plant glyphosate-resistant seed in the spring of 1998 for the purpose of benefiting from the application of Roundup herbicide.⁶⁴

In the fall of 1997 and spring of 1998, Mr. Schmeiser did what he had always done with regard to his canola crop.⁶⁵ He saved seed from one crop cycle for planting in the subsequent crop cycle.⁶⁶ Mr. Schmeiser believed that he had a right to the crop on his fields and that he had the right to develop his own variety of canola.⁶⁷

60. Innovest Strategic Value Advisors, *Monsanto & Genetic Engineering Risks for Investors* 6 (April 2003), available at http://www.innovestgroup.com/pdfs/Monsanto_Analysis4-03.pdf.

61. *See id.*

62. *See id.*

63. *See* Interview with Percy Schmeiser, Farmer, in Bruno, Sask., Can. (Jan. 19, 2004).

64. *See* Schmeiser v. Monsanto Can., Inc., [2004] S.C.C 34, ¶ 6.

65. *See* Monsanto Can., Inc. v. Schmeiser, [2001] F.C.T. 256, ¶ 7 (discussing the farm practices of Mr. Schmeiser).

66. *See id.* at ¶ 13.

67. *See id.*

2. *The Property Rights of Mr. Schmeiser vs. The Property Rights of Monsanto*

In *Schmeiser v. Monsanto*, the property rights of corporate giants Monsanto Canada, Inc. and Monsanto Company were pitted against the property rights of small-operation farmer, Mr. Schmeiser from Bruno, Saskatchewan, Canada.⁶⁸ Monsanto claimed that Mr. Schmeiser infringed Canadian Patent No. 1,313,830 because Mr. Schmeiser planted, cultivated, and sold a crop of canola that contained a transgene and cells comprising a transgene, both of which were claimed subject matter in Canadian Patent No. 1,313,830.⁶⁹ The transgene is claimed in Claim 1 of Canadian Patent No. 1,313,830 and in Claim 1 of the U.S. counterpart to the Canadian patent.⁷⁰ The cell comprising the transgene is claimed in Claim 22 of Canadian Patent No. 1,313,830 and in Claim 22 of the U.S. counterpart to the Canadian patent.⁷¹ Although Canadian Patent No. 1,313,830 does not contain a claim to a plant, the U.S. counterpart patent does contain such a claim. Specifically, Claim 29 of U.S. Patent No. 4,940,835 teaches: "A glyphosate-resistant dicotyledonous plant which has been regenerated from a glyphosate-resistant plant cell comprising the chimeric plant gene of Claim 1."⁷²

Upon close inspection of this Claim 29 of U.S. Patent No. 4,940,835, it becomes clear that even if Canadian Patent No. 1,313,830 contained Claim 29 of U.S. Patent No. 4,940,835, the plants and crop on the fields of Mr. Schmeiser could not infringe the patent rights of Monsanto.⁷³ The logic of this statement is explained *infra*.

The scope of the rights of Monsanto are defined by the scope of the claims in Canadian Patent No. 1,313,830.⁷⁴ I propose that the metes and bounds of Canadian Patent No. 1,313,830 do not include the crops found growing in the field of Mr. Schmeiser. The property rights properly belonging to Monsanto should be exercised by Monsanto. However, Monsanto must not be found to be exercising those property rights to which it does not have ownership. The nature

68. See *id.* at ¶ 4 (discussing Monsanto's patent rights against a farmer who allegedly infringed on those rights).

69. See *id.* at ¶¶ 1-2; Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

70. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986); U.S. Patent No. 4,940,835, at [30-47] (filed July 7, 1986).

71. See U.S. Patent No. 4,940,835, at [39-40] (filed July 7, 1986); Can. Patent No. 1,313,830, at [claim 22] (filed Aug. 6, 1986).

72. U.S. Patent No. 4,940,835, at [60-63] (filed July 7, 1986).

73. *Id.*

74. Can. Patent No. 1,313,830, at [claims 1-52] (filed Aug. 6, 1986).

of the property rights of the farmer and the nature of the property rights of the seed manufacturer have been well ventilated in a previously published article.⁷⁵

C. *Marking the Boundaries*

A central tenet of patent law is that the boundaries must be clearly specified within the patent so the public will know where it may tread and where it may not tread.⁷⁶ Justice Binney, of the Supreme Court of Canada, put the issue more succinctly as follows: “The monopoly is enforceable by an array of statutory and equitable remedies and it is therefore important for the public to know what is prohibited and where they may safely go while the patent is still in existence.”⁷⁷

Economic and technological advancement results when individuals are allowed to study, experiment, and innovate within an area of interest. When the individual is free to experiment and innovate, new results are produced that may be of superior quality and of lower cost than a product that is in the marketplace and is protected by a patent. The existing product or process is likely to be cast aside by the market because of its quality, price, or both. To experiment and innovate, the individual must know the metes and bounds defined in the relevant patent. When the boundaries are clear, the innovator may experiment and innovate to the boundary with impunity and be secure that a lawsuit will not be the reward for the effort.⁷⁸ If the boundary is uncertain, then the individual may choose to neither experiment nor innovate; to the detriment of the greater society.

In the case of the farmer, this rule is of considerable import. Consider the case of Mr. Schmeiser. For nearly fifty years, he has exercised his skill and ability as a plant breeder.⁷⁹ His canola was of a unique variety, capable of resisting infection by blackleg and sclerotinia.⁸⁰ Mr. Schmeiser was able to plant canola in multiple, consecutive growing seasons with little, if any, risk of a rise of plant diseases.⁸¹ Mr. Schmeiser had experimented for years with his canola, developing and innovating to create a product that was of value because of its superior quality and economic efficiency.⁸² Each year, Mr. Schmeiser saved some of

75. See Busch, *supra* note 33, at 1.

76. See *Howe v. Gen. Motors Corp.*, 252 F. Supp. 924, 936 (N.D. Ill. 1966).

77. *Camco Inc. v. Whirlpool Corp.*, [2000] S.C.R. 1067, 1089.

78. To avoid unnecessary complications, I will ignore the doctrine of equivalents with respect to patented subject matter.

79. See Interview with Percy Schmeiser, Farmer, Bruno, Sask., Can. (Jan. 19, 2004); see also *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶ 4.

80. Interview with Percy Schmeiser, Farmer, in Bruno, Sask., Can. (Jan. 19, 2004).

81. *Id.*; see also *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶¶ 14-15.

82. Interview with Percy Schmeiser, Farmer, in Bruno, Sask., Can. (Jan. 19, 2004).

his seed for planting in a subsequent planting cycle.⁸³ In the fall of 1997 and spring of 1998, he believed he could save seed and plant that seed as he had always done without interfering with the property rights of Monsanto.⁸⁴

Apparently, Monsanto believed, and believes, that the intangible property rights protected by Canadian Patent No. 1,313,830 extend to all canola plants in which the transgene might be found.⁸⁵ The validity of this assertion is well founded upon the statements made by Mr. Hughes to the Supreme Court of Canada. Early in the comments of the Respondents, Mr. Hughes was attempting to define the claim narrowly in order to preserve the validity of the patent. Consider the following brief exchange between Justice Bastarache and Mr. Hughes during that phase of the hearing:

MR. JUSTICE BASTARACHE: But aren't you saying basically that you're claiming a patent over the plant because it contains the gene?

MR. HUGHES: No.

MR. JUSTICE BASTARACHE: Well, what is the difference then? If you had patented the plant, what would be the difference between what you would be claiming and what you're claiming now?

MR. HUGHES: Because the whole plant is not my invention. My invention is part of the plant.⁸⁶

Later, Mr. Hughes was attempting to define the claim broadly in order to argue that Mr. Schmeiser "used" the transgene by planting the glyphosate-resistant seed.⁸⁷

MADAM JUSTICE ARBOUR: Sorry, I think I mis-expressed myself. The invention is not the plant. Assuming he was aware he had the plant, that's not the question. The question is, in what sense, in what legal or factual sense can we say he had what is patent-protected which is the isolated cell in which the modified gene was implanted prior to differentiation? He had it post-differentiation, but you say, there's no patent in that, not in all the cells in the plant nor in the plant itself.

MR. HUGHES: If I left the Court with the impression that I said the invention was the isolated cell, I did not mean to say that.

MADAM JUSTICE ARBOUR: Well, what do you mean by it when you agree with me that it was prior to differentiation, what is it, then, if it's not isolated?

83. *Id.*; see also *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶ 14.

84. Interview with Percy Schmeiser, Farmer, in Bruno, Sask., Can. (Jan. 19, 2004).

85. Transcript of Cassettes at 33, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

86. *Id.*

87. *Id.* at 42-43.

MR. HUGHES: What is new is this particular kind of cell which then finds itself incorporated into the plant. We are not claiming the invention is a cell as isolated, we're claiming the invention as a cell wherever found and, in particular in this case, it's found in the commercial crop of canola and Mr. Schmeiser knew exactly what he had, he had canola containing the cell. I do not claim the isolated cell.⁸⁸

In defining the scope, Mr. Hughes stated that the "whole plant is not my invention," rather, "[m]y invention is part of the plant."⁸⁹ In trying to prove infringement, Mr. Hughes stated that "[w]e are not claiming the invention is a cell as isolated, we're claiming the invention as a cell wherever found and, in particular in this case, it's found in the commercial crop of canola."⁹⁰ It might be argued that Mr. Hughes was claiming only the cell. However, the following interchange between Mr. Justice LeBel and Mr. Hughes indicates that Monsanto was not claiming only the cell.

MR. JUSTICE LeBEL: So how do you draw a distinction between a patent in the gene, in the cell and in the plant?

MR. HUGHES: No, no, I don't.⁹¹

Mr. Hughes was trying to have it both ways. It might be argued that Mr. Hughes was claiming the cell wherever it is found, which includes the entire plant. That is exactly the point being made in this work! Thus, Mr. Hughes did not, in fact, claim only the cell, but the entire plant for purposes of infringement. Monsanto has taken the classical, and forbidden, tactic of asking the Court to construe the claim narrowly for purposes of validity and broadly for purposes of infringement.⁹²

Monsanto used their claims to reach into the fields of Mr. Schmeiser and, as a consequence, Mr. Schmeiser was excluded as a participant in the market because he was prohibited from continuing to study, experiment, and innovate.

88. *Id.*

89. *Id.* at 33.

90. *Id.* at 43.

91. *Id.* at 43.

92. Justice Grove gave a very candid discussion of an attempt to claim both the composition and the individual elements in an infringement case in *Westinghouse v. Lancashire & Yorkshire Railway Co.*, REPORTS OF PATENT CASES 229, 246 (1887). Justice Grove stated that:

"[s]o that every element of the combination, although all are old . . . is to be claimed in aid of including an infringer; but to be disclaimed and to be treated only as a particular combination of five or six elements when you come to treat the question of the safety of the patent and the question of whether the patent is new or not."

He then concluded that the word must be used "rationally and in the same sense" in both situations.

Essentially, he was prohibited from developing a better variety of canola.⁹³ Furthermore, the progress of technology and economic development is inhibited because he is no longer able to produce his unique variety of canola.⁹⁴ If the patent rights of Monsanto reach into the fields of Mr. Schmeiser, or any other farmer so situated, then the market becomes inefficient and the possibility for new development is hindered.⁹⁵

The patentee must not be allowed to extend the scope of the patent claim so that he may reach into the field of the farmer. If the patentee is allowed to exclude the farmer from his own fields by an exercise of rights presumably granted by the patent, then those rights are too broad. The patentee may properly claim a transgene and a plant cell comprised of the transgene. However, the claim to the transgene cannot reach into the field of the farmer nor can the claim to the plant cell so reach.⁹⁶

D. Regarding Knowledge of the Infringement

An inventor who produces something already patented infringes the patent regardless of his knowledge of its existence.⁹⁷ The intent or knowledge of the alleged infringer is not material to the issue of patent infringement.⁹⁸ While the intent of the alleged infringer is relevant to the issue of damages, it is not relevant to the issue of infringement.⁹⁹ Infringement may be found even though the infringer did so inadvertently, unintentionally, and “without knowledge of the patent.”¹⁰⁰ “The patent is to be construed as a contract, with . . . intent of the par-

93. Monsanto Can., Inc. v. Schmeiser, [2001] F.C.T. 256, ¶ 5.

94. See Memorandum of Fact & Law of the Respondents at ¶ 93, Schmeiser v. Monsanto Can., Inc., [2004] S.C.C. 34.

95. See *id.*

96. See *id.* at ¶ 46.

97. Schnadig Corp. v. Gaines Mfg. Co., Inc., 620 F.2d 1166, 1168 (6th Cir. 1980).

98. Crane Co. v. Aeroquip Corp., 364 F. Supp. 547, 560 (N.D. Ill. 1973), *reconsideration denied* 180 U.S.P.Q. (BNA) 126, *aff'd in part, rev'd in part on other grounds* 504 F.2d 1086, 183 U.S.P.Q. (BNA) 577, *on remand* 185 U.S.P.Q. 509 (BNA); Cummings Engine Co. v. Gen. Motors Corp., 299 F. Supp. 59, 92, (D.C. Md. 1969), *aff'd*, 424 F.2d 1368, 165 U.S.P.Q. (BNA) 618, 166 U.S.P.Q. (BNA) 234.

99. See Roller Bearing Co. of Am. v. Bearings, Inc., 328 F. Supp. 923, 937 (E.D. Ill. 1971) (citing Thurber Corp. v. Fairchild Motor Corp., 269 F.2d 841 (5th Cir. 1959); Baut v. Pethick Constr. Co., 262 F. Supp. 350, 360 (D.C. PA. 1966); Hartford Nat'l Bank & Trust Co. v. E.F. Drew & Co., 188 F. Supp. 353 (D. Del. 1960)); Ames Shower Curtain Co. v. Heinz Nathanson, Inc., 285 F. Supp. 640, 645 (S.D.N.Y. 1968) (citing Thurber Corp. v. Fairchild Motor Corp., 269 F.2d 841, 845, 849 (5th Cir. 1959); Upjohn Co. v. Italian Drugs Imp. Co., 190 F. Supp. 361, 367 (S.D.N.Y. 1961).

100. Blair v. Westinghouse Elec. Corp., 291 F. Supp. 664, 670 (D.C.D.C. 1968).

ties as the lodestar [and i]t is the real invention claimed and granted protection which” is sought to be determined.¹⁰¹

To infringe a method or process claim, “all of the steps or stages of the process” must be used by the alleged infringer.¹⁰² “The fact that the claims [in the patent were] broad enough [so as] to cover [a certain] process [did] not establish infringement” of the patent by an accused process, since claims “are to be read in connection with the specifications, and a patentee’s broadest claim can be no broader than his actual invention.”¹⁰³ There can be no infringement of the patented process if the accused process does not include those steps that distinguish the patented process from the prior art.¹⁰⁴

A claim to a result of a process is infringed only if that result is obtained by following precisely the same steps claimed in the process claim.¹⁰⁵ The fact that the accused process utilizes the same natural laws and produces the same product does not necessarily mean that the process claim is infringed.¹⁰⁶

III. ANALYSIS BASED UPON THE “LAWS OF NATURE” RULE

While plants are considered patentable subject matter under U.S. patent law,¹⁰⁷ the issue before the Supreme Court of Canada in the *Schmeiser v. Monsanto* case has never been litigated in the United States. In the following analysis, I will examine the issue of whether the cells in a plant, the transgene in those cells, and indeed the plant itself are patentable subject matter in Canada. Upon extension of the analysis, I will show that a patent, issued by the United States Patent and Trademark Office, for a plant may not be valid if the plant was regenerated from a single transfected cell.

101. *Laitram Corp. v. Deepsouth Packing Co.*, 443 F.2d 928, 933 (5th Cir. 1971).

102. *Engelhard Indus., Inc. v. Research Instrumental Corp.*, 324 F.2d 347 (9th Cir. 1963); *Winget Kickernick Co. v. Sil-O-Ette Underwear Corp.*, 89 F.2d 635 (2nd Cir. 1937); *Darsyn Lab., Inc. v. Lenox Lab., Inc.*, 120 F. Supp. 42, 50 (D.N.J. 1954), *aff’d*, 217 F.2d 648, 104 U.S.P.Q. (BNA) 39; *Beverige Ice Marketers, Inc. v. Bateman Foundary & Mach. Co.*, 93 F. Supp. 535, 536 (N.D. Tex. 1950); *see also Charles Beseler Co. v. J. Y. Taylor & Co.*, 103 F. Supp. 201 (Tex. 1952); *Am. Aerovap, Inc. v. Cauthorn*, 103 F. Supp. 9, 10 (1952).

103. *Kemart Corp. v. Printing Arts Research Lab., Inc.*, 201 F.2d 624, 629 (9th Cir. 1953).

104. *Tex. Co. v. Anderson-Prichard Ref. Corp.*, 122 F.2d 829, 841 (10th Cir. 1941).

105. *Id.*

106. *Phillips Petroleum Co. v. Sid Richardson Carbon & Gas. Co.*, 293 F. Supp. 555, 569 (N.D. Tex. 1968), *aff’d*, 416 F.2d 10, 163 U.S.P.Q. (BNA) 141.

107. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 127 (2001) (holding that utility patents may be issued for plants).

A. *The Current State of the Law Regarding Patenting of Living Organisms*

One of the four cornerstones of the appeal in the *Schmeiser v. Monsanto* case was that the plants on the field of Mr. Schmeiser were not an invention and, therefore, not patentable.¹⁰⁸ The Canadian courts have typically engaged in a line-drawing exercise to determine whether a genetically modified organism is patentable as a “lower life form,” rather than as a “higher life form.”¹⁰⁹ In the following discussion, I will demonstrate that such line drawing exercises lead to arbitrary distinctions that are not based upon sound principles of either science or law.

1. *The Patent Had Already Issued, and Therefore, According to Monsanto, the Patent Is Valid*

In *Schmeiser v. Monsanto*, Monsanto presented arguments, apparently without proper support, that the subject matter claimed in Canadian Patent 1,313,830 was patentable under the Patent Act.¹¹⁰ Monsanto specifically directed the attention of the Court towards finding the claims contained in Canadian Patent 1,313,830 valid because the patent had already been issued.¹¹¹ Monsanto asserted that because the Commissioner of Patents had already issued the patent then: first, the Commissioner had already decided that the transgene and cells containing that transgene are patentable subject matter, and that decision is owed deference by the Supreme Court of Canada; and second, the patent is *prima facie* valid because the patent had been issued.¹¹² Although an issued patent is considered *prima facie* valid, that *prima facie* validity is rebuttable, and rebut the validity is precisely what Mr. Schmeiser did in the argument before the Court. Monsanto further stated, in their Memorandum, that the patent was valid and incontestable because the Commissioner allowed the patent to issue.¹¹³ Monsanto gave no reason as to why the Supreme Court of Canada should give deference to the Commissioner of Patents, other than that: “the Patent Office has drawn the line

108. See *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶¶ 21-24.

109. See generally *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76; *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶¶ 21-24.

110. See Memorandum of Fact & Law of the Respondents at ¶¶ 72-90, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

111. See *id.* (The argument for patent validity is based upon a factual difference between the patent application in the *Harvard Mouse Case* and the patent underlying the *Schmeiser v. Monsanto* case).

112. See *id.* at ¶ 75.

113. See *id.*

so as to allow the claims at issue to be patented,”¹¹⁴ and therefore, the “Court should not interfere with the patent so granted.”¹¹⁵

During oral argument, Mr. Schmeiser argued that the rationale underlying the basis for the issuance of Canadian Patent No. 1,313,830 was not known.¹¹⁶ Mr. Terry Zakreski, counsel for Mr. Schmeiser, specifically argued that if the Commissioner of Patents had construed the claims narrowly, such that the claims would cover only a transgene and a single, undifferentiated, transfected, progenitor plant cell, then the patent, as issued, was valid.¹¹⁷ However, Mr. Zakreski argued that if the Commissioner thought that the claims would cover the plant or seeds on the fields of a farmer then the Commissioner had construed the claims too broadly and the patent was not valid.¹¹⁸ Thus, argued Mr. Zakreski, the Court must “interfere with the patent so granted” if the Commissioner interpreted the claims broadly.¹¹⁹ However, if the claims were interpreted narrowly by the Commissioner then Mr. Schmeiser, admittedly, was in agreement with Monsanto that “the Court should not interfere with the patent so granted.”¹²⁰ The position of Mr. Schmeiser was that the granted patent was not valid because the subject matter was not an “invention” within the interpretation allowed by the Patent Act.¹²¹

In the *Harvard Mouse Case*, the Supreme Court of Canada held that “higher life forms” are not patentable because higher life forms are neither a “manufacture” nor a “composition of matter” and hence are not an “invention” within an allowable interpretation of the Patent Act.¹²² The Court then found that the claimed oncomouse was not patentable because it was a higher life form.¹²³ The Court refused to articulate what constituted a “higher life form.” However, it did conclude that “Parliament did not intend to include higher life forms within the definition of invention found in the Patent Act.”¹²⁴

Rather than argue as to why either plants or plant cells should be considered as “lower life forms,” Monsanto simply assumed the position that the patent had already been issued and the Supreme Court of Canada “should not interfere

114. *Id.* at ¶ 85.

115. *Id.*

116. Transcript of Oral Argument at 79-80, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

117. *Id.* at 80.

118. *Id.*

119. *Id.*

120. *Id.*

121. Interview with Terry Zakreski, Solicitor, Saskatoon, Sask., Can. (Jan. 19, 2004).

122. *See Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76, ¶ 201.

123. *See id.* at ¶ 120.

124. *Id.* at ¶ 155.

with the patent so granted.”¹²⁵ To have avoided presenting a coherent argument as to why plants or plant cells should be considered as “lower life forms,” and hence not patentable, seems to have been a very dangerous tactic for Monsanto to have taken. The Supreme Court of Canada had already given an indication that plants were “higher life forms”¹²⁶ and one of the issues before the Court in *Schmeiser v. Monsanto* was whether either a plant or a plant cell was a “higher life form” and hence not “within the definition of invention found in the Patent Act.”¹²⁷ Also, the Supreme Court of Canada was fully aware that the *Schmeiser v. Monsanto* case was making its way through the Federal Court of Appeal and, at the time the decision in the *Harvard Mouse Case* was being drafted, the *Schmeiser v. Monsanto* case was likely to be appealed to the Supreme Court of Canada.¹²⁸ It is reasonable to assert, then, that the Court was preparing for the *Schmeiser v. Monsanto* case while rendering a decision in the *Harvard Mouse Case*.

2. *The Supreme Court of Canada Reduced the Issue to a Line-Drawing Exercise in the Harvard Mouse Case*

In the *Harvard Mouse Case*, the Supreme Court of Canada all but held that plants were higher life forms.¹²⁹ An analysis of part of the decision handed down by the Court supports this observation. In observing that the law of Canada accepts “that lower life forms are patentable,” the Court was clear that the patentability of lower life forms does “not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize a lower life form as a ‘composition of matter’ or ‘manufacture’ than it is to conceptualize a higher life form in these terms.”¹³⁰ The Court proceeded to articulate several reasons in support of its position that higher life forms cannot be conceptualized as either a “composition of matter” or a “manufacture.”¹³¹

In the first of these reasons, the Court stated that: “micro-organisms 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

125. Memorandum of Fact & Law of the Respondents at ¶ 85, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

126. *See* *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76, ¶¶ 201-03.

127. *Id.*

128. *See id.* at ¶ 48. Evidence that the Supreme Court of Canada was fully aware of *Schmeiser v. Monsanto*, is found in the dissenting opinion of Justice Binnie.

129. *See id.* at ¶¶ 201-03 (stating that “higher life forms such as plants start off from a cell and then grow and differentiate into a complete plant”).

130. *Id.*

131. *Id.*

characteristics”¹³²; and the Court added that “[t]he same cannot be said for plants and animals.”¹³² The fact that plants were included in the same class as animals and not in the class of micro-organisms is important. The Court clearly recognized that plants, like animals, were not produced “en masse as chemical compounds are prepared.”¹³³ The issue before the Court was whether animals were patentable subject matter, and therefore the Court could have remained silent on the issue of whether plants could be classified, as are micro-organisms, as “lower life forms.”¹³⁴ However, in light of the possibility that the *Schmeiser v. Monsanto* case would reach the Court, the Court evidently identified the necessity to prepare to hold that plants also were “higher life forms” and not patentable.¹³⁵ In articulating the first reason plants and animals were not “lower life forms,” the Court accepted the reasoning of the U.S. Court of Customs and Patent Appeals in the case *In re Bergy, Coats, and Malik*.¹³⁶ The U.S. Court of Customs and Patent Appeals stated that, “[t]he nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses.”¹³⁷ The question before the *Bergy I* court was not whether higher life forms, such as “horses and honeybees or raspberries and roses” were patentable but rather whether a micro-organism was patentable.¹³⁸

The *Bergy I* court reasoned that micro-organisms are used “in much the same way as ... [chemists and chemical manufacturers] use chemical elements, compounds, and compositions which are not considered to be alive,”¹³⁹ and therefore, the court held, “the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance.”¹⁴⁰ The court, therefore, recognized micro-organisms as “a new and useful tangible industrial tool,” and if that tool “is unobvious, so that it complies with the prerequisites to patentability,” then the micro-organism should not be excluded “from the § 101 categories of patentable invention on the sole ground that it is alive.”¹⁴¹ It is important to recognize that the Supreme Court of Canada, in the *Harvard Mouse*

132. *Id.* at ¶ 202 (quoting *Re Application of Abitibi Co.*, [1982] 62 C.P.R. 2d 81, 89).

133. *Re Application of Abitibi Co.*, [1982] 62 C.P.R. 2d 81, 89.

134. *See id.*

135. *See id.*

136. *See Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76, ¶ 202 (quoting *In re Bergy, Coats & Malik*, 195 U.S.P.Q. (BNA) 344, 350 (1977)).

137. *In re Bergy*, 195 U.S.P.Q. (BNA) at 350.

138. *See id.*

139. *See Id.* at 351.

140. *Id.*

141. *Id.*

Case, did not accept the reasoning of the U.S. Supreme Court that either micro-organisms were patentable¹⁴² or that a patent could issue for a new, useful, and non-obvious breed of plant¹⁴³ even though both *Chakrabarty* and *J.E.M. Ag Supply, Inc.* were decided after *Bergy I* was decided. It may very well have been that the Supreme Court of Canada was not willing to accept that, under Canadian law, “statutory subject matter [was] to ‘include anything under the sun that is made by man.’”¹⁴⁴

It is of interest to note that U.S. Court of Customs and Patent Appeals dismissed the position of the Board of Patent Appeals that the holding in *Bergy I* would “of necessity, or ‘logically,’ make all new, useful, and unobvious species of plants, animals, and insects created by man patentable,” as a “far-fetched” fear.¹⁴⁵ Three years later, the U.S. Supreme Court held that a nonnaturally occurring human-made micro-organism is patentable subject matter.¹⁴⁶ Twenty-one years after *Chakrabarty* was decided, the U.S. Supreme Court held that: “newly developed plant breeds fall within the terms of § 101, and that neither the PPA nor the PVPA limits the scope of § 101’s coverage.”¹⁴⁷ Therefore, under U.S. law a patent may issue for a plant breed that if it is “new, useful, and nonobvious”¹⁴⁸ and the applicant for patent has “describe[d] the plant with sufficient specificity to enable others to ‘make and use’ the invention after the patent term expires.”¹⁴⁹ Further, a patent has issued in the United States for the oncomouse, which was the subject matter at issue in the *Harvard Mouse Case* before the Supreme Court of Canada.¹⁵⁰ The concern that the holding in *Bergy I* will “of necessity, or ‘logically,’ make all new, useful, and unobvious species of plants, animals, and insects created by man patentable,”¹⁵¹ was dismissed by the U.S.

142. See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

143. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 127 (2001).

144. *Diamond*, 447 U.S. at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

145. *In re Bergy, Coats & Malik*, 195 U.S.P.Q. (BNA) 344, 351 (1977).

146. *Diamond*, 447 U.S. at 309. The Court stated that the micro-organism is “a non-naturally occurring manufacture or composition of matter — a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Id.* at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

147. *J.E.M. Ag Supply*, 534 U.S. at 145.

148. *Id.* at 142.

149. *Id.* While the Court held that plants are potentially patentable, the holding does not alter the outcome of the analysis presented in this Article. Also, the holding in *J.E.M. Ag Supply* does not preclude a case such as *Schmeiser v. Monsanto* from being brought before the Supreme Court of the United States.

150. *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76.

151. *In re Bergy, Coats & Malik*, 195 U.S.P.Q. (BNA) 344, 351 (1977).

Court of Customs and Appeals as a “far-fetched” fear. This dismissal seems to have been in error.

In the second reason “that it is easier to conceptualize a lower life form as a ‘composition of matter’ or manufacture than it is to conceptualize a higher life form in these terms,”¹⁵² the Supreme Court of Canada recognized that:

Several important features possessed by animals distinguish them from both micro-organisms and plants and remove them even further from being considered a “composition of matter” or a “manufacture.” In particular, the capacity to display emotion and complexity of reaction and to direct behavior in a manner that is not predictable as stimulus and response, is unique to animal forms of life.¹⁵³

The quoted language suggests that the Court might consider plants and plant cells as “lower life forms,” and therefore patentable subject matter because they are not sentient organisms. However, the following language most certainly dispels any such conclusion:

Of course, if sentience is the determining factor that renders a higher life form incapable of receiving patent protection, then the current line between higher and lower life forms is misplaced. As stated earlier, given the complexity of the issues involved, it is not the task of the Court to situate the line. It may well be that Parliament chooses to exclude plants from patentability for other reasons, such as their capability to self-propagate and the infringement issues that this raises.¹⁵⁴

It appears, therefore, that the Court has signaled that whether an organism is sentient is not dispositive of the issue of whether the organism is a “lower life form” or a “higher life form.”¹⁵⁵ In fact, based upon the decision in the *Harvard Mouse Case*, it was not clear that the Court would even consider the issue of whether an organism is sentient in deciding whether plants or plant cells are “higher life forms.”¹⁵⁶

In the last reason “that it is easier to conceptualize a lower life form as a ‘composition of matter’ or manufacture than it is to conceptualize a higher life form in these terms,”¹⁵⁷ the Supreme Court of Canada considered the argument of the respondent that because both TRIPS and NAFTA “contain an article whereby members may ‘exclude from patentability’ certain subject matter, including plants and animals other than micro-organisms” implies that both “plants and animals are considered patentable, unless specifically excluded from patentabil-

152. Harvard Coll., [2002] S.C.C. at ¶ 201.

153. *Id.* at ¶ 204.

154. *Id.* at ¶ 202.

155. *Id.* at ¶ 49.

156. *See id.* at ¶ 45.

157. *Id.* at ¶ 201.

ity.”¹⁵⁸ In dismissing this argument, the Court stated that: “the fact that there is a specific exception in TRIPS and NAFTA for plants and animals does however demonstrate that the distinction between higher and lower life forms is widely accepted as valid.”¹⁵⁹

Mr. Schmeiser directly asked the Supreme Court of Canada to determine whether either a plant or a plant cell is a “higher life form.”¹⁶⁰ Monsanto failed to give any argument as to why neither a plant nor a plant cell should be considered a “higher life form,” but rather depended upon the Court to grant deference to the decision of the Commissioner of Patents.¹⁶¹ While deference should be accorded to the Commissioner of Patents regarding whether a patent should be issued for a transgene and a plant cell containing the transgene, such deference must not be dispositive of the issue before the Court. If the deference was dispositive, then the Court necessarily should have ignored the issue placed before it by Mr. Schmeiser. However, by granting review of the decisions of the Trial Court and Federal Court of Appeals, the Supreme Court of Canada had indicated that it was willing to address the issue of the validity of the patent placed before it by Mr. Schmeiser.¹⁶² Thus, the Court had tacitly accepted that the deference to be accorded to the Commissioner of Patents was not dispositive in the present case.

One issue before the Supreme Court of Canada in *Schmeiser v. Monsanto* was whether “Monsanto should not be allowed to accomplish indirectly that which it cannot do directly.”¹⁶³ If the patent on the transgene gives Monsanto the right to control the planting, growth, harvesting, and disposition of canola containing the transgene then Monsanto has the ability to accomplish indirectly that which it cannot do directly under existing Canadian patent law. Therefore, “it is necessary to consider whether the Gene Claims, Cell Claims, and Canola Cell Claims of Patent ‘830 are sustainable as pertaining to lower life forms.”¹⁶⁴ Monsanto asserted that: “[o]stensibly, [they] are merely for a gene and cell,” and allowed by the Patent Office.¹⁶⁵ The position of Mr. Schmeiser was that the claims for a gene and cell are invalid when the transgene is found in a plant. If the claim were to be valid with respect to a transgene in a plant, then the plant is,

158. *Id.* at ¶ 205.

159. *Id.*

160. Interview with Terry Zakreski, Solicitor, Saskatoon, Sask., Can. (Jan. 19, 2004).

161. *Id.*

162. *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, Part III, § A.

163. Appellant’s Factum at ¶ 49, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

164. *Id.* at ¶ 56.

165. *Id.*; see also Memorandum of Fact and Law of the Respondants at ¶ 78, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (stating the claims “are expressly confined to plant genes, plant cells expressing those genes and transformation methods).

effectively, circumscribed within the rights of the patentee.¹⁶⁶ Thus, the patent on the transgene is, in effect, a patent on the plant. However, if a patent on a plant is not valid then the patent on a transgene in a plant must not be valid.

Monsanto states that “[e]ven if one accepts Schmeiser’s argument that Monsanto’s patent effectively claims whole plants, nothing in *Harvard Mouse* supports the conclusion that whole plants are unpatentable subject matter.”¹⁶⁷ This statement is simply not true. In fact, the Court, in the *Harvard Mouse* case stated exactly the opposite as to what Monsanto had asserted. Specifically, the Court stated,

In my opinion, Parliament did not intend higher life forms to be patentable. Had Parliament intended every conceivable subject matter to be patentable, it would not have chosen to adopt an exhaustive definition that limits invention to any “art, process, machine, manufacture or composition of matter”. In addition, the phrases “manufacture” and “composition of matter” do not correspond to common understandings of animal and plant life.¹⁶⁸

The support, found in the *Harvard Mouse Case*, for the proposition that plants are not subject matter for which a patent may issue is found in the language: “the phrases ‘manufacture’ and ‘composition of matter’ do not correspond to common understandings of animal and plant life.”¹⁶⁹ If the subject matter is neither a “manufacture” nor a “composition of matter,” then that subject matter is not an “invention” within the framework of the Patent Act.¹⁷⁰ If the subject matter is not an “invention” then a patent cannot be issued that claims that subject matter. If the Court tried, it could not have made itself more clear that “plant life” is neither a “manufacture” nor a “composition of matter.”¹⁷¹ Therefore, the *Harvard Mouse Case* does support the proposition “that whole plants are unpatentable subject matter.”¹⁷² The question left standing was whether the plant cells constituting the plant were patentable subject matter.

166. *Id.* at ¶ 59.

167. Memorandum of Fact and Law of the Respondents at ¶ 78, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

168. *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76, ¶ 120.

169. *Id.*

170. *Id.* at ¶156 (explaining that in order for a higher life form to be an invention, it must be a manufacture or a composition of matter).

171. *See id.*

172. Memorandum of Fact and Law of the Respondents at ¶ 78, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

3. *Whether a Plant is a “Higher-Life Form” or a “Lower-Life Form”*

In its arguments, Monsanto attempted to convince the Court that plant cells and plants must be classified as “lower life forms.”¹⁷³ In support, Monsanto quoted language from *Abitibi* indicating that “all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity possess uniform properties and characteristics”¹⁷⁴ are patentable.¹⁷⁵ Then, Monsanto argued that “cell lines derived from ‘*higher life forms*’,”¹⁷⁶ “deep frozen non-human mammalian sperm,”¹⁷⁷ and a “fertilized, genetically altered oncomouse egg”¹⁷⁸ are patentable. Monsanto then concluded that the claimed transgene and plant cell should be patentable.¹⁷⁹

The argument presented by Monsanto necessarily fails on a number of points. First, Monsanto evidently recognized, while securing the patent, that plants are not patentable subject matter in Canada; however, Monsanto argued that the aggregate of cells constituting the plant must be patentable as a lower-life

173. Interview with Terry Zakreski, Solicitor, in Saskatoon, Sask., Can. (Jan. 19, 2004).

174. Re Application of *Abitibi Co.*, [1982] 62 C.P.R. 2d 81, 89.

175. The quoted language was an explanation of why micro-organisms are patentable. The use of this language out of context can be misleading.

176. Memorandum of Fact and Law at ¶ 81, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

177. *Id.* at ¶ 82.

178. *Id.* at ¶ 83. Specifically, Monsanto states that “[i]n *Harvard Mouse*, all nine members of the Court found that the fertilized, genetically altered oncomouse egg, ... was an invention which is proper subject matter for the grant of a patent.” However, the majority in *Harvard Mouse* was not as definitive:

Owing to the fact that the technology by which a mouse predisposed to cancer is produced involves injecting the oncogene into a fertilized egg, the genetically altered egg would appear to be cognizable as ‘[a] substance or preparation formed by combination or mixture of various ingredients’ or as [TRANSLATION] ‘[a]ction or manner of forming a whole ... by assembling several parts.’ However, it does not thereby follow that the oncomouse itself can be understood in such terms. Injecting the oncogene into a fertilized egg is the but-for cause of a mouse predisposed to cancer, but the process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention. The body of a mouse is composed of various ingredients or substances, but it does not consist of ingredients or substances that have been combined or mixed together by a person.

Harvard Coll. v. Canada (Comm’r of Patents), [2002] S.C.C. 76, ¶ 162. The quoted language was clearly not the holding of the *Harvard Mouse* Court, but rather part of the analysis the Court employed in determining whether the oncomouse was a composition of matter. The Court used the example of the oncomouse egg as an example of what *might* be considered a composition of matter, not that the oncomouse *would* be considered as a composition of matter. Thus, the conclusion suggested by Monsanto regarding the quoted language is clearly without merit.

179. Interview with Terry Zakreski, Solicitor, Saskatoon, Sask., Can. (Jan. 19, 2004).

form.¹⁸⁰ By reclassification of the subject matter, Monsanto was attempting to make patentable that that cannot otherwise be patentable. Second, as argued by Mr. Schmeiser,¹⁸¹ the cells containing the transgene and found in a plant are not “cell lines derived from ‘higher life forms’,”¹⁸² rather the cells in a plant are differentiated cells. The claimed transgene would be found in “all [differentiated] cells found within the canola plant, including pollen cells, seed cells, leaf cells, stem cells, root cells, and the innumerable other cell types within a canola plant.”¹⁸³ A “cell line” is a type of cell, with a unique set of characteristics, that can be cultured to generate a large number of individual, disperse cells all of which are clones of a single progenitor cell. The concept of a “cell line” is the antilogy of the concept of an organism. An organism contains a collection of different types of cells, all of which are organized such that the function and fate of each individual cell is dependent upon the proper functioning and fate of all the other cells in the organism. The fate and function of each individual cell of a “cell line” is independent of the fate and function of any other given cell of that “cell line.” Thus, the collection of cells that constitute a plant cannot fit within the definition of a “cell line.”

The third shoal upon which the argument of Monsanto foundered was as follows. Under a reasonable interpretation of *Abitibi*, the collective of cells constituting an organism, such as a mature plant, are not patentable, nor can the collective be circumscribed by the claims of a patent. It is simple to determine that “any measurable quantity [of these cells do not] possess uniform properties and characteristics,”¹⁸⁴ and hence do not fall within the classification of “life forms which are produced en masse as chemical compounds”¹⁸⁵ considered patentable by the Patent Appeal Board of Canada. Common sense indicates that a plant is comprised of a number of different types of cells. Although all of these cells may share a set of common characteristics, each of the myriad of types of cells within a plant possess a unique set of characteristics and functions. That is, a root cell of a plant is different in character, that is shape, size, coloration, etc., than a leaf cell; also, the function of a root cell is different than the function of a leaf cell. Thus, any measurable quantity of root cells will possess a set of characteristics and functions that is different than any given measurable quantity of leaf

180. *Id.*

181. Memorandum of Fact and Law of the Respondents at ¶ 59, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

182. *Id.* at ¶ 81.

183. *Id.* at ¶ 59.

184. *Re Application of Abitibi Co.*, [1982] 62 C.P.R. 2d 81, 89.

185. *Id.*

cells will possess. As such, the collective of cells constituting the plant does not satisfy the requirements of patentable life forms articulated in *Abitibi*.¹⁸⁶

Neither the cells containing the transgene and found in a plant nor the seeds from that plant are patentable within the construct relating to genetically altered eggs articulated by the Supreme Court of Canada in the *Harvard Mouse Case*.¹⁸⁷ In the *Harvard Mouse Case*, the Court stated that “the genetically altered egg would appear to be cognizable as ‘[a] substance or preparation formed by combination or mixture of various ingredients’,”¹⁸⁸ and as such might be subject matter for which the Commissioner of Patents could grant the issue of a patent. However, neither the cells in the plant nor the seeds from that plant fall within the same class as a genetically altered egg. The genetically altered egg, was “cognizable as ‘[a] substance or preparation formed by combination or mixture of various ingredients’,”¹⁸⁹ that were assembled by the hands of man. That is, with the fertilized genetically altered murine egg, the various ingredients comprising the egg were collected and compounded by a human being.¹⁹⁰ Neither the cells in the plant nor the seeds produced by that plant are “substance[s] or preparation[s] formed by combination or mixture of various ingredients,”¹⁹¹ rather both the cells in the plant and the seeds of that plant are produced by processes that “obey the laws of nature.”¹⁹² Even if there is human intervention in the reproduction of the cells within the plant and the production of the seeds on the plant, that human intervention “does not alter the actual rules of reproduction, which continues to obey the laws of nature.”¹⁹³ The reasoning behind this statement is simple, and easily derived by study of the steps required to produce a fully mature plant the cells of which contain the transgene.

186. *See id.* at 81.

187. *See* Harvard Coll. v. Canada (Comm’r of Patents), [2002] S.C.C. 76, Part B (1).

188. *Id.* at ¶ 162.

189. *Id.*

190. Whether this is a sufficient condition for patentability is an issue that is best left to the side.

191. *Id.* (citations omitted). From the discussion presented *infra*, it is possible to conclude that the first transformed single cell, which constitutes the progenitor cell, might fall within the composition of matter class as the “genetically altered egg” considered by the Supreme Court of Canada. *Id.* at ¶¶ 161-162. However, under the laws of nature rule, it is possible to conclude that neither the genetically altered egg nor the progenitor plant cell is patentable subject matter. Pioneer Hi-Bred Ltd. v. Canada (Comm’r of Patents), [1989] 1 S.C.R. 1623, 1633.

192. *Id.*

193. *Id.* at 1632-33.

B. *The “Laws of Nature” Rule Comes to the Rescue*

The line-drawing exercise to distinguish subject matter for which a patent may issue from that subject matter for which the patent may not issue results in confusion and arbitrary decisions. The line-drawing exercise is the result of a lack of understanding of the invention and the process of intellectual development that gave rise to that invention. To decide patent cases based merely upon a line-drawing exercise is to reveal an ignorance about the scientific principles that gave rise to the invention and how those principles must inform the application of the law. One of the central hypotheses of this work is that the “laws of nature” rule informs whether a genetically manipulated organism is an invention. If the genetically manipulated organism is an invention, then it may be subject matter for which a patent may issue.

1. *Constructing the Single, Transfected, Progenitor Cell*

To understand where and how the “laws of nature” rule is applicable to genetically manipulated plants, it is first necessary to examine, in rough terms, the process by which genetically manipulated plants are produced. The steps to produce a fully mature plant, the cells of which contain a transgene, are as follows: (1) obtain and modify, for expression in dicotyledonous plants, an EPSPS coding sequence; (2) ligate the EPSPS coding sequence to a strong promoter, which creates a chimeric gene; (3) insert the chimeric gene into a plant transformation vector, such as *Agrobacterium tumefaciens*; (4) use the natural propensity of the *Agrobacterium tumefaciens* to invade plant cells to insert the chimeric gene into the plant cell, thus creating a single transformed plant cell; (5) multiply the single transformed plant cell, using standard plant cell culture techniques, to form a callous; (6) and use standard culture techniques to cause the callous to generate a plant.¹⁹⁴ Each of the aforementioned six steps are disclosed in the specification of Canadian Patent Number 1,313,830.¹⁹⁵

The chimeric gene identified in step (2) *supra* consists of three parts.¹⁹⁶ The “promoter sequence” instructs the biochemical machinery of the cell to initi-

194. Can. Patent No. 1,313,830, at [3-4] (filed Aug. 6, 1986).

195. *Id.*

196. *Id.* at [68]. The specification of the patent discloses:

[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

ate the production of a protein molecule.¹⁹⁷ The coding sequence instructs the biochemical machinery as to what is that protein molecule.¹⁹⁸ The 3' non-translated region instructs the biochemical machinery when the construction of the protein molecule is complete.

The promoter sequence instructs the RNA polymerase as to where to start the transcription of the transgene.¹⁹⁹ The promoter must work in the plant cell to initiate the transcription of the EPSP synthase coding sequence. If the promoter sequence is defective or does not normally function in the target plant cell, then the protein molecule for which the transgene coding sequence encodes will not be produced.²⁰⁰ The EPSP synthase encoding sequence²⁰¹ was described, in the patent at issue, as being derived as follows: "[t]he sequence encoding a EPSPS polypeptide can be obtained from numerous sources," including "bacteria, fungi and plants."²⁰² It is reasonable, therefore, to assert that the promoter sequence may be derived from the plant variety into which the transgene is to be inserted.

The plant cell will not properly translate the EPSP synthase protein unless the chimeric gene contains a 3' non-translated region.²⁰³ It is easiest to

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. *Id.*

197. See Christopher K. Matthews & K. E. van Holde, BIOCHEMISTRY 917-24 (Benjamin/Cummings Publishing Company, Inc.) (1990).

198. See *id.* (explaining the process of RNA transcription).

199. See *id.*

200. Can. Patent No. 1,313,830, at [5-6] (filed Aug. 6, 1986). The promoter sequences were described in the patent as follows:

Promoters which are known or found to cause transcription of the EPSPS gene in plant cells can be used in the present invention. Such promoters may be obtained from plants or viruses and include, but are not necessarily limited to, the 35S and 19S promoters of cauliflower mosaic virus and promoters isolated from plant genes such as EPSPS, ssRUBISCO genes and promoters obtained from T-DNA genes of *Agrobacterium tumefaciens* such as nopaline and mannopine synthases. The particular promoter selected should be capable of causing sufficient expression to result in the production of an effective amount of EPSPS polypeptide to render the plant cells and plants regenerated therefrom substantially resistant to glyphosate. *Id.*

201. The EPSP synthase coding sequence instructs the biochemical machinery of the plant to generate the EPSP synthase polypeptide.

202. Can. Patent No. 1,313,830, at [8] (filed Aug. 6, 1986).

203. The 3' non-translated region was described as:

think of the 3' non-translated region as tying off the end of the transcript mRNA, which encodes the EPSP synthase, and causing the mRNA to be clipped free from the transgene.²⁰⁴ The biochemical machinery of the plant cell then uses the mRNA transcript to express the EPSP synthase polypeptide.²⁰⁵

The method for transfection of the single cell by insertion of the transgene encoding the EPSPS polypeptide was not disclosed in detail in the specification of the patent.²⁰⁶ When the patent application was drafted, Monsanto evidently understood that the technology for inserting DNA into cells was already well developed.²⁰⁷ Monsanto chose to use *Agrobacterium tumefaciens* as the

The 3' non-translated region contains a polyadenylation signal which functions in plants to cause the addition of polyadenylate nucleotides to the 3' end of the EPSPS mRNA. In cases where the EPSPS sequence is derived from a plant source one can use the 3' non-translated region naturally associated with the particular EPSPS gene. Examples of other suitable 3' regions are the 3' transcribed, non-translated regions containing the polyadenylation signal of the nopaline synthase (NOS) gene of the *Agrobacterium* tumor-inducing (Ti) plasmid or the conglycinin (7S) storage protein gene.

Id. at [9]. Note the language: "where the EPSP sequence is derived from a plant source...." This is indicative that the plants typically express EPSP synthase polypeptide.

204. See Matthews, *supra* note 197, at 923-25. The 3' non-translated region functions to cause the addition of multiple adenine nucleotides on the 3' end of the mRNA encoding the EPSP synthase polypeptide. Initially, the adenine-rich region is transcribed to give a series of weak adenine-uracil pairings with the template DNA. Uracil is a nucleotide found in RNA. Once a "hairpin" termination has been formed by the association of guanine and cytosine nucleotides at the end of the mRNA, then the weak adenine-uracil bonds dissociate, releasing the transcript mRNA.

205. See *id.* at 925.

206. The method of transfection was described as:

The EPSPS gene of the present invention is inserted into the genome of a plant by any suitable method. Suitable plant transformation vectors include those derived from a Ti plasmid of *Agrobacterium tumefaciens* as well as those described in, e.g. Herrera-Estrella 1983, Bevan 1983, Klee 1985 and EPO publication 120,516 (Schilperoort et al.). In addition to plant transformation vectors derived from the Ti or root-inducing (Ri) plasmids of *Agrobacterium*, alternative methods can be used to insert the EPSPS genes of this invention into plant cells. Such methods may involve, for example, liposomes, electroporation, and the use of viruses or pollen as vectors.

Can. Patent No. 1,313,830, at [9-10] (filed Aug. 6, 1986).

207. The parent patent application that eventually issued as U.S. Patent No. 4,940,835 was filed on August 7, 1985. By the date of the filing of the application, the process for inserting DNA into bacteria and plant cells was already well established. See generally Luca Comai, Louvmina C. Sen and David M. Stalker, *An Altered aroA Gene Product Confers Resistance to the Herbicide Glyphosate*, 221 SCI. 370 (1983) (discussing the insertion of wild-type and mutant aroA gene loci into *Salmonella typhimurium* and *Escherichia coli* bacteria); Luis Herrera-Estrella, Ann Depicker, Marc Van Montagu, & Jeff Schell, *Expression of Chimeric Genes Transferred into Plant Cells Using a Ti-Plasmid-Derived Vector*, 303 NATURE 209 (1983) (discussing the insertion of a

vector for inserting the transgene encoding the EPSPS polypeptide into the target plant cells.²⁰⁸ Specifically, Monsanto disclosed the production of glyphosate-resistant petunia cells using *Agrobacterium tumefaciens*,²⁰⁹ and glyphosate-resistant oil seed rape cells using *Agrobacterium tumefaciens*.²¹⁰ Of particular interest in the disclosure of the production of glyphosate-resistant oil seed rape cells is that the transgene encoding the EPSP synthase coding sequence was obtained from oil-seed rape plant cells.²¹¹ In Canadian Patent Letters Number 1,313,830, Monsanto effectively admits that the biochemical pathway that produces the EPSP synthase polypeptide as well as the biochemical pathway that engages the function of the EPSP synthase polypeptide exist in the oil-seed rape plant.²¹² Reasonably, if neither pathway existed, then it would not be possible to obtain the transgene encoding the EPSPS sequence “from rape plant such as *Brassica napus*.”²¹³ The biochemical pathway is a physical manifestation of the

gene encoding octopine polypeptide and the chloramphenicol acetyltransferase gene into tobacco cells using *Agrobacterium tumefaciens*).

208. Can. Patent No. 1,313,830, at [9] (filed Aug. 6, 1986).

209. The disclosure of the production of the petunia cells was as follows:

Leaf discs with diameters of 6 mm ... were taken from surface-sterilized petunia leaves. They were cultivated on MS104 agar medium for 2 days to promote partial cell wall formation at the wound surfaces. They were then submerged in a culture of *A. tumefaciens* cells containing both pMON546 and GV3111-SE which had been grown overnight in Luria broth at 28°C, and shaken gently.

Can. Patent No. 1,313,830, at [33] (filed Aug. 6, 1986).

210. The production of oil seed rape cells was disclosed as follows:

A plant transformation vector similar to pMON546 is prepared following the procedure outlined in Example 1 except that the CTP/EPSPS coding sequence is obtained from rape plant such as *Brassica napus* (see Example 17).

The four terminal intervals from *B. napus* plants (growth chamber grown in soil) are surface sterilized in sodium hypochlorite and cut into 5 mm sections. The upper surface of each piece is inoculated with an overnight liquid culture of *A. tumefaciens* containing the above described transformation vector and helper plasmid pTiT37-SE and incubated for 2 to 3 days on nurse culture plates containing 1/10 MS medium with 1 mg/l BA. The ex-plants are then transferred to MS medium containing 1 mg/l BA, 500 mg/l carbenicillin and 100 mg/l kanamycin. After 3 to 6 weeks, leaf tissue from developed transgenic shoots is transferred to the same medium, but with 0.5 mM glyphosate, rather than kanamycin, to test for tolerance.

Can. Patent No. 1,313,830, at [41] (filed Aug. 6, 1986).

211. The production of oil seed rape cells was disclosed as follows: “[a] plant transformation vector . . . is prepared following [a previously defined] procedure . . . except that the CTP/EPSPS coding sequence is obtained from rape plant such as *Brassica napus*.” *Id.*

212. *See id.* at [14-17].

213. *Id.* at [17].

“laws of nature” relating to the production and development of EPSP synthase polypeptide.²¹⁴

Indeed, of the eight transfections disclosed by example in the specification of Canadian Patent Number 1,313,830, all were transfected using the naturally occurring property of *Agrobacterium tumefaciens* to insert the Ti-plasmid into the plant cell.²¹⁵ Specifically: 1) petunia leaf discs²¹⁶ were “submerged in a culture of *A. tumefaciens* cells containing both pMON546 and GV3111-SE”;²¹⁷ 2) tobacco (*N. tabacum*) leaf discs were “treated as described above with *A. tumefaciens* cells containing pMON546 . . . and helper plasmid GV3111-SE . . .”;²¹⁸ 3) *Glycine canescens* pieces “were infected with the *A. tumefaciens* strain containing the chimeric EPSPS . . . gene”;²¹⁹ 4) hypocotyls and cotyledons were “innoculated [sic] with a tumorous strain of *A. tumefaciens* containing . . .” a “plant transformation vector similar to pMON546 . . . [that was] prepared following the general procedure outlined in Example 1 except that the CTP/EPSPS coding sequence . . . [was] obtained from . . . [cotton]” plants²²⁰; 5) terminal intervals from *Brassica napus* were “inoculated with an overnight liquid culture of *A. tumefaciens* containing the above described transformation vector and helper plasmid pTiT37-SE . . .”;²²¹ 6) flax hypocotyls were “inoculated with *A. tumefaciens* cells containing . . .” a “plant transformation vector similar to pMON546 . . . [that was] prepared following the procedure outlined in Examples 1, and 14-17 except that the CTP/EPSPS coding sequence is obtained from flax”;²²² 7) potato stem internodes were inoculated with “*Agrobacterium* carrying binary vector pMON542 and helper plasmid pTiT37-SE”;²²³ 8) sunflower seed-

214. See *id.* at [41].

215. See *id.*

216. Leaf discs are used because the cells that are injured on the circumference of the leaf disc are those most susceptible to transfection with *Agrobacterium tumefaciens*. Further, those same cells are also the site of regeneration resulting from rapid cell division and induction of shoots. See R. B. Horsch, ET AL., *A Simple and General Method for Transferring Genes into Plants*, 227 SCI. 1229, 1230 (1985).

217. Can. Patent No. 1,313,830, at [33] (filed Aug. 6, 1986).

218. *Id.*

219. *Id.* at [34].

220. *Id.* at [40-41]. As is the case with the oil-seed rape plant cells, Monsanto admits that the biochemical pathway that produces the EPSP synthase polypeptide as well as the biochemical pathway that engages the function of the EP EPSP synthase SPS polypeptide exist in the cotton plant.

221. *Id.* at [41].

222. *Id.* at [42]. As is the case with the oil-seed rape plant cells, Monsanto effectively admits that the biochemical pathway that produces the EPSPS polypeptide as well as the biochemical pathway that engages the function of the EPSPS polypeptide exist in the flax plant.

223. *Id.* at [48].

lings were “inoculated with overnight cultures of *Agrobacterium* strains carrying pTiB6S3-SE.”²²⁴

While Monsanto claims that “alternative methods can be used to insert the EPSPS genes . . . into plant cells,”²²⁵ Monsanto used only *Agrobacterium tumefaciens* for the transfection process. It is of considerable import to recognize that in no case were the seeds of the various types of plants inoculated with the transformation vector, nor were the cells in the fully mature plant inoculated with the transformation vector.²²⁶ In fact, in each of the types of plant cells transformed, Monsanto identifies that glyphosate-resistant *cells* were produced. Specifically, Monsanto describes the transformation product as: 1) glyphosate-resistant petunia cells in Example 2;²²⁷ 2) glyphosate-resistant tobacco cells in Example 3;²²⁸ 3) glyphosate-resistant soybean cells in Example 4;²²⁹ 4) glyphosate-resistant cotton cells;²³⁰ 5) glyphosate-resistant oil-seed rape cells;²³¹ 6) glyphosate-resistant flax cells;²³² 7) glyphosate-resistant potato cells;²³³ and 8) glyphosate-resistant sunflower cells.²³⁴ Indeed, had Monsanto actually transfected any seed with the gene encoding the EPSPS polypeptide they would have both disclosed such a transfection in the specification of the patent and would have claimed the method for transfecting a seed. Further, had Monsanto actually transfected all of the cells of a fully mature plant with the gene encoding the EPSPS polypeptide then that, also, would have been disclosed in the specification of the patent. Monsanto did not transfect either a seed or all of the cells of a

224. *Id.* at [49].

225. *Id.* at [10].

226. Also, nowhere in the patent does Monsanto indicate that anything other than the chimeric gene is inserted into the single plant cell. *See id.*

227. *Id.* at [33-34].

228. *Id.* at [34]. In the case of tobacco, Monsanto clearly identified that neither the seeds nor the cells in the fully mature plant were transformed, but rather the excised cells were transformed. Specifically, the language used by Monsanto to support this assertion is as follows: “[t]he *cells* transformed with the CaMV/EPSPS gene created substantial amounts of callus tissue . . . whereas the *cells* which did not contain that gene did not create any detectable callus tissue” [emphasis added]. Also, Monsanto was careful to identify that cells that contained the transgene yielded “callus *tissue*” and those that did not contain the transgene did not create “callus *tissue*” [emphasis added]. This means *tissue* was generated from the transformed *cells*, rather than *plants* or *seeds* generated from transformed *cells*.

229. *Id.*

230. *Id.* at [40].

231. *Id.* at [41].

232. *Id.* at [42].

233. *Id.* at [48].

234. *Id.* at [48-50].

fully mature plant.²³⁵ Leaf disks were taken from a single plant of a particular variety. These disks were treated and the fully mature plants were regenerated from a single cell contained in the disk. Leaf disks were used in the transfection process because “leaves provide a source of genetically uniform cells that have the capacity to regenerate whole plants when simple manipulations of the tissue culture are performed.”²³⁶ Monsanto transfected only single cells from a particular variety of plant. At most, then, only the single transfected cell was an article of “manufacture” or a “composition of matter.”

2. *Plant Cells and Plants Are Not “Lower Life Forms”*

Monsanto recognized that the technology for regenerating a fully mature plant from a single cell, which contained the transgene encoding the EPSPS polypeptide, existed at the time that the claimed subject matter was produced and that that technology was well known to a person of ordinary skill in the art.²³⁷ Specifically, Monsanto stated that:

glyphosate-resistant plant cells that have been transformed with EPSPS genes can be regenerated into differentiated plants using standard nutrient media supplemented with selected shoot-inducing or root-inducing hormones, using methods described in PCT WO84/02920 or other methods known to those skilled in the art.²³⁸

The disclosure of the specification illuminates the methods for producing fully mature differentiated plants from the glyphosate-resistant plant cells. Specifically, Monsanto stated that: 1) “[t]ransformed petunia plants were produced by regeneration from the transformed leaf disks ... by the procedure described in Horsch et al [sic] 1985”;²³⁹ 2) “[t]ransformed ... plants grow from the explants” of tomato seedlings;²⁴⁰ 3) “[t]ransformed tobacco plants ... were produced and grown by the method described in Example 4, substituting transformed tobacco

235. *See id.* at [10] (stating that “glyphosate-resistant plant cells that have been transformed with EPSPS genes can be regenerated into differentiated plants....”)

236. Horsch, *supra* note 216, at 1230.

237. Can. Patent No. 1,313,830, at [10] (filed Aug. 6, 1986).

238. *Id.*

239. *Id.* at [50]. The reference to “Horsch et al. (1985)” refers to Horsch, *supra* note 216, at 1229.

240. Can. Patent No. 1,313,830, at [53] (filed Aug. 6, 1986). Monsanto states that hypocotyls and cotyledons are excised from seedlings of VF36 tomato and “infected with the *A. tumefaciens* vector, containing the chimeric EPSPS gene described in Example 2, by immersing for about 30 seconds in a culture of *A. tumefaciens* containing the chimeric EPSP synthase gene.... [E]xplants are obtained by cutting sections from the seedlings. The explants are blotted dry and incubated as described previously in Example 2.... [and] [t]ransformed tomato plants grow from the explants.”

leaf discs for transformed petunia leaf discs.”²⁴¹ In those cases where leaf discs were used in the process of regenerating fully mature plants, it was recognized by Horsch that only a single transformed cell, from the circumference of the leaf disc, would produce a single fully mature plant.²⁴² This is because those injured cells on the circumference of the leaf disc are susceptible to transfection with *Agrobacterium tumefaciens*. Further, those cells are also the site of plant regeneration resulting from rapid cell division and induction of shoots.²⁴³ According to Horsch, the use of a leaf disc in the transfection process “results in effective targeting of transformation and regeneration to the same set of cells at the edge of the disk.”²⁴⁴ In particular, Horsch stated that “a meristem is thought to originate from a single cell and subsequent shoot regeneration to represent a clonal process” although the clonal process might not occur in all cases.²⁴⁵

Nowhere, in either the specification or the claims, does Monsanto disclose that the transgene is inserted into each cell of an existing plant. Also, nowhere does Monsanto disclose that cells, which contain the transgene, are inserted into the plant. In fact, Monsanto recognized that it is currently impossible to insert either a transgene or a cell containing the transgene into an existing plant.²⁴⁶ Therefore, the plant cannot be either a “manufacture” or a “composition of matter” within the meaning of the Patent Act.²⁴⁷ A fully mature plant constituted of cells that contain a transgene, is necessarily regenerated from a single transformed progenitor plant cell. Indeed, Monsanto has admitted that the plant is regenerated from the single transformed plant cell using well known cell culture techniques.²⁴⁸ Beyond inserting the transgene into the single cell, Monsanto did nothing that was new in producing the plant. Monsanto did not alter any biochemical pathway in the plant cells. Although a new piece of DNA was inserted

241. *Id.* at [54].

242. *See* Horsch, *supra* note 216, at 1230.

243. *See id.*

244. *Id.*

245. *Id.*

246. Currently, the only means of obtaining a mature plant containing a transgene is to grow that plant from either a single transfected progenitor cell or from a plant seed harvested from a plant containing the transgene. Had Monsanto identified either of these methods, the company could have filed an application for a patent on the process.

247. *See* Patent Act, R.S.C., ch. P-4, § 2 (1985) (Can.).

248. *See* Can. Patent No. 1,313,830, at [10] (filed Aug. 6, 1986) (stating that “glyphosate-resistant plant cells that have been transformed with EPSPS genes can be regenerated into differentiated plants ... using methods described in PCT WO84/02920 or other methods known to those skilled in the art”); *see* Horsch, *supra* note 216, at 1229 (describing one method for regenerating transformed plant cells).

into the plant cell, the DNA did nothing to alter the manner in which the existing biochemical pathways function.²⁴⁹

While it is true that the gene encoding the EPSP synthase polypeptide might have increased the amount of EPSP synthase polypeptide produced in the plant,²⁵⁰ the plant already possessed a pathway that produced the EPSP synthase polypeptide and the plant cell already had a fully functioning biochemical pathway in which the existing EPSP synthase polypeptide functioned. The transgene represents either new information provided to the machinery of the cell or the same information in greater quantity. The transgene is not a new biochemical pathway, or new machinery, because the transgene is only DNA and the biochemical pathways operate based only upon proteins and non-DNA substrates. Adding copies of the gene encoding EPSPS did not cause the biochemical pathways in the cell, by which the EPSP synthase polypeptide is either expressed or engaged, to be altered.²⁵¹

Even if the transgene causes the expression of a mutant form of the EPSP synthase polypeptide, the result of the present analysis is not altered. This is because the biochemical pathways, in the cells, by which the mutant EPSP synthase polypeptide is either expressed or engaged are the same as the biochemical pathways by which the native EPSP synthase polypeptide is either expressed or engaged.²⁵² The biochemical pathways are not altered by the insertion of the transgene, only the result of the operation of those existing pathways is altered. No new biochemical pathways were created, and none were destroyed. The point is, that adding the transgene that encodes the EPSP synthase polypeptide did nothing to the biochemical pathways in the cell that either generate or utilize EPSP synthase.²⁵³

The addition of the gene encoding the EPSP synthase polypeptide also did not modify the manner in which the first cell multiplied. The gene did not cause the multiplication of the cell to function necessarily faster nor necessarily slower.²⁵⁴ The collective of progeny cells, constituting the entire plant, appeared to be no different than the collective of cells, constituting the entire plant, which lacked the gene encoding the EPSP synthase polypeptide. Aside from causing a drain on the resources of the plant, due to the production of multiple copies of the EPSP synthase polypeptide or the production of mutant EPSP synthase, the

249. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

250. *Id.* The mutant gene encoding EPSP synthase can also produce a mutant form of EPSP synthase not susceptible to inhibition by glyphosate.

251. See *id.*

252. See U.S. Patent No. 4,940,835 at 3 (filed July 7, 1986).

253. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

254. See Transcript of Oral Arguments at 4, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

transgene neither introduced nor depreciated any biochemical pathway responsible for the multiplication of the progenitor cells and growth of the plant.²⁵⁵

3. *The Derivation of the “Laws of Nature” Rule in the Case of Genetically Manipulated Plants*

During the process of multiplying cells, which yields a plant, the progeny cells take on a spectrum of shapes, sizes, and functions. Some progeny cells become root cells with the attendant function. Some progeny cells become leaf cells with the attendant function. The leaf cells are perceptively different, in both form and function, from the root cells. The leaf and root cells are different in form and function from those progeny cells that become seeds. None of these cells possess the same full set of characteristics and functions. Therefore, the collective of cells constituting a plant cannot be a lower-life form.²⁵⁶

Even though there is human intervention in producing a plant comprised of the transgene, that intervention did nothing to “alter the actual rules of reproduction, which continues to obey the laws of nature.”²⁵⁷ At the point where the single transfected progenitor cell starts to develop either root cells or stem cells, the “Laws of Nature” rule becomes involved.²⁵⁸ Indeed, once the single transfected progenitor cell divides such that the progeny cells are distinguishable from the progenitor cell, then the “Laws of Nature” rule applies.²⁵⁹

Monsanto made it abundantly clear, in both Horsch, et al., and in the disclosure of Canadian Letter Patent Number 1,313,830, that single cells were transfected using *Agrobacterium tumefaciens* and mature plants were regenerated from those transfected single plant cells.²⁶⁰ The transfected single progenitor plant cells, from which the fully mature plants were regenerated, did not originate from cell lines. Plant cell lines were not produced from the single transfected plant cells; rather, fully mature plants were regenerated.²⁶¹ Cells from plant cell lines were not used in the transfection process, but, a single plant cell on the circumference of a leaf disk was transfected and a plant was regenerated from that

255. Our analysis depends upon whether the presence of a gene modifies any biochemical pathway.

256. See Re Application of Abitibi Co., [1982] 62 C.P.R. 2d 81, 89.

257. Pioneer Hi-Bred Ltd. v. Canada (Comm’r of Patents), [1989] S.C.R. 1623, 1632-33.

258. See Horsch, *supra* note 216, at 1229.

259. See *id.*

260. See Can. Patent No. 1,313,830, at [9-10] (filed Aug. 6, 1986); Horsch, *supra* note 216, at 1229.

261. U.S. Patent No. 4,940,835, at [33] (filed July 7, 1986) (claiming a “glyphosate-resistant dicotyledonous plant ... has been regenerated from a glyphosate-resistant plant cell”).

transfected cell.²⁶² Also, cells from a plant cell line were not transfected, however, a single cell from a single plant was transfected. Monsanto never claimed that a cell line was either used in or produced from the transfection process. No mention was ever made by Horsch, or Monsanto, that cell lines were involved in the development of the transgenic process. The method reported in 1985 by Horsch, et al., to which reference was made in Canadian Patent Number 1,313,830, specifically stated that leaf disks were used and that single cells on the circumference of the leaf disks were the situs of both the transfection and regeneration.²⁶³ Therefore, to claim that the progenitor cell constructed by Monsanto is a “cell line” is in direct contradiction to the position assumed by Monsanto since 1985 regarding those particular progenitor cells.²⁶⁴

The biochemical pathways within the cell are the physical manifestation of the “rules of nature” by which the cell is produced, continues to function, and reproduces to yield progeny cells.²⁶⁵ No magic functions to bring the cell into existence, and no magic is operational by which the cell functions. A mystical, unseen, and unknown force is not required for the cell to exist and reproduce. All the machinery and information required for the cell to function properly is contained within the biochemical pathways and genome, respectively. To change the “rules of nature” by which the cell functions requires a modification of the machinery of the cell: that is, the biochemical pathways must be altered.²⁶⁶ The reproductive function of the cell is not different simply because the cell contains the transgene encoding the EPSP synthase polypeptide. To alter the existing rules of nature the biochemical pathways within the plant cell must be modified. The modification may take the form of either deleting certain existing steps or inserting new steps into the already existing pathway, or completely deleting or inserting an entire pathway. Such operations would be complex, require that multiple genes be eliminated or replaced, and would most likely yield a cell that could not reproduce even if it did survive.²⁶⁷

By inserting the chimeric gene to express a mutant form of EPSP synthase, Monsanto did nothing to the cell to change the rules by which that cell reproduced and eventually yielded a fully-mature plant. The reproduction of the

262. It is difficult, if not impossible, to identify precisely which cell in a leaf disc will successfully generate a fully mature plant. Furthermore, it is equally difficult to identify precisely which cell actually generated the plant.

263. See Horsch, *supra* note 216, at 1229.

264. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986); see Horsch *supra* note 216, at 1229.

265. See *Pioneer Hi-Bred Ltd. v. Canada (Comm’r of Patents)*, [1989] 1 S.C.R. 1623, 1633.

266. See *id.*

267. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

first transfected plant cell continued to obey the rules of nature that existed in the un-transformed plant cell. The Supreme Court of Canada has held that inventions that do nothing more than continue to obey the rules of nature are considered discoveries and are not patentable.²⁶⁸ Since the single transfected progenitor cell developed by Monsanto does nothing more than obey the rules of nature during the reproductive process, the progeny cells are mere discoveries and are not patentable.²⁶⁹

Of course, there is the issue that the transgene encoding the EPSP synthase polypeptide confers glyphosate resistance on the cells of the plant.²⁷⁰ Plant cells normally have biochemical pathways by which EPSP synthase is expressed and plant cells also normally have biochemical pathways by which the function of EPSP synthase is engaged.²⁷¹ If the plant lacked either of these pathways, it would not survive even without the application of glyphosate. Inserting copies of the transgene, which encodes EPSP synthase polypeptide, does nothing more than enhance an already existing biochemical pathway by making more EPSP synthase polypeptide available to the cell, or by producing a mutant form of the EPSP synthase polypeptide. The gene encoding the EPSP synthase polypeptide did not create a new biochemical pathway in the cell. The transgene only made the existing pathway produce more EPSP synthase polypeptide or produce mutant EPSP synthase polypeptide. The rules of nature by which the cell functioned before the transgene was inserted into the cell are the same as the rules of nature by which the cell functioned after the transgene was inserted. Thus, Monsanto did not change the rules by which the cell existed and reproduced by insertion of the transgene.²⁷²

Once the first single transformed plant cell is formed, no inventive steps are taken to generate the plant. In fact, the biochemical operations occurring within the single transformed plant cell between the transformation with *Agrobacterium tumefaciens* and the fully mature plant are the direct consequence of naturally occurring rules.²⁷³ Both the gene encoding the EPSPS polypeptide and the EPSPS polypeptide existed in all of the types of plant cells transformed using *Agrobacterium tumefaciens* and disclosed in the specification of Canadian Patent Number 1,313,830.²⁷⁴ The evidence to support this assertion is found in the

268. See Pioneer Hi-Bred Ltd., [1989] 1 S.C.R. at 1632-1633.

269. See Can. Patent No. 1,313,830 at [7] (filed Aug. 6, 1986).

270. The overall success of this analysis does not depend upon the genetic manipulation technique involving the transgene that encodes the EPSP synthase polypeptide, but applies to any case in which a transgene is inserted into a cell.

271. See U.S. Patent No. 4,940,835 at [3] (filed July 7, 1986).

272. See *id.*

273. *Id.* at column 3.

274. See Can. Patent No. 1,313,830, at [5] (filed Aug. 6, 1986).

specification of the patent: 1) purified EPSPS polypeptide was extracted from the MP4-G petunia cell line;²⁷⁵ 2) glyphosate-resistant petunia cells were constructed using *Agrobacterium tumefaciens* containing the plasmid pMON546,²⁷⁶ resulting in the insertion of the CaMV 35S/EPSPS transgene into the petunia cell;²⁷⁷ 3) glyphosate-resistant tobacco cells and glyphosate-resistant soybean cells were constructed using *Agrobacterium tumefaciens* containing the plasmid pMON546, resulting in the insertion of the CaMV 35S/EPSPS gene into the target cells;²⁷⁸ 4) glyphosate-resistant cotton cells were constructed using *Agrobacterium tumefaciens* containing a plasmid similar to pMON546, but containing a gene encoding the EPSP synthase polypeptide that was obtained from cotton;²⁷⁹ 5) glyphosate-resistant oil-seed rape cells were constructed using *Agrobacterium tumefaciens* containing a plasmid “similar to pMON546, ... [but] prepared following the procedure outlined ... [elsewhere in the specification] except that the CTP/EPSPS coding sequence is obtained from rape plant such as *Brassica napus*;²⁸⁰ 6) glyphosate-resistant flax cells were constructed using *Agrobacterium tumefaciens* containing a plasmid similar to pMON546, but containing a

275. See *id.* at [13].

276. Plasmid pMON546 contains the following:

(1) the CaMV 35S/EPSPS gene; (2) a selectable marker gene for kanamycin resistance (Kan^R); (3) a nopaline synthase (NOS) gene as a scorable marker; and (4) a right T-DNA border, which effectively caused the entire plasmid to be treated as a “transfer DNA” (T-DNA) region by *A. tumefaciens* cells. This plasmid was inserted into *A. tumefaciens* cells which contained a helper plasmid, pGV3111SE. The helper plasmid encodes certain enzymes which are necessary to cause DNA from pMON546 to be inserted into plant cell chromosomes.

Id. at [32]. Neither the plasmid pMON546 nor the helper plasmid pGV3111SE contained the genes necessary to construct an entire biochemical pathway within the target cell. The plasmid functioned only as a vehicle for transporting the gene encoding the EPSP synthase polypeptide into the target cell.

277. *Id.*

278. *Id.* at [34]. Since neither the plasmid pMON546 nor the plasmid pGV3111SE contained the information to insert an entire biochemical pathway into the target cell, both the tobacco cells and the soybean cells contained biochemical pathways to express the EPSP synthase polypeptide and to engage the function of the polypeptide.

279. *Id.* at [40-41]. It is logical that the cotton cells must contain the biochemical pathways to both express the EPSP synthase polypeptide and to engage the function of the polypeptide. If the cotton cells did not contain both of these biochemical pathways before transformation with *Agrobacterium tumefaciens* containing the transfection plasmid, then it would not be possible to obtain the gene encoding the EPSP synthase polypeptide from the cotton cells.

280. *Id.* at [41]. It is logical that oil-seed rape cells must contain the biochemical pathways to both express the EPSP synthase polypeptide and to engage the function of the polypeptide. If the oil-seed rape cells did not contain both of these biochemical pathways before transformation with *Agrobacterium tumefaciens* containing the transfection plasmid, it would not be possible to obtain the gene encoding the EPSP synthase polypeptide from the oil-seed rape cells.

gene encoding the EPSP synthase polypeptide that was obtained from flax.²⁸¹ Because both the gene and the polypeptide existed in the plant cells before transformation using *Agrobacterium tumefaciens*, then two biochemical pathways necessarily existed in the plant cell before transformation using *Agrobacterium tumefaciens*: the biochemical pathways existed by which the EPSP synthase polypeptide was expressed within the plant cell; and the biochemical pathways existed by which the function of the EPSP synthase polypeptide was engaged by the plant cell.²⁸²

While the only human intervention, between the single transformed cell and the fully mature plant, was to provide a set of environments conducive to the multiplication of the cell, no human intervention occurred that altered or modified the set of naturally occurring rules. The only thing that was created, as either a “manufacture” or a “composition of matter,” was the first single transformed plant cell. As such, Mr. Schmeiser conceded that, like the fertilized genetically altered oncomouse egg, the transformed progenitor plant cell might be patentable subject matter.²⁸³ However, because no inventive human operations were necessary to cause the single transformed plant cell to multiply, the collective of cells, which exist beyond the first single transformed plant cell, cannot be claimed nor can such cells be within the boundaries of the patent rights conferred upon the patentee by Canadian Patent Number 1,313,830.

C. Analysis of the “Laws of Nature” Rule

A cell into which a transgene has, or several transgenes have, been inserted by genetic manipulation technology is not subject matter for which a patent may be issued because the resulting cell is not an invention within the interpretation of 35 U.S.C. § 101; rather, the cell is nothing more than a discovery of the phenomena of nature.²⁸⁴ The law is well settled that a phenomenon, or rule, of nature is not patentable subject matter.²⁸⁵ In *Funk Bros. Seed Co.*, the U.S. Supreme Court stated that:

We have here only product claims. Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the

281. *Id.* at [42].

282. *See id.* at [3-4].

283. *See* Transcript of Oral Argument at 5, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

284. *See* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

285. *See id.* at 303.

heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end. The Circuit Court of Appeals thought that Bond did much more than discover a law of nature, since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that the aggregation of species fell short of invention within the meaning of the patent statutes.²⁸⁶

In reaching its conclusion, the Court reasoned that:

Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.²⁸⁷

The rule articulated in *Funk Bros. Seed Co.* is that: “a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery.”²⁸⁸ In finding the underlying patent invalid, the Court reasoned that:

[O]nce nature’s secret of the non-inhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of

286. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130-31 (1948) (internal citations omitted).

287. *Id.* at 131.

288. *Id.* at 131-32 (citing *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 90-91 (1941) (citations omitted); Patent Act, 35 U.S.C. § 31, (2005); R.S. § 4886).

the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed.²⁸⁹

Even if a product is “new and useful” and “satisf[ies] the requirements of invention or discovery,”²⁹⁰ that invention may still not be patentable if it constitutes the mere “discovery of the phenomena of nature.”²⁹¹

While concurring with the majority opinion, Justice Frankfurter gave what might be a more reasonable explanation of why the subject matter was not patentable.²⁹² He stated that, to find the composite culture of bacteria patentable:

[w]ould require, for instance in the field of alloys, that if one discovered a particular mixture of metals, which when alloyed had some particular desirable properties, he could patent not merely this particular mixture but the idea of alloying metals for this purpose, and thus exclude everyone else from contriving some other combination of metals which, when alloyed, had the same desirable properties. In patenting an alloy, I assume that both the qualities of the product and its specific composition would need to be specified. The strains that Bond put together in the product which he patented can be specified only by the properties of the mixture.²⁹³

Justice Frankfurter, however, disagreed with the bases of the opinion of the Court.²⁹⁴ Regarding the “law of nature” rule, Justice Frankfurter stated, “the suggestion that ‘if there is to be an invention from such a discovery, it must come from the application of the law of nature to a new and useful end’ may readily validate Bond’s claim.”²⁹⁵ Justice Frankfurter reasoned that the composite culture did have a “new and useful end,”²⁹⁶ but it was not patentable because “the strains by which Bond secured compatibility are not identified and are identifiable only by their compatibility.”²⁹⁷ In rejecting the “laws of nature” rule, and concurring that the patent was invalid for want of invention, Justice Frankfurter stated that:

289. Funk Bros., 333 U.S. at 132.

290. *Id.* at 131-32.

291. *Id.* at 130.

292. *See id.* at 132 (Frankfurter, J., concurring).

293. *Id.* at 134. I note here that the analysis of Mr. Justice Frankfurter is an application of the *Le Roy* doctrine examined elsewhere in this Article.

294. *See id.* at 132.

295. *Id.* at 135.

296. *Id.* In reaching his conclusion, Mr. Justice Frankfurter stated that: “[i]nsofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention and as such patentable, I agree, provided not only that a new and useful property results from their combination, but that the particular strains are identifiable and adequately identified.” *Id.* at 133.

297. *Id.* at 133.

It only confuses the issue, however, to introduce such terms as “the work of nature” and the “laws of nature.” For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed “the work of nature,” and any patentable composite exemplifies in its properties “the laws of nature.” Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.²⁹⁸

Further, Justice Frankfurter rejected the notion that the composite culture had no new properties:

[i]t [cannot] be contended that there was no invention because the composite has no new properties other than its ingredients in isolation. Bond’s mixture does in fact have the new property of multi-service applicability. Multi-purpose tools, multivalent vaccines, vitamin complex composites, are examples of complexes whose sole new property is the conjunction of the properties of their components. Surely the Court does not mean unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged.²⁹⁹

Three threads of analysis are possible: (1) whether “there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end”;³⁰⁰ (2) whether the “composite has no new properties other than its ingredients in isolation”;³⁰¹ or (3) whether “the particular strains are identifiable and adequately identified,”³⁰² and whether the strains “can be specified ... by the properties of the mixture.”³⁰³ To Justice Frankfurter, the dispositive analysis is not found in either the first or second thread; rather the dispositive analysis is found in the third thread.³⁰⁴ While the reasoning of Justice Frankfurter leads to an attractive point, it has not been accepted by the Court in subsequent cases. In particular, the Court has continued to use the “laws of nature” standard for determining whether the subject matter of a claim is an “invention” within the interpretation of 35 U.S.C. § 101.³⁰⁵ However, the rationale ap-

298. *Id.* at 134-35.

299. *Id.* at 135.

300. *Id.* at 130.

301. *Id.* at 135 (Frankfurter, J., concurring).

302. *Id.* at 133.

303. *Id.* at 134. Justice Frankfurter held subject matter must be an invention because of its utility, that is, its “multi-service applicability.” *Id.* at 135. I do not dispute that subject matter constituting the discovery of an operation of a law of nature may have considerable utility, or “multi-service applicability.” However, subject matter utility alone does not ensure patentability.

304. *See id.* at 132 (finding that Bond’s combination of strains does not satisfy the requirements of a new and useful property).

305. *See Diamond*, 447 U.S. at 309.

plied by Justice Frankfurter may illuminate the “laws of nature” rule apparently first developed in *Le Roy v. Tatham*³⁰⁶ and explained in *Funk Bros. Co.*³⁰⁷

In the case of genetically modified cells, such as is the case with the subject matter claimed in Canadian Patent 1,313,830, a transgene is inserted³⁰⁸ into the genome of the cell to cause the expression of a particular protein or a particular biochemical compound. The process of mixing the vector carrying the transgene and the single cell for inserting the transgene into the genome of the cell may be patentable and is, therefore, outside the area of interest for the present analysis.³⁰⁹ As a composite, a culture of bacteria is reasonably considered to be a “composition of matter,” such a composite is not necessarily subject matter for which a patent may be issued.³¹⁰ Analogously, while the composite of a particular transgene and the already existing genome of a cell might be considered as a “composition of matter,” the composite may not be patentable subject matter because the composite is merely the application of an already-discovered natural principle.³¹¹

In a cell, whether it be a plant cell or an animal cell, biochemical pathways exist that function to cause the expression of proteins and other chemical compounds. Each of these biochemical pathways are the physical manifestation of the “laws of nature” by which substrates are converted into products. The biochemical pathways existed before discovery by the scientific investigator and continue to exist unaltered after discovery by the scientific investigator. The biochemical pathways consist of a number of steps. Each step is comprised of one or more biochemical reactions by which the information contained in the nucleotide sequence of DNA is converted into either a protein product or a non-protein biochemical product. The transgene consists of a sequence of nucleotides and is DNA. The transgene does not constitute a law of nature because it can, by itself, yield no effect.

The transgene is similar, in that respect, to a rock. A rock, by itself, can yield no effect. If it is stationary, relative to some frame of reference, then it tends to remain stationary; if it is in motion, then it tends to remain in motion. That it will either remain stationary or remain in motion are examples of “laws of

306. See *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (noting that the subject of a patent must “effectuate a practical result and benefit no previously attained”).

307. See *Funk Bros.*, 333 U.S. at 130.

308. Can. Patent No. 1,313,830 (filed Aug. 6, 1986). The insertion itself does not require human intervention to occur; rather, the insertion relies entirely on the laws of nature.

309. See *Funk Bros.*, 333 U.S. at 133 (stating the packaging of a particular mixture is an invention and as such is patentable).

310. *Id.* at 130.

311. The already-discovered natural principle is the insertion of the transgene by the bacteria or other vector.

nature.” But the concept of “laws of nature” does not apply to the mere existence of the rock. The effect yielded by the aforementioned “laws of nature” is that the rock is considered to be in some state relative to a given frame of reference. Once in a particular state, the rock will remain in that state until it is acted upon by some other body according to yet another set of “laws of nature.”

So it is with the transgene. The information contained in the sequence of nucleotides constituting the transgene remains silent, unable to effect any change in the state of any other biochemical compound or substrate. Such is clearly illustrated by a cell that has lost the capacity to respire and maintain its integrity (that is the cell is dead). That particular cell contains long sequences of nucleotides, all of which may be in their proper order and properly connected. However, none of the genes in that particular cell are able to effect any change in the compounds surrounding them. They, by themselves, are unable to cause the production of either proteins or non-protein biochemical compounds. The genes, by themselves, are unable to cause the biochemical pathways to spontaneously start to function properly. The gene, in such a cell, is inert, stationary and quiescent. It is, therefore, analogous to a rock.

In contrast, the biochemical pathways, are the “laws of nature.” The biochemical pathways function by converting substrates into biochemical products. Certain pathways may even move substrates and other biochemical compounds from one place in the cell to another. The set of steps, comprising the biochemical pathways, are, therefore, analogous to the set of laws that cause the rock to change its state. When the set of steps operate, objects, in the form of molecules or atoms, change state and orientation with respect to other objects.

Consider the case where a biochemical pathway produces a particular compound, say Compound X. Presume that the transgene, which when inserted into the genome of the cell, causes the biochemical pathway to produce more of Compound X. All that has been discovered is that the resultant functioning cell produces more of Compound X; that is, the insertion of the transgene has caused “no more than the discovery of some of the handiwork of nature.”³¹² The already existing biochemical pathways are capable of producing Compound X at a higher concentration, and “hence is not patentable.”³¹³ The biochemical pathways, acting on precisely the same information³¹⁴ produces precisely the same compound, although in a greater amount. Neither the transgene nor the existing genome of the cell acquires a different use. The combination of the transgene and the already existing genome does not produce a different cell nor does it alter the cell in any

312. *Funk Bros.*, 333 U.S. at 131.

313. *Id.*

314. Admittedly the information is present in greater concentration, but this does not alter the outcome of the present analysis.

manner. Both the sequence of nucleotides comprising the transgene and the existing genome of the cell have precisely the same effect that each had before being combined. The biochemical pathways in the cell continue to function in precisely the same manner as before the transgene was inserted into the genome of the cell. The combination of the transgene and the genome of the cell does not improve, in any way, the existing function of the biochemical pathways or the existence, respiration, reproduction, and eventual cessation of function of the cell. Finally, both the cell and the biochemical pathways within the cell continue to “serve the ends nature originally provided and act quite independently of any effort of” the actor that caused the insertion of the transgene into the cell.³¹⁵ Even though the insertion of the transgene into the already existing genome of the cell might have been the product of skill, the resulting cell was not the product of invention.³¹⁶

Again, consider the case where a biochemical pathway produces a particular compound, say Compound X. Presume that the transgene, which when inserted into the genome of the cell, causes the biochemical pathway to produce not Compound X, but Compound Y. Even in this case, while the insertion of the transgene into the already existing genome of the cell might have been the product of some considerable skill, the resulting functioning cell cannot be considered the product of invention. Upon combining the transgene, which encodes for Compound Y, with the already existing genome of the cell, “without harmful effect to the properties of either,”³¹⁷ is nothing more than the discovery that the existing biochemical pathway, which is capable of producing Compound X, is also capable of producing Compound Y. “It is no more than the discovery of some of the handiwork of nature”³¹⁸ that a particular biochemical pathway can produce Compound Y and, as such, “is not patentable.”³¹⁹ Neither the transgene, the already existing genome of the cell, nor the biochemical pathways “acquires a different use.”³²⁰ The biochemical pathway uses the same set of substrates and applies the same basic set of biochemical reactions. Although the biochemical pathway yields a different product, that particular biochemical pathway is not put to some other use within the cell. That is, the existence of the transgene, which encodes Compound Y, does not cause the biochemical pathway, by which Compound X was produced, to start effecting some other function or operation within the cell, such as effecting the repair of genomic DNA. The combination of the

315. *Id.*

316. *See id.* at 131-32.

317. *Id.* at 131.

318. *Id.*

319. *Id.*

320. *Id.*

transgene and the already existing genome “does not improve in any way their natural functioning.”³²¹ The transgene remains an inert object until acted upon by a biochemical pathway, the existing genome of the cell remains an inert object until acted upon by a biochemical pathway, and the biochemical pathways are still constituted of the same set of biochemical reactions that function in the same sequence by acting upon the same set of substrates. The only difference is the product of the biochemical pathway. The transgene, the genome, and the biochemical pathways “serve the ends nature originally provided and act quite independently of any effort of the patentee.”³²²

Two other strands of analysis lead to the same conclusion. Consider the case wherein the transgene is inserted into the cell by the employment of a bacterium, or other “carrier cell,” such as *Agrobacterium tumefaciens*. In this case, the biochemical pathways and cellular machinery of the carrier cell operate to transport the transgene into the plant cell. The biochemical pathways and cellular machinery operate as they have always done. They have not acquired a different use, they have not acquired a different method of operation. The biochemical pathways employ the same set of biochemical reactions on the same set of substances within the carrier cell and within the target host cell. The carrier cell continues to infect the same type of host cell in precisely the same manner after the transgene was inserted into the carrier cell as before the transgene was inserted into the carrier cell. The only difference, from the perspective of the carrier cell, is that the additional baggage, that is the transgene, must be injected into the target plant cell. The biochemical pathways and cellular machinery of the carrier cell continue to “serve the ends nature originally provided and act quite independently of any effort of the patentee.”³²³

Transportation of the transgene from the cell body into the nuclear genome occurs by the already existing biochemical pathways. The analysis just presented for the insertion of the transgene into the cell by the carrier cell is also applicable to this case. The result is that no human intervention is required to move the transgene from the cell body into the nuclear genome of the plant cell.

Now, consider the case where the transgene is inserted into the cell by a mechanical means, such as micro-injection. In this case, the composition of the transgene and the cell might be patentable. However, the cell with the transgene fully integrated into the nuclear genome and is not patentable. The transgene is transported into the genome, be it nuclear, mitochondrial, or in the chloroplast, by the already existing pathways within the host cell. Under the analysis already given, the resulting host cell, with the transgene integrated into the genome and

321. *Id.*

322. *Id.*

323. *Id.*

which is functional, is not patentable because it is the result of the operation of the laws of nature, and also because the transgene was integrated into the genome without the intervention of the patentee. Therefore, under the analysis set forth in *Funk Bros., Inc.*, the single, transfected, progenitor plant cell comprised of a cell and a transgene is not patentable subject matter.³²⁴

It has long been known that glyphosate inhibits native EPSP synthase, an enzyme that functions in the shikimate acid pathway present in plants and bacteria.³²⁵ The shikimate pathway functions to provide the precursors to aromatic amino acids.³²⁶ In the case of glyphosate-resistant plant cells, it was already known that plants possessed biochemical pathways for the expression of 5-enolpyruvylshikimate-3-phosphate (EPSP synthase, or EPSPS) polypeptide and that plants also possessed biochemical pathways for engaging the function of the EPSP synthase polypeptide.³²⁷ EPSP synthase polypeptide is an enzyme that “catalyzes the conversion of phosphoenolpyruvate and 3-phosphoshikimic acid to 5-enolpyruvyl-3-phosphoshikimic acid.”³²⁸ Early on, it was discovered that glyphosate inhibits the biochemical pathway by which the function of the EPSP synthase polypeptide is engaged.³²⁹ Therefore, blocking the action of glyphosate in cells could have been accomplished by one of three methods: neutralizing glyphosate, up-regulating the production of EPSP synthase polypeptide in the cell, or instructing the biochemical pathway in which the EPSP synthase polypeptide is expressed to express a mutant form of EPSP.³³⁰

324. See *id.* at 127.

325. See Heike Holländer & Nikolaus Amrhein, *The Site of Inhibition of the Shikimate Pathway by Glyphosate, I. Inhibition by Glyphosate of Phenylpropanoid Synthesis in Buckwheat (*Fagopyrum esculentum* Moench)*, 66 *PLANT PHYSIOLOGY* 823-29 (1980); Nikolaus Amrhein, Brigitte Bens, Peter Gehrke & Hans Christian Steinrücken, *The Site of Inhibition of the Shikimate Pathway by Glyphosate*, 66 *PLANT PHYSIOLOGY* 830-34 (1980); Hans Christian Steinrücken & N. Amrhein, *The Herbicide Glyphosate is a Potent Inhibitor of 5-enolpyruvyl-shikimic acid-3-phosphate Synthase*, 94 *BIOCHEM. BIOPHYS. RES. COMM.* 1207-12 (1980); Comai, *supra* note 207, at 370-71; see also U.S. Patent No. 4,535,060 (filed Jan. 5, 1983); U.S. Patent No. 4,769,061 (filed Feb 4, 1985).

326. See U.S. Patent No. 4,535,060, at ¶ 2, (filed Jan. 5, 1985).

327. See *id.*

328. See *id.*

329. It was later discovered that glyphosate actually inhibits the EPSP synthase polypeptide. See Comai, *supra* note 207, at 370-71. In light of this information, it would have been obvious to a person of ordinary skill in the relevant art to design a mutant EPSP synthase polypeptide that was not inhibited by glyphosate. See *Id.* at 370 (stating that: “[t]he properties of this mutant gene make it potentially useful for the introduction and expression of herbicide resistance in plant cells, which is our long-range goal.”).

330. A mutant form of a protein is the native version of the protein with one or more amino acid substitutions. The amino acids can be readily changed simply by changing, at minimum, one or, at most, three nucleotides for each amino acid to be substituted in the native protein.

It is now known that glyphosate can be neutralized, within the plant cell, by the action of glyphosate oxidoreductase enzyme.³³¹ The over-production of proteins within the cell could be accomplished by several techniques, one of which was to increase the number of copies of the DNA that encoded the protein of interest.³³² Such a strategy is problematic for two primary reasons: first, the production of proteins within the cell consumes cellular resources, and therefore there is a cost to producing proteins simply for the purpose of protecting the cell against a herbicide; and second, the EPSP synthase polypeptides are still labile to inhibition by glyphosate.³³³

This second reason deserves some limited analysis. If each cell contains only a certain number of EPSP synthase polypeptide molecules, and each of them becomes inhibited by the action of a single glyphosate molecule, then when the total number of glyphosate molecules in the cell exceed the total number EPSP synthase polypeptide molecules, the cell will be terminated.³³⁴ Apparently, an optimal strategy would be to instruct the plant cell to express multiple copies of mutant EPSP synthase. In this manner, even if several mutant EPSP synthase polypeptide molecules were inhibited by glyphosate, the biochemical pathway that engaged the function of EPSP synthase would still be functional.³³⁵ Independent of the method used to confer glyphosate resistance upon the cell, constants remain. These constants are: the biochemical pathway by which EPSP synthase is expressed, in either native or mutant form, remains unchanged; and the biochemical pathway that engages the function of EPSP synthase, in either native or mutant form, remains unchanged.³³⁶ The only difference between a plant cell that is glyphosate resistant and a plant cell that is glyphosate susceptible is that the former contains a mutant gene, which results in the expression of a mutant EPSP synthase polypeptide, and the latter contains a native gene, which results in the expression of a native EPSP synthase polypeptide.³³⁷ When the mutant EPSP synthase polypeptide is expressed, the cell is resistant to glyphosate; when the native EPSP synthase polypeptide is expressed, the cell is susceptible to glyphosate.³³⁸

331. U.S. Patent No. 5,463,175 (filed Feb. 21, 1995).

332. *See generally id.* (explaining the process by which DNA is inserted into the plant cell).

333. *See generally id.*

334. *See generally id.* (discussing the creation of glyphosate tolerant plants with a capacity to produce EPSP synthase).

335. *See generally* U.S. Patent No. 4,940,835 (filed July 7, 1986).

336. *Id.*

337. *Id.*

338. *Id.*

The glyphosate-resistant plant cells, produced by Monsanto, fall into the second case. That is, the plant cells already produced native EPSP synthase polypeptide, all that the transgene did was to cause the plant cells to generate mutant EPSP synthase that was not inhibited by glyphosate.³³⁹ The transgene, the genome, the biochemical pathways that express EPSP synthase protein, and the biochemical pathways that engage the function of EPSP synthase polypeptide continue to “serve the ends nature originally provided and act quite independently of any effort of the patentee.”³⁴⁰ Under this rule and standard articulated in *Funk Bros. Seed Co.*, the cells claimed by Monsanto containing the transgene that encodes EPSP synthase polypeptide are not subject matter for which a patent may be issued.³⁴¹ This is because, those cells are not an “invention” or “discovery” within the interpretation of 35 U.S.C. § 100.³⁴²

A cell into which a transgene has, or several transgenes have, been inserted by genetic manipulation technology is not subject matter for which a patent may be issued because the resulting cell is not an invention, within the interpretation of 35 U.S.C. § 100; rather, the cell is nothing more than a “discovery of the phenomena of nature.”³⁴³ The cell is also not subject matter for which a patent may be issued because it is the result of a certain process. In *Le Roy*, the U.S. Supreme Court stated that: “[a] patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever.”³⁴⁴

The Court reasoned that by creating monopolies for the “result of a certain process,” the “arts and manufactures [would be discouraged], against the avowed policy of the patent laws.”³⁴⁵ Thus, if the subject matter is the “result” of the application of either human ingenuity or skill of a craftsman, that “result” is not patentable subject matter.³⁴⁶ For instance, in Canadian Patent Number 1,313,830, Monsanto claimed “a glyphosate-resistant oil seed rape cell of claim 22.”³⁴⁷ Claim 22 recited “[a] glyphosate-resistant plant cell comprising a chimeric

339. It remains an open question as to whether a cell that produces the mutant EPSP synthase polypeptide also produces the native form of the polypeptide. Further, it is not at all clear as to whether all of the cells of a plant, which has been genetically modified to be resistant to glyphosate, express the mutant EPSP synthase.

340. *Funk Bros.*, 333 U.S. at 131.

341. *See id.* at 132 (refusing to allow a patent to “issue on one of the ancient secrets of nature”).

342. Patent Act, 35 U.S.C. § 100(a) (2005).

343. *Funk Bros.*, 333 U.S. at 130.

344. *Le Roy*, 55 U.S. at 175.

345. *Id.*

346. *Diamond*, 447 U.S. at 309 (noting that abstract ideas have been held not patentable).

347. Can. Patent No. 1,313,830, at [claim 45] (filed Aug. 6, 1986).

plant gene of Claim 1.”³⁴⁸ In Claim 1, a transgene, which encodes the EPSP synthase polypeptide, is claimed.³⁴⁹ Monsanto alleged, and both the Trial Court and the Federal Court of Appeals so found, that Mr. Schmeiser infringed the rights conferred upon Monsanto by Claim 45 of Canadian Patent Number 1,313,830.³⁵⁰ Monsanto did not allege merely that Mr. Schmeiser infringed those rights by having the transgene on his land; rather Monsanto alleged that Mr. Schmeiser had glyphosate-resistant canola plants upon his land.³⁵¹ The “glyphosate-resistant plant cell” is comprised of the transgene, which encodes the EPSP synthase polypeptide, and the native genome of the oil-seed rape plant variety.³⁵² The presence of the transgene confers upon the oil-seed rape plant a resistance to glyphosate. In the absence of the transgene, the oil-seed rape plant, would likely be susceptible to glyphosate. When the transgene is present and EPSP synthase polypeptide, encoded by the transgene, is expressed, then the plant is glyphosate-resistant. The glyphosate resistance is the result of the transgene having been inserted into the native oil-seed rape plant cells.³⁵³

Under the *Le Roy* doctrine, the glyphosate resistance cannot be subject matter for which a valid patent can be issued.³⁵⁴ This is because the glyphosate resistance is the “effect,” or “the result of a certain process”;³⁵⁵ that “effect” or “result” arises from the insertion of the transgene, which encodes the EPSP synthase polypeptide, into the plant cell. If the transgene is absent, the cell is likely to be susceptible to glyphosate.³⁵⁶ If the transgene is present, and the polypeptide is expressed, then the cell is likely to be resistant to glyphosate.³⁵⁷

To clarify that glyphosate resistance is a “result” or an “effect,” it is necessary to study the definition of each of these words. The term “result” is interpreted to mean “to proceed, spring or arise as a consequence, effect, or conclusion.”³⁵⁸ Thus, the “result” is that which arises as a consequence or an effect of an action. The term “effect” is something that is produced by an agent or cause: something that follows immediately from an antecedent.”³⁵⁹ Therefore, the term “result” means that which arises by an agent or a cause; or, it is that which arises

348. *Id.*

349. *Id.* at [claim 1].

350. Monsanto Can., Inc. v. Schmeiser, [2001] F.C.T. 256, ¶ 146.

351. *Id.* at ¶ 8.

352. U.S. Patent No. 4,940,835, at [col. 2] (filed July 7, 1986).

353. The plant containing the transgene and the cells containing the transgene are also “results” of a process.

354. *See Le Roy*, 55 U.S. at 156.

355. *Id.* at 175.

356. *See* Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

357. *See id.*

358. WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1937 (2002).

359. *Id.* at 725.

immediately from an antecedent. The transgene, which encodes EPSP synthase polypeptide, is an agent or a cause that gives rise to glyphosate resistance by the cell into which the transgene is transfected.³⁶⁰ The transgene is antecedent to glyphosate resistance by the cell.

The effect of inserting the transgene into the plant cell is the characteristic of glyphosate resistance by the cell.³⁶¹ The antecedent, agent, or cause of the characteristic of glyphosate resistance is the transgene in the plant cell.³⁶² Therefore, a “glyphosate-resistant plant cell” cannot be subject matter for which a valid patent may be issued. A “glyphosate-resistant plant cell” is not the product of the application of the skill of a craftsman, nor is it the product of human ingenuity. A plant cell into which the transgene, which expresses the EPSP synthase polypeptide, has been transfected and that expresses the EPSP synthase polypeptide is either the product of the application of the skill of a craftsman, or the product of human ingenuity.³⁶³ Therefore, under this standard, the plant cell into which the transgene, which expresses the EPSP synthase polypeptide, has been transfected and that expresses the EPSP synthase polypeptide is subject matter for which a valid patent may be issued.³⁶⁴ However, the result of the transfection, being the glyphosate-resistance, is not patentable subject matter.³⁶⁵

A second reason a “glyphosate-resistant plant cell” is not subject matter for which a valid patent can be issued is that the policy of promoting the arts and sciences would be defeated.³⁶⁶ This is because such a patent “would prohibit all other persons from making the same thing by any means whatsoever.”³⁶⁷ One can certainly derive methods by which glyphosate-resistant plant cells and plants may be produced by means other than the manipulation of the information provided to the biochemical pathways that express EPSP synthase polypeptide and to the biochemical pathways that engage the function of the EPSP synthase polypeptide.³⁶⁸

One example of a cell that exhibits glyphosate resistance, but in which that resistance is not dependent upon the transgene that encodes the EPSP syn-

360. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

361. See *id.* at [3].

362. See *id.*

363. This method of analysis is crude in application and allows the judge, or judges, to avoid grappling with the real issue of a particular case.

364. Note that the conclusion reached by application of the standard analysis is different than the analysis reached by application of the “laws of nature” analysis.

365. See Can. Patent No. 1,313,803 (filed Aug. 6, 1986).

366. See *Le Roy*, 55 U.S. at 175.

367. See *id.*

368. Can. Patent No. 1,313,830, at [1-2] (filed Aug. 6, 1986).

these polypeptide, is found in U.S. Patent Number 5,463,175.³⁶⁹ Specifically, the patentee, Monsanto, stated that the “invention provides structural DNA constructs which encode a glyphosate oxido-reductase enzyme and which are useful in producing glyphosate degradation capability in heterologous microorganisms (e.g. bacteria and plants) and in producing glyphosate tolerant plants.”³⁷⁰ Careful study indicates that the patented subject matter is a plant cell with a transgene, which encodes a glyphosate oxidoreductase enzyme.³⁷¹ Specifically, “[a] glyphosate tolerant plant cell comprising a DNA molecule of claim 2”³⁷² is claimed as an invention. As is the case with U.S. Patent Number 4,940,835 and Canadian Patent Number 1,313,830, “[a] glyphosate tolerant plant cell” is not subject matter for which a valid patent can issue.³⁷³ It is the plant cell that contains the transgene conferring the glyphosate resistance, or tolerance, that is the subject matter for which a patent can be issued: however, the cell that expresses EPSP synthase and has the property of glyphosate resistance might be patentable.³⁷⁴

369. See U.S. Patent No. 5,463,175, at [col. 1, line 25 & col. 2, line 40] (filed Feb. 21, 1995). The priority date for U.S. Patent Number 5,463,175 is 25 June 1990. Therefore, the patent is set to expire on 25 June 2007. The derivation of these dates is as follows. Monsanto states that: “[t]his is a File Wrapper Continuation of application Ser. No.08/156,968, filed Nov. 23, 1993, now abandoned, which is a continuation of application Ser. No. 07/717,370, filed Jun. 24, 1991, now abandoned, which is a continuation-in-part of application Ser. No. 07/543,236, filed Jun. 25, 1990, now abandoned. “ *Id.* at [col. 1].

370. See *id.* at [col. 2, lines 41-45].

371. See *id.* at [claim 1, col. 73, lines 7-8].

372. See *id.* at [claim 5, col. 73, lines 25-26].

The DNA molecule of claim 2 is derived as follows:

1. A recombinant, double-stranded DNA molecule comprising in sequence:
 - a) a promoter region which functions in plants to cause the production of an RNA sequence, operatively linked to;
 - b) a structural DNA sequence that causes the production of an RNA sequence which encodes a glyphosate oxidoreductase enzyme having the sequence of SEQ ID NO: 5, operatively linked to;
 - c) a 3' non-translated region which functions in plants to cause the addition of polyadenylated nucleotides to the 3' end of the RNA sequence;

where the promoter region is heterologous with respect to the structural DNA sequence and causes sufficient expression of said enzyme in plant tissue to enhance the glyphosate tolerance of a plant transformed with said gene.

2. A DNA molecule of claim 1 in which said structural DNA sequence further comprises a 5' sequence encoding an amino-terminal chloroplast transit peptide.

373. *Contra* Monsanto Can., Inc. v. Schmeiser, [2001] F.C.T. 256, *aff'd by*, Monsanto Can., Inc. v. Schmeiser, [2002] F.C.A. 309.

374. Whether the subject matter is patentable depends, of course, upon the accepted method of analysis.

U.S. Patent Number 4,940,835,³⁷⁵ or Canadian Patent Number 1,313,830, and U.S. Patent Number 5,463,175 are similar in that both teach a glyphosate-resistant plant cell. In both cases, the glyphosate-resistant plant cell cannot be subject matter for which a valid patent may be issued because the glyphosate-resistant plant cell is the “result” of the process of transfecting the plant cell with a transgene that, when acted upon by the existing biochemical pathways within the plant cell, confer upon the plant cell the characteristic of resistance to glyphosate.³⁷⁶ In U.S. Patent Number 4,940,835, or Canadian Patent Number 1,313,830, the characteristic arises from the existence of a transgene encoding the EPSP synthase polypeptide³⁷⁷ and the characteristic arises in U.S. Patent Number 5,463,175 from the proper functioning of a transgene encoding the glyphosate oxidoreductase enzyme.³⁷⁸ The subject matter claimed in the two patents represent two different strategies for achieving the same result.³⁷⁹ To allow the result in one case to be subject matter for which a patent can issue would be to prohibit the development of an alternative strategy for achieving that same result. The

375. U.S. Patent No. 4,940,835 (filed July 7, 1986). The priority date for U.S. Patent Number 4,940,835 is August 7, 1985. Therefore, the patent is set to expire on August 7, 2005. The derivation of these dates is as follows. Monsanto states that: “[t]his application is a Continuation-in-Part of application, Ser. No. 792,390 filed Oct. 29, 1985, now abandoned, which, in turn, is a Continuation-in-Part of application, Ser. No. 763,482, filed Aug. 7, 1985, now abandoned.” U.S. Patent No. 4,940,835, at [col. 1] (filed July 7, 1986).

376. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986); U.S. Patent No. 5,463,175 (filed Feb. 21, 1995).

377. See U.S. Patent No. 4,940,835 (filed July 7, 1986).

378. See U.S. Patent No. 5,463,175 (filed Feb. 21, 1995).

379. The same result need not necessarily arise from two different courses of action by an actor; rather in one case the result may be due to a course of action by an actor and the other may be due to a natural course of action. Consider the case where the result is a vancomycin-resistant bacteria *Staphylococcus aureus* that arose due to an intentional transfection with the Tn1546 transposon. Presumably the transfected bacteria cell is subject matter for which a patent can be issued. Further, consider that a vancomycin-resistant bacteria *Staphylococcus aureus* is isolated from foot ulcers of a diabetic patient. The issue is, whether the making, using, offering for sale, or selling the isolate would constitute an infringement of the patent rights of the patentee. See Dan Ferber, *Triple-Threat Microbe Gained Powers from Another Bug*, 302 SCI. 1488 (2003); see also Linda Weigel, *Genetic Analysis of a High-Level Vancomycin-Resistant Isolate of Staphylococcus aureus*, 302 SCI. 1569 (2003). In the cited case, the vancomycin-resistant bacteria *Staphylococcus aureus* arose by the interspecies transfer of a TN1546 transposon from *Enterococcus faecalis* to a vancomycin-susceptible *Staphylococcus aureus*. In the case where a native species was transfected by a transgene, it would defy logic if the naturally occurring vancomycin-susceptible *Staphylococcus aureus* were held to be protected by the patent on the human-made vancomycin-susceptible *Staphylococcus aureus*. This is because the naturally occurring vancomycin-susceptible *Staphylococcus aureus* is the product of the “laws of nature,” and a naturally occurring product. It arose without human intervention. It continued to obey the laws of nature independent of the interaction of any human. The naturally occurring vancomycin-susceptible *Staphylococcus aureus* most certainly must not be protected by the patent rights of the patentee.

allowance of a valid patent to issue in one case and creating a monopoly “would discourage arts and manufactures, against the avowed policy of the patent laws.”³⁸⁰

The Trial Court found, and the Federal Court of Appeals agreed, that “seed saved in 1997 which was known or ought to have been known by [Mr. Schmeiser] to be Roundup tolerant”³⁸¹ was planted by Mr. Schmeiser in 1998. Upon planting the seed saved from his 1997 crop,³⁸² Mr. Schmeiser, the Trial Court held, infringed the rights conferred upon Monsanto by Canadian Patent Number 1,313,830.³⁸³ The importance of this holding is that it mattered not, to either the Trial Court or the Federal Court of Appeals, whether the Roundup resistance was conferred upon the canola by CaMV 35S/EPSPS gene, as described in Canadian Patent 1,313,830, or by some other mechanism. All that concerned the courts was that Mr. Schmeiser knew or ought to have known that the seed obtained from the 1997 crop was Roundup resistant.³⁸⁴ It appears therefore, that the courts found the knowledge of the characteristic of Roundup resistance to be sufficient to constitute infringement. Thus, it appears that the courts understood the claimed subject matter to be the “glyphosate-resistant plant cell” and it appeared irrelevant, for the purposes of the holding in the case, whether the cell actually contained the transgene claimed in Canadian Patent Number 1,313,830.³⁸⁵

Under the *LeRoy* doctrine, such a holding by the Trial Court could not stand. This is because the “glyphosate-resistant cell” was the “result” of inserting the transgene into the plant cell and, as such, is not subject matter for which a patent could issue.³⁸⁶ The “glyphosate-resistant cell” was not the invention; it was the result of a process.³⁸⁷ The process was the insertion of the transgene into the cell; the consequence of which was the establishment of glyphosate resistant upon the cell. Not even the establishment of the glyphosate resistance could be considered as the “invention” because it was well known within the art that the transgene encoding the EPSP synthase polypeptide conferred upon cells, which

380. *Le Roy*, 55 U.S. at 175.

381. *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256, ¶ 146.

382. *See Id.* at ¶ 102. The Trial Court found that: “[t]he surviving plants were Roundup resistant and their seed constituted the source of seed stored in the old Ford truck.”

383. *Id.* at ¶ 146.

384. *Id.*

385. *See id.*

386. *See id.* at ¶ 15.

387. *See id.*

contained the transgene, resistance to glyphosate.³⁸⁸ Monsanto could not patent the establishment of glyphosate resistance in a cell, as this was not the invention. The claimed subject matter was a “plant cell comprising a chimeric gene.”³⁸⁹ That the plant cell is glyphosate resistant is a consequence of the presence of the chimeric gene. The claimed subject matter is not “[a] glyphosate-resistant plant cell.” The Trial Court incorrectly held that Mr. Schmeiser infringed the patent rights of Monsanto because he had “glyphosate-resistant plant cell[s]” on his land, and because he either “knew or ought to have known” that those plant cells were glyphosate resistant.³⁹⁰ The cells in the plants on the fields of Mr. Schmeiser were not the result of the transfection process employed by Monsanto. The cells were generated by a different method employing the “laws of nature” and some sunshine and rain.³⁹¹

The language “glyphosate-resistant plant cell” is considered to be the preamble to the claim because a “glyphosate-resistant plant cell” is not patentable subject matter.³⁹² A “glyphosate-resistant plant cell” is the result of the insertion of the transgene into the plant cell; the glyphosate resistance is the consequence of the biochemical pathways acting upon the information contained in the transgene.³⁹³ Given that Canadian and U.S. law hold that the language “glyphosate-resistant plant cell” is merely the preamble, then it was an error for the Trial Court to hold that Mr. Schmeiser infringed the patent rights of Monsanto merely for having the “glyphosate-resistant plant cell” on his land.³⁹⁴ To render a proper decision, the Trial Court necessarily had to look at the claimed subject matter. The subject matter was a “plant cell comprising a chimeric gene.”³⁹⁵ To be found guilty of infringement, Mr. Schmeiser would have had to make, use, offer for sale, or sell the “plant cell comprising a chimeric gene,” and to know that he was doing so.³⁹⁶ It was, and is, impossible for Mr. Schmeiser to know that he was

388. See Heike *supra* note 325, at 823; Amrhein, *supra* note 325, at 830; H. C. Steinruecken, *supra* note 325, at 1207; Comai, *supra* note 207, at 370; see also, U.S. Patent Number 4,535,060 (filed Jan. 5, 1983); U.S. Patent No. 4,769,061 (filed Feb. 4, 1985).

389. Can. Patent No. 1,313,830, at [claim 22] (filed Aug. 6, 1986).

390. See Monsanto Can., Inc. v. Schmeiser, [2001] F.C.T. 256, ¶ 146.

391. See *id.* at ¶ 117.

392. See *id.* at ¶ 82.

393. See *id.* at ¶ 83.

394. See *id.* at ¶ 121-123.

395. *Id.* at ¶ 21-22.

396. See *id.* at ¶¶ 22, 101, 120. The Trial Court did hold that Mr. Schmeiser also infringed the patent rights of Monsanto by selling the seed harvested from the 1998 canola crop. Even this does not fit with a correct analysis of the law and facts of the case. The seed, containing the chimeric gene, was not subject matter for which the patent was issued. Mr. Schmeiser did not sell a “plant cell comprising a chimeric gene,” he sold a plant *seed* comprising a chimeric gene. Therefore, even in this instance the Trial Court was seriously in error. See *Id.* at ¶ 127.

either making, using, offering for sale, or selling a “plant cell comprising a chimeric gene.”³⁹⁷ Merely planting a seed from which a glyphosate resistant plant might grow is not sufficient to constitute infringement. Three reasons exist for this conclusion: first, such a seed was not claimed subject matter; second, the actor may not have known that he was planting a seed “comprising a chimeric gene”; and third, planting the seed does not constitute either making, using, offering for sale, or selling the claimed subject matter.

In this result-oriented construction of the patent at issue and in articulating its decision the Trial Court and the Federal Court of Appeals lost sight of the principles of reason and logic. Upon careful reading of both the Trial Court decision and the decision of the Federal Court of Appeals, it becomes apparent that both courts knew in advance of the trial, in the former case, and the hearing, in the latter case, what the ultimate decision was going to be. Reason, logic, and proper interpretation of the law clearly stood in the path to that end for both courts and ultimately became casualties in the war upon the rights of Mr. Schmeiser. Rather than grappling with the law by application of sound reason and logic, both courts made up the law to suit the outcome and discarded both logic and reason along the way. Mr. Schmeiser held hope that the Supreme Court of Canada would see the folly of both lower courts and, at the least, apply reason and logic to the interpretation of the law. Only then could a just outcome be had by Mr. Schmeiser.

IV. DERIVATION

We now turn to a derivation of the logic by which it will be concluded that the subject matter claimed in either the Canadian Patent No. 1,313,830 or U.S. Patent No. 4,940,835 is neither an invention nor a discovery. Further, by extending the logic, I will show that the plant variety is also not patentable.

A. Whether the Subject Matter Amounted to an Invention or Discovery

To be patentable, the claimed subject matter must be novel, have utility, and be a composition of matter.³⁹⁸ Along with satisfying these three require-

397. Under both Canadian and U.S. law it is not relevant whether the actor knew that a patent had issued claiming the subject matter. Knowledge regarding whether the patent had issued is not of concern in the present discussion. The position assumed in the present analysis is whether the actor knew he was doing a particular act that was proscribed by existing law, not whether that act was proscribed by the existing law. *See Schmeiser v. Monsanto Can., Inc.*, [2002] F.C.A. 309, ¶¶ 55-58.

398. The balance of the classifications articulated in the Patent Act is not relevant for purposes of the present discussion. *See Patent Act*, R.S.C., ch. P-4 (1985) (Can.).

ments, the subject matter must be an invention before a valid patent may issue for claimed subject matter.³⁹⁹ The analysis of whether a claimed transgenic plant cell or a transgenic plant is an invention is far more difficult than determining whether a screwdriver or a hydraulic pump is an invention. Before reaching the required analysis, some time must be invested in understanding what is meant by the word “invention.”

To be patentable subject matter, the level of inventive genius that produced the claimed subject matter must reach the level that the Constitution grants Congress the authority to reward a patent.⁴⁰⁰ It has long been the doctrine in patent law of the United States that:

[I]t is not enough that a thing shall be new, in the sense that in shape or form in which it is produced it shall not have been before known, and that it shall be useful, but it must, under the Constitution and the statute, amount to an invention or discovery.⁴⁰¹

The *Thompson* Court made it clear that before reaching the issue of whether the claimed subject matter is a “manufacture” or a “composition of matter,” the courts must first address whether the claimed subject matter is new, useful, and an invention or a discovery.⁴⁰² The criteria that the subject matter must be an invention has, apparently, fallen into disuse.⁴⁰³ Any “trifling device which would naturally and spontaneously occur to any skilled mechanic or operator, in the ordinary progress of manufactures”⁴⁰⁴ is not entitled to a patent as an invention. This is true, even if “the thing claimed was new, in the sense that it had not been anticipated by any previous invention, and it was shown to have superior utility.”⁴⁰⁵ To be patentable, the subject matter must “spring from that intuitive faculty of the mind put forth in the search for new results, or new methods, creating what had not before existed, or bringing to light what lay hidden from vision;” also, a subject matter must be “the creative work of that inventive faculty

399. The criteria for patentability is identical under patent statutes of both the United States and Canada. See Patent Act, 35 U.S.C. §§ 100-04 (2005); Patent Act, R.S.C., ch. P-4 (1985) (Can.).

400. See U.S. CONST. art. I, § 8, cl. 8.

401. *Thompson v. Boisselier*, 114 U.S. 1, 11 (1885).

402. See *id.* at 1. In spite of the *Thompson* decision it stuns the mind that the courts still consider whether the subject matter was new and not found in nature as the criteria for whether the subject matter is patentable. See *In re Bergy*, Coats & Malik, 195 U.S.P.Q. (BNA) 344, 350 (1977); *Application of Bergy*, 596 F.2d 952 (C.C.P.A., 1979); *Diamond*, 447 U.S. at 303; *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001).

403. This is apparently because either the federal courts have written this criteria out of the Patent Act or the courts are unable to properly grapple with the issue.

404. *Thompson*, 114 U.S. at 12.

405. *Id.*

which it is the purpose of the Constitution and patent laws to encourage and reward.”⁴⁰⁶ The subject matter is not patentable if it is merely the “display of the expected skill of the calling,” involving “only the exercise of the ordinary faculties of reasoning upon the materials supplied by a special knowledge, and the facility of manipulation which results from its habitual and intelligent practice.”⁴⁰⁷ An “invention” requires that a volitive act be involved and that volitive act must arise from a purposeful, creative, mental processing of information.⁴⁰⁸ The analysis of the *Thompson* Court and of the *Hollister* Court support this derivation.

When applied to subject matter, such as a computer chip or a new type of central processing unit cooling, the definition of invention is easily applied. When the subject matter is animate or is a self-replicating entity,⁴⁰⁹ then considerable care must be exercised when determining whether what is claimed is actually an invention within the meaning of the Patent Act. The analysis is aided considerably by examination of certain claimed subject matter. In U.S. Patent No. 4,940,835, the patentee claims:

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 fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell; and

406. *Hollister v. Benedict & Burnham Mfg.*, 113 U.S. 59, 72-73 (1885).

407. *Id.* at 73.

408. The Patent Act, of both the United States and Canada, contemplate that a patent should issue for subject matter that is, or was, an “invention.” See Patent Act, 35 U.S.C. § 101 (2005) (stating “[w]hoever *invents* . . . any . . . manufacture, or composition of matter . . . may obtain a patent therefor”); Patent Act, R.S.C., ch. P-4 (1985) (Can.) (stating: “‘invention’ means any . . . manufacture or composition of matter”). The dictionary definition of “invention” is: (1) “an act of finding or of finding out”; (2) “the power to conceive new ideas and relationships”; (3) “a product of creative imagination or fertile wit”; or (4) “the creation of something not previously in existence: purposeful experimentation leading to the development of a new device or process.” WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1188 (2002) (The common definition of invention gives that a volitive act must be involved and that volitive act must arise from a purposeful creative, mental processing of information. This is, perhaps, one reason why a “product of nature” cannot be patented; and, perhaps, why obvious subject matter is also not patentable).

409. An example of a self-replicating entity is paroxetine hydrochloride hemihydrate (Paxil) which converts paroxetine hydrochloride anhydrate to the hemihydrate form. See *Smith-Kline Beecham v. Apotex Corp.*, 2005 WL 2436662 (E.D. Pa.).

(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.⁴¹⁰

Consider whether the subject matter of Claim 1 is an "invention." The preamble of the claim is important in addressing this issue. The authors of the patent give a clean, concise description of how the chimeric gene was generated.⁴¹¹ The chimeric gene is produced by a well known and well defined set of biochemical protocols.⁴¹² The design of the chimeric gene, that is the sequence of nucleotides in the gene, was the product of mental processing of information. The actor is aware that the gene of interest⁴¹³ may or may not be properly expressed by the plant cell.

The transgene may not be properly expressed because of a number of reasons, including: first, the nucleotide sequence of the transgene may not be readable by the biochemical machinery of the cell because of the fraction of adenine and thymine nucleotides relative to the fraction of guanine and cytosine nucleotides;⁴¹⁴ second, the start and stop codons for the transgene may not be prop-

410. U.S. Patent No. 4,940,835, at [col. 32, lines 30-47] (filed July 7, 1986). Claim 1 of U.S. Patent No. 4,940,835 is identical to Claim 1 of Canadian Patent No. 1,313,830. See Can. Patent No. 1,313,830, at [68] (filed Aug. 6, 1986). While Monsanto was, perhaps, the first to exploit the technology on a large scale, the company was certainly not the first to develop the technology. See Comai, *supra* note 207, at 370; L. Comai et al., *Expression in Plants of Mutant *aroA* Gene from Salmonella typhimurium Confers Tolerance to Glyphosate*, 317 NATURE 741 (1985).

411. See generally Robert B. Horsch et al., *Inheritance of Functional Foreign Genes in Plants*, 223 Sci. 496 (1984) (describing the expression of a chimeric gene in plant tissues); Horsch, *supra* note 216, at 1229 (describing a method for transferring genes into plant cells).

412. See, e.g., L. Herra-Estrella et al., *Chimeric Genes as Dominant Selectable Markers in Plant Cells*, 2 The EMBO J. 987 (1983) (explaining the construction of chimeric genes).

413. Consider the case of the transgene that causes the biochemical machinery of the cell to express EPSP synthase. The genome of the plant cell is comprised of a gene that causes the expression of native EPSP synthase. However, if the actor desires that the plant cell express a mutant form of EPSP synthase polypeptide that is not inhibited by glyphosate then the mutant EPSP synthase polypeptide might not be properly expressed by the plant cell. The actor must analyze available information on the molecular biology of the shikimate pathway to identify possible alternative strategies by which the objective could be achieved. Then, the actor must identify the strategy that is most likely to succeed. By doing so, the actor has engaged in a purposeful mental processing of information, the result of which is the selection of a strategy that is most likely to succeed.

414. Introduction of a gene from one genus and species into another genus and species does not necessarily imply that the gene will be expressed. In fact, the plant cellular machinery requires a different nucleotide composition for expression than does the insect or animal genome.

erly read and processed by the biochemical machinery of the cell; third, the promoter sequence of the transgene may not be appropriate for the cellular machinery; fourth, the transgene may be degraded by the cellular machinery before it becomes integrated into the genomic background of the cell; fifth, the transgene might have been integrated into an incorrect location within the genomic background of the plant cell and, subsequently, not be expressed; and sixth, the transgene might be properly processed by the biochemical machinery of the plant cell but the polypeptide might be expressed in the wrong location and not properly utilized.⁴¹⁵

To transfect the plant cell with a transgene such that the transgene functions properly, the actor must collect and process a considerable amount of information about plant biochemistry, genomic theory, plant physiology, plant biology, and a number of other fields of science. Once the information has been collected, the actor must be creative in designing a strategy for the transfection. Finally, the actor must complete a set of volitive acts to cause the proper expression of the transgene by the biochemical machinery of the plant cell. That set of volitive acts is necessarily based upon a purposeful, creative, mental processing of the information collected by the actor. As such, the chimeric gene of Claim 1 is an invention within the meaning of the Patent Act of both the United States and of Canada.⁴¹⁶ At this point in the analysis, the issue arises as to whether the claim, for the chimeric gene, covers the gene when that gene is in the plant cell. However tempting it might be to address this issue at this point, clarity requires that it be addressed elsewhere.

The second relevant claim of U.S. Patent No. 4,940,835 is in Claim 22 as follows: “[a] glyphosate-resistant plant cell comprising a chimeric plant gene of Claim 1.”⁴¹⁷

For instance, the introduction of the *Bacillus thuringiensis*, a gram-positive bacterium, δ -endotoxin gene into maize may yield a genetically modified plant that does not express the desired δ -endotoxin. See Michael G. Koziel et al., *Transgenic Maize for the Control of European Corn Borer and Other Maize Insect Pests*, 792 ANNALS N. Y. ACAD. SCI. 164 (1996).

415. The EPSP synthase polypeptide is an excellent example of this cause for improper expression of the polypeptide. The transgene for the mutant EPSP synthase is integrated into the nuclear genome of the cell. Thus, the polypeptide is expressed into the cellular cytoplasm. However, the shikimate pathway is active in the chloroplasts. Thus, the EPSP synthase polypeptide must include a chloroplast transit peptide to transfer the EPSP synthase polypeptide to the location where it might function in the presence of glyphosate. See U.S. Patent No. 4,940,835, at [col. 3, lines 7-24] (filed July 7, 1986).

416. At this point, I will avoid analyzing the other criteria, established under 35 U.S.C. § 101, for determining whether a patent may issue for claimed subject matter.

417. U.S. Patent No. 4,940,835, at [col. 33, lines 39-40] (filed July 7, 1986). Claim 22 of U.S. Patent No. 4,940,835 is identical to Claim 22 of Canadian Patent No. 1,313,830. See Can. Patent No. 1,313,830, at [70] (filed Aug. 6, 1986).

As with Claim 1, quoted *supra*, Claim 22 raises two principal issues: first, whether the subject matter is actually an invention; and second, whether the scope of the claim includes a plant cell situated in a plant, which is growing on the field of the farmer. The first is addressed presently, the second is deferred until later.

The chimeric gene is of little, if any, use unless it is contained in and expressed by a cell. Thus, the actor has the objective of transfecting a plant cell with the transgene. To be an invention the actor must have performed a set of volitive acts yielding the claimed subject matter, which were based upon the creative processing of relevant information.⁴¹⁸

With the chimeric gene in hand, the actor is faced with the problem of inserting the gene into a cell. The actor must first collect information on the available methods for transfecting a cell.⁴¹⁹ If a suitable method is not available, then the actor must act to identify an alternative method. Such identification process certainly includes designing and conducting experiments, the objective of which is to determine the pathways in the plant cell that are or might be susceptible to infection by the transgene.⁴²⁰ Once the biochemical pathways of the cell are identified, then the actor must enumerate a set of vectors⁴²¹ that might be suitable and then conduct the experiments necessary to select the candidate vector or vectors to be used in the transfection process.

Once both the transgene has been obtained and the method of transfection has been designed, the actor must complete the transfection. Such is easier said than done. The susceptible cell and the vector are co-cultivated to allow the transfection to occur.⁴²² The vector is then removed from the presence of the

418. See Patent Act, 35 U.S.C. §§ 101, 103 (2005).

419. The currently available methods include the Ti plasmid of *Agrobacterium tumefaciens*. However, when Comai did the fundamental work on transfecting plant cells in the early 1980's, *Agrobacterium tumefaciens* was either unknown or was not accepted as a standard method of transfecting plant cells. It is now known that *Agrobacterium tumefaciens* is either not efficient or ineffective in transfecting some species of plants. Thus, if the actor is interested in transfecting a particular species or variety of plants that are not sensitive to *Agrobacterium tumefaciens*, then the actor must identify a viable alternative. See Can. Patent No. 1,313,830, at [9] (filed Aug. 6, 1986).

420. See *id.* at [9].

421. In the area of biotechnology and medicine, a "vector" is a vehicle for transporting a piece of DNA, a genome, a virus, or a micro-organism. See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1090 (1987).

422. The cell is made to be susceptible to transfection by a number of methods. A plant cell can be made susceptible by mechanical means. A disc is punched from a leaf of the plant. The injured cells on the circumference of the disc are allowed to mend the damaged cell wall for a relatively short period of time. Those cells that have rehabilitated the cell wall, at least in part, are those that are most susceptible to transfection.

plant cell and the plant cell is then cultured to produce a shoot initially and, ultimately, a fully-mature plant.⁴²³

Now consider the aforementioned transfected cell. That cell is the product of a set of volitive acts, on the part of the actor; and those volitive acts are based upon purposeful mental processing of information, which was creative in nature. As such, the cell might subject matter for which a valid patent may issue because it is an invention within the Patent Act of the United States and Canada.⁴²⁴

A third relevant claim of the patent, U.S. Patent No. 4,940,835, is as follows:⁴²⁵ “45. A glyphosate-resistant oil seed rape cell of Claim 22.”⁴²⁶ The analysis of whether a plant is an “invention” within the meaning of the Patent Act is based upon and similar to the analysis of whether a plant cell is an “invention.”

Once the actor has transfected a single plant cell in the petri dish then it is natural for the actor to desire to obtain a fully-mature plant.⁴²⁷ An alternative objective is to produce a plant-cell line from the original transfected progenitor plant cell. The production of a plant cell line will be analyzed and then the pro-

423. See F. A. Krens et al., *In vitro transformation of plant protoplasts with Ti-plasmid DNA*, 296 NATURE 72 (1982).

424. I fully acknowledge that the application of the definition of “invention” derived in this Article leads to exactly the opposite conclusion as does the application of the “laws of nature” rule. It would appear, then, that the “invention” rule and the “laws of nature” rule are in direct conflict. However, that is not necessarily a valid conclusion. The two laws must be used consecutively in the process of determining whether any particular subject matter is patentable. The “invention” rule must be applied first to satisfy Section 101 of Title 35, 35 U.S.C. § 101 (2005), or Section 2 of the Patent Act, R.S.C., ch. P-4 (1985) (Can.), then the “law of nature” rule must be applied to satisfy the common-law criteria for patentability. Under this proposed analytical scheme, it is possible that the claimed subject matter could be an “invention” and the result of the “laws of nature” analysis could indicate that the subject matter is not patentable.

425. See generally U.S. Patent No. 4,940,835, at [col. 341, lines 58-59] (filed July 7, 1986) (because plants have long been thought to be unpatentable in Canada, the Canadian version of U.S. Patent No. 4,940,835 does not contain a claim to a plant, nor does the Canadian patent contain a claim to a plant seed. It is of interest to note that U.S. Patent No. 4,940,835 does not contain a claim to a plant seed. It is a wonder then, that Monsanto has been able to successfully win so many lawsuits and settlements against farmers in the United States when Monsanto has no intangible personal property rights in the plant seed).

426. Can. Patent No. 1,313,830, at [72] (filed Aug. 6, 1986) (claim 45 of Can. Patent No. 1,313,830 is the same as claim 52 of U.S. Patent No. 4,940,835). See U.S. Patent No. 4,940,835, at [col. 34, lines 58-59] (filed July 7, 1986).

427. The following narrative is meant to help clarify the nomenclature. The actor starts with a single plant cell. Upon inserting the transgene into the plant cell then that cell is denoted as being a “single transfected plant cell.” Because that particular cell is used to produce either a plant-cell line or a mature plant, then the cell is denoted as being a “single, transfected, progenitor, plant cell.”

duction of a fully mature plant from a single, transfected, progenitor, plant cell will be analyzed.

In the event that the actor has the objective of producing a plant-cell line, the ultimate result might be a patentable subject matter for two reasons: first, the plant-cell line might be an "invention" within the meaning of the Patent Act of the United States and Canada; and second, because the plant-cell line would qualify as a micro-organism within the meaning of *Bergy*⁴²⁸ and *Abitibi*.⁴²⁹ A transfected cell will not, in general, spontaneously produce a plant-cell line.⁴³⁰ A set of clearly defined steps must be executed to yield a cell line from an initial progenitor cell.⁴³¹ The actor must collect available information on transforming a cell of a particular variety of plant into a cell line. The actor must then process the information to develop a strategy to cause the conversion. At this point, two paths diverge into the thicket. Along one, a person of ordinary skill in the art would, by processing the available information, be able to perform the steps necessary to produce the cell line. In this case, a process might be well known and used for converting a plant cell of variety X of a particular species. If the actor has a plant cell of variety Y of the same species or of a closely related species, then a person of ordinary skill in the relevant art would be able to perform the required conversion without an investment of creative effort. In this event, the effort of processing the information does not rise to that "intuitive faculty of the mind [that was] put forth in the search for new results, or new methods."⁴³² Rather, there was the mere "display of the expected skill of the calling."⁴³³ There-

428. See *In re Bergy*, 195 U.S.P.Q. at 350; Application of Bergy, 596 F.2d 952 (C.C.P.A., 1979).

429. Re Application of Abitibi Co., [1982] 62 C.P.R. 2d 81, 89. The Patent Appeal Board of Canada determined that the following would be considered patentable subject matter in Canada:

all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced en masse as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.

As to why the plant-cell line qualifies as a micro-organism is not of central import to the current analysis and, hence, will not be examined.

430. A cell line involves a type of cell that is capable of the following: a single cell that will replicate to generate progeny cells that are clones of the original progenitor cell; and any particular cell that is capable of replicating indefinitely.

431. See generally Can. Patent No. 1,139,691 (filed Jan. 18, 1983).

432. *Hollister*, 113 U.S. at 72.

433. *Id.* at 73.

fore, the plant-cell line is not an “invention” within the meaning of the Patent Act.⁴³⁴

An alternative path leads to a different outcome. Suppose the actor has a plant cell from a variety or species for which the known conversion techniques are ineffective or for which no known conversion technique exists. In such a case, the actor must process the available information in a manner so as to develop a creative strategy for effecting the conversion to a cell line. A person of ordinary skill in the relevant art would not be able to take the available information and produce the desired cell line in a straightforward manner. To produce the desired result, more than a mere “display of the expected skill of the calling” is required.⁴³⁵ This is so because a “display of the expected skill of the calling” does not allow the actor to produce the desired cell line.⁴³⁶ Required is a “faculty of the mind put forth in the search for new results” that exceeds that displayed by a person of ordinary skill in the relevant art.⁴³⁷ Such faculty of the mind might be called “creative genius.” If the information is not available, then the actor must generate the necessary information.⁴³⁸ Here, the actor must still process the information in a creative manner to develop a strategy for obtaining the ultimate result. The actor must then perform the volitive acts, based upon the processed information, to cause the single plant cell to become a cell line. The cell line produced as a result of traveling this path satisfies the definition of “invention.”⁴³⁹

U.S. Patent No. 4,940,835, contains claim 29 to a glyphosate-resistant plant as follows: “[a] glyphosate-resistant dicotyledonous plant which has been regenerated from a glyphosate-resistant plant cell comprising the chimeric plant gene of claim 1.”⁴⁴⁰

I shall leave to the side, for the time being, the analysis of why this claim does not, and cannot, allow the patentee to extend the intangible personal property rights granted by the issue of U.S. Patent No. 4,940,835 to include the glyphosate-resistant dicotyledonous plant growing in the field of the farmer. In the

434. To be complete, a claim to the plant-cell line would be rejected as obvious under 35 U.S.C. § 103(a) (2005).

435. *Hollister*, 113 U.S. at 73.

436. *Id.*

437. *Id.* at 72; see Patent Act, 35 U.S.C. § 103(a) (2005).

438. The mere generation of the information does not make the ultimately-claimed subject matter an “invention.” This is because the generation of the information might be of such a nature that any person of ordinary skill in the relevant art would be able to obtain the information by a “display of expected skill of the calling.” Even if extraordinary skill is required, the generation of information may not yield the conclusion that the ultimate cell line is an “invention.”

439. *Hollister*, 113 U.S. at 73.

440. U.S. Patent Number 4,940,835, at [col. 33, lines 60-62] (filed July 7, 1986); see Can. Patent No. 1,313,830 (filed Aug. 6, 1985) (Can. Patent No. 1,313,830 does not contain a claim to a plant).

event that the actor has the objective of producing a mature plant then the ultimate result is not patentable subject matter.⁴⁴¹ To produce a fully-mature plant from a single transfected progenitor plant cell, the actor, as usual, must collect the available information on culturing cells to produce a shoot and, subsequently, a plant.⁴⁴²

The practice of culturing plant cells, which were transfected using *Agrobacterium tumefaciens*, to regenerate plants, has been in existence for more than twenty years.⁴⁴³ In fact, the knowledge was considered to be common place in 1985 when Horsch, et al., filed the parent application that eventually lead to U.S. Patent No. 4,940,835.⁴⁴⁴ Horsch et al., did not describe the single-cell culture method as novel and it was not described in the detail that would be expected of a method reported for the first time.⁴⁴⁵ A review of the patents issued to Monsanto since 1985 indicates that none of the patents covered a method for culturing a single plant cell to produce a mature plant.⁴⁴⁶ In fact, one of the earliest articles reporting the cell-culture method was published by Luis Herrera-Estrella, et al.⁴⁴⁷

At the time that the claims in U.S. Patent No. 4,940,835 were filed, the technology for culturing single plant cells to yield shoots was already well known.⁴⁴⁸ The information on the technology available to the actor would al-

441. It might be argued that a claim to a mature plant is invalid for obviousness. This argument will not be examined in this study.

442. See generally Krens, *supra* note 423, at 72.

443. See generally *id.*

444. See U.S. Patent No. 4,940,835, at [col. 1, lines 1-8] (filed July 7, 1986) (U.S. Patent No. 4,940,835 issued from application number 879,814, filed on 7 July, 1986. Application number 879,814 was a continuation-in-part of application serial number 792,390, filed 29 October 1985, and subsequently abandoned. That application was a continuation-in-part of application serial number 763,482, filed on 7 August 1985 and subsequently abandoned).

445. See Horsch, *supra* note 411, at 496; Horsch, *supra* note 216, at 1229.

446. See e.g. Can. Patent No. 1,31,830 (filed Aug. 6, 1986); U.S. Patent No. 4,940,835 (filed July 7, 1986).

447. See Krens, *supra* note 423, at 72-74; L. Herrera-Estrella, *supra* note 412, at 987-995. L. Herrera-Estrella, et al., stated that:

Dicotyledonous plants are transformed by *Agrobacterium* by the transfer, integration and expression of part of the Ti plasmid (T-DNA) in the plant genome. The hormone-independent growth of crown gall tumors . . . is a natural dominant selectable marker, and has been used successfully to develop transformation systems for plants. This natural dominant selectable marker, however, interferes with plant morphogenesis, and differentiation, and prevents the formation of whole plants from single cells or from callus tissue. *Id.* at 993 (citations omitted). L. Herrera-Estrella, et al., reported the method by which the natural dominant selectable marker was removed, thus allowing the regeneration of whole plants from a single cell.

448. In fact, Horsch et al., admit that the technology was already well known by 1985. Specifically, Horsch, et al., state that “[I]n addition, glyphosate-resistant plant cells that have been

ready be available to a person of ordinary skill in the relevant art. A person of ordinary skill in the art would be able, with the available information, to produce a shoot and a mature plant from a given single cell. No “intuitive faculty of the mind” would be required because a person of ordinary skill in the art would be able to produce the desired result.⁴⁴⁹ For this reason alone, neither the shoot nor the fully-mature plant is an “invention” within the meaning of the Patent Act.⁴⁵⁰

A further argument exists for why neither the shoot nor the plant is an invention. Presume that the standard protocols do not work to make the single, transfected plant cell yield a shoot. The remaining criterion is that the actor must perform a volitive act based upon a creative, purposeful, mental processing of information.⁴⁵¹ In the case at hand, the actor must first collect information on why the known culture techniques do not operate to produce a shoot or a fully-mature plant. To do so, the actor must carefully design and implement a sequence of experimental protocols aimed at understanding the relevant cellular biochemistry of the plant cell in issue. The outcome of the experiments is new information about the protocol required to achieve the desired objective. Such information is readily obtained by a person of ordinary skill in the relevant art. The creative input is to take the information from one set of experiments to identify how new experiments should be designed. The purposeful, creative, mental processing of information led to the creation of the process of experimentation. Ultimately the experimentation leads to the formulation of a cocktail for inducing shoot development from a single plant cell in issue. The cocktail might be an invention within the meaning of the Patent Act.

The production of the cocktail does not mean that either the shoot or the resulting plant is an invention. Our starting premise was that standard protocols already exist for inducing a single cell to produce a shoot. The volitive act based upon a purposeful, creative, mental processing of information was not directed at producing a shoot, it was aimed at producing a cocktail that would induce the formation of a shoot. Once the cocktail was produced, then a person of ordinary skill in the relevant art would exercise that ordinary skill to cause the production of the shoot. Further, if the experiment entailed changing the ratios of the various plant growth hormones and growth factors, then such an activity is certainly nothing more than the mere “display of the expected skill of the calling” of an

transformed with EPSPS genes can be regenerated into differentiated plants using standard nutrient media supplemented with selected shoot-inducing or root-inducing hormones, using methods described in PCT WO No. 084/02920 or other methods known to those skilled in the art.” U.S. Patent No. 4,940,835, at [col. 5, lines 54-60] (filed July 7, 1986).

449. *Hollister*, 113 U.S. at 71.

450. *See id.* at 73.

451. *See id.*

ordinary research scientist. In fact, a low-level laboratory technician would have the skill set required to vary the ratios of the growth factors to induce shoot formation. Under such circumstances, not even the root-inducing cocktail is an invention. An argument could be made that the inventive step was producing the cocktail that induced shoot formation in this particular type of plant cell.⁴⁵² This argument actually mixes two concepts. The first, the production of the root-inducing cocktail, was just considered.

The second concept relates to whether a volitive act based upon the purposeful, creative, mental processing of information by an actor occurred in inducing shoot formation from a single transformed progenitor plant cell. The criteria requires that the actor must have performed a volitive act based upon a purposeful, creative, mental processing of information to cause the biochemical machinery to process the set of genes resulting in the genesis of a shoot.⁴⁵³ The actor did not do this.

The analysis here is independent of whether the biotechnology for inducing shoot formation already exists. Let us suppose that the essential plant growth factor to induce shoot formation is Factor M. When the technician adds Factor M to the cocktail, into which the single, transformed, progenitor, plant cell has been placed, in a certain concentration, the cell produces a shoot. Perhaps the cocktail with Factor M is an invention; and perhaps the cocktail with Factor M is patentable subject matter. However, neither the shoot nor the resultant plant is an invention.⁴⁵⁴ In the absence of human intervention, the single, transformed, progenitor plant-cell is unlikely to spontaneously produce a shoot. The single cell of interest is but a complete set of instructions for reproduction and shoot formation combined with the biochemical machinery required for executing those instructions. By adding Factor M to the cocktail, the actor has done nothing to alter the set of instructions for reproduction or for inducing root formation.⁴⁵⁵

The reasoning here is quite simple. To alter the set of instructions requires a nucleotide sequence be either deleted or added, or both. Factor M is not a nucleotide sequence. By adding Factor M, the actor has done nothing to alter

452. Even if such subject matter were patentable, a claim for such subject matter would be so narrow as to be completely useless.

453. See *Hollister*, 113 U.S. at 72-73.

454. An argument is founded upon an analysis of 35 U.S.C.A. § 271 (2001 & Supp. 2005). If a product is produced by the employment of a patented process, then the actor has infringed the rights of the patentee. 35 U.S.C.A. § 271 (2001 & Supp. 2005). Section 271 is inapposite to the case at hand. 35 U.S.C.A. § 271 (2001 & Supp. 2005). Here, I have admitted that the cocktail is patentable subject matter. However, the process of placing the plant cell into the cocktail to induce root formation is not patentable for obviousness under 35 U.S.C. § 103(a). The product of a process that is not patentable is, itself, not patentable.

the biochemical machinery necessary for reading and executing the set of instructions. The biochemical machinery is comprised of a complex set of biochemical pathways, and Factor M is only a chemical compound, not a complex set of biochemical pathways. Therefore, the volitive act of adding Factor M has done nothing to alter either the set of instructions or the biochemical machinery of the plant cell.

Factor M acts only as the compound to initiate a long and complex set of events, the result of which is the production of a shoot and, ultimately, a plant. An excellent analogy here is a complex manufacturing plant that produces blue widgets. I envision this manufacturing plant as being several stories tall and covering five city blocks. Inside is a web of conveyor belts, many machines with Dr. Seuss-like levers, and hammers, and moving parts, gauges, bells, and whistles. At the beginning of this process is a single switch that drops a small cube of recycled soda bottles on the first of many conveyor belts. At the end of the process a blue widget drops into a van for delivery. The manufacturing plant is silent and no blue widgets are being produced because that small switch at the beginning of the process is in the "off" position. Factor M walks into the factory and places the switch into the "on" position and does nothing more because Factor M can do nothing more and is needed for nothing more. The machinery and conveyor belts of the manufacturing plant operate without assistance from Factor M, and eventually a blue widget drops into the van for delivery. Factor M, in the single, transformed, progenitor, plant cell sets an already existing set of machinery into motion. It does nothing more. Once initiated, the biochemical machinery of the cell, operating according to the already existing set of instructions, completes the process necessary to form a shoot. The shape of the cell may become altered and the structural components of the cell might become elongated in this way or that. However, the biochemical machinery and the instructions to the cell remain unaltered.

Indeed, one could counter with the argument that without the addition of Factor M, the cell would not have replicated and formed a shoot. That is true. However, that is not relevant to deciding whether the shoot is an "invention." The issue is whether a volitive act was performed based upon the purposeful, creative, mental processing of information. If a plant cell had never before been cultured in a medium to induce shoot formation then the given argument might obtain a differential amount of traction. However, even then the shoot is not an invention because the purposeful, creative, mental processing of information related to inducing the shoot to form, not to the production of a shoot where none had existed before.

This point deserves to be expanded. Presume the following: the state of the knowledge indicated that a particular cell would not produce a shoot;⁴⁵⁶ the actor collected information on how to insert biochemical machinery into the plant cell along with the requisite set of instructions to cause the cell to produce a shoot; and the actor creatively processed that information to develop a strategy; then performed volitive acts to implement that strategy. Then, the shoot produced by the altered cell would be an “invention.”⁴⁵⁷ If the mental processing and volitive act is related to producing a result that did not exist before, then the resulting subject matter is well on its way to being an “invention.”

It is important here to keep the concepts of “invention” and “novelty” distinct. If no creativity is required in the mental processing and volitive act, then the subject matter does not rise to the level of an “invention.”⁴⁵⁸ This is independent of whether the subject matter is novel. Where the volitive act and purposeful, creative, mental processing of information relate to designing and installing the biochemical machinery for causing a shoot to form, then the result, both the transformed cell and the shoot, are an “invention.” Where the volitive act and purposeful, creative, mental processing of information relate to turning on an already existing biochemical machinery then neither the cell nor the shoot are an “invention” within the meaning of the Patent Act. The “invention,” in this case, is the method or process for turning on the already existing biochemical machinery. The biochemical machinery and the process for turning the machinery on are two different, separate, and distinct things. That the second is an invention does not entitle the actor to claim exclusive rights to the first thing.⁴⁵⁹

In summary, I have shown that the shoot produced by a single, transfected, progenitor, plant cell cannot be an “invention” within the meaning of the Patent Act. I have also shown that a plant-cell line is an “invention,” but only if

456. Such a case is an extreme. My mother would propagate geraniums, African violets, and certain other species of plants by using leaf cutting. To do this, she would pinch off a leaf of the donor plant and place the stem of that leaf into a small jar of water. With proper sunlight and temperature cycle in the kitchen, some roots would soon appear. The cells at the end of the leaf stem produced shoots that became roots. My mother learned this method from her mother. The knowledge that certain plant cells would produce shoots is older than the knowledge that plants are comprised of cells. But such knowledge is ignored for the moment.

457. With modern technology, such a feat is not possible. Even the ability to insert a single gene into a particular location within the genome is not well developed. The methods for transfecting the plant cell with a transgene and hoping that the transgene ends in the proper location is well developed. To build an entire piece of biochemical machinery “from whole cloth” and insert that machinery into a plant cell is far beyond the primitive technology of the modern world.

458. See generally Patent Act, 35 U.S.C. §§ 101-03 (2005) (stating the patentability of inventions and the conditions of novelty and nonobvious for patentability).

459. I note here that the “laws of nature” argument applies here. However, the argument presented is stronger because it illuminates exactly what acts were performed and what is the result.

existing technology is not available to convert a particular plant cell into a cell line.⁴⁶⁰ The analysis used to demonstrate why a shoot is not an “invention” is apposite to demonstrating why a fully-mature plant produced from a shoot is not an invention. To be complete, if the biotechnology already exists for causing a single, transformed, progenitor, plant cell to produce a shoot and for causing a plant to form from the shoot, then no “inventive activity” is required once the progenitor plant cell is in hand.⁴⁶¹ If the biotechnology does not exist, then the foregoing analysis may be used to demonstrate that neither the shoot nor the plant is an invention.

The last claim of interest is to a transgenic seed. However, neither Canadian Patent 1,313,830 nor U.S. Patent No. 4,940,835 contain a claim to a transgenic seed.⁴⁶² Because a patent cannot be issued to a seed in Canada, then any claim to a seed in Canada would not be valid.⁴⁶³ As I have examined elsewhere in this Article, Monsanto probably believed that a claim to a “glyphosate-resistant cell” was also a claim to a glyphosate-resistant seed.⁴⁶⁴ Under the patent law of Canada, this conclusion cannot be valid because a claim to a plant seed is invalid in Canada.⁴⁶⁵ Monsanto cannot do indirectly, that is make the claim to a glyphosate-resistant cell include a plant seed, what Monsanto cannot do directly, that is claim a glyphosate-resistant plant seed.

To be complete, presume that the draftsman of U.S. Patent No. 4,940,835 had included a claim to a transgenic seed. The claim to a transgenic seed would not be valid because the seed is not an invention. The logic in support of this analysis is simple. First, the actor performed no volitive act to insert the transgene into the plant seed. In the case of the single, transformed, progenitor plant cell, the volitive act was the compounding of the transgene and the host cell. No analogous operation was performed with the transgene and the plant seed. To be an invention, the actor must have performed a set of volitive acts whereby the transgene was inserted into the plant cell. Such an event did not occur.

460. See generally Patent Act, 35 U.S.C. §§ 100-105 (2005) (describing the patentability of invention).

461. See generally *id.* at §§ 100-103 (2004) (defining what constitutes an invention for patenting purposes).

462. See Can. Patent No. 1,313,380 (filed Aug. 6th, 1986); U.S. Patent No. 4,940,835 (filed July 7, 1986).

463. See *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 76, ¶ B(1).

464. See *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶¶ 69-77.

465. See *Harvard Coll.*, [2002] S.C.C. at ¶ B(1); see generally Patent Act, R.S.C. ch. P-4 (2003) (Can.) (discussing patentable processes and materials).

The second alternative analysis is as follows. The plant, comprised of cells containing the transgene, grew and produced seeds following the laws of nature.⁴⁶⁶ As such the seeds are not patentable.

Even if we accept that the phrase “plant cell” includes a plant seed,⁴⁶⁷ the result of the analysis presented in this Article does not change. There are two reasons in support of this assertion. First, no disclosure exists in the specification of either Canadian Patent No. 1,313,830 or U.S. Patent No. 4,940,835 regarding the making or construction of a glyphosate-resistant plant seed.⁴⁶⁸ Therefore, Claim 22 of both patents cannot include glyphosate-resistant plant seeds within the meaning of a glyphosate-resistant cell.⁴⁶⁹ Consider this a bit further. Presume that a glyphosate-resistant seed had been claimed.⁴⁷⁰ Because no support exists in the specification for making or constructing the glyphosate-resistant seed, then the claim would be invalid under 35 U.S.C. § 112.⁴⁷¹ Subject matter cannot be included into one claim by stretching that claim if the subject matter cannot be claimed explicitly.

Second, the glyphosate-resistant plant seed is not patentable subject matter for want of invention. The method for producing a cell comprised of a transgene is necessarily separate, different, and distinct from the method for producing a seed comprised of a transgene. The first requires a volitive act by a human, the second does not. Either because of a lack of disclosure or a lack of invention, a glyphosate-resistant plant seed is not patentable, and our conclusions do not change if the phrase “glyphosate-resistant plant cell” is interpreted to include glyphosate-resistant plant seed.

It might be argued that, had the transgene not been inserted into the host cell then it would not have been in the seed. This argument is flawed on two grounds. First, it asserts but-for causation is the basis for patentability. Nothing in either the case law or the Patent Act supports but-for causation as a basis for patentability.⁴⁷² Second, it presumes the mere presence of the transgene makes

466. The laws of nature are encoded into the genome of the native cell.

467. See U.S. Patent No. 5,034,322, at [col. 1, lines 48-50] (filed Apr. 5, 1989).

468. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986); U.S. Patent No. 4,940,835 (filed July 7, 1986).

469. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986); U.S. Patent No. 4,940,835 (filed July 7, 1986).

470. The seed was not claimed, but it should have been.

471. “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such, clear, concise, and exact terms as to enable any person skilled in the art at which it pertain, or with which it most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.” (quoting Patent Act, 35 U.S.C. § 112 (2005)).

472. See Patent Act, 35 U.S.C. §§ 100-105 (2005) (noting nothing in the text of the Patent Act support the but-for causation as a basis for patentability).

the seed patentable. By this argument, if the transgene is in my desk drawer then my desk is patentable.

The transgene was replicated into the seed because the already existing biochemical machinery of the plant cells were so instructed. A set of instructions were placed into the cell and the machinery acted upon those instructions. The actor did nothing to alter the manner in which the biochemical machinery functioned. The actor did not insert new machinery into the plant cell that would produce a different type of reproduction vehicle: say an egg instead of a seed. The actor did none of these things.

The foregoing analysis permits the formulation of a pair of concise rules. First, the product of a volitive act based upon the purposeful, creative, mental processing of relevant information is an invention within the meaning of the Patent Act.⁴⁷³ Second, the product arising from the normal functioning of an organism is not an invention within the meaning of the Patent Act if only the instructions provided to the organism are altered.⁴⁷⁴ The analysis to establish the first rule has been well ventilated and need not be aired once again. The second rule can stand some elaboration.

It might be argued that the intangible personal property right in the transgene follows the transgene no matter where the transgene is located. Based upon this position, the claim to a plant cell is valid no matter where that cell is located. The argument leads to the conclusion that the property right in the transgene extends to any cell, wherever situated, which is comprised of the transgene. The result of this conclusion is that the claim to a transgene would include every cell in a plant that is comprised of the transgene. It stands to reason then that the applicant for a patent would claim a plant cell comprised of the transgene, a plant comprised of plant cells containing the transgene, and the seeds comprised of the transgene. The applicant for a patent followed precisely such a course of action in the application that issued to U.S. Patent No. 4,940,835.⁴⁷⁵

By a direct attack on the core premise, that the property rights follow the transgene, the task of showing that the claim to the cell and plant are not valid is partially accomplished. In the course of doing so, the second rule, articulated

473. *See id.*

474. *See id.*; *see also* Patent Act, R.S.C., ch. P-4 (1985) (Can.).

475. Except that the seed was not claimed. From experience, such a described strategy is considered to be the standard in the patent prosecution industry. For instance, if the subject matter is a new circuit on an integrated chip, then the patent draftsman would claim the circuit, the chip, and a computer containing the chip. The tactic, when applied to genetically manipulated organisms permits the draftsman to claim the transgene, the plant cell, and the plant. The difference between the electronic circuit and the transgene is that the latter is replicated without intervention by an actor and the former is not. U.S. Patent No. 4,940,835, at [col. 33, lines 39-40, 60-62] (filed July 7, 1986).

supra, will be demonstrated. As already discussed, the chimeric gene is an invention within the meaning of the Patent Act.⁴⁷⁶ The claim to the chimeric gene covers only those genes that are constructed by the volitive actions of an actor.⁴⁷⁷

Towards understanding this concept, consider a patentable composition of matter that is obtained by mixing ingredients A, B, and C and elevating the temperature to 205°C to complete a chemical reaction. Presume that the resulting composition of matter is an “invention” and properly claimed in a patent. The patent rights follow the composition of matter to the extent that: if an actor performs the volitive acts to produce the composition of matter, then an act of infringement occurs.

In U.S. Patent No. 4,940,835, the patentee discloses the protocol for constructing the chimeric gene, or transgene, which encodes glyphosate-tolerant EPSP synthase.⁴⁷⁸ In Claim 1, the patentee properly claims “a chimeric plant gene.” The intangible personal property rights follow the chimeric gene, or transgene, to the extent that if any actor performs the volitive acts required by the protocol disclosed in U.S. Patent No. 4,940,835 to produce the transgene, then an act of infringement occurs.⁴⁷⁹ However, if neither the applicant for patent nor the alleged infringer performed any volitive acts required to replicate the transgene then the resultant transgene is not within the scope of the claim. If the transgene can be replicated without any direct volitive acts on the part of an actor, then the transgene so produced is not protected by the patent.⁴⁸⁰

If the actor has not performed a volitive act directed at producing the subject matter at issue, then the subject matter cannot be an invention. Consider the following example. Suppose that the inventor planted a seed into a pot of soil and provided water and a sunny place near his kitchen window for the pot. A couple of months later the actor has a nicely formed plant growing in the pot. Is the actor entitled to a patent on the plant? The answer is no because the actor performed no volitive act based upon a purposeful, creative, mental processing of information to cause the plant to grow. Planting the seed into the soil, providing water, and providing a source of sunlight are volitive acts that would be expected of an ordinary person who desired to grow a plant from a seed. In this case, the actor is passive relative to the functioning of the biochemical machinery of the

476. See Patent Act, 35 U.S.C. § 100(a), 101 (2005) (defining the requirement necessary to qualify as an invention); see also U.S. Patent No. 4,940,835 (filed July 7, 1986) (citing M.M. Zoller et al., *METHODS ENZYMOL* 100, 468 (1983) (listing the components of a chimeric gene)).

477. For obvious reasons, the use of the plant itself as a tool or process by which the transgene is inserted into the seed does not make the seed patentable subject matter.

478. See U.S. Patent No. 4,940,835, at [col. 6, lines 20-26] (filed July 7, 1986).

479. I will allow that the disclosed protocol might be modified here and there to allow for a more efficient protocol, and the resulting transgene still be covered by the patent.

480. This is the problem of “self-replicating entities.”

seed to produce a plant. The actor provided the component, Factor M, that turned on the switch to initiate the germination. But doing so does not entitle the actor to claim either the seed or the resulting plant as an invention.

Now, suppose that the seed contained a transgene that encoded a mutant EPSP synthase polypeptide. Presume further, that the jurisdiction is Canada.⁴⁸¹ No intangible personal property rights exist with respect to the seed.⁴⁸² The plant grows and the transgene is replicated into each cell of the plant.⁴⁸³ The replication occurred as the result of the normal and usual functioning of the biochemical machinery of the plant cells. When a given cell replicates, the genome of that cell is replicated into each of the daughter cells. The transgene is part of the genome and is replicated. The plant is the result of the operation of the laws of nature; the transgene becomes situated into each of the cells of the plant by the operation of the laws of nature, which are encoded in the genome of the plant cell. As was the case with the immediately preceding example, the actor is passive relative to the functioning of the biochemical machinery of both the seed and the plant cells to produce a plant. The actor was passive with regard to the replication of the transgene into each cell of the plant. Again, the actor supplied the Factor M that turned on the switch to initiate the germination and, in turn, the replication of the transgene. But, supplying Factor M is an act that would be expected of an ordinary person without any particular skill in the art of plant husbandry. But, as examined *supra*, such actions do not raise the plant, or the plant cells, to the level of invention within the meaning of the Patent Act. The same argument applies to the production of seeds by the plant. Neither the plant, the plant cells, nor the seeds in this example is an “invention” within the Patent Act of the United States or of Canada.

In the previous explored example, the actor propagated the plant and seeds from a single seed. That single seed contained a transgene. The only difference between the single seed of each of the two previously discussed examples is that one contains instructions for producing a particular chemical compound

481. The result of the instant analysis is not strictly dependent upon the jurisdiction. Canada is chosen to simplify part of the argument.

482. See *Pioneer Hi-Breed Ltd. v. Canada*, [1989] 1 S.C.R. 1623, 1634 (As thoroughly examined *supra*, a patent cannot be obtained for either a plant or a plant seed in Canada).

483. An issue is whether plant cells, comprising the plant, produced from a seed not claimed in a patent, are covered by the patent. Such an issue is more than a mere curiosity for the idle ruminator. In the case of Mr. Schmeiser, the seeds that were planted on his land in 1998 were not circumscribed by the patent rights of Monsanto. See Can. Patent No. 1,313,830 (filed Aug. 6, 1986) (indicating the disclosure and patentability of the glyphosate-resistant cells by Monsanto). Nevertheless, he was sued by Monsanto when those seeds grew to produce a plant, the cells of which contained a transgene. See *Monsanto Can., Inc. v. Schmeiser*, [2001] F.C.T. 256.

and the other does not.⁴⁸⁴ That is, one contains a transgene and the other does not. Expressed in another way, the only difference between each of the single seeds is that one is provided with a particular set of instructions and another does not have that particular set of instructions. However, the fact that one contained an instruction, call it Instruction X, and the other contained a modified instruction, call it Instruction X', did not enter into the analysis. The analysis was concerned only with the type of the actions performed by the actor. In the analysis, it was discovered that, in both examples, the plant was the result of the normal functioning of the biochemical machinery of the seed and plant cell. In the normal functioning of the biochemical machinery, Instruction X was executed in the first example and Instruction X' was executed in the second example. The actor merely stood by, observing. Even if Instruction X was not executed in the first example, the conclusion of the analysis is not changed. That is because whether the subject matter is an invention derives from the actions of the actor, not upon the result of already existing biochemical machinery.⁴⁸⁵

Let Instruction X' be the transgene claimed in Claim 1 of Canadian Patent No. 1,313,830 and Claim 1 of U.S. Patent No. 4,940,835. Normally, plants possess a shikimate pathway that utilizes EPSP synthase polypeptide.⁴⁸⁶ Thus, in the absence of the transgene, the seed and plant cells execute Instruction X. In neither case does the actor do more than provide Factor M; otherwise, the actor is passive with respect to the functioning of the existing biochemical machinery of the plant cell. The actor did nothing that a person of ordinary skill in the relevant art could not have done. Indeed, the actor did nothing that an ordinary person with no particular skill in the relevant art could not have done. As such, the plant is not an invention; and neither are the plant cells. Finally, because the actor did nothing to cause the replication of the gene that an ordinary person could not have done, then the transgene in the plant cannot be an invention. This conclusion is strengthened by the observation that the actor did nothing at all to cause the transgene to exist in each plant cell in the plant.⁴⁸⁷ Therefore, a claim to a transgene such as that found in U.S. Patent No. 4,940,835 and Canadian Patent No. 1,313,830 does not grant an exclusive intangible personal property right to

484. *See generally* U.S. Patent No. 4,940,835 (filed July 7, 1986); Can. Patent No. 1,313,830 (filed Aug. 6, 1986) (noting that Monsanto did not claim the mutant EPSP synthase polypeptide in either the U.S. patent or the Canadian patent).

485. *See generally* Patent Act, 35 U.S.C. § 101 (2005); Patent Act, R.S.C., ch. P-4 (1985) (Can.) (noting the definition of a patentable invention is a useful improvement in any "process . . . manufacture or composition of matter").

486. *See* U.S. Patent No. 4,535,060, at [col. 2, lines 1-12] (filed Jan. 5, 1983).

487. This conclusion differs considerably from the conclusion obtained from the application of the same analytical technique to the micro-chip in a computer.

the transgene located in the cells of the plant. Nor does the claim grant an exclusive right to the transgene located in the plant seed.

Now, consider the seed produced by the first plant that grew from the original, single, transformed, progenitor plant cell. As was the case with the two preceding examples, the actor did nothing, other than to supply Factor M, to cause the plant to produce seeds. When the seeds were produced, the biochemical machinery of the relevant plant cells functioned normally to replicate the transgene into the seeds. The actor did not go into the laboratory and mix the proper compounds together to compound a seed. Nor did the actor place a non-transfected seed into a cocktail with a transfection vector to cause the transgene to be inserted into the seed. The actor did not inject the transgene into the nucleosome of the seed by micro-injection techniques. The actor simply allowed the biochemical machinery of the cells, which give rise to the seeds, to operate in a completely normal and natural way. Even in this case, the seed of the first transgenic plant is not an invention.

The common feature of these examples is that in each, the normal functioning of the plant cells produces a result independent of any actions of the actor. Further, the only difference amongst the examples is the particular instruction given to the plant cells: in some cases Instruction X' is given and in others Instruction X is given. The Second Rule is, then, firmly derived. If the only difference between two particular organisms, be it plant cells or a plant, or seeds, is the instructions provided to each of them the result of the normal functioning of one organism is not an invention if the result of the normal functioning of the other organism is not an invention.

Applying the analysis, then, the following conclusions are obtained. A plant cell, in a plant, that contains Instruction X' is not an invention because a plant cell, in a plant, that contains Instruction X is not an invention. The seeds of a plant, the cells of which contain Instruction X', are not an invention because the seeds of a plant that contains Instruction X are not an invention. The rationale behind this conclusion rests upon the fact that in neither case did the actor perform any volitive act in bringing about the plant cell, or the plant, or the seed.

At the end of the analysis, all that remains is a transgene outside of any plant cell or plant seed produced by the volitive acts of the actor, and the single, transformed, progenitor, plant cell produced by the volitive acts of the actor. The transgene is an invention within the Patent Act; however, the single, transformed, progenitor plant cell might be an invention within the meaning of the Patent

Act.⁴⁸⁸ A claim to anything beyond either of these two remaining classes of subject matter is invalid for want of invention.

B. *Whether the Plant Variety is Patentable*

The issue of whether a plant variety is patentable under the Plant Patent Act of 1930 should not be confused with the question addressed within the scope of this work: that is, whether a plant, or plant cell, is patentable within the meaning of 35 U.S.C. § 101 or Section 2 of the Patent Act of Canada. The Plant Patent Act proposed to provide incentive to preserve new varieties of plants, though not those that would be propagated by seed.⁴⁸⁹ The House and Senate reported that: “in order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties, and it is immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing varieties.”⁴⁹⁰

Essential to the issue of patentability under the Plant Patent Act is whether the plant represents a new variety.⁴⁹¹ On the problem of identifying a variety, Carleton R. Ball stated that “[i]t is not always easy to recognize a variety from its description. Often two varieties really different look very much alike. Sometimes the visible difference is very small. Sometimes there is no visible difference at all, although there is a real difference in yielding power.”⁴⁹² A new variety, within the meaning of the Plant Patent Act, may arise as a new sport, a mutation, or a graft, amongst others.⁴⁹³ The key to patentability under the Plant Patent Act is that the new variety must be asexually propagated.⁴⁹⁴ If the new variety arises by one of the aforementioned methods, the issue to be addressed is whether that variety is an invention within the meaning of 35 U.S.C. § 101.⁴⁹⁵ As examined elsewhere in this work, if the variety is subject matter that is an invention, then a valid patent may be issued.⁴⁹⁶

488. See generally Patent Act, 35 U.S.C. § 101 (2005); Patent Act, R.S.C., ch. P-4 (1985) (Can.) (noting the definition of a patentable invention is a useful improvement in any “process . . . manufacture or composition of matter”).

489. See Patent Act, 35 U.S.C. § 161 (2005).

490. H.R. REP. NO. 1129, at 5 (1930).

491. See Patent Act, 35 U.S.C. § 161 (2005).

492. Carleton R. Ball & J. Allen Clark, *Varieties of Hard Spring Wheat*, 680 U.S.D.A. FARMERS' BULLETIN 1 (1915).

493. 35 U.S.C. § 161 (2005).

494. See *id.*

495. See generally *Id.* at § 101 (describing which inventions are patentable).

496. See *id.*

Let us presume that a particular plant is comprised of cells that contain a transgene. If a sport or mutation is discovered then the plant that is subsequently cultivated is not an invention.⁴⁹⁷ One might argue that such subject matter is a discovery and hence should be within the boundary set by the Patent Act. Certainly, the cultivated plant would be subject matter for which a patent could issue under 35 U.S.C. § 161. However, discovery within the meaning of 35 U.S.C. § 101 does not have a meaning separate and distinct from the meaning of invention.⁴⁹⁸ Because the discoverer of the sport or mutant comprised of the transgene did not “invent” the sport or mutant plant then it is not subject matter for which a valid patent may issue under 35 U.S.C. § 101.⁴⁹⁹

C. The U.S. P.T.O. Yielded On the Issue

In 1987, the United States Patent and Trademark Office (U.S. P.T.O.) finally yielded on the issue of whether non-human living multi-cellular organisms were indeed patentable.⁵⁰⁰ The U.S. P.T.O. simply stated:

The Patent and Trademark Office now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101. . . . A claim directed to or including within its scope a human being will not be considered to be patentable subject matter within 35 U.S.C. § 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multi-cellular organism which would include a human being within its scope include that limitation “non-human” to avoid this ground of rejection.⁵⁰¹

To the lay patent practitioner, this statement forecloses any challenges to an issued patent in which a claim is made for a multi-cellular living organism based upon 35 U.S.C. § 101.⁵⁰² It is a routine practice for a patent practitioner to draft claims directed towards an organism containing a transgene, which encodes for this protein or that protein. In fact, it would be considered malpractice for the

497. *Id.*

498. The relevant language of 35 U.S.C. § 101 is as follows: “[w]hoever invents or discovers any new and useful . . . composition of matter . . . may obtain a patent therefore.” To determine if the words “invents” or “discovers” have distinct meanings within the scope of 35 U.S.C. § 101, one looks to 35 U.S.C. § 100, which provides that: “[t]he term ‘invention’ means invention or discovery.” Thus, invention and discovery or “invents” and “discovers” have the same meaning within the Patent Act.

499. *See id.*

500. PATENT AND TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 21, 1987).

501. *Id.*

502. *See* Patent Act, 35 U.S.C. § 101 (2005).

practitioner to not include such a broad claim. While the U.S. P.T.O. would issue a patent for such a multi-cellular organism, it is not clear that the organism actually falls within 35 U.S.C. § 101.⁵⁰³ In *Ex parte Allen*, the Board of Patent Appeals and Interferences came remarkably close to properly formulating the underlying issue.⁵⁰⁴ There, the Board stated:

The issue, in our view, in determining whether the claimed subject matter is patentable under Section 101 is simply whether that subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable subject matter under Section 101. The fact, as urged by the examiner, that the oysters produced by the claimed method are “controlled by the laws of nature” does not address the issue of whether the subject matter is non-naturally occurring manufacture or composition of matter. The examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man, nor has the examiner urged that polyploid oysters occur naturally. The record before us lead to no conclusion other than that the claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under 35 U.S.C. 101. Accordingly, the rejection under Section 101 must be reversed.⁵⁰⁵

While coming remarkably close, the Board still failed to properly articulate the critical issue.⁵⁰⁶ The issue is not whether the claimed product is naturally occurring or whether it is a non-naturally occurring manufacture or composition of matter, as the board claimed.⁵⁰⁷ Those issues serve only as distractions meant to divert attention away from the tough question. The issues that 35 U.S.C. § 101 demands to be decided are whether the subject matter is an invention and whether the claimed subject matter is a “manufacture” or a “composition of matter.”⁵⁰⁸ The Allen Board recognized that the subject matter must be “made by man.”⁵⁰⁹ However, rather than deciding whether the subject matter was an invention, the Board confused the entire issue by deciding whether the subject matter was a “non-naturally occurring manufactures or composition of matter.”⁵¹⁰ Subject matter may be “non-naturally occurring manufacture or composition of matter” and still not be an invention within the Patent Act.⁵¹¹ The Board of Patent Appeals and Interferences, and many courts including the U.S. Supreme Court have fallen into the trap of believing that issue to be addressed in deciding if the 35 U.S.C. § 101 test is met is whether the claimed subject matter is non-naturally

503. *See id.*

504. *See Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1426-27 (1987).

505. *Id.*

506. *See id.*

507. *Id.*

508. *See Patent Act*, 35 U.S.C. § 101 (2005).

509. *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1426 (1987).

510. *Id.* at 1427.

511. *See Patent Act*, 35 U.S.C. § 101 (2005).

occurring.⁵¹² The language of 35 U.S.C. § 101 is clear: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁵¹³

While the terms “manufacture” or “composition of matter” are not defined within the U.S. Patent Act, these terms certainly do not, at least in the ordinary sense, mean non-naturally occurring living matter.⁵¹⁴ Specifically, the Board in *Ex parte Allen* stated that: whether the polyploid oysters “are ‘controlled by the laws of nature’ does not address the issue of whether the subject matter is a non-naturally occurring manufacture or composition of matter.”⁵¹⁵ The Board was reading meaning into the language of 35 U.S.C. § 101 that Congress did not intend.⁵¹⁶ The language of 35 U.S.C. § 101 clearly articulates the classes of invention for which a patent may issue.⁵¹⁷ Specifically, of relevance to the current argument, those classes are “manufacture or composition of matter.”⁵¹⁸ Furthermore, the claimed subject matter must be an invention. The language of the statute does not specify the classes as being a “non-naturally occurring manufacture” or a “non-naturally occurring composition of matter.”⁵¹⁹ Perhaps treading too closely to being overly pedantic, the language of 35 U.S.C. § 101 specifies the classes of relevance here as being a “manufacture” or a “composition of matter.” Therefore, the proper issue to be resolved, in determining whether the 35 U.S.C. § 101 test is passed, is whether the claimed subject matter is a man-made “manufacture” or whether the claimed subject matter is a man-made “composition of matter”;⁵²⁰ and, if man made, it must be determined whether the claimed subject matter is an invention.

512. *See id.*

513. *Id.*

514. *See* THE NEW LEXICON WEBSTER’S DICTIONARY OF THE ENGLISH LANGUAGE 200, 608 (Lexicon Publishers, Inc. 1988).

515. *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) at 1427.

516. *See id.* (discussing the decision of the board); *see also* Patent Act, 35 U.S.C. § 101 (2005).

517. *See* Patent Act, 35 U.S.C. § 101 (2005).

518. *Id.*

519. *See id.*

520. The reader will certainly readily identify that if the “manufacture” is the product of nature then it is not subject matter for which a patent may issue. Similarly, if the subject matter is a naturally occurring “composition of matter” then it is also not patentable. However, the question to be addressed is not whether the subject matter is a naturally occurring “manufacture” or a naturally occurring “composition of matter;” rather whether the subject matter is a man-made “manufacture” or a man-made “composition of matter.” If the subject matter is neither a man-made “manufacture” nor a man-made “composition of matter” then it may be a naturally occurring “manufacture” or a naturally occurring “composition of matter.” However, classifying it as naturally occurring is not part of the issue to be addressed in the 35 U.S.C. § 101 test.

D. *The Logic is Flawed Because ...*

During the drafting of this article, it was observed that the logic used here is fundamentally flawed because the utility of the transgene is found when the transgene is in the plant cells that comprise the plant.⁵²¹ Otherwise, it was argued, Monsanto would never have developed the transgene.⁵²² Hence, Monsanto must have intended for the patent rights to extend to the plant cell and to the entire plant.⁵²³ In the words of Mr. Hughes, counsel for Monsanto, Monsanto did not intend the transgene to be a “laboratory curiosity” to be placed in a bottle on the laboratory shelf.⁵²⁴ However, let us take the argument apart and see why my logic and conclusions remain standing.

The Patent Act of neither the United States nor Canada indicate that the state of mind of the actor is relevant to whether a patent should issue.⁵²⁵ Let us look carefully at the relevant provisions. Section 101 of the Patent Act of the United States provides that: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁵²⁶

There is nothing in the language of the provision that comes even remotely close to indicating that an intended “invention” or “discovery” may be patented. The language is clear in that the actor must invent or discover the subject matter in order for a patent to issue.⁵²⁷ The language does not state that: whoever *intends to invent or discover* “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore. . . .” If Congress had intended to allow a patent to issue to a person who intends to invent or discover some particular subject matter, then such was completely within the power and ability of Congress to do. Upon the face of the statutory provision, and any reasonable interpretation thereof, only one conclusion is possible: intent is not an element to the pat-

521. See Transcript of Oral Argument at 32-33, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

522. See *id.*

523. See *id.*

524. This was the basis of the argument put forward by Mr. Hughes in response to the position of the interveners for Appellant Mr. Percy Schmeiser that the patent rights on the transgene and plant cell extended no further than the door of the laboratory. See Transcript of Oral Argument at 32, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

525. See Patent Act, 35 U.S.C. (2005); Patent Act, R.S.C., ch. P-4 (1985) (Can.).

526. Patent Act, 35 U.S.C. § 101 (2005). The corresponding language of the Canada Patent Act is found in R.S.C. 1985, ch. P-4, § 2 (1985) (Can.).

527. Patent Act, 35 U.S.C. § 101 (2005).

entability of the subject matter. Either the actor has invented the subject matter or the actor has not invented the subject matter. If the actor has not invented the subject matter then a patent may not issue under 35 U.S.C. § 101. Paragraph two of section 112 provides that: “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”⁵²⁸

As is the case with section 101, no mental state is to be found in the language of section 112. The language is clear that the invention must exist. Specifically, the statutory language provides that the applicant must claim “the subject matter which the applicant regards as his invention.”⁵²⁹ The statute does not provide that the applicant may claim “the subject matter which the applicant” *intends to be his invention*.⁵³⁰ Had Congress wanted patents to be granted for what the applicant intends to be his invention, then Congress would have drafted section 112 to so read. That, Congress did not do. The parallel language of the Patent Act of Canada is found in Section 27 as follows:

The Commissioner shall grant a patent for an invention to the inventor or the inventor’s legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.⁵³¹

As with the Patent Act of the United States, no mental state is mentioned in this provision of the Patent Act of Canada.⁵³² Specifically, the statute does not provide that the Commissioner of Patents shall “grant a patent for an [*intended*] invention to the inventor or the inventor’s legal representative. . . .”⁵³³ If it was the objective of Parliament to have the Commissioner of Patents grant a patent for an intended invention, then Parliament was certainly capable of drafting the language to achieve such an objective.

Perhaps the Congress of the United States and the Parliament of Canada both recognized that the grant of a patent for an intended subject matter would be a *reductio ad absurdum* of the law. Even if it were accepted that the Patent Act could provide that a patent could issue for an intended invention, the language of the patents in issue indicate what Monsanto intended to claim.⁵³⁴ Therefore, the next step in the assault upon the counter argument of Mr. Hughes is to look care-

528. *Id.* at § 112, ¶ 2.

529. *Id.*

530. *Id.*

531. Patent Act, R.S.C., ch. P-4, §. 27(1) (1985) (Can.).

532. *See id.*

533. *See id.*

534. *See generally* U.S. Patent No. 4,940,835 (filed July 7, 1986); Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

fully at the claims of the patents at issue in the *Schmeiser v. Monsanto* case.⁵³⁵

The relevant claims of Canadian Patent 1,313,830 are:

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.

8. A cloning or expression vector comprising a chimeric plant gene of Claim 1.
15. A plant transformation vector which comprises a chimeric gene of Claim 1.
22. A glyphosate-resistant plant cell comprising a chimeric plant gene of Claim 1.
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.
45. A glyphosate-resistant oil seed rape cell of claim 22.⁵³⁶

Claims 1 through 28 of U.S. Patent 4,940,835 are identical to claims 1 through 28 of Canadian Patent 1,313,830.⁵³⁷ Claims 36 through 59 of U.S. Patent 4,940,835 are identical to claims 29 through 52 of Canadian Patent 1,313,830.⁵³⁸ Claims 29 through 35 of U.S. Patent 4,940,835 are not to be found

535. See *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶ 80.

536. Can. Patent No. 1,313,830, at [claims 1, 8, 15, 22, 29, 45] (filed Aug. 6, 1986).

537. See U.S. Patent No. 4,940,835, at [col. 32-33] (filed July 7, 1986); Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

538. See U.S. Patent No. 4,940,835, at [col. 34] (filed July 7, 1986); Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

in Canadian Patent 1,313,830.⁵³⁹ Claims 29 through 35 of U.S. Patent No. 4,940,835 read as follows:

29. A glyphosate-resistant dicotyledonous plant which has been regenerated from a glyphosate-resistant plant cell comprising the chimeric plant gene of claim 1.
30. A glyphosate-resistant plant of claim 29 in which the promoter sequence is a plant virus promoter sequence.
31. A glyphosate-resistant plant of claim 30 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).
32. A glyphosate-resistant plant of claim 31 in which the promoter sequence is the CaMV38S promoter sequence.
33. A glyphosate-resistant plant of claim 29 in which the chimeric plant gene comprises a coding sequence encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.
34. A glyphosate-resistant plant 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 glyphosate-resistant plant cell of claim 29 in which the chloroplast transit peptide is from a plant EPSPS gene.⁵⁴⁰

The basic rules of the analysis of the language of the claims are as follows:⁵⁴¹ (1) multiple claims to the same subject matter are not permissible;⁵⁴² (2) multiple claims that include the same subject matter are not permissible;⁵⁴³ (3) if the claimed subject matter is not an invention within the meaning of the Patent Act, then a valid patent cannot issue for the subject matter;⁵⁴⁴ (4) the scope of a narrower claim cannot be broader than the scope of a broad claim.⁵⁴⁵ In the following analysis, I will show that Monsanto could never have anticipated that the claims of U.S. Patent 4,940,835 and of Canadian Patent 1,313,830 would afford it an exclusive property right in the plants found in the field of the farmer.

It has long been settled law that the meaning of written documents is, in general, to be determined from the language of the instruments, and not from

539. See U.S. Patent No. 4,940,835, at [col. 33-34] (filed July 7, 1986); Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

540. See U.S. Patent No. 4,940,835, at [col. 34, lines 12-14] (filed July 7, 1986).

541. Hereinafter, this set of rules shall be denoted as the FOUR BASIC PATENT RULES.

542. See 37 C.F.R. § 1.75(b) (2004).

543. *Id.*

544. See Patent Act, 35 U.S.C. § 101 (2005).

545. See *id.* at § 112.

parol evidence.⁵⁴⁶ The language of the patent application must be of sufficient clarity and certainty before a patent may be issued.⁵⁴⁷ The *Davoll* court stated the reasoning as follows; first, the Patent Act requires such clarity and certainty; second, without a clear and certain description of the invention, the public will be unable to know if and how the rights of the patentee are infringed; and third, without certainty and clarity in the description, the public will be unable to correctly reconstruct the invention claimed and obtain the advantages asserted in the patent.⁵⁴⁸ While the inventor may claim that which is the genuine product of his own ingenuity, the applicant for a patent may not claim that which already belonged in the universe of public knowledge or that which existed before the inventor acted.⁵⁴⁹ In determining that which is claimed by the patentee, the claims must be interpreted in light of the entire specification, including, where necessary, the preface and the body of the specification.⁵⁵⁰

Consider Claim 1 of U.S. Patent 4,940,835 and of Canadian Patent 1,313,830, which I shall denote as “the transgene claim.”⁵⁵¹ If the transgene claim included the transgene in the field, then the patentee has, *de facto*, control of the plant in the field.⁵⁵² In this case, the claim to a plant cell is redundant and unnecessary. Now consider claim 22 of U.S. Patent 4,940,835 and of Canadian Patent 1,313,830, which I shall denote as “the plant cell claim.”⁵⁵³ If the plant cell claim covered the plant cells in the field, then the patentee has, *de facto*, control of the entire plant in the field. If both the transgene claim and the plant cell claim include the respective subject matter in the field, then the patentee has, *de facto*, control of the plant in the field by one of two claims.⁵⁵⁴ Thus, claim 1 and

546. See *Davoll v. Brown*, 1 Wood. & Min. 53, 56 (1st Cir. 1845).

547. See 35 U.S.C. § 112, ¶ 1 (2005).

548. *Davoll*, 1 Wood. & Min. at 57.

549. In his analysis in *Davoll*, Justice Woodbury stated that:

The patent laws are not now made to encourage monopolies of what before belonged to others, or to the public, —which is the true idea of a monopoly, —but the design is to encourage genius in advancing the arts, through science and ingenuity, by protecting its productions of what did not before exist, and of what never belonged to another person, or the public. *Davoll*, 1 Wood. & Min. at 57.

550. *Id.* at 59.

551. See U.S. Patent No., 4,940,835, at [col. 32, lines 31-47] (filed July 7, 1986); Can. Patent No. 1,313,830, at [68] (filed Aug. 6, 1986).

552. See Appellants Factum at ¶¶ 20-21, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (explaining, simplistically, the invention and its ability to replicate naturally in the field).

553. See U.S. Patent No. 4,940,835, at [col. 33, line 22] (filed July 7, 1986); Can. Patent No. 1,313,830, at [70] (filed Aug. 6, 1986).

554. See Memorandum of Fact & Law of the Respondents at ¶ 70, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (explaining the reach of Monsanto’s patent).

claim 22 of U.S. Patent 4,940,835 and of Canadian Patent 1,313,830 operate to include precisely the same subject matter, that is the plant in the field.

Under the Patent Act of Canada, neither a plant seed nor a plant may be claimed in patent issued by the Canadian Intellectual Property Office.⁵⁵⁵ If the patentee has, de facto, control of the plant by either of the transgene claim or the plant cell claim, or both, then the patentee has accomplished indirectly that which could not be accomplished directly.⁵⁵⁶ Had Parliament intended for either plant seeds or plants to be patentable subject matter, then the Patent Act would have been so drafted. The Supreme Court of Canada stated that the existence of the Plant Breeders Rights Act indicates that Parliament did not intend for plants or seeds to be patentable.⁵⁵⁷ Further, Parliament did not intend the patent applicant to be able to accomplish, by means of clever drafting, indirectly what could not be accomplished directly.⁵⁵⁸ Thus, the transgene claim cannot cover the transgene in the field; and the plant cell claim cannot cover the plant cell in the field.⁵⁵⁹

Under the Patent Act of the United States, plants and plant seeds are patentable subject matter.⁵⁶⁰ In claim 29 of U.S. Patent No. 4,940,835, Monsanto claims a “glyphosate-resistant dicotyledonous plant.”⁵⁶¹ Suppose for an instant that claim 29 had been properly drafted to read: “A glyphosate-resistant dicotyledonous plant which has been grown from a glyphosate-resistant seed comprising the chimeric plant gene of claim 1.”

Further, suppose that support for this claim was to be found in the specification of the patent as issued.⁵⁶² Then if the modified claim 29, as opposed to the claim 29 articulated in U.S. Patent No. 4,940,835, were sufficient to include the plant in the field, then a claim to the chimeric gene, a claim to the glyphosate-resistant plant cell, and a claim to the glyphosate-resistant oil seed rape cell would not be necessary, and, in fact, would be in direct violation of the Patent Act of both the United States and Canada for multiple patenting.⁵⁶³ Also, if the

555. See Patent Act, R.S.C., ch. P-4 (1985) (Can.) (defining invention as any new and useful art, process, machine, manufacture or composition of matter).

556. See Memorandum of Fact & Law of the Respondents at ¶ 70, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (explaining the reach of Monsanto’s patent).

557. See *Harvard Coll. v. Canada (Comm’r of Patents)*, [2002] S.C.C. 4, ¶ 120.

558. See *id.*

559. *Id.* at ¶ 30 (Binnie, J., dissenting).

560. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001).

561. For additional reasons that will be explored elsewhere in this report, this claim cannot include plants in the field.

562. See 35 U.S.C. § 112 (2005). Of course, the patent as issued does not support the hypothetical claim.

563. 37 C.F.R. § 1.75(b) (2004).

transgene, plant cell, and oil seed rape cell claims included the plant in the field then the plant claim would be unnecessary and in violation of the Patent Act.⁵⁶⁴

One could argue that the claims cover different components of the plant: the claim to the glyphosate-resistant dicotyledonous plant is the broadest claim, the claim to a glyphosate-resistant cell being somewhat narrower, the claim to a glyphosate-resistant oil rape cell being narrower still, and the claim to the transgene being the narrowest.⁵⁶⁵ Such an argument cannot hold. If any one of these four listed types of claims were to be held as invalid then any one of the other three types of claims would allow the patentee to exercise exclusive rights over the entire plant within the field. In fact, if any given three of the types of claims were held as invalid, then the remaining claim would allow the exercise of exclusive rights, over the entire plant in the field, by the patentee.⁵⁶⁶ Thus, each of the four types of claims gives the patentee *de facto* control over precisely the same subject matter.⁵⁶⁷ Under the rule that multiple patenting is not permissible,⁵⁶⁸ then at least three of the four listed types of claim cannot include the plant in the field. Also, under the rule that narrower claims must exclude some subject matter that is included within the scope of the broader claims,⁵⁶⁹ not all of the four types of claims can allow, *de facto*, control of the entire plant. Again the conclusion is obtained that, at least, three of the four types of claims cannot include the plant in the field.

Further analysis reveals yet another reason as to why all four types of claims cannot operate to protect the exclusive rights over the plant in the field. Consider the plant cell claim and the glyphosate-resistant dicotyledonous plant claim.⁵⁷⁰ If the glyphosate-resistant plant cell included the plant cell in the field, then that claim would include the entire plant in the field.⁵⁷¹ Thus, the glyphosate-resistant plant cell claim and the glyphosate-resistant dicotyledonous

564. *Id.*

565. If indeed such is the intended ordering by the patentee, then the structure of these claims, as issued, is incorrect. The United States Patent and Trademark office indicates that the claims should be ordered from the broadest to the narrowest. See 37 C.F.R. § 1.75(g) (2004) (stating that the "least restrictive claim" be listed first). If the rule of the Patent Office is followed, then the transgene claim must be the broadest and the plant claim must be of intermediate scope.

566. *See generally id.* at § 1.75(c) (stating that "[a] multiple dependent claim shall not serve as a basis for any other multiple dependent claim").

567. *See generally id.* (prohibiting multiple dependent claims that provide a basis for other multiple dependent claims)

568. *See* Rule 1 of the FOUR BASIC PATENT RULES.

569. *See id.* at Rule 4.

570. To be completely formal, the claim to a glyphosate-resistant oil rape cell should be included in the analysis. However, for the sake of brevity the claim is not specifically included.

571. *See* Appellants' Factum at ¶¶ 48-49, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

plant claim would cover precisely the same subject matter. Under the FOUR BASIC PATENT RULES, identified *supra*, one or the other of the claims is either invalid or cannot reach into the field of the farmer. As to which cannot reach the plant in the field is determined by application of the rule that narrower claims cannot cover precisely the same subject matter as broader claims.⁵⁷² Since the claims to a glyphosate-resistant dicotyledonous plant appear to be the broadest claim, then the claim to the glyphosate-resistant cell cannot include the cells in the plant found growing in the field. If the claim to the glyphosate-resistant cells is determined to be the broadest claim, then the claim to a glyphosate-resistant dicotyledonous plant cannot include the plant in the field of the farmer.

None of the four types of subject matter include subject matter growing in the field. This is because the plant, or plant cells, or transgenes found growing within the field is, or are, not and cannot be an invention within the meaning of the Patent Act.⁵⁷³ Further, had Monsanto believed that any one of the four types of claims included corresponding subject matter found in the field, then such would have been specifically so stated in the patent. Again, referring to 35 U.S.C. § 112, the inventor must conclude the specification “with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”⁵⁷⁴ If the patentee desired or believed that the invention was a glyphosate-resistant dicotyledonous plant cultivated in the field then the patentee must so claim.⁵⁷⁵ To claim a glyphosate-resistant dicotyledonous plant and expect that a glyphosate-resistant dicotyledonous plant is circumscribed where ever it is found is to claim too broadly.⁵⁷⁶ The patentee did not invent every glyphosate-resistant dicotyledonous plant that may be found in the

572. See Rule 4 of the FOUR BASIC PATENT RULES.

573. See Patent Act, R.S.C., ch. P-4 (1985) (Can.).

574. 35 U.S.C. § 112 (2005). The relevant version in the Patent Act of Canada reads: “The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.” Patent Act, R.S.C., ch. P-4, § 27(4) (1985) (Can.).

575. 35 U.S.C. § 112 (2005) (discussing what a claim must include).

576. Such a claim would allow Monsanto to assert control over plants that have been pollinated by the adventitious spread of pollen containing the transgene. In effect, such a claim would allow Monsanto to assert control over every dicotyledonous plant on the face of the planet. Patent Act, U.S.C. § 163 (2005) (stating that a patent grants the right to exclude others from asexually reproducing the plant).

field.⁵⁷⁷ Thus, such a broad claim is invalid for want of particularity under 35 U.S.C. § 112, ¶ 2.⁵⁷⁸

Even if a claim to a glyphosate-resistant dicotyledonous plant was interpreted broadly, sufficient disclosure must be given in the specification to support such a broad interpretation.⁵⁷⁹ Monsanto disclosed only the production of a glyphosate-resistant dicotyledonous plant by regeneration from a single, transformed, progenitor plant cell.⁵⁸⁰ Had Monsanto intended for the plant claim to cover the plant found in the field, then the disclosure of the protocol for producing that plant in the field must exist in the specification.⁵⁸¹ This, Monsanto did not do.

It is a well accepted canon of patent claim construction that a narrower claim cannot be broader than a broader claim.⁵⁸² Consider claim 29 of U.S. Patent No. 4,940,835 in detail. The claim provides that “[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.”⁵⁸³

The operative phrase of the claim is “regenerated from a glyphosate-resistant plant cell.” Support is found in the specification, of U.S. Patent No. 4,940,835 for only a single glyphosate-resistant plant cell producing a shoot, and eventually a plant.⁵⁸⁴ Neither the disclosure in the specification nor the claim indicates that a glyphosate-resistant plant is grown from a glyphosate-resistant seed.⁵⁸⁵ In fact, nowhere in either U.S. Patent No. 4,940,835 or Canadian Patent No. 1,313,830, does Monsanto either mention or claim a glyphosate-resistant seed.⁵⁸⁶ The lack of either a disclosure of or a claim to a glyphosate-resistant seed is a clear and unmistakable indication that Monsanto intended to disclaim

577. If, indeed, the claim to a glyphosate-resistant dicotyledonous plant did include every such plant, then even those plants which, by repeated and sustained exposure to a glyphosate-based herbicide, become glyphosate-resistant would be circumscribed by the patent. The claim must be narrow so as to not allow such a result to occur.

578. 35 U.S.C. § 112 ¶ 2 (2005).

579. *See id.*

580. *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34, ¶ 17; U.S. Patent No. 4,940,835, at [col. 33, line 60] (filed July 7, 1986).

581. *See* 35 U.S.C. § 112 (2005).

582. *See* Rule 4 of the FOUR BASIC PATENT RULES.

583. U.S. Patent No. 4,940,835, at [claim 36] (filed July 7, 1986).

584. *Id.*

585. *See generally id.*

586. *See generally* Can. Patent No. 1,313,830 (filed Aug. 6, 1986); U.S. Patent No. 4,940,835 (filed July 7, 1986).

such a seed.⁵⁸⁷ Because a “glyphosate-resistant dicotyledonous plant” grown from a seed was not claimed, then Monsanto disclaimed such a plant.⁵⁸⁸ Because the plant was disclaimed then the claim to a “glyphosate-resistant dicotyledonous plant regenerated from a plant cell” cannot include the glyphosate-resistant plant found growing in the field.⁵⁸⁹

If the claim to a glyphosate-resistant plant cell included plant cells found in the field, then the claim to a glyphosate-resistant cell can be no broader than the claim to a glyphosate-resistant dicotyledonous plant.⁵⁹⁰ This is because a plant is comprised of plant cells. Because two claims cannot cover precisely the same subject matter, the claim to the glyphosate-resistant cell must be narrower than the claim to a glyphosate-resistant plant.⁵⁹¹ Since the claim to a plant cell is narrower than the claim to a plant, the claim to the plant cell cannot cover the plant cells found in the field.⁵⁹² By an analogous analysis, the transgene cannot include a transgene found on the field of the farmer.

In summary, by a careful analysis of the language of the patent in issue, the intangible property rights in issue do not include any part of the plant growing in the field.

The final step in the assault upon the counter argument of Mr. Hughes is to carefully examine that counter argument. The statement is that because the utility of the transgene is found when the transgene is present in the plant cells, the claim to the transgene should extend to the plant cell and to the plant.⁵⁹³ This position is unsound because it makes the scope of the claim to the transgene de-

587. See *Patents, Trademarks, and Copyrights*, 37 C.F.R. § 1.71, 1.75 (2004).

588. An interesting question is as follows: if the glyphosate-resistant dicotyledonous plant grown from a glyphosate-resistant seed is claimed but the glyphosate resistant seed is not claimed then is the claim to the plant valid? See *generally* Can. Patent No. 1,313,830 (filed Aug. 6, 1986); U.S. Patent No. 4,940,835 (filed July 7, 1986); *Patents, Trademarks, and Copyrights*, 37 C.F.R. §§ 1.71, 1.75 (2004).

589. See U.S. Patent No. 4,940,835, at [col. 33, lines 60-62] (filed July 7, 1986) (claiming the plant); but *cf.* *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (suggesting that the plant may also be covered by the patent. “[W]e 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 isolated laboratory form.”)

590. See U.S. Patent No. 4,940,835, at [col. 33, lines 39-40, 60-62] (filed July 7, 1986) (claiming both a glyposate-resistant plant cell and a glyposate-resistant dicotyledonous plant).

591. Because a plant seed is not considered to be a plant cell, then the claim to a plant cell must necessarily be narrower than the claim to a plant. Even if a plant seed was considered to be a plant cell then the claim to a plant cell could include exactly the same subject matter as a claim to a plant. Such an outcome is prohibited. See Patent Act, 35 U.S.C. § 102 (2005) (describing the prohibition on issuing patents if the invention was used or patented by others).

592. See *generally id.*

593. Memorandum of Fact & Law of the Respondents at 30, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

pend, in part, upon the utility of the transgene. Patent law, in both the United States and Canada, requires that the invention have utility before a valid patent may be issued.⁵⁹⁴ Once the patent has been issued, a utility other than what was originally identified by the applicant may be discovered.⁵⁹⁵ However, the newly identified utility does not extend the originally identified scope of the claim.⁵⁹⁶ The scope of the claim is, necessarily, identified by the language of the claim and the disclosure contained within the specification.⁵⁹⁷ In the “Summary of the Invention” of U.S. Patent No. 4,940,835 disclose that:

This invention involves a cloning or expression vector comprising a gene which encodes 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) polypeptide which, when expressed in a plant cell contains a chloroplast transit peptide that allows the polypeptide, or an enzymatically active portion thereof, to be transported from the cytoplasm of the plant cell into a chloroplast in the plant cell, and confers a substantial degree of glyphosate resistance upon the plant cell and plants regenerated therefrom.⁵⁹⁸

Indeed, the utility of the invention is to confer “a substantial degree of glyphosate resistance upon the plant cell and plants.”⁵⁹⁹ However, to determine whether the claim to the chimeric gene⁶⁰⁰ includes a chimeric gene found in the plant cell comprising a fully mature plant standing in the field of Mr. Schmeiser does not depend upon the utility of the claimed subject matter. Such a determination goes to identifying the scope of the claim, and the utility and scope of the subject matter are necessarily decoupled. The utility of the claimed subject matter is used to determine only whether a patent may issue for the claimed subject matter.⁶⁰¹ The utility of the subject matter may help to illuminate the question of whether the claimed subject matter was “used” to determine whether the patent

594. See Patent Act, 35 U.S.C. § 101 (2005); Patent Act, R.S.C., ch. P-4 (1985) (Can).

595. This statement represents the second part of the “red-spider test” for utility of an invention. If one has an invention the utility of which is not immediately obvious, it could be claimed that the invention is useful for killing red spiders. In the case of a chemical composition, the test is to put a red spider in a vat of the chemical composition. If the red spider dies, which it invariably will, then the chemical composition is useful for killing red spiders. If the invention is then later employed for a function other than the originally identified utility, an infringement may be alleged. Thus, an infringing use of an invention may not necessarily be the originally identified utility of the invention.

596. See 35 U.S.C. § 112 (2005).

597. See *id.*

598. U.S. Patent No. 4,940,835, at [col. 2, lines 21-30] (filed July 7, 1986). Identical language is found in Can. Patent No. 1,313,830, at [3] (filed Aug. 6, 1986).

599. U.S. Patent No. 4,940,835, at [col. 2, lines 36-38] (filed July 7, 1986).

600. See U.S. Patent No. 4,940,830, at [claim 1]; Can. Patent No. 1,313,830, at [claim 1] (filed Aug. 6, 1986).

601. See Patent Act, 35 U.S.C. § 101 (2005).

rights of the patentee have been infringed.⁶⁰² The scope of the claim is used only to determine whether the patent rights of the patentee have been infringed.⁶⁰³ If the claimed subject matter was “used” within the scope of the claim, then the patent rights have been infringed.⁶⁰⁴ The meaning of “utility” and of “scope” are different within the Patent Act and within the relevant case law.⁶⁰⁵ The utility of the patent is not relevant to the issue of infringement within the meaning of the Patent Act.⁶⁰⁶ The scope or use of the claim is not relevant to the issue of whether a patent may issue under 35 U.S.C. § 101 as no mention of the scope or “use” of the subject matter is to be found in the language of 35 U.S.C. § 101.⁶⁰⁷ Thus, the utility of the claimed subject matter cannot be used to determine the scope of the claim. Even in determining the question of infringement the originally identified utility need not be the same as the use to which the alleged infringer put the claimed subject matter.⁶⁰⁸

In summary, the intention of the applicant regarding the nature of the claimed subject matter is irrelevant in determining whether the claimed subject matter is an invention. The language of the patent claims, quoted *supra*, indicates that Monsanto did not believe the claimed subject matter included any part of a plant standing in the field of Mr. Schmeiser.⁶⁰⁹ Third, the utility of the claimed subject matter cannot be used to determine the scope of the claim in the patent.

602. *See id.* at § 271(a).

603. *See id.* at § 271.

604. *See id.*

605. *See id.*; Patent Act, R.S.C., ch. P-4 (1985) (Can.); Appellants’ Factum at 18-21, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

606. *See* Patent Act, 35 U.S.C. § 271 (2005).

607. The same conclusion holds under Section 2 of the Patent Act of Canada.

608. During the oral hearing, Mr. Zakreski, counsel for Mr. Percy Schmeiser, argued that “use” of the claimed subject matter did not occur because Mr. Schmeiser did not employ the subject matter according to the stated utility of the claimed subject matter. *See* Transcript of Oral Argument at 8-13, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34. At the time, I supported the position argued by Mr. Zakreski. Now, with the benefit of proper reflection, I believe that the position argued by Mr. Zakreski falls short of the proper argument for “use” of an invention. Mr. Zakreski couples the definition of the “use” of claimed subject matter with the definition of the “utility” of the claimed subject matter. In fact, the “use” and the “utility” of claimed subject matter have separate and distinct meanings within the Patent Act and must be analyzed as separate and distinct concepts. It is possible to “use” an invention for any purpose whatsoever, even one not imagined by the applicant for the patent, and be an infringer. The question is whether the alleged infringer, in this case Mr. Schmeiser, “used” the invention for any purpose at all.

609. U.S. Patent No. 4,940,835, at [col. 2, lines 21-30] (filed July 7, 1986). Identical language in Can. Patent No. 1,313,830, at [3] (filed Aug. 6, 1986).

VI. CONCLUDING REMARKS

The battle between the farmers and the seed manufactures regarding the respective rights was not resolved by the *Schmeiser* Court.⁶¹⁰ The battle will not be fully resolved by the Parliament, or the Congress in the United States. Ultimately, this battle will be resolved by the free market. The farmers will cease to use genetically manipulated seeds when the farmers realize that their products will not fetch a premium price in the consumer market,⁶¹¹ that the genetically manipulated crops do not produce as high a yield as conventional crops with comparable genomic background, that the farmer has to bear the burden of liability for genetic contamination of crops on neighboring fields,⁶¹² and that the crops are not as economical to produce as once believed. The temporal course of this “Modern Range Battle” is not yet clear, what is known is that Monsanto has encroached too far into the fields of Mr. Schmeiser. Both Mr. Schmeiser and Monsanto have their respective property rights and both have the right to be participants in the market place. Monsanto does not have the right to push Mr. Schmeiser out of the marketplace using a patent that, on its face, does not even cover either the plants or the seeds on the fields of Mr. Schmeiser.

610. See *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34.

611. It is of interest to note that Ms. Mona G. Brown, counsel for intervener Canadian Canola Growers Association, agreed, during oral arguments, that the “[m]arket is indifferent as to whether the oil [from crushed canola] is from a product that is Roundup Ready.” Transcript of Oral Argument at 74, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34 (quoted from a question posed to Ms. Brown by Madam Justice Arbour). Over the past several years, news reports have indicated that exactly the opposite proposition is true.

612. Ms. Brown stated that: “[t]he scientific evidence confirms that advantageous spreading of genetically modified canola is minute and manageable.” Transcript of Oral Argument at 75-76, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34. The adventitious spread of glyphosate-resistant onto the fields of Mr. Percy Schmeiser during the summer of 1997 was neither minute nor manageable. It is of some import that: first, the undisputed evidence and finding of the Trial Court indicated that of the area test-sprayed by Mr. Percy Schmeiser, 60% proved to Roundup-tolerant with the Roundup-tolerant plants growing in clumps with the highest number of Roundup-tolerant plants growing nearest the field and fewer growing as the distance into the field increased, Transcript of Oral Argument at 17, *Schmeiser v. Monsanto Can., Inc.*, [2004] S.C.C. 34; second, Monsanto initially alleged that Mr. Percy Schmeiser obtained “brown-bag” seed and planted it, an allegation that was later withdrawn for want of evidence. Therefore, the canola that was on the fields of Mr. Percy Schmeiser in 1997 did not get there by some nefarious actions on the part of Mr. Schmeiser; however, the contamination was substantial and not manageable. Therefore, the assertion of Ms. Brown, quoted *supra*, is simply without merit.