An Agricultural Law Research Article

Genetically Modified Plants are Not "Inventions" and Are, Therefore, Not Patentable

Part One

by

Nathan A. Busch

Originally published in DRAKE JOURNAL OF AGRICULTURAL LAW
10 DRAKE J. AGRIC. L. 387 (2005)

GENETICALLY MODIFIED PLANTS ARE NOT "INVENTIONS" AND ARE, THEREFORE, NOT PATENTABLE

Nathan A. Busch[1]

---

1. J.D. University of Minnesota Law School, 2002; Ph. D. Chemical Engineering, Rutgers University, 1995; Ph. D. Biomedical Engineering, Louisiana Tech University, 1984.; B.S. Chemical Engineering, Purdue University, 1978. Currently, I am practicing in the area of intellectual capital law, and complex intellectual property litigation. I also wish to recognize the continuing assistance of the librarians of the University of Minnesota Law School law library. Without their patient assistance this work would never have been brought forward.

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

---

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. 34.

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 ... [adventitiously], there is absolutely no evidence put in here about the so-called ... [adventitious] spreading.[49]

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

MR. HUGHES: With respect, Justice Iaccobucci, 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] Innovest, 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 Valve 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 in[v]ention 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'"; 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 patentable[142] or that a patent could issue for a new, useful, and non-obvious breed of plant[143] 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 sequence[201] 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 explants 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 discs[216] 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]" plants[220]; 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] glyphosate-resistant tobacco cells in Example 3;[228] 4) glyphosate-resistant soybean cells in Example 4;[229] 5) glyphosate-resistant cotton cells;[230] 6) glyphosate-resistant oil-seed rape cells;[231] 7) glyphosate-resistant flax cells;[232] 8) glyphosate-resistant potato cells;[233] and 9) 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 disks 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 inserted[308] 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 information[314] 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 in 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); Nikolas 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-enolypruvyl-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).

thase 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 polypeptide[377] 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.).