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

Part Two

by

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

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

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

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

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

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

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

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

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

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

405. *Id.*

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

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

> 1. A chimeric plant gene which comprises:
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> (a) a promoter sequence which functions in plant cells;
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> (b) a coding sequence which causes the production of RNA, encoding a chloroplast transit peptide/5-enolpyruvylshikimate-3-phosphate synthase fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell; and

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

407. *Id.* at 73.

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

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

> (c) a 3′ non-translated region which encodes a polyadenylation signal which functions in plant cells to cause the addition of polyadenylate nucleotides to the 3′ end of the RNA;
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> the promoter being heterologous with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with the gene.[410]

Consider whether the subject matter of Claim 1 is an "invention." The preamble of the claim is important in addressing this issue. The authors of the patent give a clean, concise description of how the chimeric gene was generated.[411] The chimeric gene is produced by a well known and well defined set of biochemical protocols.[412] The design of the chimeric gene, that is the sequence of nucleotides in the gene, was the product of mental processing of information. The actor is aware that the gene of interest[413] may or may not be properly expressed by the plant cell.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

With the chimeric gene in hand, the actor is faced with the problem of inserting the gene into a cell. The actor must first collect information on the available methods for transfecting a cell.[419] If a suitable method is not available, then the actor must act to identify an alternative method. Such identification process certainly includes designing and conducting experiments, the objective of which is to determine the pathways in the plant cell that are or might be susceptible to infection by the transgene.[420] Once the biochemical pathways of the cell are identified, then the actor must enumerate a set of vectors[421] that might be suitable and then conduct the experiments necessary to select the candidate vector or vectors to be used in the transfection process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

> all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced en masse as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.
>
> As to why the plant-cell line qualifies as a micro-organism is not of central import to the current analysis and, hence, will not be examined.

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

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

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

433. *Id.* at 73.

fore, the plant-cell line is not an "invention" within the meaning of the Patent Act.[434]

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

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

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

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

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

436. *Id.*

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

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

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

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

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

The practice of culturing plant cells, which were transfected using *Agrobacterium tumefaciens*, to regenerate plants, has been in existence for more than twenty years.[443] In fact, the knowledge was considered to be common place in 1985 when Horsch, et al., filed the parent application that eventually lead to U.S. Patent No. 4,940,835.[444] Horsch et al., did not describe the single-cell culture method as novel and it was not described in the detail that would be expected of a method reported for the first time.[445] A review of the patents issued to Monsanto since 1985 indicates that none of the patents covered a method for culturing a single plant cell to produce a mature plant.[446] In fact, one of the earliest articles reporting the cell-culture method was published by Luis Herrera-Estrella, et al.[447]

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

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

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

443. *See generally id.*

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

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

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

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

> Dicotyledonous plants are transformed by *Agrobacterium* by the transfer, integration and expression of part of the Ti plasmid (T-DNA) in the plant genome. The hormone-independent growth of crown gall tumors . . . is a natural dominant selectable marker, and has been used successfully to develop transformation systems for plants. This natural dominant selectable marker, however, interferes with plant morphogenesis, and differentiation, and prevents the formation of whole plants from single cells or from callus tissue.

Id. at 993 (citations omitted). L. Herrera-Estrealla, et al., reported the method by which the natural dominant selectable marker was removed, thus allowing the regeneration of whole plants from a single cell.

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

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

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

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

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

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

450. *See id.* at 73.

451. *See id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Even if we accept that the phrase "plant cell" includes a plant seed,[467] the result of the analysis presented in this Article does not change. There are two reasons in support of this assertion. First, no disclosure exists in the specification of either Canadian Patent No. 1,313,830 or U.S. Patent No. 4,940,835 regarding the making or construction of a glyphosate-resistant plant seed.[468] Therefore, Claim 22 of both patents cannot include glyphosate-resistant plant seeds within the meaning of a glyphosate-resistant cell.[469] Consider this a bit further. Presume that a glyphosate-resistant seed had been claimed.[470] Because no support exists in the specification for making or constructing the glyphosate-resistant seed, then the claim would be invalid under 35 U.S.C. § 112.[471] Subject matter cannot be included into one claim by stretching that claim if the subject matter cannot be claimed explicitly.

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

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

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

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

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

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

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

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

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

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

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

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

It might be argued that the intangible personal property right in the transgene follows the transgene no matter where the transgene is located. Based upon this position, the claim to a plant cell is valid no matter where that cell is located. The argument leads to the conclusion that the property right in the transgene extends to any cell, wherever situated, which is comprised of the transgene. The result of this conclusion is that the claim to a transgene would include every cell in a plant that is comprised of the transgene. It stands to reason then that the applicant for a patent would claim a plant cell comprised of the transgene, a plant comprised of plant cells containing the transgene, and the seeds comprised of the transgene. The applicant for a patent followed precisely such a course of action in the application that issued to U.S. Patent No. 4,940,835.[475]

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

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473. *See id.*

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

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

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

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

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

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

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

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

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

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

480. This is the problem of "self-replicating entities."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. *Whether the Plant Variety is Patentable*

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

Essential to the issue of patentability under the Plant Patent Act is whether the plant represents a new variety.[491] On the problem of identifying a variety, Carleton R. Ball stated that "[i]t is not always easy to recognize a variety from its description. Often two varieties really different look very much alike. Sometimes the visible difference is very small. Sometimes there is no visible difference at all, although there is a real difference in yielding power."[492] A new variety, within the meaning of the Plant Patent Act, may arise as a new sport, a mutation, or a graft, amongst others.[493] The key to patentability under the Plant Patent Act is that the new variety must be asexually propagated.[494] If the new variety arises by one of the aforementioned methods, the issue to be addressed is whether that variety is an invention within the meaning of 35 U.S.C. § 101.[495] As examined elsewhere in this work, if the variety is subject matter that is an invention, then a valid patent may be issued.[496]

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

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

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

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

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

493. 35 U.S.C § 161 (2005).

494. *See id.*

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

496. *See id.*

Let us presume that a particular plant is comprised of cells that contain a transgene. If a sport or mutation is discovered then the plant that is subsequently cultivated is not an invention.[497] One might argue that such subject matter is a discovery and hence should be within the boundary set by the Patent Act. Certainly, the cultivated plant would be subject matter for which a patent could issue under 35 U.S.C. § 161. However, discovery within the meaning of 35 U.S.C. § 101 does not have a meaning separate and distinct from the meaning of invention.[498] Because the discoverer of the sport or mutant comprised of the transgene did not "invent" the sport or mutant plant then it is not subject matter for which a valid patent may issue under 35 U.S.C. § 101.[499]

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

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

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

To the lay patent practitioner, this statement forecloses any challenges to an issued patent in which a claim is made for a multi-cellular living organism based upon 35 U.S.C. § 101.[502] It is a routine practice for a patent practitioner to draft claims directed towards an organism containing a transgene, which encodes for this protein or that protein. In fact, it would be considered malpractice for the

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497. *Id.*

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

499. *See id.*

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

501. *Id.*

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

practitioner to not include such a broad claim. While the U.S. P.T.O. would issue a patent for such a multi-cellular organism, it is not clear that the organism actually falls within 35 U.S.C. § 101.[503] In *Ex parte Allen*, the Board of Patent Appeals and Interferences came remarkably close to properly formulating the underlying issue.[504] There, the Board stated:

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

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

503. *See id.*
504. *See Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426-27 (1987).
505. *Id.*
506. *See id.*
507. *Id.*
508. *See* Patent Act, 35 U.S.C. § 101 (2005).
509. *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (1987).
510. *Id.* at 1427.
511. *See* Patent Act, 35 U.S.C. § 101 (2005).

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

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

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512. *See id.*

513. *Id.*

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

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

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

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

518. *Id.*

519. *See id.*

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

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

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

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

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

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

522. *See id.*

523. *See id.*

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

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

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

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

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

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

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

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

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

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528. *Id.* at § 112, ¶ 2.
529. *Id.*
530. *Id.*
531. Patent Act, R.S.C., ch. P-4, §. 27(1) (1985) (Can.).
532. *See id.*
533. *See id.*
534. *See generally* U.S. Patent No. 4,940,835 (filed July 7, 1986); Can. Patent No. 1,313,830 (filed Aug. 6, 1986).

fully at the claims of the patents at issue in the *Schmeiser v. Monsanto* case.[535] The relevant claims of Canadian Patent 1,313,830 are:

1. A chimeric plant gene which comprises:

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

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

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

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

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

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

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

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

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

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

45. A glyphosate-resistant oil seed rape cell of claim 22.[536]

Claims 1 through 28 of U.S. Patent 4,940,835 are identical to claims 1 through 28 of Canadian Patent 1,313,830.[537] Claims 36 through 59 of U.S. Patent 4,940,835 are identical to claims 29 through 52 of Canadian Patent 1,313,830.[538] Claims 29 through 35 of U.S. Patent 4,940,835 are not to be found

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

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

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

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

in Canadian Patent 1,313,830.[539] Claims 29 through 35 of U.S. Patent No. 4,490,835 read as follows:

> 29. A glyphosate-resistant dicotyledonous plant which has been regenerated from a glyphosate-resistant plant cell comprising the chimeric plant gene of claim 1.
>
> 30. A glyphosate-resistant plant of claim 29 in which the promoter sequence is a plant virus promoter sequence.
>
> 31. A glyphosate-resistant plant of claim 30 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).
>
> 32 A glyphosate-resistant plant of claim 31 in which the promoter sequence is the CaMv38S promoter sequence.
>
> 33. A glyphosate-resistant plant of claim 29 in which the chimeric plant gene comprises a coding sequence encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.
>
> 34. A glyphosate-resistant plant of claim 29 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.
>
> 35. A glyphosate-resistant plant cell of claim 29 in which the chloroplast transit peptide is from a plant EPSPS gene.[540]

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

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

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

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

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

542. *See* 37 C.F.R. § 1.75(b) (2004).

543. *Id.*

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

545. *See id.* at § 112.

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

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

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

547. *See* 35 U.S.C. § 112, ¶ 1 (2005).

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

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

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

550. *Id.* at 59.

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

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

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

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

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

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

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

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

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

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

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

558. *See id.*

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

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

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

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

563. 37 C.F.R. § 1.75(b) (2004).

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

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

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

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564. *Id.*

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

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

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

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

569. *See id.* at Rule 4.

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

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

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

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

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

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

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

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

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

field.[577] Thus, such a broad claim is invalid for want of particularity under 35 U.S.C. § 112, ¶ 2.[578]

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

It is a well accepted canon of patent claim construction that a narrower claim cannot be broader than a broader claim.[582] Consider claim 29 of U.S. Patent No. 4,940,835 in detail. The claim provides that "[a] method for producing a glyphosate-resistant dicotyledonous plant which comprises (a) transforming plant cells using an Agrobacterium transformation vector comprising a chimeric plant gene of Claim 1; and (b) regenerating glyphosate-resistant plants from said transformed plant cells."[583]

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

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

578. 35 U.S.C. § 112 ¶ 2 (2005).

579. *See id.*

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

581. *See* 35 U.S.C. § 112 (2005).

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

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

584. *Id.*

585. *See generally id.*

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

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

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

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

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

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

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

589. *See* U.S. Patent No. 4,940,835, at [col. 33, lines 60-62] (filed July 7, 1986) (claiming the plant); but *cf.* Schmeiser v. Monsanto Can., Inc., [2004] S.C.C. 34 (suggesting that the plant may also be covered by the patent. "[W]e do not believe this fact requires reading a proviso into the claims that would provide patent protection to the genes and cells only when in isolated laboratory form.")

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

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

592. *See generally id.*

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

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

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

Indeed, the utility of the invention is to confer "a substantial degree of glyphosate resistance upon the plant cell and plants."[599] However, to determine whether the claim to the chimeric gene[600] includes a chimeric gene found in the plant cell comprising a fully mature plant standing in the field of Mr. Schmeiser does not depend upon the utility of the claimed subject matter. Such a determination goes to identifying the scope of the claim, and the utility and scope of the subject matter are necessarily decoupled. The utility of the claimed subject matter is used to determine only whether a patent may issue for the claimed subject matter.[601] The utility of the subject matter may help to illuminate the question of whether the claimed subject matter was "used" to determine whether the patent

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

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

596. *See* 35 U.S.C. § 112 (2005).

597. *See id.*

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

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

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

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

rights of the patentee have been infringed.[602] The scope of the claim is used only to determine whether the patent rights of the patentee have been infringed.[603] If the claimed subject matter was "used" within the scope of the claim, then the patent rights have been infringed.[604] The meaning of "utility" and of "scope" are different within the Patent Act and within the relevant case law.[605] The utility of the patent is not relevant to the issue of infringement within the meaning of the Patent Act.[606] The scope or use of the claim is not relevant to the issue of whether a patent may issue under 35 U.S.C. § 101 as no mention of the scope or "use" of the subject matter is to be found in the language of 35 U.S.C. § 101.[607] Thus, the utility of the claimed subject matter cannot be used to determine the scope of the claim. Even in determining the question of infringement the originally identified utility need not be the same as the use to which the alleged infringer put the claimed subject matter.[608]

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

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602. *See id.* at § 271(a).

603. *See id.* at § 271.

604. *See id.*

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

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

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

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

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

VI. CONCLUDING REMARKS

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

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

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

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