

Commissioner's Decision #1305

Décision du Commissaire #1305

TOPIC: J00, K10

SUBJECT: J00, K10

Application No: 2,094,511

Demand No: 2,094,511

COMMISSIONER'S DECISION SUMMARY

C.D. 1305 Application No. 2,094,511

The subject application relates to analogs of botanic seeds, comprising either a unit of totipotent plant tissue, a unit of embryonic plant tissue or a plant embryo comprising a shoot and a radicle encapsulated in a hydrated gel coating, capsules comprising the hydrated gel capsule devoid of living material and methods for manufacturing the analog of a botanic seed. In the Final Action, the Examiner rejected claims 1 to 28 for being directed towards higher life forms and thus for falling outside the definition of invention under Section 2 of the *Patent Act*. The Examiner acknowledged that capsule claims 41 to 68 and method claims 29 to 40 were in allowable form. The Board recommended that the rejection of claims 1 to 28 be upheld.

The Commissioner of Patents agreed with the Board's recommendation and claims 1 to 28 were refused.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,094,511 having been rejected under Subsection 30(3) of the *Patent Rules*, the Final Action of the Examiner has been reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

Agent for the Applicant

Smart & Biggar

Box 11560 Vancouver Centre

2200-650 W. Georgia Street

VANCOUVER British Columbia

V6B 4N8

INTRODUCTION:

(1) This decision deals with a review of the Examiner's Final Action on patent application number 2,094,511 entitled "Analog of Botanic Seed". The Applicant is Weyerhaeuser and the inventors are William C. Carlson, Jeffery E. Hartle and Barbara K. Bower. Examiner C.

Bruce-Payne issued a Final Action on May 24, 2006 rejecting claims 1 to 28 as encompassing higher life forms and thus for being noncompliant with Section 2 of the *Patent Act*.

(2) The invention claimed in the pending application relates to analogs of botanic seeds, comprising either a unit of totipotent plant tissue, a unit of embryonic plant tissue or a plant embryo comprising a shoot and a radicle encapsulated in a hydrated gel coating, capsules comprising the hydrated gel devoid of living matter and methods for manufacturing the analogs of botanic seeds.

BACKGROUND:

Prosecution History

(3) The instant application 2,094,511, was filed on October 24, 1991 and contained 65 claims. Request for Examination was made on May 21, 1993 and a first report issued dated March 14, 1995. The first report raised a unity objection and limited the search of the prior art to product and method claims 1 to 63 and 65, objecting to the breadth of the claim language and for encompassing seed analogs of the prior art. In the Applicant's response dated August 2, 1995, the claims were amended to remove claim 64, and 15 new claims were added which increased the total number of claims to 81. Claim 64, was independently prosecuted in divisional application 2,161,814 which issued on April 21, 1998 with one claim to an apparatus for providing oxygen to the instant analogs of botanic seeds.

(4) The Office issued four additional Office Actions for the instant application objecting to the broad and indefinite language of some product and method claims, in particular, for not sufficiently defining the hydrated gel component of the seed analogs. In addition plant and plant germinant

claimed subject matter was objected to as being outside the definition of invention set out by Section 2 of the *Patent Act*. Claims which recited totipotent plant tissue, plant embryonic plant tissue and plant embryos comprising a shoot and a radicle were first included in a Section 2 objection in the fifth Office action, dated April 7, 2005 (the pre-Final Action). A unity of invention objection was also raised at that time, citing three alleged inventions, following which the Applicant elected to prosecute Group A, product and method claims 1 to 40, and cancelled all other claims.

(5) The Final Action dated May 24, 2006, had only one objection. Claims 1 to 28 were rejected for encompassing higher life forms and thus falling outside the definition of invention under Section 2 of the *Patent Act*. In the Applicant's response, dated November 24, 2006, the Applicant traversed the objection and introduced new claims 41 to 68. The response failed to satisfy the Examiner, with respect to claims 1 to 28, and the instant application was subsequently forwarded to the Board for review on September 19, 2007 in accordance with Subsection 30(6) of the *Patent Act*. The Examiner provided a Summary of Reasons to the Board which was forwarded to the Applicant.

(6) An oral hearing (the hearing) was scheduled on April 8, 2009. Representing the Applicant was Brian Kingwell, Michael Manson and Jeffery Morton. The Applicant also provided Exhibits A to C, suspension and solid callus cultures obtained from a laboratory at Simon Fraser University in Burnaby, British Columbia, together with an affidavit from Dr. Mark S. Pidkowich. The Office was represented by Examiner Kalie Pedersen and Section Heads Linda Brewer and Kathleen Murphy. Examiner Cynthia Bruce-Payne, who issued the Final Action, was on extended leave.

(7) At the time of the hearing the Board consisted of three members. Subsequent to Examiner Cynthia Bruce-Payne's return to the Office following the hearing, it came to our attention that

Mr. Ed MacLaurin, the third member, had been the supervisor of Cynthia Bruce-Payne when she prepared a draft of the Final Action and therefore may have been involved to some extent with the case before being tasked as a Board member with reviewing the Final Action. In an effort to promote fairness to the Applicant, Mr. MacLaurin recused himself from the case, prior to any deliberation or analysis on the facts of the case by the Board.

Overview of Manufactured and Artificial Seeds

(8) An overview of the claimed elements under review will be useful. This overview is consistent with the knowledge of a person skilled in the art, the description of the invention, and the Applicant's submissions and statements at the hearing.

(9) A typical seed as understood by a person skilled in the art, comprises three basic components, a seedcoat, an endosperm and a zygotic embryo (comprising cotyledons, epicotyl, hypocotyl and radical). The seedcoat provides a protective environment and the endosperm provides nutrients to the developing embryo. While the seedcoat and endosperm are integral to the successful germination and development of the embryo, it is the embryonic tissues of the seed which ultimately develops into the whole plant. In the case of an analog of a botanic seed of the instant case, the "a unit of totipotent plant tissue", "a unit of plant embryonic tissue" and "a plant embryo comprising a shoot and a radicle", are analogous to the zygotic embryo of a traditional botanic seed. Consequently, the Applicant uses the term "a embryo" broadly to refer to totipotent plant tissue (page 12, lines 3 to 5).

(10) For the analog of a botanic seed to function as an "a artificial" seed it is essential that the living matter of the analog retain the potential to produce an entire plant; a characterization known as totipotency. The term totipotent is derived from the Latin word *totus*, meaning entire, and is

used to define the potential of cells or fertilized eggs to produce a mature organism (see the National Institutes of Health >Stem Cell Information= included in tab K of the Applicant=s hearing submissions). Unlike animal cells, plant cells generally are classified as totipotent. The instant application defines totipotency as the Acapacity [of plant tissue] to grow and develop into a normal plant@ (page 11, lines 19 to 24), consistent with our understanding.

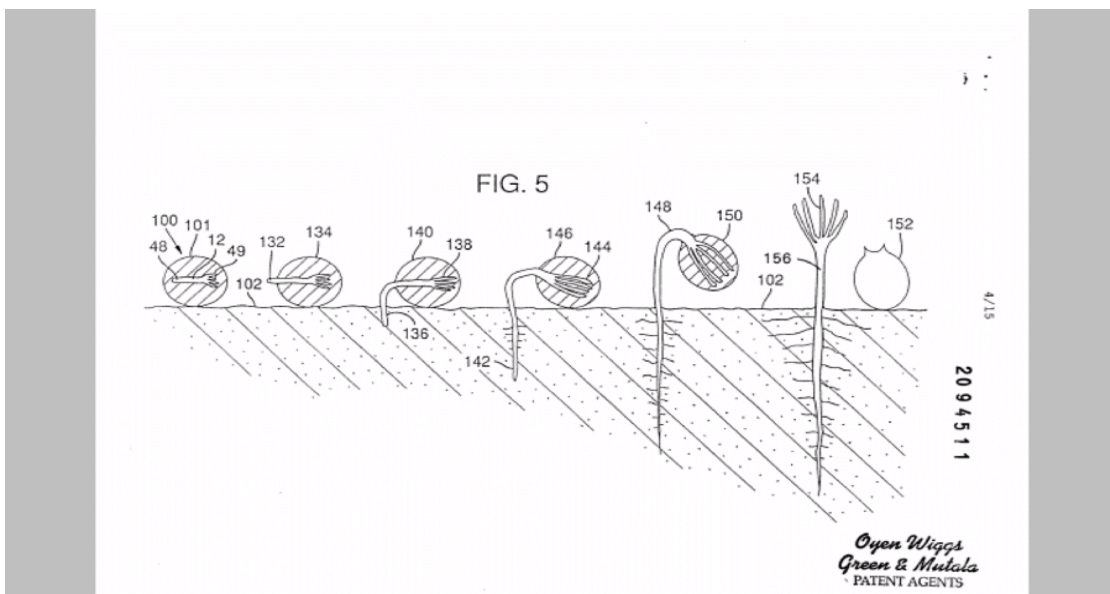
(11) Totipotent plant tissue is obtainable from several areas of a plant, such as meristematic tissue and plant embryonic tissues. For example, meristematic tissue, comprised of both undifferentiated and differentiated plant cells, when cultured under laboratory conditions, de-differentiates into totipotent cells, which through further manipulation and proliferation regenerate into complete embryos, termed somatic embryos. One such example provided by the Applicant in the hearing submissions, (Vasil and Vasil, *Totipotency and Embryogenesis in Plant Cells and Tissue Culture, In Vitro*, vol. 8, no. 3, pp 117-125, 1972), denotes methods of disassociating plant tissue into single cells and culturing plant cells or undifferentiated plant cell mass (callus) in synthetic media to produce embryo-like structures.

(12) These somatic embryos can be further cultured in a laboratory or encapsulated into artificial seed coats to develop into entire plants. A piece of plant meristematic tissue or plant embryonic tissue that can be individually handled, placed on or encapsulated in a gel and which will develop into a germinate and ultimately a plant under favourable conditions is defined in the instant application as a Aunit@ of tissue (page 12, lines 6 to 10) .

(13) Methods of encapsulating individual somatic or zygotic plant embryos in a hydrated gel to form artificial or manufactured seeds are known in the art, for example EP 0107141 and US 4808430 which were discussed in the instant description, but such Aseeds@ generally exhibit poor permeability of atmospheric gases, i.e. oxygen, and low percentage of successful

germinations. Therefore, there was considerable interest, at the time of filing of the instant application, in improving the oxygen permeability of hydrated gels to provide artificial or manufactured seeds with increased numbers of successful normal germinates.

(14) A schematic of an analog of a botanic seed of the instant application, illustrating the germination of an embryo from the encapsulating gel, is provided below.



ISSUE:

(15) There is one issue before the Board. Claims 1 to 28 were objected to as encompassing higher life forms and thus for falling outside the definition of invention in Section 2 of the *Patent Act*.

CLAIMS:

(16) Subsequent to the Final Action, before the hearing, the Applicant provided new claims 69 to 70 (the use of claims 1 to 28) in tab B of the hearing submissions. The Board did not consider these claims, since claim amendments are not admissible after the Final Action, unless the Applicant is informed that the amendment is necessary (to correct a defect or newly identified

defect) in accordance with Rule 31(c).

(17) In the response to the Final Action, dated November 24, 2006, the Applicant submitted a new set of 68 claims. The new set included claims 1 to 40, which were before the Examiner at the time of the Final Action, as well as newly introduced claims 41 to 68. According to the Examiner claims 29 to 40 (methods for manufacturing an analog of a botanic seed and methods of germinating said seed) remain allowable, as do, newly introduced claims 41 to 68 (a capsule absent living matter). Claims 1 to 28 were not amended and thus remain objectionable and include the following representative claims:

1. An analog of a botanic seed, comprising:

(a) a unit of totipotent plant tissue; and

(b) a unit of non-phytotoxic hydrated gel in direct or indirect contact with the unit of totipotent plant tissue so as to form a seed analog in which gases and liquids necessary for germination of the totipotent plant tissue can pass from the hydrated gel to the totipotent plant tissue, the hydrated gel comprising an oxygen-absorbing substance so as to provide the hydrated gel with a concentration of molecular oxygen that is higher than a concentration of molecular oxygen that would otherwise be absorbed from the atmosphere by molecules of the hydrated gel at standard temperature and pressure, the oxygen-absorbing substance comprising a compound selected from the group consisting of perfluorocarbons, silicone oils, and mixtures thereof.

15. An analog of a botanic seed, comprising:

(a) a unit of plant embryonic tissue; and

(b) a non-phytotoxic hydrated gel contacting the unit of embryonic plant tissue, the hydrated gel including an oxygen-carrying substance and plant nutrients, the oxygen-carrying substance conferring on the hydrated gel an ability to absorb a greater amount of molecular

oxygen from the atmosphere than would otherwise be absorbable by the hydrated gel, lacking the oxygen-carrying substance, from the atmosphere at standard temperature and pressure, the oxygen-carrying substance comprising a compound selected from a group consisting of perfluorocarbons, silicone oils, and mixtures thereof.

18. An analog of a botanic seed, comprising:

(a) a unit of totipotent plant tissue; and

(b) a non-phytotoxic hydrated gel in direct or indirect contact with the unit of totipotent plant tissue so as to facilitate access of gases and liquids necessary for germination to the plant embryonic tissue, the hydrated gel including an oxygen-carrying substance conferring on the hydrated gel an ability to absorb a greater amount of molecular oxygen from the atmosphere than would otherwise be absorbable by the hydrated gel, lacking the oxygen-carrying substance, from the atmosphere at standard temperature and pressure, the oxygen-carrying substance comprising a compound selected from a group consisting of perfluorocarbons, silicone oils, and mixtures thereof; and

(c) an outer shell enclosing the plant embryonic tissue and the hydrated gel.

21. An analog of a botanic seed, comprising:

(a) a unit of plant embryonic tissue; and

(b) a non-phytotoxic hydrated gel contacting the unit of plant embryonic tissue, the hydrated gel including an oxygen-absorbing compound so as to enable the hydrated gel to acquire a concentration of molecular oxygen therein that is higher than a concentration of molecular oxygen that would otherwise be absorbable from the atmosphere by molecules of hydrated gel at standard temperature and pressure, the oxygen-absorbing compound being selected from a group consisting of perfluorocarbons, silicone oils, and mixtures thereof; and

(c) a shell in surrounding relationship to the unit of plant embryonic tissue and the hydrated gel.

22. An analog of a botanic seed, comprising:

(a) a plant embryo comprising a shoot and a radicle and

(b) a non-phytotoxic hydrated gel encapsulating the plant embryo, the hydrated gel including emulsified droplets of an oxygen-carrying substance suspended therein, the oxygen-carrying substance conferring on the hydrated gel an ability to absorb a greater amount of molecular oxygen from the atmosphere than would otherwise be absorbable by the hydrated gel, lacking the oxygen-carrying substance, from the atmosphere at standard temperature and pressure, the oxygen-carrying substance comprising a compound selected from a group consisting of perfluorocarbons, silicone oils, and mixtures thereof.

(18) Any findings as to patentable subject matter, in respect of claims 1, 15, 18, 21 and 22 may be extended to all claims dependent thereon.

PATENTABLE SUBJECT MATTER

Invention defined

(19) Section 2 of the *Patent Act* sets out the definition of invention as:

"invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

Approach to assessing subject matter

(20) The approach to assessing patentable subject matter which will be applied is that which is set out in *Amazon.com* [CD 1290, "*Method and System for Placing a Purchase Order via*

a Communications Network", paragraphs 124 to 162].

(21) For convenience, particulars of the approach set out in *Amazon.com* are reproduced below.

- *Consider both the form and the substance of the claims*

An assessment of patentable subject matter involves a consideration of both the form and substance of the claims.

- Form of the claims

By "form" is meant what the language of a claim, on its face, appears to be defining as the invention.

- Substance of the claims (What has been discovered?)

The approach to assess the substance is to fully understand the nature of the claimed invention, and determine what has been added to human knowledge ["what has been discovered"] by the claimed invention.

- *Subject matter must fit the definition of a category*

The judicial interpretation of each of the terms art, process, machine, manufacture and composition of matter must be considered to assess whether the subject matter of the claims fits under one of these categories.

- *Excluded (non-statutory) subject matter*

Certain types of subject matter are excluded from patentability. For example, computer programs if the discovery involved is a method of calculation, methods of medical treatment, higher life forms, business systems and methods and professional skills and methods, have been excluded by judicial interpretation of Sections 2 and 27(8) of the *Patent*.

- *Non-technological subject matter is not statutory*

Each of the five categories of invention inherently relate to subject matter that is technological in nature. It follows that subject matter that is not technological is not statutory subject matter, and cannot fit under one of the categories of invention.

(22) To summarize the above, for a claim to be patentable, the form of the claim (the claim on its face) must relate to one of the five patentable categories of invention (art, process, machine, manufacture or composition of matter). Also, the form of the claim must be neither excluded subject matter nor non-technological subject matter. Similarly, the substance of the claimed invention, or "what has been added to human knowledge", must fit under one of the five patentable categories of invention, and must not be directed towards either excluded subject matter or non-technological subject matter.

(23) A claimed invention may be excluded for any one or more of the aforementioned reasons. The analysis need not be performed in any particular order.

Patentability of life forms

(24) Under Canadian law, it is not "life" *per se* which is non-patentable (*Harvard College v. Canada (Commissioner of Patents)* [2002] S.C.C. 76; 21 C.P.R. (4th), 417 (S.C.C.); *Harvard*).

Of particular relevance to the present case is the interpretation of life forms, which in view of jurisprudence, has been divided into two categories; lower life forms (statutory) and higher life forms (non-statutory). The distinction between lower and higher life forms, in general, is whether the life form is unicellular (lower) or multicellular (higher). To address the question of whether a particular life form is to be classified as a higher life form or a lower life form, the Supreme Court stated at paragraph 151 of *Harvard* that:

...the Commissioner's scientific expertise suggests that the courts defer to his decision in respect to whether he is satisfied that the life form falls within a category of patentable subject matter.

Lower Life forms are not excluded from patentability

(25) Unicellular life forms which can be produced *en masse*, as chemical compounds are produced and formed, and in such large numbers that any measurable quantity will possess uniform properties and characteristics, are deemed to fall within the scope of Section 2 (*Re: Abitibi Co.*, (1982), 62 C.P.R. (2d) 81, Commissioner's Decision No. 933; *Abitibi*). In addition, cells derived from a higher life forms⁶ cultured through the *in vitro* manipulation of the natural processes of cell proliferation and replication are also considered patentable lower life forms (*Re: Connaught Laboratories*, (1982), 82 C.P.R. (2d) 32, Commissioner's Decision No. 962; *Connaught*). The lower life forms, therefore, include microscopic algae; unicellular fungi (including moulds and yeasts); bacteria; protozoa; viruses; transformed cell lines; and hybridomas.

Higher life forms are excluded from patentability

(26) Higher life forms are excluded from patentability as set out in *Harvard*. Animals, plants and seeds are included in the proscription; see *Monsanto Canada Inc. v. Schmeiser* [2004] S.C.C. 34; [(2004), 31 C.P.R. (4th), 161 (S.C.C.)], para 21; *Schmeiser*.

The dividing line between lower and higher life forms

(27) With respect to establishing the line dividing lower and higher life forms the Supreme Court stated at paragraph 199 of *Harvard* that [emphasis added] :

...Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to plants and animals and to attach appropriate conditions to the right that is granted. In the interim, I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two.

(28) Moreover, it is settled that higher life forms are non-patentable subject matter, regardless of the fact that there is no explicit exclusion for higher life forms in the *Patent Act* (*Harvard*, para 205).

Patentability of coated seeds

(29) The Applicant brought to our attention *Re: Pallos* (1978), Commissioner=s Decision No. 517; *Pallos*. The Applicant noted that in *Pallos* the inventive contribution was not the living matter, the seed, but rather the coating which was placed on the seed. The coated seeds were deemed

patentable subject matter despite the fact that they claimed living subject matter.

(30) The Board must note that *Pallos* is not binding on the Commissioner especially since the exclusion of higher life forms by *Harvard* occurred subsequent to that decision. Moreover, the approach to accessing patentable subject matter was most recently set forth in *Amazon.com*. Although the *Amazon.com* decision issued around the same time as the Hearing, and thus was not discussed, as will be seen below, our analysis is based on the claim on its face (the *Aform*), which is well grounded in Canadian law.

APPLICANT'S POSITION:

i) Degree of Man-made efforts

(31) The Applicant alleged that *An analog of a botanic seed* (claims 1 to 28) constituted a *Acomposition of matter* or *Amanufacture* within the meaning of the definition of invention and was therefore patentable subject matter. Further, at the hearing the Applicant alleged that the analogs of botanic seeds equated to *Aman-made efforts to replicate the function of a seed*. Specifically, that *Athe Applicant packaged material that can become a plant into an artificial package which when placed in the ground will turn into a plant* whereby both the living matter and coating are man-made. The *Aunits of totipotent plant tissue*, which were the man-made equivalent to the zygotic embryo of a traditional botanic seed, were claimed in combination with a novel hydrated gel. According to the Applicant, the analogs therefore were *Aeven more man-made than a coated seed* and *Aa unit of totipotent plant tissue* the biological subject matter, required more human intervention than the seeds of previously issued patents including *Pallos*.

ii) The claimed subject matter is comparable to lower life forms

(32) In the Applicant=s response dated February 17, 2004 to a previous Office Action, the Applicant dismissed the relevancy of the *Harvard* decision to the patentability of plants and aligned plants, plant embryos and plant germinants with cultures of microorganisms which were not considered higher life forms. The Applicant submitted that [emphasis added]:

...The individual units [of totipotent plant tissue] are present in such large numbers that any measurable quantity of them will possess more or less homogeneous qualities and characteristics. Furthermore, they (particularly embryos and germinants) are relatively simple compositions of matter. They do not have the specialized sense organs and powers of voluntary movement associated with animals, and particularly with the higher mammals which are the real focus of the Court=s decision in the *Harvard Mouse* decision. At the embryonic or germinant stage, although they have the potential to develop into far more complex grown plants if properly nurtured, they have not yet undergone such a developmental change. Such units of tissue, and artificial seed structures containing them, may be produced on a commercial scale in the same way that chemicals and microorganisms are manufactured. Like cultures of microorganisms they can be expected to be transported and sold in bulk quantities on the understanding that the individual units thereof have consistent characteristics.

iii) A plant tissue or plant embryo is like a fertilized egg which is patentable as per Harvard

(33) In the Applicant=s response to the pre-Final Action dated October 7, 2005, the Applicant noted the lack of Canadian jurisprudence in support of the proposition that something with the potential to grow and develop into a life form (i.e. embryo or a seed) was unpatentable under Section 2 of the *Patent Act*. Further, in the response to the Final Action, in reference to *Harvard* the Applicant contended that:

...the Supreme Court of Canada has acknowledged that, even if a transgenic mouse does not constitute statutory subject matter, the fertilized egg from which the mouse develops is eligible for patent protection.

...if a fertilized egg, with potential to develop into an intact, adult mammal, constitutes a patentable composition of matter, then a unit of totipotent plant tissue, a unit of plant embryonic tissue or a plant embryo, must also constitute patentable compositions of matter.

iv) Plant tissue is patentable since plant cells, which can become plants, are patentable as per Schmeiser

(34) Further, in the response to the Final Action the Applicant submitted that the objected claims were not directed to a seed *per se*, but were analogs of seeds that contained plant tissue which had the potential to develop into a plant. By reference to *Schmeiser* the Applicant contended that:

...the plant cells of the [1,313,830] patent held by the Supreme Court to be patentable subject matter had the potential to and did become fully differentiated plants. This did not detract from patentability.

...a cell, *per se* is patentable irrespective of the ultimate development of the cell into an intact organism.

v) Patenting totipotency is consistent with Harvard and Schmeiser

(35) The Applicant provided additional reasons with the written submissions for the hearing. Beginning at paragraph 35 of the submissions, stating in part that:

...The *Harvard College* decision is entirely consistent with the patentability of totipotent plant tissue. In particular, the Court's comments to the effect that a fertilized, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse, is authoritative *obiter dicta* on this precise point. It is in fact an explicit rejection of the notion that the property of totipotency can, in and of itself, serve to exclude living matter from the scope of Section 2 of the *Act*.

...The consensus of the entire Court [in *Harvard*] on the issue of the patentability of a fertilized egg clearly supports the view that totipotent plant tissues are patentable subject matter.

...*Harvard College* and *Schmeiser* clearly stand for the proposition that totipotent cell is patentable. Specifically, the Applicant submits that a clear reading of *Harvard College* and *Schmeiser* supports the view that a totipotent cell is a composition of matter and thus within the scope of the wording of Section 2 of the *Act*.

(36) In addition, the Applicant noted that although the term totipotent was not found in *Schmeiser per se*, the issue of totipotency was addressed, at paragraph 19, as the Court construed the claims to cover cells which were totipotent. The Applicant, thus referred to *Schmeiser* as the authority for totipotent plant tissue being patentable subject matter. Paragraph 19 reads as follows [emphasis added]:

A purposeful construction therefore recognizes that the invention will be practised in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory.

vi) Similar inventive matter has been previously patented

(37) The Applicant contended that living matter could confer inventiveness and form a constituent of an allowable product claim and provided several examples of Canadian patents issued for coated seeds and totipotent plant cells (by inference from the capability of the claimed cells to generate a whole plant). With respect to coated seeds, in particular, The Applicant stated that Acoated seed claims claim totipotent plant material as an integral component of the coated seed@ and stated that the present invention Afalls squarely within the ambient of [previously patented] subject matter@ including *Pallos*.

ANALYSIS:

(38) As stated earlier, the approach to assessing patentable subject matter that will be applied is that which is set out in *Amazon.com*. However, as will be seen below, our analysis and recommendation is based on Aform@ of the claims, or the claim on its face. The Board will endeavour to address the arguments provided by the Applicant as set out in *i)* to *vi)* above.

Form of the claims

Is the form of the claims directed to excluded matter? (Does it fit into a category of Ainvention@ under Section 2 ?)

(39) The Applicant contended that the instant case is analogous to the coated seeds of *Pallos* and like the seeds of *Pallos*, is patentable subject matter. In *Pallos* the Board concluded that Ait is proper to allow claims directed to the treated seed where the invention resides in the coating given to them, *in this case* the treatment does not alter the life process of the seed and there is no new living matter@. However, as was noted previously by the Board in the present case, *Pallos* is non-binding on the Office especially in view of the more recent Supreme Court decisions namely, *Harvard* and *Schmeiser*.

Are plant tissue, plant embryonic tissue and plant embryos excluded from patentability ?

(40) In *Schmeiser*, at paragraphs 129 to 130, the Supreme Court concluded that the gene patent claims and the plant cell claims should not be construed to grant exclusive rights over the plant and all of its offspring. Arbour J, writing in dissent, distinguished the point at which the claims would begin to protect higher life forms as follows [emphasis added]:

130 It is clear from the specification that Monsanto's patent claims do not extend to plants, seeds, and crops. It is also clear that the gene claim does not extend patent protection to the plant. The plant cell claim ends at the point where the isolated plant cell containing the chimeric gene is placed into the growth medium for regeneration. Once the cell begins to multiply and differentiate into plant tissues, resulting in the growth of a plant, a claim should be made for the whole plant. However, the whole plant cannot be patented. Similarly, the method claim ends at the point of the regeneration of the transgenic founder plant but does not extend to methods for propagating that plant. It certainly does not extend to the offspring of the regenerated plant.

In sum, at paragraph 138 [emphasis added]:

138 In short, properly construed, Monsanto's claims both for products and processes are valid. Neither extends patent protection to the plant itself, a higher life form incapable of patent protection. In order to avoid the claim extending to the whole plant, the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant tissues, at which point the claim would be for every cell in the plant, i.e., for the plant itself.

(41) Considering the instant case, it is understood that what is being claimed is neither an encapsulated plant cell nor a whole plant. The *units* of totipotent plant tissue, embryonic tissue and plant embryos, thus, can be said to reside somewhere amidst a developmental continuum between the two. As noted earlier, the Supreme Court indicated in *Harvard* (paragraph 151) that the Commissioner's scientific expertise would likely be accorded deference in deciding whether a particular life form is a higher (or lower) life form and whether it falls within a category of patentable subject matter.

(42) Even though claims 1 to 28 on file were directed to plant tissue the majority of the arguments presented by the Applicant at the hearing focussed on the patentability of totipotent cells, more particularly totipotent plant cells. When asked to comment on this discrepancy, the Applicant acknowledged that there was a distinction between plant cells and plant tissue.

(43) Nonetheless, the Applicant aligned a plant embryo with a fertilized egg on the basis of the potential to develop into an entire organism, *viz* totipotency. The Applicant further submitted that while plants were considered higher life forms plant embryos were not, noting that it was *an easy line to draw*, being that the *capacity to become a plant does not make something in and of itself a plant*.

(44) However, as discussed in paragraph 41 above, the claimed plant tissues and plant embryos reside somewhere between plant cells and whole plants, as does the dividing line between lower and higher life forms. To elucidate the patentability of the claimed plant tissues and embryos a comparison to both plant cells and plants is required. Similar to a whole plant, plant tissue and plant embryos are multi-cellular organisms created by complex processes including cell division, expansion and differentiation, -elements of which require no human intervention. In particular, the plant cells contained within the tissue or embryo are differentiated

cells which are morphologically and functionally organized and thus different from the initial starting cells or culture, despite the fact of containing the same characterizing genetic information. Given the complexity of the cellular organization within plant tissue and plant embryos, a unit of totipotent plant tissue, a unit of embryonic tissue or a plant embryo comprising a shoot and a radicle of the instant application, are not equivalent to the fertilized egg of *Harvard*, or the plant cells of *Schmeiser*. That is not to say that the fertilized egg of *Harvard* and the plant cells of *Schmeiser* are equivalent. Moreover, the plant embryo is an integral part of the plant seed; a life form which, itself, is explicitly excluded from patentability (*Schmeiser*). Further, the Board notes that what is claimed is not the capacity or potential to develop into an entire organism but the higher life form itself. Since higher life forms are already excluded from patentability, a further consideration of totipotency is not necessary in this case.

(45) For the aforementioned reasons, the Board is unable to agree with the Applicant's views [see the Applicant's position *ii)* to *v)*] that the claimed subject matter is comparable to lower life forms; that a plant tissue or plant embryo is like a fertilized egg; and that totipotent plant tissue, plant embryonic tissue and plant embryos, which can become plants, are patentable per *Schmeiser*. Further, neither *Harvard* nor *Schmeiser* support any general rule that the characteristic of totipotency connotes that something is patentable subject matter.

Relevancy of the degree of man-made effort and patenting of similar inventive matter.

(46) As set out in *i)* above, the Applicant considers the man-made effort to replicate the function of a seed, to be a deciding factor, because both the living matter and coating are man-made. While the Applicant does not purport to have discovered any new type of plant tissue or plant embryo, it can be argued that the plant cells and tissue must be manipulated in order to produce units of tissue which are then encapsulated in the non-phytotoxic hydrated gel.

Without human intervention the Aunits® would not include cells characterized as or derived from totipotent cells and thus be incapable of plant regeneration.

(47) With respect to the degree of man-made effort to replicate the function of a seed, the Board notes that this factor was similarly applied to the patentability of a genetically modified oncomouse in *Harvard* (paragraph 162). Based on *Harvard*, as long as the claimed invention sets out a higher life form, it is excluded. A higher degree of man-made effort in the claimed invention cannot impact this determination.

(48) Regarding the Applicant's comment that inventive coated seeds have been previously patented *vi*), as pointed out in *Amazon.com*, (paragraph 182), if that practice was inconsistent with a proper interpretation of the *Patent Act*, then it must be corrected. Policy and practice are not matters for *stare decisis*, and should be changed if found to be wrong.

(49) The Board thus concludes that claims setting out "a unit of totipotent plant tissue"; "a unit of plant embryonic tissue"; or "a plant embryo comprising a shoot and a radicle" encompass higher life forms. Therefore, claims 1 to 28 are excluded from patentability under Section 2 of the *Patent Act*.

(50) Generally, an issue with the form of a claim can be corrected by removing reference to the excluded matter, in particular, when the substance of that claim is found to be patentable subject matter. However, since the Applicant submitted claims 41 to 68 having adequate scope to protect this invention, albeit without reciting excluded matter, amendment is not warranted, nor is it necessary for the Board to determine or assess the substance of the invention in claims 1 to 28.

(51) As to whether or not claims 1 to 28 are non-technological, the Board need not address this matter (as set out in *Amazon.com*) because these claims are non-compliant with Section 2, by form.

SUMMARY:

(52) Claims 1 to 28 setting out "a unit of totipotent plant tissue"; "a unit of plant embryonic tissue"; or "a plant embryo comprising a shoot and a radicle" are setting out higher life forms. Therefore, claims 1 to 28 on their face, recite higher life forms and are for this reason excluded from patentability under Section 2 of the *Patent Act*.

RECOMMENDATION OF THE BOARD:

(53) The Board has found that claims 1 to 28 are outside the definition of invention in Section 2 of the *Patent Act*.

Therefore, the Board recommends that the Commissioner:

- 1) inform the Applicant that the Examiner=s rejection of claims 1 to 28 is upheld;
- 2) inform the Applicant that claims 29 to 68 remain in allowable form; and
- 3) inform the Applicant in accordance with paragraph 31(c) of the *Patent Rules*, that the following amendments, and only these amendments, of the application are necessary for compliance with the *Patent Act* and *Patent Rules*:

- a) deletion of claims 1 to 28, and
- b) renumbering of claims 29 to 68, with renumbering of the claim dependencies to the respective claim(s) where appropriate.

Nicole Harris

Paul Sabharwal

Member

Member

COMMISSIONER'S DECISION

(54) I concur with the findings and the recommendation of the Patent Appeal Board.

Given that all outstanding issues have been addressed, this application complies with the *Patent Act* and *Rules* and once amended as prescribed, should proceed to allowance. Accordingly, I invite the Applicant to make the above amendments, and only these amendments, within three (3) months from the date of this decision, failing which I intend to refuse the application.

Mary Carman

Commissioner of Patents

dated at Gatineau, Quebec,

this 16 day of July, 2010