

Citation: Rijk Zwaan Zaadteelt en Zaahandel B.V. (Re), 2021 CACP 5
Commissioner's Decision #1558
Décision du Commissaire #1558
Date: 2021-01-29

TOPIC:	C00	Adequacy or Deficiency of Description
	K10	Living Things (Animals, Plants, Seeds, Sperm)
	B00	Ambiguity or Indefiniteness
SUJET:	C00	Caractère adéquat ou inadéquat de la description
	K10	Matières vivantes (animaux, plantes, graines, sperme)
	B00	Caractère ambigu ou indéfini

Application No. : 2,636,084

Demande n° 2 636 084

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,636,084 having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Patent Rules*), has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application unless necessary amendments are made.

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INTRODUCTION

- [1] This recommendation concerns the review of rejected Canadian patent application number 2,636,084, which is entitled “Screening Method for Selecting Plants That Show a Reduced Wound-Induced Surface Discolouration and Plant and Plant Parts Thus Obtained” and is owned by Rijk Zwaan Zaaateelt en Zaahandel B.V. (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 199(3)(c) of the *Patent Rules*.
- [2] As explained in more detail below, our recommendation is that the Commissioner of Patents notify the Applicant that specific claim amendments are considered necessary amendments under subsection 86(11) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules* and that the patent application be allowed if amended accordingly.

BACKGROUND

The Application

- [3] The application was filed under the provisions of the Patent Cooperation Treaty and has an effective filing date in Canada of January 8, 2007. It was laid open to public inspection on July 12, 2007.
- [4] The rejected application relates to screening methods for the identification of plants that show a reduced wound-induced surface discolouration. Specifically disclosed are lettuce plants with reduced discolouration upon wounding that are resistant to post-harvest processing disorders such as enzymatic browning or pinking which affect the overall quality of processed lettuce.
- [5] The application has 7 claims on file, which were received at the Patent Office on July 16, 2014.

Prosecution History

- [6] On October 25, 2016, a Final Action (FA) was written pursuant to subsection 30(4) of the former *Patent Rules*. The FA stated that claim 7 on file was allowable; however, claims 1–6 on file were rejected for lack of disclosure, lack of enablement, lack of support and lack of clarity.

- [7] In a response to the FA (RFA) dated April 24, 2017, the Applicant proposed an amended set of 2 claims (proposed claims set-1) and submitted arguments addressing the defects raised in the FA.
- [8] As the Examiner still considered the application not to comply with the *Patent Act* and the former *Patent Rules*, pursuant to paragraph 30(6)(c) of the former *Patent Rules*, the application was forwarded to the Board on June 29, 2017 for review along with an explanation outlined in a Summary of Reasons (SOR). Specifically, the SOR indicated that claim 2 of proposed claims set-1 did not overcome any of the defects raised in respect of the claims on file.
- [9] In a letter dated July 5, 2017, the Board forwarded to the Applicant a copy of the SOR and requested that the Applicant confirm its continued interest in having the application reviewed.
- [10] In a letter dated October 4, 2017, the Applicant confirmed its interest in having the review proceed.
- [11] The present panel (the Panel) was formed to review the instant application under paragraph 199(3)(c) of the *Patent Rules*. The Panel sent a preliminary review letter (PR letter) dated December 10, 2020, which set out our preliminary opinion that claims 1 and 3–6 were defective as indicated in the FA and SOR but that claim 2 did comply with the *Patent Act* and *Patent Rules*. Further, in accordance with subsection 86(9) of the *Patent Rules*, we identified a new defect in respect of two of the claims on file. We also expressed the view that the proposed claims did not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*. The PR letter also provided the Applicant with an opportunity to make oral and/or written submissions.
- [12] The Applicant responded to the PR letter on January 7, 2021 (RPR), providing written submissions, as well as proposing an amended set of 10 claims (proposed claims set-2) “to obviate all bases for rejecting the present application by restricting the claims to subject matter deemed allowable by the Panel.” The Applicant did not indicate a need for a hearing.

ISSUES

- [13] In view of the above, the following issues are considered in this review:

- whether claims 1–6 on file are insufficiently disclosed and not enabled and are therefore non-compliant with paragraphs 27(3)(a) and (b) of the *Patent Act*;
- whether claims 1–6 on file are directed to the desired result and do not comply with section 84 of the *Patent Rules* as they read immediately before October 30, 2019 (under the former *Patent Rules*, now section 60 of the *Patent Rules*) and subsection 27(4) of the *Patent Act*; and
- whether claims 6 and 7 on file are directed to a method of traditional plant breeding and are therefore non-complaint with section 2 of the *Patent Act*.

[14] After considering the claims on file, we will consider proposed claims set-2.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICES

Purposive construction

[15] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66, essential elements are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings (see also *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49(f) and (g) and 52). Purposive construction is performed from the point of view of the person of ordinary skill in the art (POSITA) in light of the relevant common general knowledge (CGK).

[16] The Office’s current practice with regard to purposive construction is explained in the Practice Notice dated 2020-11-03, entitled “*Patentable Subject-Matter under the Patent Act*” (PN 2020-11-03). The Office’s practice was revised after the sending of the SOR, in response to the Federal Court decision in *Yves Choueifaty v Attorney General of Canada*, 2020 FC 837.

[17] According to PN 2020-11-03, the purposive construction of a claim is carried out in light of the whole of the specification and takes into account what the POSITA would understand from the whole of the specification to be the nature of the invention. During purposive construction of a claim, the elements of the claimed invention are identified as either essential elements or non-essential elements. In carrying out this identification, all elements set out in a claim are presumed essential, unless it is established otherwise or is contrary to the language used in the claim.

Sufficiency of disclosure

- [18] Subsection 27(3) of the *Patent Act* requires, among other things, a specification to correctly and fully describe an invention, and to enable its practice:

The specification of an invention must:

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it

- [19] A determination of whether the specification complies with paragraphs 27(3)(a) and 27(3)(b) of the *Patent Act* requires that three questions be answered: What is the invention? How does it work? Having only the specification, can the person of skill in the art produce the invention using only the instructions contained in the disclosure? (*Teva Canada Ltd v Novartis AG*, 2013 FC 141, citing *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 [*Teva SCC*] and *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 526, 1981 CanLII 15).

- [20] An affirmative answer to the third question requires that the person skilled in the art not be called upon to display inventive ingenuity or undertake undue experimentation: *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283; *Mobil Oil Corp v Hercules Canada Inc* (1995), 63 CPR (3d) 473 (FCA); *Merck & Co v Apotex Inc*, [1995] 2 FC 723, 1995 CanLII 3586 (CA).

- [21] The relevant date for assessing compliance with subsection 27(3) of the *Patent Act* is the filing date: *Teva SCC*, at para 90.

- [22] As discussed below, the present invention relies on the deposit of two biological materials (seeds) in an International Deposit Authority. Under subsection 38.1(1) of the *Patent Act*, deposited biological material is considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, such deposits are taken into consideration in determining whether the specification complies with that subsection.

- [23] Subsection 38.1(2) of the *Patent Act* clarifies that the deposit of a biological material does not create the presumption that the deposit is required for compliance.

Indefiniteness

- [24] The defects raised in the FA under subsection 27(4) of the *Patent Act* and section 84 of the former *Patent Rules* concern the question of whether the claims are directed to the desired result for not defining the genetic determinant. Any concern over non-compliance with section 84 of the former *Patent Rules* we take as subsumed within the indefiniteness analysis. Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define subject-matter:

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.

- [25] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized both the obligation of an Applicant to make clear in the claims the ambit of the monopoly sought and the requirement that the terms used in the claims be clear and precise:

By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

Processes of traditional plant breeding

- [26] The jurisprudence indicates that processes of traditional plant breeding are not within the definition of invention under section 2 of the *Patent Act*: *Pioneer Hi-Bred Ltd v Commissioner of Patents* (1987), 14 CPR (3d) 491.
- [27] With regard to producing a plant solely by traditional cross-breeding techniques as patentable subject-matter, subsection 23.02.03 of MOPOP states:

An especially important consideration in determining the patentability of a method or process to produce a higher life form is the degree of human intervention embodied in the claimed process. A process which occurs essentially according to nature, with no significant human intervention, is not patentable. Thus, for example, a claim construed to be directed to a process for producing a plant solely by traditional cross-breeding techniques is not patentable (even where one of the cross-bred plants is transgenic or otherwise modified). A process that is a result of both human intervention and the laws of nature, however, is patent-

eligible subject-matter where at least one step of human intervention is an essential element of the claim.

“Use” claims and patentable subject-matter

- [28] Related to the issue of patentable subject-matter, discussed above, and claim construction is the question of whether the adoption of the “use” claim format means that the subject-matter defined by such a claim necessarily falls within the definition of invention under section 2 of the *Patent Act*. In our view, it does not.
- [29] A claim framed as a “use” may constitute patentable subject-matter. For instance, in the field of medical arts, the “use” of a known medicament for the purposes of treating a new disease may be claimed as such and would not be regarded as an excluded method of medical treatment: *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77. However, presentation of a claim in “use” format does not automatically mean that it defines statutory subject-matter. Indeed, the case law in the field of medical uses also recognizes that a claim framed as a “use” can still be considered non-statutory if, following a purposive construction, it is found to amount to an excluded method of medical treatment: *Novartis Pharmaceuticals v Cobalt Pharmaceuticals*, 2013 FC 985, aff’d 2014 FCA 17; *Janssen Inc v Mylan Pharmaceuticals ULC*, 2010 FC 1123.
- [30] Further, in *Canada (Attorney General) v Amazon.com, Inc [Amazon]* the Federal Court of Appeal stated at para 44 that:

Purposive construction will necessarily ensure that the Commissioner is alive to the possibility that a patent claim may be expressed in language that is deliberately or inadvertently deceptive. Thus, for example, what appears on its face to be a claim for an “art” or a “process” may, on a proper construction, be a claim for a mathematical formula and therefore not patentable subject matter.

ANALYSIS OF THE CLAIMS ON FILE

Purposive construction

The claims on file

- [31] There are 7 claims on file. On page 7 of the PR letter, we expressed our preliminary view that independent claims 1, 6 and 7 are representative of the claims on file:

1. Use of a lettuce plant showing a reduced wound-induced surface discolouration, wherein the reduced wound-induced discolouration is caused by a genetic determinant, which genetic determinant is as found in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441, as a crop.

6. Use of a lettuce plant as defined in claim 1 or 2 for conferring the trait of reduced wound-induced discolouration to another lettuce plant.

7. Use of seed that were deposited under accession number NCIMB 41454 or 41441 for transferring the trait of reduced wound-induced discolouration into a lettuce plant.

[32] In the RPR, the Applicant did not contest the Panel's consideration presented in the PR letter of claims 1, 6 and 7 as being representative of the claims on file for the purposes of our analysis. Likewise, the Applicant did not contest our characterization of dependent claim 2 as providing further limitations with regard to the origin of the genetic determinant responsible for the trait of reduced wound-induced discolouration.

The POSITA and the relevant CGK

[33] In the RPR, the Applicant did not contest or comment on the Panel's characterization of the POSITA and their relevant CGK as set out on page 7 of our PR letter. Accordingly, we adopt those characterizations for this review:

In view of statements in the description, such as those found on page 3, line 11 to page 6, line 6; and page 12, line 18 to page 13, line 5 which indicate the alleged invention is directed to the screening and selecting of lettuce plants to identify those that have reduced wound-induced surface discolouration, wherein said plant population can be mutagenized (using chemicals and/or irradiation) to increase the chance of finding such a plant, the person skilled in the art to whom the application is directed can be characterized as a team of plant breeding scientists, with expertise in plant genetics, molecular biology and the design and execution of a plant breeding programme.

The CGK of the person skilled in the art would be the screening of plant populations for desired traits, as well as the identification and characterisation of the allele responsible for said trait.

Essential elements

[34] On page 7 of the PR letter, we expressed our preliminary view that all of the elements in the claims are essential:

Consistent with the practice guidance provided in *PN 2020-11-03*, there is no use of language in the claims indicating that any of the elements are optional, a preferred embodiment or one of a list of alternatives. Therefore, our preliminary view is that the skilled person would consider all of the elements in the claims to be essential.

- [35] The RPR did not express disagreement with our preliminary view and so our analysis will therefore proceed on the basis that all of the claim elements are essential.

Meaning of the terms

- [36] The RPR did not address or comment on the meaning of any of the terms in the claims or suggest any alternative interpretations of the claims on file. Therefore, in view of the analysis put forth in the PR letter (pages 8-9), we adopt the construction of the terms “as found” (claim 1), “for conferring the trait of reduced wound-induced discolouration” (claim 6) and “for transferring the trait of reduced wound-induced discolouration” (claim 7) as follows:

In claim 1, the term “as found” is used to help define the genetic determinant that is responsible for the reduced wound-induced surface discolouration exhibited by a lettuce plant encompassed by the claim.

On page 3 of the response dated October 6, 2015 reference is made to the description to explain the intended scope of the expression:

As set out in the present description, the genetic determinant need not be identical so long as it retains the absence of wound-induced leaf discolouration “as found” in the parent (page 7, lines 22–28):

“The invention further relates to progeny of a parent plant of the invention that retains the absence or reduction of wound-induced leaf discolouration as found in the parent plant. Such progeny may be many generations removed from the parent. As long as the feature ‘reduced or absent wound-induced surface discolouration’ is retained, the plant is a plant of the invention.” (Emphasis added)

Accordingly, irrelevant variations which neither destroy the phenotype nor cause segregation in the allelism test do not fundamentally change the genetic determinant. As such, all such variants are “as found” in the deposited seeds and encompassed within the claim.

The FA, on page 4, disagrees with this interpretation and maintains that “as found” is construed to mean that the genetic determinant referred to in this context is the “same as” or “identical to” the genetic determinant that is in the deposited seeds referred to in the claim.

We acknowledge the Applicant’s assertion that the genetic determinant need not be identical—as long as the desired phenotype is retained in progeny of a parent plant, the genetic determinant will be “as found” in the parent. However, the scope of claim 1 is not limited to progeny of the deposited seed. As drafted, the claim encompasses any lettuce plant having the desired phenotype that is caused by a genetic determinant, which genetic determinant is “as found” in the deposited seed. Therefore, we agree with the construction put forth in the FA. In our preliminary view, the skilled person would consider that a genetic determinant that is “as found” in the deposited seeds effectively means that the genetic determinant must be the “same as” or “identical to” the genetic determinant that is in the deposited seeds; however, this does not mean that a lettuce plant as claimed has necessarily obtained the genetic determinant from the deposited seeds.

The terms “for conferring the trait of reduced wound-induced discolouration” (claim 6) and “for transferring the trait of reduced wound-induced discolouration” (claim 7) also merit further consideration as neither a plant nor a seed can be directly used to transfer the trait of reduced wound-induced discolouration to another plant. In this regard, the description explains:

The invention further relates to plants having a reduced or absent wound-induced surface discolouration and that are obtainable by crossing a plant of the invention with another plant of the same species. The feature “reduced or absent wound-induced surface discolouration” can thus be brought into other plants that originally do not have the feature.

In our preliminary view, the skilled person would understand that the scope encompassed by the manner in which conferring or transferring the desired trait to another lettuce plant is to be achieved is effectively limited to cross-breeding the plant of the invention with another lettuce plant in order to obtain a descendant lettuce plant showing reduced wound-induced surface discolouration. No other means of transfer are suggested.

This understanding is consistent with Applicant’s submissions, provided in the RFA at page 3, with regard to the enablement defect:

Solely in the interest of clarifying the Applicant's view on enablement of the previous claims, for the public record, it is submitted that in the Applicant's view the skilled person would be enabled to produce the invention using only the instructions contained in the disclosure. A lettuce plant showing a reduced wound-induced surface discolouration, wherein the reduced wound-induced surface discolouration is caused by a genetic determinant as found in the deposits, can be produced by using the deposits as provided in the description. A person skilled in the art does not need to know the sequence of the causal genetic determinant in order to be able to transfer it to another plant. A skilled

person simply crosses a plant grown from the deposit with a plant that does show wound-induced surface discolouration and selects in the F1 and/or F2 for plants showing reduced wound-induced surface discolouration. The skilled person can thus produce the invention using only the deposits provided in the disclosure. [Emphasis added]

Therefore, it is our preliminary view that the POSITA would construe the terms “for conferring” and “for transferring” as being directed to the transfer of the trait of reduced wound-induced discolouration solely through a traditional plant cross-breeding process.

Correct and full description under paragraph 27(3)(a) of the *Patent Act*

[37] Our preliminary analysis was put forth on pages 9–12 of the PR letter as follows:

The SOR, on page 2, maintains the defect in the FA that the description does not provide a sufficient description of the genetic determinant that results in the reduced wound-induced discolouration phenotype as claimed in claims 1–6. As explained on page 4 of the FA, the lack of any structural characterization of the genetic determinant is problematic when the scope of the claims encompasses a genetic determinant that is “as found” in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441:

Although cells of the biological deposits themselves are correctly and fully described and enabled by the description by virtue of having been deposited, their genotypes and alleles are not disclosed in the application. The instant claims are not restricted to the use of lettuce plants grown from the seed, or even to an F2 generation grown therefrom. As drafted, the claims are unlimited in their breadth, encompassing the use of any and all lettuce plants having the desired phenotype, with the only requirement that these plants have the same genetic determinant “as found” in the seeds deposited under accession number NCIMB 41454 and 41441.

Thus, the claimed use of a lettuce plant encompasses plants that have an unknown genotype and comprises an undefined allele for reduced wound-induced surface discolouration. Such an uncharacterized genetic determinant cannot be said to be correctly and fully described by the description.

The FA, on pages 4–5, also refers to the MOPOP as providing relevant guidance in support of this position:

[T]he applicant is referred to section [23.06.01] of the Manual of Patent Office Practice (MOPOP), which states the following pertaining to an example claim directed to an uncharacterized nucleic acid molecule defined by reference to biological deposits containing the molecule:

Given that it is possible to define the nucleic acid molecule in clear and explicit terms (e.g. by its DNA sequence) and despite the fact that the skilled person in the art may be able to isolate the molecule from the deposit and characterize it (e.g. determine its sequence), the mere inclusion of the deposit information in the specification is not a substitute for a full and correct description of the molecule itself. In the absence of a disclosure of the DNA sequence of the molecule in the specification, subsection 27(3) of the *Patent Act* is not satisfied.

In the present analogous case, the deposited seed is not a substitute for a full and correct description of the reduced wound-induced surface discoloration genetic determinant, and thus the lettuce plant comprising said allele is also not fully and correctly described by the description, even if the skilled person could carry out an allelism test without burden. Whereas cells of the deposited seed are considered to be fully and correctly described by the specification, unrelated plant cells that may comprise the same uncharacterized allele as the deposited seed fall outside the scope of subject matter that is fully and correctly described by the description because the allele itself is not defined in the description except as part of said deposited seed.

Finally, on page 5 of the FA, Applicant's arguments presented in their response dated October 6, 2015, that "a simple allelism test with the lettuce in question would confirm the presence/or absence of the genetic determinant as found in the deposited seed" were rebutted:

An allelism test is a useful tool for determining the number of genes that control the phenotype and whether these genes are recessive or dominant. Complementation can be further used if the gene causing the phenotype is determined to be recessive, but cannot be used if dominant. In their letter of 6 October 2015, Applicant contends that when no segregation for the reduced discoloration trait occurs in F1 or F2 plants a skilled person can conclude that "the allele causing the reduced discoloration is as found in the deposit."

However, if no segregation occurs, one of two possibilities exist. The first is that the alleles are the same. The second, and most important for the purpose of this report, is that there are two independent mutations on the same gene and the genetic determinants are not "as found" in the deposited seeds. Only by comparing genomic information can it be determined if the genetic determinants are "as found" in the deposited seeds. As such, on its face, the allelism test is of little value for correctly and fully describing the invention.

In the RFA, the Applicant did not argue that the claims were compliant with paragraph 27(3)(a) of the *Patent Act*. Instead, the Applicant submitted new proposed claims 1 and 2 which do not recite a genetic determinant and indicated that the proposed claims "are not directed to the use of any seed/plant that comprises the genetic determinant as found in the

deposited seeds, but is instead limited to the use of the deposited seeds or further generation seeds.”

We agree with the analysis presented in the FA and are of the preliminary view that the claims which encompass a genetic determinant that is “as found” in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441, are not correctly and fully described across their scope and the specification does not comply with paragraph 27(3)(a) of the *Patent Act* in that respect.

The deposited seeds are not a substitute for a full and correct description of the genetic determinant responsible for the desired phenotype. Further, as explained in the FA, the use of the deposited seeds in an allelism test with a lettuce plant having the desired phenotype would not allow the skilled person to confirm the presence/or absence of the genetic determinant as found in the deposited seed. In the absence of any structural characterization of the genetic determinant there is no basis for the skilled person to determine whether a lettuce plant which exhibits reduced wound-induced discolouration has a genetic determinant that is “as found” in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441. Accordingly, it is our preliminary view that claims 1 and 3–6 which encompass lettuce plants wherein the origin of the genetic determinant is not identified as the deposited seeds fail to satisfy paragraph 27(3)(a) of the *Patent Act* in that respect.

However, it is our preliminary opinion that the skilled person would consider that the deposited seeds provide a correct and full description for progeny plants having the desired phenotypic trait of reduced wound-induced discolouration. In that regard, we note that the scope of dependent claim 2 is limited to a lettuce plant showing a reduced wound-induced discolouration that has obtained the genetic determinant responsible for this trait from the deposited seeds. Therefore, it is our preliminary view that the specification provides a correct and full description of the lettuce plant of claim 2 and satisfies paragraph 27(3)(a) of the *Patent Act* in respect of such subject-matter.

- [38] In the RPR, the Applicant did not express disagreement with the preliminary conclusions reached in the PR. Our conclusion is therefore that claims 1 and 3–6, which encompass lettuce plants wherein the origin of the genetic determinant is not identified as the deposited seeds, are non-compliant with paragraph 27(3)(a) of the *Patent Act*. By contrast, claim 2, which defines progeny lettuce plants that have obtained the genetic determinant responsible for the trait of reduced wound-induced discolouration from the deposited seed, is compliant with paragraph 27(3)(a) of the *Patent Act*.

Enablement under paragraph 27(3)(b) of the *Patent Act*

- [39] Our preliminary analysis was put forth on pages 12–13 of the PR letter as follows:

The SOR, on page 2, maintains the defect in the FA that the description does not provide an enabling disclosure for the use of the claimed lettuce plants:

Although the Application sets out the instructions to mutagenize seeds and screen mutant plants for a reduced wound-induced surface discolouration, that fact remains that a POSITA would be left with an undue experimental and inventive burden to determine if the genetic determinant in a lettuce plant is “as found” in the seeds deposited under accession number NCIMB 41454 or 41441. No sequence information is provided and no hint of where the allele is located in the genome (by way of genetic markers) is provided. In fact, to identify the gene in question, both the seeds deposited under accession number NCIMB 41454 or 41441, as well as the lettuce plant having the genetic determinant as found in said seeds, would require undue experimentation and necessitate the undertaking of a substantial research project that would take a small team of researchers a significant period of time to complete. Many articles published in peer reviewed journals, such as *Theoretical and Applied Genetics*, are dedicated to the identification and isolation of single genes causing desired phenotypes in plants. This speaks to the fact that such an endeavour is not routine experimentation. Furthermore, as indicated above, the allelism test referred to by the Applicant in their letter of 6 October 2015 will not allow a POSITA to determine that a lettuce plant has an allele causing a reduced wound-induced surface discolouration that is “as found” in the seed defined in the instant claims.

On page 3 of the RFA the Applicant clarified their view on enablement of the claims:

[T]he skilled person would be enabled to produce the invention using only the instructions contained in the disclosure. A lettuce plant showing a reduced wound-induced surface discolouration, wherein the reduced wound-induced surface discolouration is caused by a genetic determinant as found in the deposits, can be produced using the deposits as provided in the description. A person skilled in the art does not need to know the sequence of the causal genetic determinant in order to be able to transfer it to another plant. A skilled person simply crosses a plant grown from the deposit with a plant that does show wound-induced surface discolouration and selects in the F1 and/or F2 for plants showing reduced wound-induced surface discolouration. The skilled person can thus produce the invention using only the deposits provided in the disclosure.

We agree with the analysis presented in the FA and are of the preliminary view that the claims which encompass a genetic determinant that is “as found” in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441, are not enabled across their scope and the specification does not comply with paragraph 27(3)(b) of the *Patent Act* in that respect.

As explained in the FA, an allelism test is not sufficient to allow the skilled person to know whether a lettuce plant exhibiting a reduced wound-induced surface discolouration phenotype has a genetic determinant which is “as found” in the deposited seed. Further, given the lack of a full and correct description of the genetic determinant responsible for the desired phenotype, the skilled person would need to further investigate the genetic basis for the reduced wound-induced surface discolouration phenotype in both the seeds deposited under accession number NCIMB 41454 or 41441 in order to determine whether a lettuce plant which exhibits the desired phenotypic characteristics is within the scope of the claims. It is our preliminary view that the skilled person would not be able to practise the invention without an undue burden of experimentation to determine if the genetic determinant in a lettuce plant is “as found” in the seeds deposited under accession number NCIMB 41454 or 41441 and within the scope of the claims. Accordingly, it is our preliminary view that claims 1 and 3-6 which encompass lettuce plants wherein the origin of the genetic determinant is not identified as the deposited seeds fail to satisfy paragraph 27(3)(b) of the *Patent Act* in that respect.

However, as explained above, it is our preliminary opinion that the skilled person would consider that the deposited seeds provide a correct and full description for progeny plants having the desired phenotypic trait of reduced wound-induced discolouration. Therefore, we agree with the RFA that a lettuce plant showing a reduced wound-induced surface discolouration, wherein the reduced wound-induced surface discolouration is caused by a genetic determinant as found in the deposits, can be produced using the deposits as provided in the description. We also agree that the skilled person does not need to know the sequence of the causal genetic determinant to transfer the reduced wound-induced surface discolouration phenotype to descendant generations. Given the deposited plant lines of the invention, the skilled person could use the leaf disc pinking assay disclosed in the specification to screen for the phenotype in descendant plants.

In view of the above, it is our preliminary view that the specification complies with paragraph 27(3)(b) of the *Patent Act* in respect of claim 2 which is the only claim that is limited to lettuce plants that are descendants of the deposited plant lines.

- [40] In the RPR, the Applicant did not express disagreement with the preliminary conclusions reached in the PR. Our conclusion is therefore that claims 1 and 3–6, which encompass lettuce plants wherein the origin of the genetic determinant is not identified as the deposited seeds, are non-compliant with paragraph 27(3)(b) of the *Patent Act*. By contrast, claim 2, which defines progeny lettuce plants that have obtained the genetic determinant responsible for the trait of reduced wound-induced discolouration from the deposited seed, is compliant with paragraph 27(3)(b) of the *Patent Act*.

Indefiniteness of claims 1–6 on file

- [41] Our preliminary analysis was put forth on pages 13–15 of the PR letter as follows:

The FA considers that the subject-matter of claims 1–6 is indefinite because the recited genetic determinant is defined as a statement of desired result. As explained in the FA on page 6:

The claims are directed to a use of a lettuce plant showing reduced wound-induced surface discolouration, wherein this phenotype is “caused by a genetic determinant” that is “as found” in seed deposited with NCIMB on 10 October 2006 under accession number 41441 and 3 January 2007 under accession number 41454. The alleles (“genetic determinant”) responsible for the reduced wound-induced surface discolouration phenotype in the recited seeds have not been characterized and structurally defined in the originally filed description, or in the claims and as such, lettuce plants comprising said undefined (“genetic determinant”) and uses thereof are also undefined. It is noted that the statement that “the reduced wound-induced discolouration is caused by a genetic determinant, which genetic determinant is as found in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441” does not distinctly and explicitly define the allele (“genetic determinant”) and is considered to be directed to a mere statement of desired result that cannot serve to define said alleles or lettuce plants comprising them.

In the RFA, the Applicant did not argue that the claims were compliant with paragraph 27(4) of the *Patent Act*. As indicated above, the Applicant submitted new proposed claims 1 and 2 which do not recite a genetic determinant and indicated that the proposed claims “are not directed to the use of any seed/plant that comprises the genetic determinant as found in the deposited seeds, but is instead limited to the use of the deposited seeds or further generation seeds.”

The test for claim clarity analogizes claim terminology to fences that define its boundaries. It also considers whether the “public will be able to know not only where it must not trespass but also where it may safely go.” As such, we agree with the reasoning in the FA and it is our preliminary view that the skilled person would not be able to readily determine the scope of the monopoly defined by the term “genetic determinant” as used in claim 1. Taken in the context of claim 1, the genetic determinant is no more than a restatement of the desired result.

Only the deposited seeds and their progeny have been shown to exhibit the desired phenotype. Therefore, in the absence of providing a detailed characterization of the genetic basis for the desired phenotype of reduced wound-induced surface discolouration, the genetic determinant is being defined by the desired result without defining the structural features necessary to achieve that result and as such fails to distinctly and explicitly define the recited lettuce plant. Further, as indicated above, Applicant’s suggestion in their response dated October 6 2015 that an allelism test will allow a person skilled in the art to determine whether a lettuce plant having the desired phenotype contains the genetic determinant as found in the deposited seeds is unfounded.

Although the phenotypic characterization “reduced wound-induced discolouration” provides a functional limitation to the scope of the contemplated lettuce plant and the genetic determinant found in said lettuce plant it does not serve to make the scope of the claim clear to the skilled person. Likewise, the requirement that the genetic determinant is “as found” in the deposited seed does not serve to define the scope of the lettuce plants encompassed by the claim. Accordingly, it is our preliminary view that the genetic determinant, and therefore the lettuce plant, as characterized in claims 1 and 3-6, is not distinctly and explicitly defined.

However, it is our preliminary opinion that the skilled person would consider that the deposited seed, which are defined clearly in their own right by deposit number, provide a distinct and explicit definition for a lettuce plant comprising the genetic determinant that is retained in progeny plants having the desired phenotypic trait of reduced wound-induced discolouration. In that regard, we note that the scope of dependent claim 2 is limited to a lettuce plant showing a reduced wound-induced discolouration that has obtained the genetic determinant responsible for this trait from the deposited seeds. Therefore, it is our preliminary view that claim 2 satisfies 27(4) of the *Patent Act*.

- [42] In the RPR, the Applicant did not express disagreement with the preliminary conclusions reached in the PR. Our conclusion is therefore that, in claims 1 and 3-6 the genetic determinant, and therefore the lettuce plant, is not distinctly and explicitly defined contrary to subsection 27(4) of the *Patent Act*. By contrast, claim 2, which defines progeny lettuce plants that have obtained the genetic determinant responsible for the trait of reduced wound-induced discolouration from the deposited seed, is compliant with subsection 27(4) of the *Patent Act*.

Non-compliance of claims 6 and 7 on file with section 2 of the *Patent Act*

- [43] In the PR letter, on pages 13-15, we expressed our preliminary view that the subject-matter defined by claims 6 and 7 is directed to a process of traditional plant breeding which, as stated above, is not within the definition of invention under section 2 of the *Patent Act*:

Notably, claim 6 and claim 7 are use claims that do not feature any steps which are the hallmark of a method or process claim. As explained in MOPOP 17.01.01 and 17.01.02:

A use claim typically sets out a manner or mode of employing something in order to accomplish a particular result without prescribing in detail how the result is to be achieved.

A “method” claim also sets out a mode or manner of accomplishing a certain result but includes one or more particular steps required to achieve the result.

A “process” implies the application of a method to a material or materials.

However, as discussed above, as a matter of claim construction, the skilled person would understand that the scope encompassed by the phrase “conferring [or transferring] the trait of reduced wound-induced discolouration to another lettuce plant” is effectively limited to the steps of a traditional plant cross-breeding process using a plant of the invention, or a seed thereof —no other means for achieving the transfer of the desired trait are contemplated. Therefore, our preliminary view is that the actual invention in claims 6 and 7 define a combination of elements that is limited to the implicit use of lettuce plants or deposited seeds in a traditional plant cross-breeding process in order to achieve the transfer of the recited trait of reduced wound-induced discolouration into other lettuce varieties.

In this particular case, the language of the claims is “inadvertently deceptive” and, as cautioned in *Amazon* at para 44, what appears on their face to be claims for a “use” are, once purposively construed, claims for a process of transferring a trait through traditional plant cross-breeding.

Therefore, it is our preliminary view that the subject-matter of claims 6 and 7 is non-compliant with section 2 of the *Patent Act*.

- [44] In the RPR, the Applicant did not express disagreement with the preliminary conclusions reached in the PR. Our conclusion is therefore that claims 6 and 7 are directed to a method of traditional plant breeding and are non-compliant with section 2 of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

- [45] In the PR letter, on pages 16-17, we set out our preliminary view that proposed claims set-1 submitted with the RFA would not alter the outcome of the assessment of statutory subject-matter:

However, we have also expressed above our preliminary view that the use of seed for “transferring a trait of reduced wound-induced discolouration” into another lettuce plant constitutes an unpatentable process of traditional plant cross-breeding. Therefore, it is our preliminary view that proposed claims 1 and 2 are directed to non-statutory subject-matter outside the definition of invention under section 2 of the *Patent Act*.

- [46] As indicated above, with the RPR the Applicant submitted proposed claims set-2. According to the RPR, claim 1 of proposed claims set-2 amends the scope of claim 1 on file to define a lettuce plant that is a progeny of the deposited seed. Claim 2 of proposed claims set-2 corresponds to dependent claim 2 on file, which was considered to comply with the *Patent Act* and *Patent Rules*, but is written in independent form. The remaining claims in proposed claims set-2 define alternative embodiments of the invention, such as use of a progeny lettuce plant showing a reduced wound-induced surface discolouration as a source of seed (claims 3 and 4), as a source of propagating material (claims 5 and 6), for

consumption (claims 7 and 8) or a cell of said progeny lettuce plant (claims 9 and 10). Notably, the claims we considered defective for non-compliance with section 2 of the *Patent Act* were deleted.

- [47] We have already expressed above our view that limiting the scope of the claims to progeny plants of the deposited seed that retain the desired phenotypic trait of reduced wound-induced surface discolouration would overcome the defects raised in respect of subsection 27(4) and paragraphs 27(3)(a) and (b) of the *Patent Act*. The POSITA would consider that the deposited seed provide a distinct and explicit definition for a progeny plant. Likewise, the POSITA would consider that the deposited seed provide a correct and full description for progeny plants and would be enabled to select for progeny having the desired phenotype using, for example, the leaf disc pinking assay disclosed in the specification.
- [48] In light of the above, it is our view that proposed claims set-2 meets the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS

- [49] We conclude that insofar as claims 1 and 3-6 on file encompass a genetic determinant that is “as found” in seed of which a representative sample was deposited under accession number NCIMB 41454 or 41441, these claims are not compliant with subsection 27(4) of the *Patent Act* and the specification does not comply with subsection 27(3) of the *Patent Act*. We also conclude that claims 6 and 7 on file do not comply with section 2 of the *Patent Act* to the extent that they are purposively construed to be claims directed to a process of transferring a trait through traditional plant cross-breeding.
- [50] Further, we conclude that claim 2 on file complies with the *Patent Act* and *Patent Rules*.
- [51] Finally, we conclude that proposed claims set-2 meets the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[52] For the reasons set out above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the deletion of the claims on file and the insertion of proposed claims 1–10 as presented in the Applicant’s letter of January 7, 2021 are necessary for compliance with the *Patent Act* and *Patent Rules*.

Christine Teixeira

Member

Marcel Brisebois

Member

Philip Brown

Member

DECISION OF THE COMMISSIONER

[53] I concur with the conclusion and recommendation of the Board. In accordance with subsection 86(11) of the *Patent Rules*, I hereby notify the Applicant that the following amendments and only the following amendments must be made in accordance with paragraph 200(b) of the *Patent Rules* within three (3) months of the date of this decision, failing which I intend to refuse the application:

- the deletion of the claims on file; and
- the insertion of proposed claims 1–10 as presented in the Applicant’s letter dated January 7, 2021.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 29th day of January, 2021.