Commissioner=s Decision # 1350
Décision du Commissaire # 1350

TOPICS: B22, F01, G00, J70
SUJETS: B22, F01, G00, J70

Application No. : 2,510,557

Demande n^{o}. : 2,510,557

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,510,557, having been rejected under subsection 30(3) of the *Patent Rules*, has been reviewed in accordance with subsection 30(6) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

Agent for the Applicant:

Smart & Biggar
P.O. Box 2999, Station D
Ottawa, Ontario
K1P 5Y6

INTRODUCTION

[1] This decision deals with a review of the rejection of patent application number 2,510,557 entitled ATOMATO PLANTS THAT EXHIBIT RESISTANCE TO *BOTRYTIS CINEREA*@ filed on 22 April 2003 by co-Applicants Seminis Vegetable Seeds, Inc. and Cornell Research Foundation, Inc.

[2] A Summary of Reasons [SOR] was sent to the Patent Appeal Board [the Board] on 05 May 2011, which identified the following grounds for rejecting this application:

- X all of the claims violate the prohibition on obviousness-type double patenting;
- X certain claims lack support because their utility cannot be soundly predicted over the entire scope of the claims;
- X the specification is not enabling in view of the lack of soundly predicted utility;
- X certain claims are anticipated;
- X certain claims are non statutory for being directed to methods of plant breeding or selection lacking significant human technical intervention; and
- X certain claims are indefinite.

[3] For the reasons that follow, we recommend that the application be amended and thereafter allowed.

BACKGROUND

[4] This application relates to the production, identification and selection of tomato plants that are resistant to the plant pathogen *Botrytis cineria* [*Botrytis*] using genetic screening techniques.

[5] *Botrytis* is a plant pathogen that causes gray mold on the stem, leaves and fruit of tomato plants. Although *Botrytis* can infect both greenhouse and field grown tomatoes, it is a more prevalent problem with greenhouse tomatoes as the greenhouse environment presents optimum growth conditions for the mold. As of the filing date of the present application, there were no commercially available tomato varieties that exhibit resistance to infection by

Botrytis. However, *Botrytis* resistance is a trait of some wild varieties of tomato.

[6] The present description teaches a method of producing *Botrytis* resistant tomato plants that relies on marker assisted selection to identify tomato plants having the desired trait. The method involves the cross breeding of a commercial variety of tomato plant, *Lycopersicon esculentum* [*L. esculentum*], with a wild variety, *Lycopersicon hirsutum* [*L. hirsutum*]. The goal is to breed a plant that stably maintains both the commercially desirable characteristics plus the disease resistance trait of the wild variety. Specifically disclosed is the production of *Botrytis* resistant hybrid tomato plants that contain a region from chromosome 10 of *L. hirsutum* that has been introgressed into the genome of *L. esculentum*. More importantly, this region has been defined by specific molecular markers that can be used to identify and select tomato plants that are highly likely to possess *Botrytis* resistance.

[7] Although *Botrytis* resistance can be assessed using traditional pathology disease screens, these types of screens are associated with many undesirable factors. Specifically, they are time and labour consuming, expensive and can be unreliable due to environmental factors. They involve challenging individual plants or parts thereof with *Botrytis* and scoring which plants are resistant or susceptible. Plants exhibiting a *Botrytis* resistance phenotype and possessing commercially desirable characteristics are selected and allowed to self-pollinate for several generations to ensure that both the disease resistance trait and the commercially desirable characteristics are maintained. This need to evaluate plants using field trials is time consuming, labour intensive and requires large plots of land/and or greenhouse space in which the large populations of plants are to be grown. Further, these types of field trials are also susceptible to environmental factors that can lead to false determinations.

[8] In the present case, the Applicant is asserting that the use of marker assisted selection provides many advantages over conventional cross breeding programs that rely on pathology disease screens. In particular, molecular markers are relatively simple to detect, occur completely independent of environmental conditions and can be detected at the seedling stage, which allows undesirable plants to be quickly eliminated. These benefits can translate into shortening the duration of breeding programs from years to months or even weeks, resulting in a huge cost savings. Further, the Applicant asserts that the claimed methods for producing *Botrytis* resistant tomato plants using marker assisted selection requires significant human intervention.

PROSECUTION HISTORY

[9] After several Office Actions, this application was rejected in a Final Action [FA] on 11 December 2009. The application was considered defective because certain claims were considered anticipated, certain claims were considered to violate the prohibition on obviousness double patenting, certain claims were considered non-statutory and certain claims were found to lack support in the description. The lack of support analysis was accompanied by an objection to the specification for not providing an enabling disclosure.

[10] In response to the FA, the Applicant chose to replace the claims on file with an amended claim set containing 37 claims and continued to argue in favour of the patentability of the claims.

[11] The Examiner maintained the rejection and indicated in an SOR submitted to the Board that the Applicant had failed to overcome all of the defects identified in the FA. The Examiner also identified a new ground for rejection: indefiniteness.

[12] A panel of three members of the Board was established and, following an initial review, a letter was sent to the Applicant setting out additional observations of the panel. In particular, it was noted that double patenting was no longer considered an outstanding defect as co-pending application 2,444,536 was abandoned and could not longer be reinstated pursuant to subsection 73(3) of the *Patent Act* [the Act]. The panel also considered that since the conclusions of lack of support and enablement were based on a lack of soundly predicted utility this defect is best addressed under section 2 of the Act. Finally, the panel requested that the Applicant distinguish between certain claims that appeared redundant in view of one another.

[13] The panel has restated the outstanding defects as follows:

- X claims 1-37 contravene section 2 of the Act for failing to meet the requirements of the test for sound prediction of utility;
- X claims 25, 26, 28 and 29 contravene subsection 28.2(1)(*a*) of the Act for being anticipated;
- X claims 1-5, 10-14, 27 and 30-36 contravene section 2 of the Act for being directed to non-statutory methods of plant breeding; and
- X claims 1, 6, 10, 15, 20, 27, 28 and 31 contravene subsection 27(4) of the Act for being indefinite.

[14] In response to the SOR and the panel=s letter, the Applicant provided written submissions to the Board, serving as the basis for their presentation at an oral hearing, which was held on 27 May 2013. In its submissions to the Board, the Applicant requested consideration of two alternative sets of claims: a main set and an auxiliary set. These were presented in order to address the defects related to a lack of soundly predicted utility over the entire scope of the claims, anticipation and indefiniteness.

[15] Although this review is conducted on the basis of the claims submitted in response to the FA, as shall be seen below, the main and auxiliary requests are also considered.

THE ISSUES

[16] In view of the grounds for rejection cited by the Examiner and the panel=s observations during the initial review we must address the following four questions:

(1) Can it be soundly predicted that introgression of *L. hirsutum* DNA comprising only one

of the markers listed in the claims, into the genome of *L. esculentum*, will confer *Botrytis* resistance?

(2) Are the claimed cells anticipated?

(3) Are the claimed methods that include conventional cross breeding steps non-statutory?

(4) Are certain claims indefinite for including redundant terms and for failing to clearly define a difference in scope relative to each other?

THE CLAIMS

[17] Claims 1-37 on file contain 10 independent claims, defining methods of producing *Botrytis* resistant tomato plants, methods of identifying *Botrytis* resistant tomato plants, cells from *Botrytis* resistant tomato plants and use of specific molecular markers from chromosome 10 to identify *Botrytis* resistant tomato plants. The following claims are representative of the claims considered to be defective:

1. A method of producing a tomato plant that in contact with a *Botrytis* fungi exhibits resistance to said *Botrytis* fungi, wherein said tomato plant is produced by a method comprisng the steps of:
   a. identifying a *Botrytis* resistant *Lycopersicon hirsutum* donor plant;
   b. crossing the *Botrytis* resistant plant from step a. with a recipient *Lycopersicon esculentum* tomato plant that is non-resistant or has an intermediate level of resistance to *Botrytis* and possesses commercially desirable characteristics;
   c. isolating genetic material from a progeny of said donor plant crossed with said recipient plant; and
   d. performing molecular marker-assisted selection with a molecular marker from chromosome 10 associated with *Botrytis* resistance comprising:
      i. identifying a *Botrytis* resistant *Lycopersicon hirsutum* introgressed region comprising a molecular marker selected from the group consisting of: TG408, TG285, CT260C, CT112B, CT203, CT42, *h*, PGAL, TG420, CD34B and CT20;
      ii. identifying an upper region comprising a homozygous *Lycopersicon esculentum* molecular marker selected from the group consisting of: CT113C, TG271, TG230, TG313, *hy*, TG399A, CT105B, CT41, TG122, CAB7, TG63, TG395, *nor*, CT16, CD77, TG303, CD56, CT125, CT60, TG540, CAB8, *u*, TG566, PTC1, CT234, TG148, CD38A, TG12, TG596, TG148, CD38A, TG12, CD45, TG11, TG560, CT91A, TG52, TG545, TG43, CT66 and CT126A; and
      iii. identifying an lower region comprising a homozygous *Lycopersicon esculentum* molecular marker selected from the group consisting of: CD72, CD34A, CT57, CP49, CP65B, *l2*, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B.

6. A method of identifying a *Botrytis* resistant *Lycopersicon esculentum* tomato plant, the method comprisng:
   a. isolating genetic material from a *Lycopersicon esculentum* tomato plant; and

b. performing molecular marker-assisted selection for molecular markers from chromosome 10 associated with *Botrytis* resistance comprising:

i. identifying a *Botrytis* resistant *Lycopersicon hirsutum* region comprising a molecular marker selected from the group consisting of: TG408, TG285, CT260C, CT112B, CT203, CT42, *h*, PGAL, TG420, CD34B and CT20;

ii. identifying an upper region comprising a homozygous *Lycopersicon esculentum* molecular marker selected from the group consisting of: CT113C, TG271, TG230, TG313, *hy*, TG399A, CT105B, CT41, TG122, CAB7, TG63, TG395, *nor*, CT16, CD77, TG303, CD56, CT125, CT60, TG540, CAB8, *u*, TG566, PTC1, CT234, TG148, CD38A, TG12, TG596, TG148, CD38A, TG12, CD45, TG11, TG560, CT91A, TG52, TG545, TG43, CT66 and CT126A; and

iii. identifying an lower region comprising a *Lycopersicon esculentum* molecular marker selected from the group consisting of: CD72, CD34A, CT57, CP49, CP65B, *l2*, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B.

25. A cell of a tomato plant produced according to Claim 1 or Claim 10, wherein said cell comprises:

i. a *Botrytis* resistant *Lycopersicon hirsutum* region of chromosome 10 comprising a molecular marker selected from the group consisting of: TG408, TG285, CT260C, CT112B, CT203, CT42, *h*, PGAL, TG420, CD34B and CT20;

ii. an upper region of chromosome 10 comprising a homozygous *Lycopersicon esculentum* molecular marker selected from the group consisting of: CT113C, TG271, TG230, TG313, hy, TG399A, CT105B, CT41, TG122, CAB7, TG63, TG395, nor, CT16, CD77, TG303, CD56, CT125, CT60, TG540, CAB8, u, TG566, PTC1, CT234, TG148, CD38A, TG12, TG596, TG148, CD38A, TG12, CD45, TG11, TG560, CT91A, TG52, TG545, TG43, CT66 and CT126A; and

iii. a lower region of chromosome 10 comprising a *Lycopersicon esculentum* molecular marker selected from the group consisting of: CD72, CD34A, CT57, CP49, CP65B, *l2*, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B.

37. Use of a molecular marker from chromosome 10 of tomato plants associated with *Botrytis* resistance therein, said molecular marker comprising a *Botrytis* resistant *Lycopersicon hirsutum* introgressed region selected from the group consisting of: TG408, TG285, CT260C, CT112B, CT203, CT42, *h*, PGAL, TG420, CD34B and CT20;

for identification of a tomato plant that in contact with a *Botrytis* fungi exhibits resistance to said *Botrytis* fungi.

PURPOSIVE CONSTRUCTION

[18] Purposive construction must be done before considering the issues of validity or infringement. During purposive construction, the elements of the claimed invention are

identified as either essential or non-essential: *Free World Trust v Electro Santé Inc*, 2000 SCC 66 [*Free World Trust*]. In order for an element to be considered Anon-essential@, Ait must be shown either (i) that on a purposive construction of the words of the claim it was clearly *not* intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention@ (*Free World Trust* at para. 55).

[19] Further, a purposive construction of the claims, Arequires that they be interpreted in light of the whole of the disclosure, including the specification@: *Whirlpool Corp. v. Camco Inc.,* 2000 SCC 67. It is also expected that one should recognize Athat a patentable invention is an inventive solution to a practical problem@ and Athat an invention must be disclosed (and ultimately claimed) so as to provide the person skilled in the art with an operable solution@: Office Patent Notice published March 8, 2013 entitled A*Practice Guidance Following the Amazon FCA Decision*@ and its accompanying memo, PN 2013-02.

The person skilled in the art

[20] The description and claims relate to plant breeding and molecular biology. This suggests that the skilled person is a team that includes a plant breeder and molecular biologist. As such, the skilled person would possess the following: expertise in traditional plant breeding and expertise in the application of molecular techniques for DNA-based marker assisted breeding to identify and select for desired traits. This characterization of the skilled person and their common general knowledge (CGK) is consistent with the background of the two trait genetic research scientists who provided declarations on behalf of the Applicant. These declarations identify more specific elements, related to CGK, that will be addressed later in the reasons.

The problem and solution that the invention addresses

[21] Based on the description, the present invention relates to methods for developing new, hybrid tomato plants that exhibit resistance to *Botrytis* and have commercially desirable characteristics. Unlike conventional breeding programs, which utilize pathology disease screens to identify hybrid tomato plants exhibiting desired traits, the present invention relates to improved methods for producing *Botrytis* resistant tomato plants that incorporate the use of marker assisted selection to identify resistant plants.

[22] Specifically, the description discloses the molecular characterization of *Botrytis* resistant and *Botrytis* susceptible tomato plants. Tomato plants exhibiting resistance to *Botrytis* contain a specific region on chromosome 10 that is not present in tomato plants susceptible to infection by *Botrytis*. This region was identified as an introgression of DNA from the wild species of tomato, *L. hirsutum,* into the genetic background of the commercial variety, *L. esculentum.* A genetic linkage map of chromosome 10 from a mix of *Botrytis* resistant and susceptible tomato lines was used to specifically identify the molecular markers from *L. hirsutum* that are associated with *Botrytis* resistance. The use of these markers to identify tomato plants that are resistant to *Botrytis* is reflected in the method of claim 1.

Claim 1, purposively construed

[23] The preamble of the claim recites its purpose: it is directed to a Amethod of producing a tomato plant that in contact with a *Botrytis* fungi exhibits resistance to said *Botrytis* fungi.@ A literal interpretation of this expression may suggest that the cross breeding of a commercial variety of tomato plant, *L. esculentum*, with a wild variety, *L. hirsutum* is sufficient to achieve this result. However, a purposive construction of the expression does not support such an interpretation because, as indicated earlier (para. [21]), the present invention relates to improved methods for producing *Botrytis* resistant tomato plants that incorporate the use of marker assisted selection to identify resistant plants. Therefore,

we construe the term Aproducing@ in the preamble to mean not only cross breeding plants but also screening the progeny and selecting only those plants having *Botrytis* resistance.

[24] The preamble is followed by the transitional phrase Acomprising@, which characterizes the elements that follow. The claim elements define a series of steps that are performed to achieve the desired result as set forth in the preamble. As shall be seen below, all of these elements are essential to the working of the claimed invention.

[25] The method comprises a series of four steps. The first two steps relate to the crossing of a donor and recipient tomato plant. The donor plant is defined as Aa *Botrytis* resistant *Lycopersicon hirsutum*@ tomato plant, while the recipient plant is A*Lycopersicon esculentum* tomato plant that is non-resistant or has an intermediate level of resistance to *Botrytis* and possesses commercially desirable characteristics.@ The crossing of these two plants is essential as the production of a tomato plant that is resistant to *Botrytis* and possesses commercially desirable characteristics requires the transfer of genetic material from the donor plant to the recipient plant.

[26] The latter two steps relate to the identification and selection of specific progeny plants from the crossing of the donor and recipient plants. These steps entail Aisolating genetic material from a progeny of said donor plant crossed with said recipient plant@ and Aperforming molecular marker-assisted selection with a molecular marker from chromosome 10 associated with *Botrytis* resistance.@ It is clear from the description that identification of the region of chromosome 10 that is linked to *Botrytis* resistance was not part of the common general knowledge at the claim date. Therefore, selection of specific progeny plants using molecular techniques to identify such a region are distinct from conventional selection techniques, which use pathology disease screens to phenotypically identify specific progeny. The skilled person would not have considered that identification using marker assisted selection could be substituted with conventional

screening techniques without affecting the working of the invention. It follows that the recited steps relating to the identification and selection of specific progeny plants are essential to the solution of providing an improved method for producing *Botrytis* resistant tomato plants.

[27] Therefore, all four steps recited in the method of claim 1 define essential features of the claimed solution. However, as shall be seen later in these reasons, not all of the molecular markers defined in the step of marker assisted selection were found to be essential. Our findings under sound prediction clarify which regions of chromosome 10 from *L. hirsutum* are associated with conferring *Botrytis* resistance and which regions of chromosome 10 from *L. esculentum* are associated with retaining the desirable characteristics of the commericial variety. It follows that only those markers which define these regions are essential in the step of marker assisted selection.

Claims 6, 15 and 20

[28] The remaining independent claims define alternative embodiments of the invention. Independent claims 6, 15 and 20 define methods for identifying a *Botrytis* resistant tomato plant. These methods rely solely on the last two steps defined by the method of claim 1, namely the identification and selection of specific progeny plants from the crossing of the donor and recipient plants. We have already established in our analysis of claim 1 that these steps are essential to the production of tomato plants that are resistant to *Botrytis*.

Claims 10, 27 and 31

[29] Independent claims 10, 27 and 31 are method claims similar to claim 1, except that each of these claims contain additional steps that occur following the crossing of the donor and recipient tomato plants but prior to the identification and selection of specific progeny. These steps involve: obtaining a seed from the first crossing; planting said first seed and growing into a first plant; obtaining a second seed from said first plant; and planting said second seed and growing into a second plant.

Claims 25 and 28

[30] Independent claims 25 and 28 define cells that are produced by the method of claims 1, 10 or 27. These cells are characterized by the presence of specific molecular markers that identify the region from chromosome 10 that has been introgressed from the *Botrytis* resistant tomato plant *L. hirsutum* and the regions from chromosome 10 that are present in the genome from the commerical variety *L. esculentum*. A hybrid tomato plant that exhibits *Botrytis* resistance and has commercially desirable characteristics being the heart of the invention, it follows that the regions of chromosome 10 that are associated with these traits are essential.

[31] As indicated at para. [27], our findings under sound prediction clarify which regions of chromosome 10 from *L. hirsutum* are associated with conferring *Botrytis* resistance and which regions of chromosome 10 from *L. esculentum* are associated with retaining the desirable characteristics of the commericial variety. Therefore, only those markers which define these regions are considered essential. As shall be seen later in these reasons, this determination is relevant in our assessment of the main and auxiliary claim sets submitted by the Applicant to the Board when considering the issue of anticipation.

Claim 37

[32] Independent claim 37 defines the use of specific molecular markers from chromosome 10 of *L. hirsutum* for the identification of *Botrytis* resistant tomato plants. Based on our reasoning above, we also find the feature of defining specific molecular markers that identify the region from chromosome 10 that has been introgressed from the *Botrytis* resistant tomato plant *L. hirsutum* to be essential.

ISSUE 1: CAN IT BE SOUNDLY PREDICTED THAT INTROGRESSION OF *L. HIRSUTUM* DNA COMPRISING ONLY ONE OF THE MARKERS LISTED IN THE CLAIMS, INTO THE GENOME OF *L. ESCULENTUM*, WILL CONFER *BOTRYTIS* RESISTANCE?

Legal Framework

[33] This issue relates to the requirement of utility of the invention under s. 2 of the *Patent Act*, which defines an Ainvention@ as:

> [a]ny 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.

[34] The general principle is that, as of the date of filing, a claimed invention must be useful on the basis of either demonstration or sound prediction: *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 [*AZT*]. Whenever a claimed invention is not based on demonstrated utility, it becomes necessary to determine whether the utility was soundly predicted.

[35] As outlined in *AZT*, the doctrine of sound prediction has three components:

1) There must be a factual basis for the prediction;
2) There must be an articulable and Asound@ line of reasoning from which the desired result can be inferred from the factual basis; and
3) There must be proper disclosure.

The Examiner's position and the panel's initial observations

[36] In the FA and SOR, the Examiner argued that there is no factual basis for the utility of the methods when the introgressed DNA contains only one of the molecular markers located between TG408 and CT20. The description discloses that the two *Botrytis* resistant lines identified had overlapping introgressions that included the entire region of chromosome 10 between markers TG408 and TG403. Therefore, the Examiner concluded that the claims must specify that the introgressed DNA contains this region.

[37] The panel also noted in our initial review memorandum that the present description disclosed several hybrid tomato lines that were not associated with the desired trait of *Botrytis* resistance. Moreover, all of these lines appeared to contain an introgression of *L. hirsutum* DNA comprising at least one of the molecular markers listed in the claims.

The Applicant's position

[38] In response to the SOR and in their written submissions to the Board the Applicant argued that the specification as filed supports a sound prediction that the presence of an introgression from chromosome 10 of *L. hirsutum* between TG408 and CT20 is associated with *Botrytis* resistance, and one or more *L. hirsutum* markers between and including these markers can be used for marker assisted breeding of a *Botrytis* resistant tomato. In support of this position, the Applicant also provided declarations filed by two trait genetic research scientists who are knowledgeable in the field of molecular plant breeding.

Analysis

Factual Basis

[39] The test for sound prediction is summarized at para. [35]. The first element of the analysis involves determining whether there is a factual basis supporting the prediction.

[40] The only factual basis given is that of the examples shown in the description and the accompanying figures. To aid in our analysis, a genetic linkage map of chromosome 10 from various *Botritys* resistant and susceptible strains provided by the Applicant in their written submissions has been partially reproduced below:

[41] The above genetic linkage map identifies the molecular markers present on chromosome 10 along with an indication of the specific regions that represent an introgression of DNA from *L. hirsutum* into the genetic background of the commerical variety *L. esculentum*. As indicated by the Examiner, the two *Botrytis* resistant lines (TA1549 and TA1551) have overlapping introgressions that include the entire region of chromosome 10 between markers TG408 and TG403. These strains also contain an upper region, relative to the introgression, comprising markers from *L. esculentum*. The region of overlap of *L. esculentum* DNA between the two *Botrytis* resistant strains comprises molecular markers TG148 and CT91A. There is no evidence that the desirable traits of the commercial variety

are retained when this upper region is absent. Therefore, minimally this upper region of *L. esculentum* DNA forms part of the basis of the sound prediction and must also be present. No lower region of *L. esculentum* DNA, relative to the introgression, is required as the *Botrytis* resistant strain TA1549 did not contain any *L. esculentum* DNA in this region.

[42] In contrast, the three strains that failed to exhibit resistance to *Botrytis* (TA1552, TA1337 and TA1555) all contain a *L. hirsutum* introgressed region between and including molecular markers CT20 and TG403. Moreover, it is clear from the schematic diagram that, for example, tomato strain TA1337 would be identified by performing the molecular marker assisted selection steps recited in claim 1. Consistent with what is defined in claim 1, strain TA1337 contains molecular marker CT20 from *L. hirsutum* and molecular markers CT126A and CD32B from *L. esculentum*. However, this strain was specifically demonstrated to lack resistance to *Botrytis*.

[43] This evidence of inutility within the scope of all of claims 1-37 renders the claims non compliant with section 2 of the Act, and we need not further assess whether there is a sound line of reasoning and proper disclsoure with respect to the claims on file.

[44] Given that the claims on file lack utility, we will assess whether the main and auxiliary claim sets submitted to the Board overcome this defect. With respect to the main claim set, we note that these claims also specify the detection of a *L. hirsutum* introgressed region comprising any one molecular marker between and including CT20 and TG403. It follows that these claims also encompass subject matter for which there has been a demonstrated lack of utility.

[45] In contrast, the auxiliary claim set overcomes this defect by characterizing the *Lycopersicon hirsutum* introgressed region as comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20, which region is not found in the strains lacking *Botrytis* resistance. Therefore, we will assess the sound line of reasoning and disclosure with respect to the auxiliary claim set submitted to the Board.

Sound line of reasoning

[46] The second element of the test for sound prediction requires that there be an articulable and sound line of reasoning from the factual basis to the predicted utility.

Region of L. hirsutum introgressed DNA associated with Botrytis resistance

[47] Using the above schematic representation of introgressed DNA the skilled person would find it reasonable to consider that it is the *L. hirsutum* introgressed region between and including molecular markers TG408 and CT20 that is associated with *Botrytis* resistance. Although a comparison of the *L. hirsutum* introgressed DNA from the two *Botrytis* resistant strains of tomatoes (TA1549 and TA1551) identifies an overlap region that includes molecular markers TG408 and TG403, the skilled person would also find the genetic makeup of three hybrid strains (TA1552, TA1337 and TA1555) that failed to exhibit resistance to *Botrytis* to be relevant. In particular, these three strains all contain a *L. hirsutum* introgressed region between and including molecular markers CT20 and TG403. Clearly, the presence of only this lower region of *L. hirsutum* introgressed DNA is not sufficient to identify tomato plants that exhibit resistance to *Botrytis*. In view of this, the skilled person would consider it reasonable to extrapolate that the minimum region of *L. hirsutum* introgressed DNA that is associated with *Botrytis* resistance includes molecular markers TG408 and CT20.

Region of L. esculentum DNA associated with desirable characteristics

[48] Although the auxiliary claim set features the identification of a *Lycopersicon hirsutum* introgressed region having an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20, these claims no longer specify any regions from chromosome 10 that are present from the genetic background of the commerical variety *L. esculentum*. The factual basis provides no evidence that the desirable traits of the commercial variety can be retained without the presence of an upper region, relative to the introgression, comprising molecular markers TG148 and CT91A from *L. esculentum* (see para. [41]). Further, the Applicant has provided evidence in the form of two declarations, which reason that a person of ordinary skill in the art would understand that if two markers are linked to a trait, any marker between the two markers would also be linked to the trait. We recognize that this logic was part of the common general knowledge of the person skilled in the art and can serve to bridge the gap between the factual basis and the sound prediction: *Teva Canada Limited v. Novartis AG*, 2013 FC 141 at para. 326. Unlike the situation with the introgressed *L. hirsutum* region, there is no evidence of lack of utility with respect to the use of any one of these markers. Therefore, the skilled person would find it reasonable to infer that the presence of any *L. esculentum* marker between TG418 and CT91A would also be linked to the desirable traits of the commercial variety.

Disclosure

[49] The third element of the test for sound prediction requires a proper disclosure. In *Apotex Inc. v. Pfizer Canada Inc. et al.*, 2011 FCA 236, the Federal Court of Appeal again confirmed that it is the factual basis and the sound line of reasoning underlying a sound prediction that must be disclosed (para. 52).

[50] In view of the above analysis, we find that a proper disclosure is provided for the predicted utility that the detection of a *L. hirsutum* introgressed region minimally comprising an upper end molecular marker TG408 and a lower end molecular marker CT20 can be used to identify *Botrytis* resistant tomato plants. A proper disclosure is also provided for the predicted utility that an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum* is associated with retention of the desirable traits of the commercial variety.

Conclusions

[51] We find that the claims on file encompass embodiments for which a lack of utility has been demonstrated. This is also a defect of the main claim set submitted to the Board.

[52] However, amendments can be made that will properly limit the scope of the claims to what can be soundly predicted. In order to satisfy the test for sound prediction, the claims must specify that the *L. hirsutum* introgressed region used to identify *Botrytis* resistant tomato plants minimally comprises an upper end molecular marker TG408 and a lower end molecular marker CT20. The claims must also specify the presence of an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum* as there is no evidence that the desirable traits of the commercial variety are retained in the absence of this region.

[53] In this regard we note that independent claims 1, 6, 10, 15, 20, 25, 27, 28 and 31 of the auxiliary claim set characterize the *Lycopersicon hirsutum* introgressed region as comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20. This limitation must be imported into independent claims 1, 6, 10, 15, 20, 25, 27, 28 and 31 of the claim set on file. Further, the claims must be amended to specify the presence of an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum*. Once these two limitations have been incorporated into the claims the test for sound prediction

will be satisfied.

[54] Neither of the required limitations are present in claim 37 of the auxiliary claim set. It follows that claim 37 must be deleted as it encompasses the detection of inoperative embodiments and corresponding claim 37 in the auxiliary claim set does not provide any features that can be imported to satisfy the test for sound prediction.

[55] Restricting the scope of the independent claims to what can be soundly predicted necessarily affects the scope of the corresponding dependent claims. It follows that dependent claims 3-5, 7-9, 12-14, 17-19, 22-24, 26, 29 and 33-35 must be deleted as their scope does not fall within the limits of what can be soundly predicted.

[56] In line with the above findings, the remaining issues will be addressed by considering the claims as though they have been amended to limit their scope to what can be soundly predicted. Specifically, the claims have been restricted to define: a *Lycopersicon hirsutum* introgressed region comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20 and, an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum*.

ISSUE 2: ARE THE CLAIMED CELLS ANTICIPATED?

Legal Framework

[57] The statutory provision relevant for assessing anticipation is subsection 28.2(1) of the *Patent Act*. That subsection provides, in part:

> The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> (*a*) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> (*b*) before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the subject-matter became available to the public in Canada or elsewhere.

[58] In *Free World Trust* (at para. 25) the Supreme Court made clear that if a single prior

art publication discloses all of the essential elements of the claimed invention in an enabling manner, there is anticipation.

[59] In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 [*Sanofi*], the Supreme Court further clarified the test for anticipation by explicitly endorsing a two-step approach in which the requirements of Aprior disclosure@ and Aenablement@ should be considered separately and proven. In *Sanofi*, the Supreme Court based this approach on the decision of the House of Lords, per Hoffman L.J., in *Synthon BV v. Smithkline Beecham plc*, [2005] UKHL 59, [2006] 1 All ER 685.

[60] If the disclosure requirement is met, the second requirement of enablement must also be satisfied; this means:

> [t]hat the person skilled in the art would have been able to perform the invention [para. 26]

and that:

> [t]he person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. [para. 27]

The Examiner's position

[61] In the FA and SOR, the Examiner argued that the claimed cells (claims 25, 26, 28 and 29) were anticipated by a hybrid tomato cell line produced in a prior study conducted with the assistance of Cornell University; see Monforte and Tanksley, Genome 2000: 43, 803-813. The cell line in question, TA1550, comprises an introgressed region from chromosome 10 of *L. hirsutum* including molecular marker TG408, surrounded by genetic material from *L. esculentum* including the upper marker CT234 and the lower marker TG241 (see para. [40]).

The Applicant's position

[62] In response to the SOR, the Applicant maintained their argument that line TA1550 Adoes not disclose a lower region comprising a *L. esculentum* marker selected from the group consisting of CD72, CD34A, CT57, CP49, CP65B, *l2*, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B.@ Specifically, Aline TA1550 has *L. hirsutum* DNA at least at markers CD72, CD34A, CT57, CP49, CP65B, *l2* and CT124.@

Purposive construction of proposed claim 25

[63] As indicated above, having found that the scope of the claims on file encompasses subject matter for which there has been a demonstrated lack of utility, the Board will not consider the claims as they presently appear in the application, but will rather consider them as though the scope of the claims were limited to what can be soundly predicted.

[64] To aid in our analysis, claim 25 on file, limited to what can be soundly predicted, is presented below. This proposed claim is representative of the claims to be considered. The amendments to the claim, i.e. with respect to the molecular markers that define the region of *L. hirsutum* introgressed DNA and the molecular markers that define the upper region, relative to the introgression, of *L. esculentum* DNA, are highlighted in bold.

25. A cell of a tomato plant produced according to Claim 1 or Claim 10, wherein said cell comprises:

i. a *Botrytis* resistant *Lycopersicon hirsutum* region of chromosome 10 **comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20**;

ii. an upper region of chromosome 10 comprising a homozygous *Lycopersicon esculentum* molecular marker **selected from the group consisting of: TG148, CD38A, TG12, CD45, TG11, TG560 and CT91A**; and

iii. a lower region of chromosome 10 comprising a *Lycopersicon esculentum* molecular marker selected from the group consisting of: CD72, CD34A, CT57, CP49, CP65B,

I2, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B.

[65] The cell of this claim is characterized by the presence of specific molecular markers that identify the region from chromosome 10 that has been introgressed from the *Botrytis* resistant tomato plant *L. hirsutum* and the regions from chromosome 10 that are present in the genome from the commerical variety *L. esculentum*. As indicated above (para. [52]), in order to satisfy the test for sound prediction, the *L. hirsutum* introgressed region used to identify *Botrytis* resistant tomato plants must minimally comprise an upper end molecular marker TG408 and a lower end molecular marker CT20. We also found that there was no evidence to indicate that the desirable traits of the commerical variety could be retained in the absence of an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum*. And earlier, we determined (at para. [41]) that it was unnecessary to specify the presence of a lower region, relative to the introgression, comprising a homozygous *Lycopersicon esculentum* molecular marker. Therefore, only the first two features which define the claimed cell are considered essential, namely the molecular markers that define the region from chromosome 10 that has been introgressed from the *Botrytis* resistant tomato plant *L. hirsutum* and the molecular markers that define the upper region, relative to the introgression, from chromosome 10 that is present in the genome from the commerical variety *L. esculentum*.

Analysis under the *Sanofi* Two-Step Approach

Disclosure

[66] Even so, the cell line, TA1550, taught by Monforte and Tanksley comprises a *Lycopersicon hirsutum* introgressed region comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20 and, an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum*.

[67] Although the feature of defining a lower region, relative to the introgression, from chromosome 10 that is present in the genome from the commerical variety *L. esculentum* is considered non-essential, this feature is also present in line TA1550. Therefore, contrary to Applicant's argument, line TA1550 also discloses a lower region comprising a *L. esculentum* marker selected from the group consisting of CD72, CD34A, CT57, CP49, CP65B, *l2*, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B. Because the lower region is defined in Markush format a cell line fitting within the scope of the claims need only recite one of the listed markers. As indicated by the Examiner, TA1550 contains a lower region of chromosome 10 comprising *L. esculentum* molecular marker TG241. Indeed, TA1550 contains the following lower markers: CT57, CP49, CP65B, *l2*, CT124, TG241, TG229, TG403, CT95, TG663, HTS1C, TG63, TG206A, CT238, CT240, CD5, TG233 and CD32B.

[68] Therefore, the cell line TA1550 fits within the scope of claims 25, 26, 28 and 29, considered as though they have been limited to what can be soundly predicted.

Enablement

[69] Monforte and Tanksley disclose the production of hybrid tomato cell lines derived from a cross between *L. esculentum* and *L. hirsutum*. Most of the lines contained a single defined introgression from *L. hirsutum* into the *L. esculentum* genetic background, including TA1550. Therefore, we find that this reference provides a disclosure that would enable the skilled person to produce tomato plant cells that fall within the scope of the claimed cells, considered as having been limited as mentioned above.

Conclusions

[70] We find that claims 25, 26, 28 and 29 on file, considered as being limited to what can be soundly predicted, are anticipated by Monforte and Tanksley in view of cell line TA1550, which contains all of the essential features of the claimed cells.

[71] The corresponding cell claims of the main and auxiliary claim sets do not provide any additional, essential features that can overcome this defect. Claims 26 and 29 are cancelled in both the main and auxiliary claim sets. Claims 25 and 28 of both claim sets are characterized as comprising an upper region of chromosome 10 comprising *L. esculentum* molecular marker TG280. This marker is not present in cell line TA1550. However, we do not consider the presence of this feature to be essential. The only region of *L. esculentum* that was determined to be associated with retaining its desirable characteristics is defined by molecular markers TG148 and CT91A. Marker TG280 lies outside of this region and there is no evidence from the above genetic linkage map that specifying an upper region, relative to the introgression, comprising molecular marker TG280 from *L. esculentum* has any material effect on the working of the invention. Indeed, cell line TA1549, which is both resistant to *Botrytis* and possesses commercially desirable characteristics, is characterized as having DNA introgressed from *L. hirsutum* at marker TG280. In view of line TA1549, the skilled person would consider that specifying the presence of molecular marker TG280 from *L. esculentum* could be substituted by the presence of molecular marker TG280 from *L. hirsutum* without affecting the working of the invention.

[72] Therefore, claims 25 and 28 of both the main and auxiliary claim sets, considered as

being limited to what can be soundly predicted, are also anticipated by Monforte and Tanksley in view of cell line TA1550, which contains all of the essential features of the claimed cells. It follows that no amendments proposed by either the main or auxiliary claim set can overcome the conclusion that claims 25, 26, 28 and 29 on file are anticipated.

ISSUE 3: ARE THE CLAIMED METHODS THAT INCLUDE CONVENTIONAL CROSS BREEDING STEPS NON-STATUTORY?

Legal Framework

[73] Section 2 of the *Patent Act* defines "invention" as:

> 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.

[74] As set out in section 17.02.02 of the Manual of Patent Office Practice:

> The patentability of a method or process is independent of whether or not the product of the method or process is statutory. Processes to produce higher life forms, organs or tissues are not, therefore, objectionable on the grounds that they produce nonstatutory products.
>
> An especially important consideration in biotechnology, however, is the degree of technical intervention embodied in the claimed process. A process which occurs essentially according to nature, with no significant technical intervention by man, is not patentable. Thus, for example, a process for producing a plant by traditional crossbreeding techniques is not patentable.
>
> Process which are considered to include significant technical intervention by man include: processes to produce a lower life form, a higher life form, an organ or a tissue through genetic transformation; processes for the in vitro culturing or manipulation of cells; processes to separate cells; and processes to generate mutants using a chemical or physical agent.

[75] As discussed in *Pioneer Hi-Bred Ltd. v.Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 [*Pioneer Hi-Bred*] processes to produce higher life forms rely on genetic engineering,

which can occur in two ways, as outlined below:

> The first involves crossing different species or varieties by hybridization, altering the frequency of genes over successive generations. [...] There is thus human intervention in the reproductive cycle, but intervention which does not alter the actual rules of reproduction, which continues to obey the laws of nature.
>
> This procedure differs from the second type of genetic engineering, which requires a change in the genetic material -- an alteration of the genetic code affecting all the hereditary material -- since in the latter case the intervention occurs inside the gene itself. [pp. 1632-1633]

[76] It has been subsequently confirmed that processes relying on the second type of genetic engineering are considered to require significant technical intervention by man and therefore can be patentable: *Harvard College v.Canada (Commissioner of Patents)*, 2002 SCC 76 [*Harvard*] and *Monsanto Canada Inc. v. Schmeiser* 2004 SCC 34 [*Schmeiser*]. However, what has not been considered is Awhether there is a conclusive difference as regards patentability between the first and second types of genetic engineering, or whether distinctions should be made based on the first type of engineering, in view of the nature of the intervention.@: *Pioneer Hi-Bred*, p. 1634

[77] As reasoned below, we find that there are essential technical elements of the claimed invention and this finding is sufficient for us to reach a conclusion with respect to the statutory subject matter question.

The Examiner's position

[78] In the FA and SOR, the Examiner argued that claims to methods of making and identifying *Botrytis* resistant tomatoes were outside the definition of invention, citing *Pioneer Hi-Bred* as authority. Specifically, the Examiner asserted that the cited decision provides the following guidance:

> The intervention made by Hi-Bred does not in any way appear to alter the soybean reproductive process, which occurs in accordance with the laws of nature. Earlier decisions have never allowed such a method to be the basis for a patent. The courts have regarded creations following the laws of nature as being mere discoveries the existence of which man has simply uncovered without thereby being able to claim he has invented them. [p. 1634]

[79] On this basis the Examiner concluded that the claimed methods were not patentable. The Examiner reasoned that in the case of *Pioneer Hi-Bred* the Aartificial intervention@ of hand pollination was not considered to require significant human technical intervention as it did not alter the reproductive process, which occurs in accordance with the laws of nature. Therefore, because the steps related to marker assisted selection did not alter the character or condition of the selected plants themselves, the Examiner concluded that the use of marker assisted selection did not require significant human technical intervention and as per *Pioneer Hi-Bred* the claimed methods Acontinue to obey the laws of nature.@

Further, the Examiner argued that the use of marker assisted selection does not involve significant human technical intervention, such as plant genetic transformation.

The Applicant's position

[80] In response to the SOR and in their written submissions to the Board the Applicant argued that *Pioneer Hi-Bred* cannot be relied upon to stand for the proposition that methods that include cross breeding of plants do not fall within the ambit of section 2 because the cited decision did not concern method claims and the Court took no position on the section 2 issue.

[81] In their submissions to the Board, the Applicant also emphasized that, contrary to the situation in Europe, in Canada there is no explicit statutory prohibition on the patenting of breeding methods excluding them from the definition of invention. Therefore, there is no basis for concluding that an otherwise patentable method becomes unpatentable by virtue of an additional step involving plant breeding. In particular, the Applicant took exception to the Examiner dissecting the claims into elements in order to assess the patentability of a claim. The Applicant argued that Airrespective of what additional steps may be present in the method, a method comprising at least one patentable step is necessarily directed to a statutory art or process within the definition of invention in section 2 of the *Patent Act*.@

[82] In this regard, the Applicant noted that the objection of non-patentable subject matter was not raised against claims 6 and 15 of record. Both claims 6 and 15 comprise steps relating to the identification and selection of specific progeny plants from the crossing of the donor and recipient plants that rely on marker assisted selection. If claims 6 and 15 are patentable subject matter, then claims that simply add more elements should also be held to be patentable subject matter. Further, the Applicant argued that considering the claims purposively as a whole is the analytical framework for assessing patentable subject matter as set out in *Canada (Attorney General) v Amazon.com Inc*, 2011 FCA 328.

Analysis

[83] We disagree with the Examiner's finding that the use of marker assisted selection did not require significant human technical intervention. We also do not read *Pioneer Hi-Bred* to say that the significant human technical intervention must result directly in a change to the character or condition of progeny plants. As indicated above (para. [76]), the Court specifically did not consider Awhether there is a conclusive difference as regards patentability between the first and second types of genetic engineering, or whether distinctions should be made based on the first type of engineering, in view of the nature of the intervention@: *Pioneer Hi-Bred*, p. 1634.

[84] In the present case, we find that the steps of marker assisted selection do require significant human technical intervention. The complexity of the selection procedures involves selective PCR amplification of regions of chromosome 10 followed by identification of specific markers. These techniques do not Afollow@ the laws of nature. Further, as indicated by the Applicant, method claims that rely solely on steps related to marker assisted selection were recognized as being patentable by the Examiner. If a method for marker assisted selection is considered patentable subject matter, it cannot be merely the discovery of the operation of a law of nature or the existence of a naturally occurring phenomenon. It must logically follow that a method that comprises cross breeding steps in addition to the marker assisted selection must also be considered to be patentable subject matter.

[85] Further, as indicated above (para. [76]), processes that are a result of both human ingenuity and the laws of nature are patentable; see *Harvard* and *Schmeiser*. Alf the laws of nature may be employed together with human ingenuity in developing an invention, it should not matter whether the laws of nature are employed at the beginning, during or at the end of the process@: *Harvard College v.Canada (Commissioner of Patents)*, [2000] 4 FC 528 (FCA) para. 167.

Conclusions

[86] We find that the features related to the steps of marker assisted selection require significant human technical intervention and, consistent with our purposive construction of the claims, are essential. The claimed methods do not merely follow the laws of nature, nor are they otherwise excluded from patentability. Consequently, the panel finds that independent claim 1 is compliant with section 2 of the Act and, by extension, so are its dependent claims. Similar reasoning applies in respect of independent claims 10, 27 and 31 and their dependent claims.

[87] ISSUE 4: ARE CERTAIN CLAIMS INDEFINITE FOR INCLUDING REDUNDANT TERMS AND FOR FAILING TO CLEARLY DEFINE A DIFFERENCE IN SCOPE RELATIVE TO EACH OTHER?

Legal Framework

[88] The relevant statutory provision for this defect is found in subsection 27(4) of the *Patent Act* which states:

> 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.

[89] In *Minerals Separation North American Corp. v. Noranda Mines Ltd.*, (1947) 12 CPR 99 (Ex Ct), Thorson P emphasized the obligation an applicant has to make clear in his claims the ambit of the monopoly sought and the requirement for terms used in the claims to 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. [page 146]

The Examiner's position and the panel's initial observations

[90] In the SOR, the Examiner stated that claims 1, 6, 10, 15, 20, 25 , 27, 28 and 31 were indefinite for containing redundant terms. Specifically, the terms TG148, CD38A and TG12 appear in duplicate in part ii of these claims.

[91] During our initial review the panel noted that independent claims 6, 15 and 20 appear to be all directed to methods comprising identical steps. We also noted that a similar issue appears in independent claims 10, 27 and 31.

The Applicant's position

[92] In their submissions to the Board, the Applicant agreed to remove the duplicate terms from part ii of claims 1, 6, 10, 15, 20, 25 , 27, 28 and 31.

[93] The Applicant also argued that the preambles of the method claims identified as redundant define different uses and therefore the claims are not identical.

Analysis

[94] To aid in our analysis, the preambles for claims 6, 15 and 20 are reproduced below:

6. A method of identifying a *Botrytis* resistant *Lycopersicon esculentum* tomato plant, the method comprising:

15. A method of screening tomato plants for resistance to *Botrytis* comprising:

20. A method of identifying a *Botrytis* resistant tomato plant having DNA regions introgressed from a *Botrytis* resistant *Lycopersicon hirsutum* donor plant on chromosome 10 comprising:

[95] Although the preambles of these claims are not identical, they are considered alternative characterizations of identifying the same thing, namely a *Botrytis* resistant tomato plant. Given that each of these methods comprise identical steps we see no practical distinction in their scope. By performing the identical series of steps each of these methods achieves the same result. If there is a difference in scope, based on the specification as a whole, it is not apparent. This lack of clarity in the difference in scope of the claims leads to avoidable ambiguity. A similar situation exists when considering the difference in scope of claims 10, 27 and 31.

Conclusions

[96] We find that the lack of clear differentiation between claims 6, 15 and 20 makes these claims indefinite. Similarly, the lack of clear differentiation between claims 10, 27 and 31 makes these claims indefinite. In order to be compliant with subsection 27(4) of the Act, claims 15, 20, 27 and 31 must be deleted. However, we also recognize that the series of dependent claims that depend directly or indirectly on each of these independent claims are not all identical. The scope of the distinct dependent claims can be retained by making these claims dependent on claims 6 and 10, respectively. Specifically, claim 16 can be made dependent on claim 6. Similarly, claim 30 can be made dependent on claim 10.

[97] It is also necessary to amend part ii of claims 1, 6 and 10 to remove the duplicate terms in order to be compliant with subsection 27(4) of the Act.

[98] No amendments to claims 25 and 28 are necessary as these claims must be deleted in view of our findings under anticipation.

SUMMARY OF FINDINGS

[99] Based on our findings under anticipation claims 25, 26, 28 and 29 must be deleted.

[100] Independent method claims 15, 20, 27 and 31 are avoidably ambiguous when considered in light of claims 6 and 10 and must be deleted. We also recognize that the series of dependent claims that depend directly or indirectly on each of these independent claims are not all identical. Therefore, in order to retain the scope of the distinct dependent claims, claim 16 can be made dependent on claim 6. Similarly, claim 30 can be made dependent on claim 10.

[101] Amendment of part ii of claims 1, 6 and 10 to remove the duplicate terms is also required to overcome the finding of indefiniteness.

[102] We also find that independent claims 1, 6, 10 and 37 encompass embodiments for which a lack of utility has been demonstrated.

[103] However, amendments can be made that will properly limit the scope of claims 1, 6 and 10 to what can be soundly predicted. These claims must import the limitation from corresponding claims 1, 6 and 10 of the auxiliary claim set of a *Lycopersicon hirsutum* introgressed region comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20. The claims must also be amended to specify an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from *L. esculentum* as there is no evidence that the desirable traits of the commercial variety can be retained in the absence of this region.

[104] Restricting the scope of the independent claims to what can be soundly predicted necessarily affects the scope of the corresponding dependent claims. It follows that dependent claims 3-5, 7-9, 12-14, 17-19, 22-24, 26, 29 and 33-35 must be deleted as their scope does not fall within the limits of what can be soundly predicted.

[105] Neither of the required limitations are present in claim 37 of the auxiliary claim set. It follows that claim 37 must be deleted as it encompasses the detection of inoperative embodiments and corresponding claim 37 in the auxiliary claim set does not provide any features that can be imported to satisfy the test for sound prediction.

[106] In respect of the Examiner's contention that claims 1-5, 10-14, 30 and 36 define non-statutory methods of plant breeding we find in favour of the Applicant and conclude that these claims and, by extension, their dependent claims are compliant with section 2 of the Act.

RECOMMENDATION

[107] We recommend that the Applicant be informed in accordance with paragraph 31(*c*) of the *Patent Rules*, that the following amendments, and only the following amendments, of the application are necessary for compliance with the *Patent Act* and *Patent Rules*:

1) amendment of claims 1, 6 and 10:

a) in line with corresponding claims 1, 6 and 10 of the auxiliary claim set, to specify a *Lycopersicon hirsutum* introgression region comprising an upper end comprising molecular marker TG408 and a lower end comprising molecular marker CT20,

b) in order to retain the desirable traits of the commercial variety, to specify an upper region, relative to the introgression, comprising any molecular marker between and including TG148 and CT91A from L. *esculentum*, and

c) to remove the duplicate terms TG148, CD38A and TG12;

2) amendment of claim 16 to depend on claim 6;

3) amendment of claim 30 to depend on claim 10;

4) deletion of claims 3-5, 7-9, 12-15, 17-29, 31-35 and 37; and

5) adjustment of all claim numbering and dependencies accordingly.

Christine Teixeira	Stephen MacNeil	Paul Fitzner
Member	Member	Member

DECISION OF THE COMMISSIONER

[108] I concur with the findings and recommendation of the Patent Appeal Board. Accordingly, I invite the Applicant to make the above amendments, and only the above amendments, within three months from the date of this decision, failing which I intend to refuse the application.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec,
this 15 day of August, 2013