

Commissioner's Decision #1468
Décision du Commissaire n° 1468

TOPICS: F00 Novelty; O-00 Obviousness; C00: Disclosure - Adequacy or Deficiency of Description; K10 Subject-matter of applications - Living Things (Animals, Plants, Seeds, Sperm); B00 CLAIMS - Ambiguity or Indefiniteness

SUJETS: F00 Nouveauté; O-00 Évidence; C00 Divulgation - Caractère adéquat ou inadéquat de la description; K10 Objets des demandes - Matières vivantes (animaux, plantes, graines, sperme); B00 Revendications - Caractère ambigu ou indéfini

Application No: 2,255,606

Demande n^o: 2 255 606

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,255,606, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423), has consequently been reviewed in accordance with paragraph 30(6)(c) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner are to allow the application provided certain claims are deleted.

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INTRODUCTION

- [1] This recommendation deals with a review of the rejection of patent application number 2,255,606 entitled “Aphid resistance in Composites”. The Applicant is Rijk Zwaan Zaadteelt en Zaadhandel B.V.
- [2] The application relates to lettuce plants resistant to small insect pests known as aphids. It was rejected during examination under subsection 30(3) of the *Patent Rules* for a number of reasons. A review of the rejected application has therefore been conducted by the Patent Appeal Board (“the Board”) pursuant to paragraph 30(6)(c) of the *Patent Rules*.
- [3] For the reasons that follow, we recommend that the application be allowed, provided certain claims are deleted.

PROCEDURAL HISTORY

- [4] The application was filed in Canada on June 4, 1997 and laid open for public inspection on December 11, 1997. Examination culminated with the issuance of a Final Action (“FA”) dated November 21, 2013. It outlined several reasons for rejection, including: lack of novelty, obviousness, lack of disclosure, lack of enablement, claiming too broadly, lack of support and lack of clarity. Since the Examiner was not persuaded by the Applicant’s response dated May 14, 2015 (“R-FA”) that the application was in a condition for allowance, a Summary of Reasons (“SOR”) was prepared and the application referred to the Board for review.
- [5] The Board informed the Applicant of its receipt of the file and provided the Applicant with a copy of the SOR in an acknowledgement letter dated July 15, 2016. Pursuant to paragraph 30(6)(c) of the *Patent Rules*, the present panel was then formed to conduct a review of the application on behalf of the Commissioner of Patents. In a Preliminary Review letter dated March 27, 2018 (the PR letter) we

informed the Applicant of our preliminary view that rejection of the application is not justified on the basis of the defects indicated in the FA and the SOR.

However, in accordance with subsection 30(6.1) of the *Patent Rules*, we identified two new defects in respect of two of the claims on file. The Applicant was invited to provide submissions in response to the PR letter and offered the opportunity to attend an oral hearing on the matter.

- [6] On April 11, 2018, the Applicant replied to our PR letter. No submissions were received in relation to our preliminary views on the issues identified in the FA and SOR or the two newly identified defects. The Applicant replied simply by submitting a proposed claim set in which the two claims we identified as defective were deleted, thereby rendering the application compliant with the Act and Rules. The offer to attend an oral hearing was declined.

- [7] What now follows is our final review of the application.

ISSUES

- [8] In accordance with the *Patent Rules* in force at the time the FA was written, the claims on file and now under review are those found in a new claim set submitted by the Applicant with the R-FA. The issues addressed in this recommendation are identified in the FA and SOR as relating to former claims 2-6 and have been considered to the extent that they also apply to substantially similar claims now on file:

- (1) the subject-matter of the claims was previously disclosed and is therefore anticipated, contrary to paragraph 28.2(1)(b) of the *Patent Act*;
- (2) the subject-matter of the claims would have been obvious to the person of skill in the art, contrary to section 28.3 of the *Patent Act*;
- (3) the specification does not comply with paragraph 27(3)(a) of the *Patent Act* for lack of disclosure of “descendant plants”;

- (4) the specification does not comply with paragraph 27(3)(b) of the *Patent Act* due to lack of enablement of “descendant plants”;
- (5) claim 2 on file omits an essential element and is therefore defective for lack of utility under section 2 of the *Patent Act* and overbreadth under section 84 of the *Patent Rules*;
- (6) the claims are not fully supported by the description and do not comply with section 84 of the *Patent Rules* because certain claim terminology is not found in the specification as filed; and,
- (7) the claims are unclear, contrary to subsection 27(4) of the *Patent Act*, because they do not indicate what a “descendant” plant of the claims would encompass.

[9] Also addressed, in accordance with subsection 30(6.1) of the *Patent Rules*, are the two new defects we identified in the PR letter:

- (1) the subject-matter defined by claim 1 is not within the definition of invention under section 2 of the *Patent Act*; and,
- (2) claim 3 does not comply with subsection 87(1) of the *Patent Rules*.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Claim construction

[10] In an issued patent, essential elements are identified through a purposive construction of the claims. The exercise is conducted from the standpoint of a person skilled in the art by considering the whole of the disclosure, including the specification and drawings: *Free World Trust v Électro Santé Inc*, 2000 SCC 66; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras. 49(f) and (g) and 52. Similarly, according to the *Manual of Patent Office Practice* §13.05, the first step in the construction of the claims of a patent application is to identify the person of ordinary skill in the art and their relevant common general knowledge. The next step is to identify the problem addressed by the inventors and the solution

disclosed in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution.

Anticipation

- [11] Paragraph 28.2(1)(b) of the *Patent Act* sets out the requirement that the subject-matter defined by a claim must not have been disclosed by a third party before the claim date:

The subject-matter defined by a claim in an application for a patent in Canada (the “pending application”) must not have been disclosed

...

(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.

- [12] To satisfy the two-part test for anticipation, a single prior art document must (1) provide a prior disclosure of the claimed subject-matter; and, (2) enable a person of skill in the art to practise it: *Apotex Inc v Sanofi Synthelabo Canada Inc*, 2008 SCC 61 at paras 24-29 [*Sanofi*].

Obviousness

- [13] Section 28.3 of the *Patent Act* requires that the subject-matter of a claim not have been obvious as of the relevant date:

The subject-matter defined by a claim in an application for a patent in Canada must be subject matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

(a) information disclosed 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 information became available to the public in Canada or elsewhere; and
(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[14] In *Sanofi*, the Supreme Court of Canada stated that it is useful in an obviousness inquiry to follow the following four-step approach:

- (1)(a) Identify the notional “person skilled in the art”;
 (b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Description and enablement

[15] Paragraphs 27(3)(a) and (b) of the Act require, respectively, that the specification of a patent (1) describe the invention, and (2) set out the steps for its production and use:

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;

- [16] A determination of whether the specification complies with paragraphs 27(3)(a) and 27(3)(b) of the 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? See: *Teva Canada Ltd v Novartis AG*, 2013 FC 141 citing *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 and *Consolboard v MacMillan Bloedel*, [1981] 1 SCR 504 at 526. An affirmative answer to the third question requires that the person of skill 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] FCJ. No. 1243; *Merck & Co v Apotex Inc*, [1995] 2 FC 723.
- [17] The present invention relies on two plant lines deposited as seeds in an International Deposit Authority. Under subsection 38.1(1) of the 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.
- [18] Subsection 38.1(2) of the Act clarifies that the deposit of a biological material does not create the presumption that the deposit is required for compliance.
- [19] The Commissioner's Decision in *Re Application no. 2,705,008 of Nunhems BV* (CD 1386) is particularly relevant to the present review since that case similarly addressed the question of enablement of plants, and their cells, that are descendants of deposited lines. In that case, the Board indicated at paras 60-65 that the specification enabled such cells of such plants through the description of predictable and reliable selection methods that would provide the skilled person

with an enabling disclosure of descendant plants, and by extension, their cells. In reaching that conclusion, the Board noted that the genetic basis for the trait of interest in that case was simple, being attributable to a single gene, inherited and traceable in a predictable manner.

Omission of an essential element, lack of utility and overbreadth

[20] Section 2 of the Act indicates that an invention must be “useful”: “invention means any new and *useful* art, process, machine, manufacture or composition of matter, or any new and *useful* improvement in any art, process, machine, manufacture or composition of matter”. Section 84 of the Rules states that the claims “shall be clear and concise and shall be fully supported by the description independently of any document referred to in the description”.

[21] Although section 2 of the Act and section 84 of the Rules are mentioned in the SOR as the relevant legislative provisions, the allegation in the present case is that the claims encompass subject-matter lacking utility due to the omission of an essential element, and are therefore also overly broad. This invokes the judicially created doctrine of “claiming broader than the invention described” as a relevant legal consideration. As stated by Thurlow J. (as he then was) in *Farbwerke Hoechst AG v Canada (Commissioner of Patents)*, [1966] Ex CR 91 at 106, 50 CPR 222, *aff’d*, [1966] SCR 604:

There are two fundamental limitations on the extent of the monopoly which an inventor may validly claim. One is that it must not exceed the invention which he has made, the other is that it must not exceed the invention which he has described in his specification.

[22] In *Amfac Foods Inc v Irving Pulp & Paper, Ltd* (1987), 12 CPR (3d) 193, *aff’d* 80 CPR (2d) 59, the Court of Appeal, after reviewing a line of previous decisions, similarly indicated that the claimed invention must not be broader than the one

described. The court in that case ultimately decided that the claims were broader than the invention described since they omitted an element indicated in the specification to be essential for achieving the promised result.

- [23] In this case, we consider a finding made on the question of claiming broader than the invention disclosed will therefore also be determinative of compliance with section 2 of the Act and section 84 of the Rules because an invention claimed and understood as including all elements indicated in the description to be essential would neither be too broad nor lacking utility.

Literal support

- [24] An allegation that the claims lack literal support because certain claim terminology is not found in the specification as filed relies on section 84 of the Rules as the relevant statutory provision.
- [25] There is no judicial guidance on the application of section 84 of the Rules, or any of its predecessor equivalents. However, §11.05 of the *MOPOP* (March 1998) states that “A claim is objected to for lack of support by the description if the terms used in the claim are not used in the description *and cannot be clearly inferred from the description*”.
- [26] Thus, a claim is not objectionable solely on the basis that the term is not explicitly found in the specification as filed. Considered from the perspective of the person skilled in the art, the term must also not be clearly inferable from the specification as filed.

Lack of clarity

[27] Subsection 27(4) of the Act states that “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”.

[28] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized 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

[29] The jurisprudence indicates that processes of traditional plant breeding are not within the definition of invention under section 2 of the Act: *Pioneer Hi-Bred Ltd v Commissioner of Patents* (1987), 14 CPR (3d) 491.

“Use” claims and patentable subject-matter

[30] 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 Act. In our view, it does not.

[31] 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.

[32] The Commissioner’s Decision in *Re Application no. 2,436,203 of Monsanto* (CD 1404) is particularly relevant to the present review since that case similarly involved “use” claims comprising a combination of non-statutory claim elements, including plants, seed mixes and processes involving traditional plant breeding. Notwithstanding the “use” format, the claims in that case were considered to be directed to non-statutory subject-matter. The Board stated the following at para 44:

Therefore, when viewed in isolation, none of the four claim elements are individually directed to patentable subject matter. In our view, their combination under the guise of a “use” claim does not render them patentable. The use of a non-patentable plant, in an excluded manner of traditional plant breeding, to produce a non-patentable seed mix cannot be considered on a purposive construction to be subject matter that falls within the definition of invention.

Subsection 87(1) of the *Patent Rules*

[33] Subsection 87(1) of the *Patent Rules* requires that a dependent claim state additional features:

Subject to subsection (2), any claim that includes all the features of one or more other claims (in this section referred to as a “dependent claim”) shall refer by number to the other claim or claims and shall state the additional features claimed.

ANALYSIS

Claim construction

The person skilled in the art

[34] The record does not indicate any disagreement over the person skilled in the art being defined in the FA, SOR and PR letter as “a team of a lettuce breeder and a plant molecular biologist”. We therefore proceed based on that understanding.

The common general knowledge

[35] In the PR letter, we referred to a textbook (*Agarwal*¹) to firmly establish the common general knowledge of the skilled person, as it relates to lettuce breeding. None of this was disputed by the Applicant. Although extensively detailed in the PR letter, two points are especially important to bear in mind for the purposes of our final review.

[36] Firstly, it was common general knowledge that a “dominant” and “qualitative” genetic trait is inherited in a predictable manner and can be easily identified in descendant generations. As *Agarwal* explains:

1: R.L. Agarwal, *Fundamentals of Plant Breeding and Hybrid Seed Production* (Enfield, New Hampshire, USA: Science Publishers Inc., 1998)

The inheritance of qualitative traits is relatively simple since these are governed by a few genes, and are relatively insensitive to environmental variations. In segregating generations, classification of individuals into discrete classes is also simple and easily done. [page 87]

- [37] Secondly, the common general knowledge also admits that genes residing in close proximity to one another on the same chromosome may be co-inherited in descendant generations by virtue of “linkage” between the two. Linkage can, however, be broken. If linkage is broken, the subsequent transfer of an unlinked dominant gene to other plant lines can apparently be easily done:

No difficulty is experienced in identifying plants carrying the desired trait, when it is governed by a dominant gene . . . Linkages, if any, between the desired gene(s) and an undesirable gene or block of genes would need to be broken. [Agarwal, pages 133-134]

- [38] In the PR letter we also fully assessed the common general knowledge of the person skilled in the art, as it relates to plant molecular biology. To do so we relied on two articles discussed in the specification². Of particular importance for the purposes of our final review is the common general knowledge that the molecular fingerprinting technique used by the inventor in this case does not rely on the structural characterization of the randomly generated DNA markers used in the technique.

The problem addressed by the application

- [39] In the PR letter, we explained that the application generally addresses the need for new agronomically valuable lettuce plants (*Lactuca sativa*) that are resistant to aphid pests.

2: P. Vos *et al.*, *AFLP: a new technique for DNA fingerprinting*, Nucleic Acids Res., vol. 23, no. 21, pp. 4407-4414, 1995 (Vos); and, V. Lefebvre & A. Chèvre, *Tools for marking plant disease and pest resistance genes: a review*, Agronomie, vol. 15, no. 1, pp. 3-19, 1995 (Lefebvre & Chèvre).

- [40] Aphids are tiny insects that feed on lettuce plants, causing reduced or abnormal growth and the spread of viral diseases. The application deals exclusively with one species of aphids: *Nasonovia ribisnigri*. Although aphid infestations can be treated with pesticides, it is an inconvenient and environmentally undesirable method. The preferred approach is to develop lettuce plants that carry a gene(s) conferring resistance to the pests.
- [41] In the PR letter, we noted that the specification indicates that by 1981 a breeding program had generated aphid resistant lettuce plants by transferring a resistance gene from a wild species of lettuce (*Lactuca virosa*) to a domesticated variety. Importantly, the specification identifies the resistance characteristic that was transferred as qualitative in nature, being determined by a single dominant gene called the “*Nr*” gene (as opposed to being quantitative in nature and determined by multiple genes).
- [42] Despite this notable advancement, the aphid resistant lettuce plants initially developed in 1981 were considered agronomically useless due to the coincident introduction of undesirable characteristics, i.e., these abnormal plants “were of an undesirable type in respect of phenotype and agronomic traits (non-heading, poor cultivation characteristics)” (page 2, lines 17-19 of the specification). The agronomically undesirable characteristics are described as the “CRA” phenotype, short for “Compact growth and Rapid Ageing”.
- [43] The undesirable CRA characteristics of the aphid resistant plants released in 1981 also seem to have persisted in descendant plants beyond the expected three to five years typically thought sufficient to remove them through standard breeding methods:

[a]lthough plants having the *Nr* gene were already released in 1981 to seed companies, the successful transfer of the *Nr* gene to agronomically acceptable lettuce plants has so far not yet been reported. [page 2, line 36 to page 3, line 2 of the specification]

[44] We therefore determined that the problem the inventor faced was, as the specification states, the need to “provide plants of the family *Compositae*, and in particular new lettuce plants, which combine resistance to aphids of the species *Nasonovia ribisnigri* with agronomically good traits” (page 3, lines 4-7 of the specification). Considered in context, a positive indication that the lettuce plants would have “agronomically good traits” means to the skilled person that they would lack bad ones, i.e., that they would never be able to display the undesirable CRA phenotype.

The proposed solution

[45] We indicated in the PR letter that the proposed solution involves the development of two particular lines of aphid resistant lettuce plants derived from those first developed in 1981. Unlike the earlier developed plants, the inventor’s plants are of considerable agronomic value since they are incapable of displaying the undesirable CRA phenotype due to the absence of the gene(s) responsible for it. Seed of each plant line has been placed in an International Deposit Authority for biological materials. The deposits are termed “NCIMB 40803” and “NCIMB 40804”.

[46] We noted that the specification reveals two important insights gained by the inventor in relation to the lettuce plants first developed in 1981 that apparently allowed for the development of the NCIMB 40803 and NCIMB 40804 lines.

[47] Firstly, the inventor discovered that there is genetic linkage between the desirable *Nr* gene and the undesirable gene(s) responsible for the CRA phenotype in the aphid resistant plants first developed in 1981. With the benefit of hindsight, this means that the existence of linkage appears to have confounded lettuce breeders’ early efforts to rid the plants released in 1981 of the CRA phenotype and thereby arrive at agronomically valuable aphid resistant lettuce plants.

[48] Secondly, the inventor discovered that the “CRA phenotype is a recessive trait which is only expressed in homozygously resistant plants” (page 4, lines 14-16 of the specification). In accordance with classical Mendelian genetics, this means that the lettuce plants first released in 1981, as well as their descendants, could never be considered agronomically valuable because the undesirable CRA phenotype would be forever capable of manifesting itself, i.e. when inadvertently released from dominant control in the usual course of plant breeding.

[49] The specification explains the essence of the proposed solution: “by breaking this link it is possible to grow resistant, agronomically acceptable plants”. The inventor therefore undertook to break the genetic linkage and was successful in doing so, as evidenced through the eventual development of the NCIMB 40803 and 40804 lines, neither of which carry the gene(s) responsible for the CRA phenotype.

[50] The inventor’s characterization of the deposited plant lines as homozygous for the dominant *Nr* gene is an important consideration to bear in mind.

The claims

[51] Two independent claims are representative of the claimed invention. Independent claim 1 concerns the use of deposited lettuce seeds for transferring aphid resistance to another lettuce plant:

Use of seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804 for transferring *Nasonovia ribisnigri* resistance into another agronomically valuable lettuce plant of the species *Lactuca sativa*.

[52] Independent 2 and the remaining claims concern the use of plants descendent from lettuce plants grown from deposited seeds for different commercial

purposes, including for use as a crop, as a source of seed, as a source of propagating material and for consumption. Claim 2 reads:

Use of a descendant plant of a cross between a lettuce plant grown from seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804 and another agronomically valuable lettuce plant of the species *Lactuca sativa*, wherein the descendant plant has *Nasonovia ribisnigri* resistance, as a crop.

[53] Claim 3 is mentioned in the SOR and also warrants analysis since it indicates that the descendant plants of claim 2 lack the undesirable CRA phenotype:

Use as claimed in claim 2, wherein the Nr resistant *Lactuca sativa* descendant plant is characterized by the absence of a CRA phenotype.

Claim terminology

[54] In the PR letter, we clarified the meaning of four terms found in the claims since a proper understanding of their meaning impacted our analyses. The terms are “agronomically valuable lettuce plant”, “crop”, “descendant plant”, and “for transferring *Nasonovia ribisnigri* resistance into another ... species of *Lactuca sativa*”.

[55] In brief, we explained that the term “agronomically valuable lettuce plant” embraces only things such as high-quality commercially cultivated lettuce plants. Lettuce plants that are genetically inferior and/or are not suitable for commercial cultivation would fall outside the meaning of the term.

[56] We said the same would be true for the term “crop”, bearing in mind that Merriam-Webster’s online dictionary defines the term as “a plant or animal or plant or animal product that can be grown and harvested extensively for *profit or subsistence*”.

[57] This led us to conclude that the lettuce plant line first released in 1981, although resistant to aphids, would not be viewed by the skilled person as “agronomically valuable lettuce plants” because they were not cultivated commercially and were considered agronomically useless due to the presence of the CRA phenotype. We commented that this understanding gives purpose to the claims since, to suggest otherwise, would be to say that there was never any need to separate the desirable *Nr* gene from the undesirable CRA gene(s) in the plants first released in 1981.

[58] In the PR letter, we expressed the view that the person skilled in the art would have no difficulty in understanding that the term “descendant plant” relates to “progeny” which, according to Merriam-Webster’s online dictionary, means “a : descendants, children; b : offspring of animals or plants”. Although the term “descendant” carries a somewhat broader meaning of “proceeding from an ancestor or source” and is not explicitly used in the specification, we noted that the term “progeny” is used throughout the specification.

[59] Based on the teachings of the specification, we interpreted the term “for transferring *Nasonovia ribisnigri* resistance into another ... species of *Lactuca sativa*” to effectively mean that the deposited NCIMB 40803 and 40804 seeds mentioned in claim 1 are implicitly “used” in a plant breeding process to transfer the aphid resistance trait into other lettuce varieties.

The essential elements of the claims

[60] Claim 1 was indicated in the SOR to be in allowable form. No construction of the claim was undertaken and its essential elements were not identified. In the PR letter, in line with the analysis outlined above, its essential elements were identified as follows:

- “use of”;

- “seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804”;
- “for transferring *Nasonovia ribisnigri* resistance”; and,
- “into another agronomically valuable lettuce plant of the species *Lactuca sativa*”.

[61] As for claim 2, the SOR indicates that the essential elements are the following:

- “The biological deposit of seed having accession number NCIMB 40803 or NCIMB 40804”;
- “Crossing a plant grown from said deposited seed with an agronomically valuable *L. sativa* plant to produce a descendant which has *N. ribisnigri* resistance”; and,
- “Using the resultant descendant plant as a crop”.

[62] Claim 3 depends from claim 2 and states that the descendant plant of claim 2 “is characterized by the absence of a CRA phenotype”.

[63] It is important to appreciate for the analyses that follow that all claims include the two deposited seed lines, termed NCIMB 40803 and 40804, as essential elements. Each line carries the desirable *Nr* gene in a homozygous dominant state, unlinked to the undesirable CRA gene(s). Plants grown from such seeds are necessarily resistant to aphids by virtue of the presence of the dominant *Nr* gene. These plants also “lack the genetic information which causes the CRA phenotype” (page 9, line 33 of the specification) and would therefore be incapable of passing on this characteristic to descendants.

Anticipation

[64] Claims 2-6 were rejected in the FA on the basis of anticipation in view of an earlier published scientific article. However, as was explained in detail in the PR

letter, it is apparent that the article is deficient in several respects and does not disclose all of the essential elements of claimed invention; in particular, the deposited seed lines termed NCIMB 40803 and 40804 which lack the genetic information that causes the problematic CRA phenotype. We therefore found that claims 2-6 were not anticipated.

[65] The scientific article (the “*Eenink*” article³) that was said to anticipate claims 2-6 was published about fifteen years before the present patent application was filed. The work done by the authors of the article is acknowledged and discussed in the background portion of the specification. In our view, the skilled person would see the article as merely representing the inventor’s starting point since it discusses the lettuce plants first released in 1981 which, although resistant to aphids, were not considered agronomically valuable due to the apparent presence of the CRA phenotype.

[66] According to the FA and SOR, the *Eeink* article is an anticipatory reference for a number of reasons:

- the aphid resistant plants of *Eeink* “do not express the CRA phenotype”;
- “... it is possible that the genetic basis of the *N. ribisnigri* resistance is the same in both the instant application and the disclosure by Eenink et al.”;
- “Eenink et al. disclose the use of *L. sativa* which is resistant to *N. ribisnigri* to produce descendants which are resistant to *N. ribisnigri*, and to produce a crop”; and,
- “a descendant plant which is a cross between the *L. sativa* grown from seed deposited under NCIMB 40803 or NCIMB 40804 and the *L. sativa* disclosed by Eenink et al. would include plants which do not have the alleged inventive features of the deposited lines, such as plants which have

3: Eenink A.H. et al., *Resistance of lettuce (Lactuca) to the leaf aphid Nasonovia ribis nigri*. 1. *Transfer of resistance from L. virosa to L. sativa by interspecific crosses and selection of resistant breeding lines*, Euphytica, vol. 31, pp. 291-300, 1982 [Eenink].

resistance to *N. ribisnigri* inherited only from the lines disclosed by Eenink et al.”

- [67] We addressed each of these reasons in the PR letter and did not agree that any could lead to a finding of anticipation.
- [68] We were unable to discern any basis for asserting that the plants disclosed by *Eenink* do not display the CRA phenotype. We noted that there is no clear discussion in the article of the lettuce plants as lacking the CRA phenotype. The authors’ observation that their plants “have a plant habit like that of *L. sativa*” (page 297, last sentence) would not, in our view, be taken by the skilled person as an indication that they do not display the CRA phenotype, or are incapable of displaying the phenotype because they lack the gene(s) that causes it. We also noted that such an assertion would appear to be at odds with the inventor’s characterization of what appear to be the same plants as being “of an undesirable type in respect of phenotype and agronomic traits (non-heading, poor cultivation characteristics)”.
- [69] We agreed that the skilled person would understand that the genetic basis of aphid resistance, the dominant *Nr* gene, appears to be the same in both the present application and in *Eenink*. We did not agree, however, that there is genetic equivalency in terms of the other key element of the inventor’s NCIMB 40803 and 40804 deposited plant lines: the absence of the gene(s) responsible for the CRA phenotype. Nowhere does *Eenink* disclose the breakage of linkage between the *Nr* gene and the gene(s) responsible for the CRA phenotype. In stark contrast, the inventor explicitly discloses that his deposited plant lines “lack the genetic information which causes the CRA phenotype”.
- [70] Regarding the third assertion, we agreed that the plants disclosed by *Eenink* could be used, as the Examiner suggests, indirectly “to produce a crop”. However, we did not agree that this indicates such plants could immediately and directly be

used “as a crop”, as claim 2 explicitly requires. At best, *Eenink* indicates that the plants could *indirectly* be used in the *future* “to produce a crop”, i.e., as part of a breeding program: the plants “will be used for introgression of resistance genes into outdoor lettuce cultivars” (page 298, second last paragraph).

[71] Lastly, we noted that the FA and SOR suggest a claim interpretation that finds a descendant plant of the claims to be one that could result from a cross between the plants grown from seed of the inventor’s deposited plant lines and those disclosed by *Eenink*. We explained that such an interpretation is not supported because the plants disclosed by *Eenink* are not “agronomically valuable” as the claims explicitly require and therefore do not fall within their scope. We also pointed out that such an interpretation would result in the skilled person reintroducing the gene(s) responsible for the CRA phenotype back into agronomically valuable lettuce lines—some thing completely at odds with what the inventor set out to achieve in the first place.

[72] Importantly, we noted that the SOR does not assert that *Eenink* discloses the inventor’s two particular deposited seed lines termed NCIMB 40803 and NCIMB 40804. These lines are featured in all the claims and, as discussed above, are essential claim elements because each solves the CRA phenotype problem evident in the plants first released in 1981. The seed of these lines inherently carry the desirable *Nr* gene in homozygous state and, unlike the plants of *Eenink*, inherently lack the gene(s) responsible for the undesirable CRA phenotype.

[73] Therefore, we are of the view that the claims are not anticipated by *Eenink* and comply with paragraph 28.2(1)(b) of the Act.

Obviousness

[74] In the PR letter, we explained that claims 2-6 would not have been obvious to the person of skill in the art, contrary to the assertions made during prosecution. The claims are therefore compliant with section 28.3 of the Act.

Identify the notional person skilled in the art and the relevant common general knowledge of that person

[75] These aspects of the analysis have been defined above as a matter of claim construction (see paras [34] and [35] to [38]).

Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

[76] In the PR letter, we stated the inventive concept as follows:

Use of a descendant plant of a cross between a lettuce plant grown from seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804 [which plants carry the *Nr* aphid resistance gene in a homozygous dominant state and lack the genetic information that causes the CRA phenotype] and another agronomically valuable lettuce plant of the species *L. sativa*, wherein the descendant plant has *N. ribisnigri* resistance [and does not display the CRA phenotype], as a crop, for consumption, as a source of seed or propagating material, or for transferring resistance to *N. ribisnigri* to another *L. sativa* plant.

[77] The inventive concept stated in these terms takes into account genotypic and phenotypic features, indicated in parentheses, inherent in the inventor's deposited plant lines. These genetic features must be considered in the obviousness analysis since the deposited lines termed NCIMB 40803 and 40804 are essential elements of the claims and each line inherently carries the desirable *Nr* gene in a homozygous dominant state. These lines also inherently lack the gene(s) that causes the CRA phenotype. As such, they qualify as agronomically valuable.

Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed

[78] Taking into account the nature of the invention, the analysis provided in the FA and SOR, and the Applicant’s submissions, we determined in the PR letter that there are five differences between the inventive concept, as stated above, and the state of the art:

- (1) the inventive concept includes particular deposited plant lines (NCIMB 40803 and 40804), whereas *Eenink* does not disclose either of these lines;
- (2) the deposited plant lines do not carry the genetic material responsible for the CRA phenotype, whereas the plants of *Eenink* apparently do;
- (3) the deposited plant lines are agronomically valuable since they cannot and do not display the CRA phenotype, whereas those of *Eenink* do not appear to be agronomically valuable since they carry the genetic material responsible for the CRA phenotype and/or display the phenotype;
- (4) the aphid resistant descendant plants of the inventive concept are agronomically valuable since they result from a cross between two parental lines that are individually considered to be agronomically valuable, whereas *Eenink* does not disclose agronomically valuable descendant plants and instead propose that they can be developed in the future; and,
- (5) the aphid resistant descendant plants of the inventive concept are also agronomically valuable since they lack the genetic information responsible for the CRA phenotype and consequently can never display the phenotype, whereas *Eenink* does not disclose agronomically valuable descendants and instead propose that they can be developed in the future.

[79] At the same time, we found it helpful to appreciate that there are similarities between the inventive concept and the state of the art:

- (1) the inventive concept and *Eenink* both feature *L. sativa* lettuce plants; and,
- (2) by virtue of common ancestral lineage and inheritance patterns, the *Nr* aphid resistance gene found in the deposited plants lines would be understood by the skilled person to be the same one found in the plants disclosed by *Eenink*.

Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[80] In the PR letter, we indicated that the five differences noted above appeared to constitute steps that would have required a degree of invention on the part of the skilled person.

[81] We expressed the view that *Eenink* merely proposed that the plants disclosed in the article could be used in the future “for the introgression of resistance genes into outdoor lettuce cultivars”. Given this suggestion, the question was then whether the skilled person, starting with the flawed plants released by *Eenink*, would have been able to routinely use them to produce agronomically valuable lettuce varieties that carry the *Nr* aphid resistance gene. A telling passage in the background portion of the specification indicated that experienced plant breeders were unsuccessful in developing such plants even long after the expected development time of three to five years:

The [plants released by *Eenink*] were of an undesirable type in respect of phenotype and agronomic traits (non-heading, poor cultivation characteristics). Because of the undesirable agronomic traits these plants were used by breeding companies as hybridization parent for the

purpose of obtaining plants by genetic recombination and selection, which combine resistance to *N. ribisnigri* with good agronomic traits.

L. sativa is an annual species but, when it is cultivated under artificial light at an increased temperature, 2-5 successive generations can be produced within a year. Backcrossing procedures are a generally known and suitable method for crossing genes from a “donor parent” into a genetic background with a high agronomic value. In general the introgression of a dominant gene into an agronomically acceptable phenotype can be achieved by 3-5 backcrosses, followed by 2-3 self-pollinations. 5-8 generations in 3-5 years are therefore required to obtain agronomically acceptable plants having the desired gene in their genome.

However, although plants having the *Nr* gene were already released in 1981 to seed companies, the successful transfer of the *Nr* gene to agronomically acceptable lettuce plants has so far not yet been reported.
[emphasis added]

[82] By comparison, the inventor actually solved the problem apparent in the prior art plants. The inventor realized that the *Nr* gene and those responsible for the undesirable CRA phenotype were genetically linked, making it difficult to separate them so as to produce agronomically valuable plants. The inventor also discovered that the CRA phenotype is inherited recessively. Through diligent plant breeding work, complemented with molecular DNA fingerprinting techniques, the inventor was successful in producing the two agronomically valuable plant lines in which the gene(s) responsible for the CRA phenotype is no longer linked to the *Nr* gene and, in fact, has effectively been deleted.

[83] It was our view that the inventor’s insights and the fifteen years that spanned the development of the plant lines of the invention did not suggest that the skilled person could have routinely developed them. On the contrary, they indicated to us that the development of plant lines possessing the properties of the ones

mentioned in the claims would not have been obvious. By extension, the descendant plants and uses of the claims would also not have been obvious.

[84] In the PR letter, we noted that neither the FA nor the SOR explained how the skilled person would have routinely gone from the flawed plants of *Eenink* to those of the claims. Instead, the FA suggests that an important consideration in the obviousness analysis is whether the inventor has characterized the *Nr* gene and the gene(s) that causes the CRA phenotype at the molecular and cellular levels. On that basis, the FA suggests that the skilled person would not be able to determine whether any differences exist between the plants of the inventive concept and those of *Eenink*.

[85] We explained that this reasoning seems to take for granted that the plants of *Eenink* are agronomically valuable and lack the gene(s) that causes the CRA phenotype. However, that is not the case. As indicated above at Step (3) of the *Sanofi* analysis, neither of these aspects are disclosed in the prior art and the analyses in the FA and SOR do not account for them. Notwithstanding a lack of characterization at the molecular level, the plants of the claims would, in our view, be readily distinguishable from any disclosed in the prior art on these bases.

[86] The claimed invention is not directed to a gene per se. Nor do any of its essential elements include a DNA sequence for either the *Nr* gene or the gene(s) that causes the CRA phenotype. Likewise, the inventive concept does not rely on a structural characterization of these elements. Rather, the invention is premised on the combination of two genetic features, neither of which necessarily require molecular or cellular analysis to assess: (1) the presence of the dominant *Nr* gene which singularly determines the qualitative trait of aphid resistance; and, (2) the absence of the gene(s) responsible for the CRA phenotype.

[87] We therefore consider claims 2-6 to be compliant with section 28.3 of the Act since they define subject-matter that would not have been obvious to the person of skill in the art in view of the cited prior art document.

Description of “descendant plants”

[88] According to the SOR, the descendant plants mentioned in the claims that result from a cross between plants grown from seed of the deposited lines and another agronomically valuable lettuce plant are “not clearly, fully and sufficiently disclosed”. The SOR explains:

The plant defined by the biological deposit is an essential feature. The descendant plant is not equivalent to the biological deposit, as the deposit is crossed with another uncharacterized *L. sativa* plant which would necessarily result in a descendant plant which is genotypically and phenotypically different from the deposited parent. In effect, the descendant is a new plant which is only characterized as having the desired phenotypic trait, *N. ribisnigri* resistance. While the method to produce such a descendant may be enabled, although it is clear from the description the inheritance pattern is complex, the descendant itself is not fully and sufficiently disclosed. A claim to a descendant plant *per se* would be defective for a lack of adequate disclosure under paragraph 27(3) of the *Patent Act*, thus, the claim to the use of the inadequately disclosed plant is, in effect, a reach through claim. Furthermore, the desired trait in the descendant may not have resulted from the deposited parent, as the applicant has not genetically characterized the basis for the *N. ribisnigri* resistance phenotype in the deposit. Thus, there is no way to verify the source of this phenotype in the descendant, and said resistance may have been inherited from the uncharacterized second parent, for example from a plant such as that disclosed by Eenink et al., or have been a spontaneous mutation.

- [89] In the PR letter, we expressed agreement with certain aspects of this analysis, but found that, overall, the record does not support a conclusion that the descendant plants have not been properly described.
- [90] As reflected in the claim construction, above, we agreed that the plant lines defined in the claims by biological deposit (NCIMB 40803 and 40804) are essential claim elements. In accordance with section 38.1 of the Act, these specific and unique biological deposits can be taken into consideration for compliance with subsection 27(3) of the Act. As such, the skilled person would therefore regard these parental lines as being properly described.
- [91] We also agreed that a plant descendent from either of these lines that results from a cross with another lettuce plant would not be entirely equivalent to its parents. Although not entirely equivalent to its parents, we were of the view that the skilled person would nonetheless understand that a descendant plant of the claims carries the same essential characteristics as the deposited lines: aphid resistance determined by the *Nr* gene and the lack of the gene(s) that causes the CRA phenotype.
- [92] The descendant plants of the claims have aphid resistance because the gene that causes it, the *Nr* gene, is described in the specification as existing in the homozygous dominant state in the deposited lines. As such, the resistance phenotype would be passed on to descendant plants. In that respect, we therefore disagreed with the assertion that “the applicant has not genetically characterized the basis for the *N. ribisnigri* resistance phenotype in the deposit” because the inventor has, in fact, provided a meaningful characterization of its genetic basis, albeit not at the molecular level.
- [93] By virtue of its inherent absence in both parents, a descendant plant also lacks the gene(s) that causes the CRA phenotype.

[94] We therefore concluded that the skilled person would regard the descendant plants of the claims as being sufficiently described in terms of the same essential elements as the deposited lines.

[95] As for the analysis set out in the SOR, we did not agree that the source of the aphid resistance trait may be a plant as disclosed by *Eenink*. To be within the scope of the claims, both parents must be agronomically valuable. This limitation excludes the plants disclosed by *Eenink*. Nor did we agree that the source of the aphid resistance trait in the descendant plants is unverifiable and can be a plant other than one of the deposited lines. In our view, the skilled person would expect the deposited parent lines to be the only source of the aphid resistance phenotype because there is nothing on record to indicate otherwise. The aphid resistance phenotype would therefore necessarily be passed on from one of the deposited lines to descendants because the *Nr* gene is a dominant qualitative characteristic for which a biological assay can be used to verify its existence in descendants. We regarded the suggestion that the aphid resistance phenotype could result in descendant plants through spontaneous mutation as unreasonable, bearing in mind the highly improbable likelihood of such an event.

[96] Therefore, it is our view that the specification complies with paragraph 27(3)(a) of the Act.

Enablement of “descendant plants”

[97] In the PR letter, we noted the suggestion in the SOR that the claims encompass descendant plants that are not enabled by the specification. More particularly, the SOR alleges that the skilled person would face an undue burden when trying to obtain descendant plants that are both aphid resistant and which lack the CRA phenotype, and which result from a cross between the deposited plants lines NCIMB 40803 and 40804 and another agronomically valuable lettuce plant:

However as noted above, the inheritance pattern of both *N. ribisnigri* resistance and the absence of a CRA phenotype is complex and as such, claim 3 is not considered to be enabled. Examples of the difficulty in transferring the phenotype are described on page 6, challenges of the methods are described on page 10 and the various possible outcomes are described on pages 13 and 14, and page 18 lines 5 to 14. As well, reference is made to the use of markers to make the selection process easier. However, it would be necessary to identify these markers with each breeding process, and no particular markers were disclosed for the provided examples. Thus, in addition to the defects identified above, it would be an undue burden to produce a descendant for use as claimed in claim 3 having both the desired *N. ribisnigri* resistance and the absence of the CRA phenotype. Therefore claim 3 is not enabled and does not comply with paragraph 27(3) of the *Patent Act*. [emphasis added]

[98] Although the discussion in the SOR focuses on claim 3, the reasoning appears to be applicable to claim 2 and 4-6 as well.

[99] As emphasized in the passage cited from the SOR, the descendant plants of the claims are not considered enabled primarily for three reasons:

- (1) the inheritance pattern of both *N. ribisnigri* resistance and the absence of a CRA phenotype is complex;
- (2) the specification indicates that the skilled person would encounter difficulties when trying to transfer the aphid resistance phenotype to descendant generations; and,
- (3) it would be necessary to identify the DNA fingerprint markers the inventor used in his breeding process, yet no particular markers are disclosed in the specification.

[100] In the PR letter, we expressed disagreement on all counts. In our view, the skilled person would not face an undue burden in obtaining the descendant plants of the claims.

[101] Contrary to the assertions made in the SOR, the inheritance pattern of the aphid resistance trait would not be regarded by the skilled person as complex. The aphid resistance trait is not a complex quantitative trait determined by multiple genes. Rather, it is qualitative in nature and is determined by a single *Nr* gene found in a homozygous dominant state in the deposited plant lines. According to the common general knowledge reviewed above, the inheritance pattern of such traits is simple:

The inheritance of qualitative traits is relatively simple since these are governed by a few genes, and are relatively insensitive to environmental variations. In segregating generations, classification of individuals into discrete classes is also simple and easily done. [*Agrawal*, page 87]

[102] In that respect, the present case is thus similar to the situation in CD 1386 (discussed above at para [19]), in which the Board likewise concluded that descendant plants and their cells were enabled.

[103] Further, the specification teaches that aphid resistance can be transferred to descendants through the commonly known backcrossing technique (i.e., akin to crossing the deposited plant lines with other agronomically valuable lettuce plants):

Plants according to the invention, which are characterized by the absence of a CRA phenotype in the presence of the *Nr* gene in homozygous condition, can be used to transfer *N. ribisnigri* resistance into other agronomically valuable lettuce types. This takes place for instance by means of standard backcrossing procedures for a dominant gene [citation omitted], followed by self-pollination of the plants for at

least two generations and the selection of lines which are homozygous for the resistance gene.

[104] Consistent with the teachings of the specification, the common general knowledge admits that, once linkages with undesirable genes have been broken (as is the case here), the transfer of a qualitative trait determined by a single dominant gene is not difficult:

Recovery of character under transfer: No difficulty is experienced in identifying plants carrying the desired trait, when it is governed by a dominant gene . . . Linkages, if any, between the desired gene(s) and an undesirable gene or block of genes would need to be broken. [Agrawal, pp. 133-134]

[105] Although the SOR refers to certain passages in the description in support of the notion that the skilled person would encounter difficulty in transferring the aphid resistance phenotype to descendant generations, a review of the cited passages (in particular, those on page 6, lines 2-25) indicated to us that they speak to the problems the inventor encountered in developing the plants lines of the invention and the success he enjoyed in realizing their development, not to problems the skilled person would encounter when using those plants to produce descendants.

[106] In our view, the “AFLP” molecular fingerprinting technique discussed in the specification was used by the inventor as an aid in developing the deposited plant lines of the claims. As such, we did not read the specification to say that the AFLP fingerprinting technique, or molecular DNA markers of any sort, *must also* be used to produce plants that are *descendants* of the deposited lines. Given the deposited plant lines of the invention, it is not necessary for the skilled person to undertake to break the linkage between the *Nr* gene and the gene(s) responsible for the CRA phenotype. Consequently, it seems unnecessary for the skilled person to continue to employ DNA fingerprinting techniques to detect uncoupling of the *Nr* gene and the gene(s) responsible for the CRA phenotype in descendant plants.

The biological assay for aphid resistance disclosed in the specification would seem sufficient to enable the skilled person to screen for the phenotype in descendant plants.

[107] We added, however, that even if there the AFLP fingerprinting technique were to be used as an aid in tracking the *Nr* aphid resistance gene through descendant generations, it seems from the common general knowledge that precise structural characterization of DNA markers at the nucleotide sequence level is not required. Contrary to assertion in the SOR, the specification teaches in a manner consistent with the common general knowledge that the precise identity of DNA markers is not critical, as many different types may be randomly generated. Instead, it is their association with a gene of interest, relative numbers and distribution that are important:

It will be apparent to the average skilled person that by choosing restriction enzymes and primers many different AFLP markers can be generated which are linked to a certain gene, and that in order to generate a set of closely linked markers with the object of detecting meiotic recombination in the vicinity of a locus, it is not of essential importance which closely linked markers are used for that purpose. Decisive are only the number of markers used plus the distribution over the chromosome fragment in which it is wished to detect recombination. [specification, page 15, line 36 to page 16, line 8]

[108] Thus, so far as the use of molecular markers in the production of descendant plants is concerned, we noted that the present case again aligns with the situation in CD 1386, wherein that consideration also supported the conclusion that such plants, and their cells, were enabled.

[109] Therefore, considering the common general knowledge and the teachings of the description, we agreed with the Applicant's submission that the "skilled person would be able to breed NCIMB 40803 or NCIMB 40804 with other *Lactuca*

sativa plants and determine whether the descendant plant has *Nasonovia ribisnigri* resistance and the absence of the CRA phenotype”. Consequently, we consider the specification to be compliant with paragraph 27(3)(b) of the Act.

Omission of an essential element, lack of utility and overbreadth

[110] In the PR letter, we noted that the SOR indicates that claim 2 omits an essential element and is therefore defective for lack of utility under section 2 of the *Patent Act* and overbreadth under section 84 of the *Patent Rules*. As discussed above as a matter of legal principle, the allegations set out in the SOR invokes the judicially created doctrine of “claiming broader than the invention described” as the relevant legal consideration. In this case, our analysis set out in the PR letter therefore proceeded on that basis.

[111] The SOR states that claim 2 is too broad because it does not indicate that the descendant plants of the claim lack the CRA phenotype. In support of this position, the SOR notes that the feature is only explicitly mentioned in dependent claim 3, the inference being the feature need not be present in parent claim 2:

Furthermore, for either analysis above, it is noted that claim 2 makes no reference to the descendant lacking a CRA phenotype even though it is clearly the disclosed intent to produce new lettuce plants both having *N. ribisnigri* resistance and lacking a CRA phenotype (for example see page 3, lines 3-34). Indeed applicant indicated this in their reply (see page 2 beginning at 'As explained...'). This desired feature is not introduced until dependent claim 3. The absence of a CRA phenotype is considered to be an essential feature which is lacking in the descendant of claim 2 (Rule 84).

...

It follows that proposed claim 2 lacks utility and does not comply with section 2 of the *Patent Act*. Claim 2 encompasses descendant plants having *N. ribisnigri* resistance with a Compact growth and Rapid Ageing (CRA) phenotype, i.e. an agronomically undesired trait.

[112] As explained in the PR letter, the analysis presented in the SOR overlooks the fact that the agronomically valuable deposited plant lines of claim 2, termed NCIMB 40803 and 40804, both inherently lack the gene(s) responsible for the CRA phenotype, as does the other parent plant of the claim (since it too must be agronomically valuable). By virtue of its inherent absence in both parents, the skilled person would understand that a descendant plant also necessarily lacks the gene(s) that causes the CRA phenotype and therefore can never display it.

[113] Claim 2 does not, therefore, run afoul with the principle of claiming broader than the invention described because the deposited plant lines and other parent are described in a manner consistent with the skilled person's understanding of claim 2, i.e., the parent plants of claim 2 "lack the genetic information which causes the CRA phenotype" (see for example page 9, line 33 of the description) and, by extension, so do their descendants.

[114] The feature in dependent claim 3 that the descendant plants of parent claim 2 are "characterized by the absence of a CRA phenotype" would, in our view, be taken by the skilled person as merely stating something already understood and implicit in the parent claim. Claim 3 would not be read as meaning the descendant plants of claim 2 may actually possess the CRA phenotype since that would be at odds with the wording of claim 2 and the inherent nature of the invention, as it has been described and how it would be understood by the skilled person.

Non-compliance of claim 3 with subsection 87(1) of the *Patent Rules*

[115] As discussed immediately above, the skilled person's understanding that parent claim 2 necessarily and implicitly includes the feature mentioned in dependent claim 3 indicates that the latter claim is defective because it does not state an additional feature.

[116] As such, our preliminary opinion expressed in the PR letter was that claim 3 is non-compliant with subsection 87(1) of the *Patent Rules*. The Applicant did not express disagreement with this opinion in its response to the PR letter. We therefore conclude that the claim is non-compliant.

Literal support

[117] According to the SOR, the appearance of the term “descendant” in the claims is problematic because, contrary to section 84 of the Rules, it is not found in the specification as filed:

Claims 2 to 6 are not fully supported by the description and do not comply with section 84 of the *Patent Rules*. The claimed features, “a descendant plant” or “a *Lactuca sativa* descendant plant”, lack literal support in the description. The term “descendant” is not found in the specification as filed.

[118] We expressed disagreement with this reasoning in the PR letter.

[119] Although it is true that the term “descendant” is not found in the specification as filed, the test for compliance with section 84 of the Rules does not rest solely on that consideration. A claim is objectionable for lack of support if the terms used in the claim are not used in the description *and cannot be clearly inferred from the description*.

[120] In our view, the term “descendant” as used in the claims is acceptable since the skilled person would infer support for the term because the term “progeny” has been used throughout the specification as filed. As discussed above as a matter of claim construction, the person skilled in the art would, in our view, have no difficulty in understanding that the meaning of “descendant” relates to the term “progeny” which itself means “a : descendants, children; b : offspring of animals

or plants”. On that basis, we consider the use of the term “descendant” in the claims to be inferable by the skilled person and therefore acceptable.

Lack of clarity

[121] According to the SOR, the use of the term “descendants” in the claims is problematic since the term would not be sufficient to differentiate the descendants of the claims from the plants previously disclosed in *Eenink*, the genetic basis of the descendant plants allegedly not being defined:

Amended claims 2 to 6 additionally have a defect under Subsection 27(4) of the *Patent Act*. The phrase “a descendant plant of a cross between a lettuce plant grown from seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804 and another agronomically valuable lettuce plant of the species *Lactuca sativa*” is not clear. Specifically, it is not clear what a descendant of a cross would encompass. The Commissioner's Decision 1386 of 5 August 2015 defines a descendant plant as a plant genetically related to a predecessor plant. In claim 2, the descendant is a product by process, specifically a plant descended from a cross between two plants, wherein the descendant has a particular phenotypic trait, i.e. *N. ribisnigri* resistance. However, the crossing process does not result in a descendant plant having a distinguishing feature that would differentiate it from the plant as described in *Eenink et al* which also has this phenotypic trait. The genetic basis of the *N. ribisnigri* resistance in proposed claims 2 to 6 and the genetic information which causes the CRA phenotype in proposed claims 3 to 6 are not defined.

Finally, in the proposed amended claim 2, the specific genetic relationship between the descendant and the plants which are crossed is undefined. The claim encompasses either a plant which is descended only one generation from the cross but may also encompass a plant which is descended many generations from the cross. Therefore, the descendant plant is not clearly defined, and the allegedly unique

phenotypic traits of the deposit cannot be verified as coming from the deposited parent plant.

[122] As explained above as matter of claim construction, the meaning of the term would be understood to be “proceeding from an ancestor or source”. Considered in the context, the descendant plants of the claims are those that proceed from the ancestors mentioned: either of the deposited plant lines, which are defined clearly in their own right by deposit number, and another agronomically valuable lettuce plant. The descendant plants are limited to those that retain the aphid resistance phenotype—a dominant characteristic that the skilled person would understand to be inherited in a simple predictable manner through multiple generations and which can be verified as originating from the deposited plant lines. Such plants are also necessarily understood by the skilled person to be lacking the gene(s) that causes the CRA phenotype and are distinguishable on that basis from prior art plants.

[123] In the PR letter, we also explained that 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”, or as the Applicant has submitted, “if a skilled person could determine its metes and bounds”. As such, we agreed with the Applicant that the scope of the claims is not obscured through the use of the term “descendants”.

[124] We are therefore satisfied that claims 2-6 comply with subsection 27(4) of the Act.

Non-compliance of claim 1 with section 2 of the *Patent Act*

[125] Although indicated in the FA and SOR to be allowable, we expressed our preliminary view in the PR letter that the subject-matter defined by claim 1 is not within the definition of invention under section 2 of the *Patent Act*.

[126] Claim 1 reads:

Use of seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804 for transferring *Nasonovia ribisnigri* resistance into another agronomically valuable lettuce plant of the species *Lactuca sativa*.

[127] In the PR letter, we noted that claim 1 had not been construed during prosecution and no reason was given for considering it allowable. As indicated above as a matter of claim construction, the claim's essential elements are the following:

- “use of”;
- “seeds that were deposited under accession number NCIMB 40803 or NCIMB 40804”;
- “for transferring *Nasonovia ribisnigri* resistance”; and,
- “into another agronomically valuable lettuce plant of the species *Lactuca sativa*”.

[128] Apart from an indication that the claim is directed to a “use”, what stands out upon reviewing the list of claim elements is that none constitute patentable subject-matter in their own right. Neither a seed, nor a plant, nor the transfer of a resistance trait through a traditional plant breeding process constitute patentable subject-matter. In our view, their combination under the guise of a “use” claim does not render them patentable. Similar to the situation in CD 1404 (discussed above at para [32]), we do not consider the use of a non-patentable seed, in an excluded manner of traditional plant breeding, so as to transfer a resistance trait to another plant to be subject-matter that falls within the definition of invention.

[129] Therefore, it was our preliminary view that claim 1 is non-compliant with section 2 of the Act. Since the Applicant did not expressed disagreement with our preliminary view, we therefore conclude that the claim is non-compliant.

Proposed claim amendments

[130] On April 11, 2018, the Applicant replied to our PR letter. A proposed claim set was submitted in which the two claims we considered defective were deleted, thereby rendering the application compliant with the Act and Rules. In accordance with subsection 30(6.3) of the *Patent Rules*, the Applicant requested that the Board recommend that the Commissioner require amendment of the application to replace the six claims on file with the proposed claim set.

Conclusions

[131] Claims 2-6 are not defective on the basis of the grounds set out in the FA or SOR because:

- (1) the subject-matter of the claims was not previously disclosed and complies with paragraph 28.2(1)(b) of the *Patent Act*;
- (2) the subject-matter of the claims would not have been obvious to the person of skill in the art and complies with section 28.3 of the *Patent Act*;
- (3) the specification complies with paragraph 27(3)(a) of the *Patent Act* because “descendant plants” are properly disclosed;
- (4) the specification complies with paragraph 27(3)(b) of the *Patent Act* because “descendant plants” are enabled;
- (5) claim 2 on file does not omit an essential element and is therefore not defective for lack of utility under section 2 of the *Patent Act* or for overbreadth under section 84 of the *Patent Rules*;
- (6) the claims are fully supported by the description and comply with section 84 of the *Patent Rules* because certain claim terminology is inferable from the specification as filed; and,

(7) the claims are compliant with subsection 27(4) of the *Patent Act* because the scope of the claims is not obscured through the use of the term “descendants”.

[132] Claim 1 is directed to subject-matter outside the definition of invention under section 2 of the *Patent Act* and claim 3 does not comply with subsection 87(1) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[133] For the reasons set out above, we are of the view that refusal of the application is not justified on the basis of the defects outlined in the FA and SOR. Refusal of the application would, however, be justified on the basis of the two defects identified in accordance with with subsection 30(6.1) of the *Patent Rules*: (1) claim 1 is directed to subject-matter outside the definition of invention under section 2 of the *Patent Act*; and, (2) claim 3 does not comply with subsection 87(1) of the *Patent Rules*.

[134] We therefore recommend that the Applicant be notified, in accordance with subsection 30(6.3) of the *Patent Rules*, that amendment of the application to replace the six claims on file with the proposed claim set of April 11, 2018 is considered necessary for compliance with the Act and Rules. If the amendment is not made within three months from the issuance of this decision, we recommend that the application be refused under section 40 of the Act.

Ed MacLaurin
Member

Marcel Brisebois
Member

Leigh Matheson
Member

COMMISSIONER'S DECISION

[135] I concur with the findings and the recommendation of the Board. In accordance with subsection 30(6.3) of the *Patent Rules*, I hereby notify the Applicant that amendment of the application to replace the six claims on file with the proposed claim set of April 11, 2018 is considered necessary for compliance with the Act and Rules. If the amendment is not made within three months from the issuance of this decision, I intend to refuse the application under section 40 of the Act.

Johanne Bélisle
Commissioner of Patents

Dated at Gatineau, Quebec,
this 13th day of December, 2018.