Citation: uniQure IP B.V., 2023 CACP 24
Commissioner's Decision #1657
Décision du commissaire nº 1657
Date: 2023-10-19

TOPIC:	A20	Double-patenting
	B00	Ambiguity or indefiniteness
	D00	Division

SUJET:	A20	Double-brevet
	B00	Caractère ambigu ou indéfini description
	D00	Division

Application No. : 2,921,594
Demande n^{o} 2 921 594

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,921,594 having been rejected under subsection 199(1) of the *Patent Rules*, has consequently been reviewed in accordance with paragraph 86(7)(c) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner are that the application be refused.

Agent for the Applicant:

Gowling WLG (Canada) LLP
1 First Canadian Place, 100 King Street West, Suite 1600
Toronto, Ontario

M5X 1G5

INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,921,594, which is entitled “AAV vectors with improved Rep coding sequences for production in insect cells”. uniQure IP B.V. is the sole Applicant. A review of the rejected application has been conducted by a Panel of the Patent Appeal Board pursuant to paragraph 86(7)(c) of the *Patent Rules*.

[2] As explained in more detail below, our recommendation is that the Commissioner of Patents refuse the application.

BACKGROUND

The Application

[3] The present application is a divisional of parent application 2,655,957 which was filed under the Patent Cooperation Treaty (PCT) and has an effective filing date in Canada of June 20, 2007. The parent application was laid open to public inspection on December 27, 2007.

[4] The rejected application relates to improved nucleic acid constructs encoding parvoviral replication protein coding sequences Rep78 and Rep52 for use in the production of adeno-associated vectors in insect cells. In particular, these nucleic acid constructs feature a single open reading frame in which the expression of both Rep78 and Rep52 is driven by a single promoter having a suboptimal initiation codon which is partially skipped by the ribosome. Due to the regulated expression of Rep78 and Rep52, insect cells comprising said nucleic acid constructs are able to produce stable and high yields of adeno-associated virus. Adeno-associated virus are one of the most promising viral vectors for human gene therapy and their production in insect cells overcomes many of the problems associated with mammalian production systems.

[5] The application has 15 claims on file that were received at the Patent Office on June 1, 2021.

Prosecution History

[6] On March 21, 2022, a Final Action was written under subsection 86(5) of the *Patent Rules*. The Final Action stated that claims 1 to 15 on file do not define an invention “other” than the one claimed in the parent patent 2,655,957, and the present application does not comply with subsection 36(2) of the *Patent Act*.

[7] The Response to the Final Action dated July 20, 2022 did not contest the improper divisional assessment and instead proposed an amended claim set, containing proposed claims 1 to 15, that it submitted are allowable.

[8] On November 9, 2022 the application was forwarded to the Patent Appeal Board for review under paragraph 86(7)(c) of the *Patent Rules* along with a Summary of Reasons which explained that the rejection was maintained as the proposed amendments presented in the Response to the Final Action did not overcome the defect identified in the Final Action. The Summary of Reasons also identified a clarity defect with proposed claim 3.

[9] In a letter dated November 14, 2022, the Patent Appeal Board forwarded a copy of the Summary of Reasons to the Applicant and requested that they confirm their continued interest in having the application reviewed.

[10] In a letter dated February 7, 2023, the Applicant confirmed their interest in having the review proceed.

[11] The present Panel was formed to review the rejected application under paragraph 86(7)(c) of the *Patent Rules*. On September 13, 2023, the Panel sent a Preliminary Review letter which detailed our preliminary analysis and opinion that the claims on file do not define an “other” invention relative to the claims of parent patent CA 2,655,957, contrary to subsection 36(2) of the *Patent Act*. In addition, the Preliminary Review letter notified the Applicant that, in accordance with subsection 86(9) of the *Patent Rules*, additional questions arose as to whether the claims on file are not patentably distinct from the claims of parent patent 2,655,957, contrary to the doctrine of obviousness double-patenting and whether claims 4 and 8 on file lack clarity, contrary to subsection 27(4) of the *Patent Act*. The Preliminary Review letter expressed our preliminary analysis and opinion that the claims on file are not patentably distinct from the claims of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting and that claims 4 and 8 on file are

indefinite, contrary to subsection 27(4) of the *Patent Act*. The Preliminary Review letter also expressed the preliminary opinion that the proposed claims would not overcome the improper divisional and double-patenting defects and that proposed claims 3 and 8 would also be indefinite. Finally, the Preliminary Review letter provided the Applicant with an opportunity to make oral and/or written submissions.

[12] In a phone call on October 10, 2023, the Applicant confirmed that the Preliminary Review letter had been received and that no reply would be forthcoming.

Issues

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

- whether the claims on file do not define an “other” invention relative to the claims of parent patent CA 2,655,957, contrary to subsection 36(2) of the *Patent Act*;
- whether the claims on file are not patentably distinct from the claims of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting; and
- whether claims 4 to 8 on file are indefinite, contrary to subsection 27(4) of the *Patent Act*.

[14] In addition to the claims on file, the proposed claims have also been considered.

PURPOSIVE CONSTRUCTION

Legal Background

[15] According to Free World Trust v Électro Santé Inc, 2000 SCC 66 [Free World Trust] and Whirlpool Corp v Camco Inc, 2000 SCC 67 [Whirlpool], a purposive construction of the claims is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge and considers the specification and drawings. In addition to interpreting the meaning of the terms of a claim, purposive construction distinguishes the essential elements of the claim from the non-essential elements. Whether or not an element is essential depends

on the intent expressed in or inferred from the claim, and on whether it would have been obvious to the person skilled in the art that a variant has a material effect upon the way the invention works.

[16] In carrying out the identification of essential and non-essential elements, all elements set out in a claim are presumed essential unless it is established otherwise or where such a presumption is contrary to the claim language.

Analysis

The person skilled in the art and the relevant common general knowledge

[17] The Preliminary Review letter, on pages 4 to 5, stated the following with regard to the identity of the person skilled in the art and their expected common general knowledge:

> Neither the Final Action nor the Response to the Final Action identify the person skilled in the art. As indicated above, purposive construction is performed from the perspective of the person skilled in the art. We therefore present our preliminary view regarding the identity of the person skilled in the art and the relevant common general knowledge.
>
> Based on the teachings of the description, the references cited therein and the subject-matter of the claims, our preliminary view is that the person skilled in the art is a team comprising a molecular biologist, a virologist and a geneticist. In addition, this team would have experience in the production of adeno-associated virus (AAV) and other parvoviral vectors, and their use in gene therapy.
>
> With regard to the common general knowledge of the person skilled in the art, based on the description, in our preliminary view the common general knowledge of this team would include the following:
>
> - AAV is one of the most promising viral vectors for human gene therapy and mammalian culture systems are commonly used for their production (page 1);
>
> - Recombinant AAV vectors are typically produced by providing DNA plasmids that contain a therapeutic gene of interest flanked by the origin of AAV replication (inverted terminal repeats), genes for AAV replication proteins Rep78, Rep68, Rep52 and Rep40, and genes for virion or structural proteins VP1, VP2 and VP3. In addition, a plasmid containing early genes from adenovirus (E2A,

E4ORF6, VARNA) is provided to enhance the expression of the AAV genes and improve vector yield (page 1);

- The genomic organization of all known AAV serotypes is very similar. The genome of AAV is a linear, single-stranded DNA molecule. Inverted terminal repeats flank the unique coding nucleotide sequences for the non-structural replication (Rep) proteins and the structural (VP) proteins (page 6);

- Large scale production of recombinant AAV in mammalian systems is problematic to obtain material required for clinical use and there is also the risk that the vector will be contaminated with undesirable, perhaps pathogenic, material present in the mammalian host cell (pages 1 and 2);

- To overcome the problems of mammalian production systems, an AAV production system has been developed using insect cells, however there are still limitations of stable and high yield production (page 3); and

- Techniques for expressing foreign genes in insect cells are well known in the art, including methods for baculovirus vectors and insect culture procedures (page 10).

[18] In the absence of submissions from the Applicant, we adopt the above characterizations of the person skilled in the art and the relevant common general knowledge for our final analysis.

The claims on file

[19] There are 15 claims on file. Claims 1 and 12 are the independent claims and read as follows:

1. An insect cell comprising a first nucleic acid construct comprising a first nucleic acid sequence which encodes both parvoviral Rep78 and Rep52 proteins from a Rep78 nucleotide sequence, wherein the initiation codon for translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG; the first nucleic acid sequence being operably linked to an expression control sequence that includes a promotor that is active in insect cells, and is constructed such that both Rep78 and Rep52 proteins are produced upon expression in the insect cell, wherein the first nucleic acid sequence is constructed such that it effects partial exon skipping upon expression in insect cells**.**

> 12. A method for producing a recombinant parvoviral virion in an insect cell, the virion comprising a second nucleotide sequence as defined in any one of claims 2, 5 and 6, the method comprising the steps of:
>
> a) culturing an insect cell as defined in any one of claims 2 – 11 under conditions such that recombinant parvoviral virion is produced; and,
>
> b) recovering the recombinant parvoviral virion.

[20] The dependent claims 2 to 11 and 13 to 15 define further limitations regarding the presence and composition of a second and third nucleotide sequence (claims 2 to 10), the type of parvovirus (claims 11 and 15) and the purification of the virion (claims 13 and 14).

Essential elements

[21] As stated above, all of the elements set out in a claim are presumed essential unless it is established otherwise or where such a presumption is contrary to the claim language. Further, a claim element is essential when it would have been obvious to the person skilled in the art that its omission or substitution would have a material effect on the way the invention works: Free World Trust at para 55.

[22] The Preliminary Review letter, on page 7, stated the following with regard to the elements in the claims that the person skilled in the art would consider to be essential:

> With respect to claim language, our preliminary view is that the person skilled in the art reading claims 1 to 15 in the context of the specification as a whole and in view of their common general knowledge would understand that there is no use of language in any of the claims indicating that any of the elements are optional, preferred or were otherwise intended as being non-essential. Therefore, our preliminary view is that the person skilled in the art would consider all of the elements in the claims to be essential.

[23] In the absence of submissions from the Applicant, we adopt the above identification of the claim elements that are essential in this recommendation.

IMPROPER DIVISIONAL STATUS

Legal Background

[24] Subsection 36(2) of the *Patent Act* sets out the provisions under which an applicant may file a divisional application:

> Where an application (the "original application") describes more than one invention, the applicant may limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.

[25] In order for an application to be a divisional application, its claims must be directed to an "other invention" than that of the claims of the original application, with any such other invention having also been described in the original application. The Manual of Patent Office Practice (CIPO) at 21.10, revised October 2022, explains how this determination is to be made:

> The content of the specification and drawings of the purported divisional application are compared to that of the parent application to determine if the claims of the divisional application are directed to a different invention than the claims of the parent, and if the divisional application was filed with new matter. […]
>
> If, at filing or during the course of prosecution, the claims in the purported divisional application are not directed to a different invention than those of the parent application, the later-filed application is not a proper divisional application within the meaning of section 36 of the *Patent Act*. Note that if the filing of a divisional application was "directed by the Patent Office", the doctrine of double-patenting does not apply between the divisional and any of its parent or sibling applications.

Analysis

[26] The Preliminary Review letter, on pages 8 to 12, explained that in our preliminary view claims 1 to 15 of the present application do not define an "other" invention relative to claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957, and the present application does not comply with subsection 36(2) of the *Patent Act*:

> The Final Action indicates that the claims of the present application do not define an invention "other" than the one claimed in the granted

parent patent 2,655,957. In particular, the Final Action indicates that claim 1 of the present application and the combination of claim 9 when it depends on claim 3 of the parent patent contain overlapping subject-matter. Further, dependent claims 2 to 15 of the present application are said to directly parallel granted claims 10 to 12, 14 to 21 and 23 to 25 of the parent patent.

Although the Final Action acknowledges that claim 1 of the present application includes a feature not explicitly present in the claims of the parent patent, “wherein the first nucleic acid sequence is constructed such that it effects partial exon skipping upon expression in insect cells”, this feature is considered to be an inherent result of the recited initiation codons present in both claims:

> Although the claims of patent CA2655957 do not explicitly recite that the element of changing the initiation codon for translation of the parvoviral Rep78 protein to a suboptimal initiation codon selected from ACG, TTG, CTG, and GTG (as found in instant claim 1 and granted claim 9, referencing claim 3) effects partial exon skipping, this is an inherit result of doing so. This is clearly taught on page 7, line 23 to page 8, line 19 of the specification of both the instant application and the CA2655957 patent; including
>
> “The suboptimal initiation codon preferably is an initiation codon that effects partial exon skipping. Partial exon skipping is herein understood to mean that at least part of the ribosomes do not initiate translation at the suboptimal initiation codon of the Rep78 protein but at an initiation codon further downstream, whereby preferably the initiation codon further downstream is the initiation codon of the Rep52 protein”.
>
> Reference is also made to the description of Figure 1B), “This promoter drives the expression of both Rep78 and Rep52 because the Rep78 initiation codon ATG is converted to the alternate ACG initiation codon and partially skipped by the ribosome” (page 21). A person of skill in the art construing the phrase “wherein the first nucleic acid is constructed such that it effects partial exon skipping upon expression in insect cells” in view of the common descriptions would necessarily understand that it is the already claimed

modification of the start codon, and nothing else, which is contemplated to effect this desired result.

The Response to the Final Action does not contest the above views and instead proposes amendments to claim 1 to “provide for a combination not present in the granted patent claims where claim 9 is dependent on independent claim 3.”

For the purpose of our assessment below we will begin by comparing claim 1 of the present application with the combination of claim 9 as it depends on claim 3 of the parent patent.

Claim comparison

Claim 1 on file	Claim 9 when it depends on claim 3 of the parent patent
An insect cell	An insect cell
Comprising a first nucleic acid construct comprising a first nucleic acid sequence which encodes both parvoviral Rep78 and Rep52 proteins from a Rep78 nucleotide sequence	Comprising a nucleotide sequence comprising a single open reading frame encoding parvoviral Rep78 and Rep52 proteins, wherein the insect cell comprises a first nucleic acid construct comprising a nucleotide sequence comprising a single open reading frame comprising nucleotide sequences encoding parvoviral Rep78 and Rep 52 proteins
Wherein the initiation codon for translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG	Wherein the initiation codon for translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG
The first nucleic acid sequence being operably linked to an expression control sequence that includes a promoter that is active in insect cells	Wherein the nucleotide sequence is operably linked to expression control sequences for expression in an insect cell
And is constructed such that both Rep78 and Rep52 are produced upon expression in the insect cell	

Wherein the first nucleic acid sequence is constructed such that it effects partial exon skipping upon expression in insect cells	

Claim similarities

Claim 1 of the present application and the combination of claim 9 as it depends on claim 3 of the parent patent both recite an insect cell comprising a first nucleic acid construct comprising a nucleotide sequence which encodes both parvoviral Rep78 and Rep52 wherein the initiation codon for translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG and wherein the nucleotide sequence is operably linked to expression control sequences for expression in an insect cell.

Claim differences

With respect to claim 1 of the present application, there are two possible differences over the combination of claim 9 as it depends on claim 3 of the parent patent, as illustrated in the claim comparison table. The first is that claim 1 of the present application specifies that the nucleic acid sequence is constructed such that both Rep78 and Rep52 are produced upon expression in the insect cell. The second is that claim 1 of the present application specifies that the nucleic acid sequence is constructed such that it effects partial exon skipping upon expression in insect cells.

In our preliminary view, the recitation of these features does not create a claim that is patentably distinct from the parent claim such that an “other” invention is present. Claim 1 of the present application and the combination of claim 9 when it depends on claim 3 of the parent patent both require the presence of expression control sequences for expression. Likewise, both claims require that the initiation codon for the translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG. As explained in the Final Action, ACG, TTG, CTG, and GTG are suboptimal initiation codons that effect partial exon skipping. In our preliminary view, the person skilled in the art would understand that in order for expression of both Rep78 and Rep52 to occur, there must be partial exon skipping at the suboptimal initiation codon of the Rep78 protein so that translation can also occur downstream at the initiation codon of the Rep52 protein. The production of both Rep78 and Rep52 and the partial exon skipping are inherent consequences of requiring that the initiation codon for the translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG. Therefore, the inclusion of these features in claim 1 of the present

> application do not constitute an “other” invention relative to the combination of claim 9 when it depends on claim 3 in the parent patent.
>
> Further, having reviewed the subject-matter of claims 2 to 15 of the present application and claims 10 to 12, 14 to 21 and 23 to 25 of the parent patent, it is our preliminary view that while there may be slight differences in the language used to describe certain features, there are no differences that would lead to a reasonable conclusion that the claims of the present application define an “other” invention than that of the parent.
>
> Although present claim 8 does not include the feature that the nucleotide sequence which has at least 60% identity to SEQ. ID NO: 7 has the same expression control function as a sequence with SEQ. ID NO: 7, the omission of this feature does not create a claim that is patentably distinct from the parent claim such that an “other” invention is present. In our preliminary view, the person skilled in the art would understand that the scope of present claim 8 includes any 60% identical sequence which has the same expression control function as a sequence with SEQ. ID NO: 7.
>
> Likewise, although present claim 9 includes the feature that the nucleotide sequence encoding the parvoviral VP1 capsid protein corresponds to SEQ ID NO: 1, the inclusion of this feature does not create a claim that is patentably distinct from the parent claim such that an “other” invention is present. There is only one nucleotide sequence referred to in the description which has the specified modifications to VP1, namely, SEQ ID NO: 1 (see page 27 of the description).
>
> In light of the above, it is our preliminary view that claims 1 to 15 of the present application do not define an “other” invention relative to claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957, and the present application does not comply with subsection 36(2) of the *Patent Act*.

[27] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claims 1 to 15 on file do not define an “other” invention relative to claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957, and the present application does not comply with subsection 36(2) of the *Patent Act*.

DOUBLE-PATENTING

Legal Background

[28] Although there are no express provisions in the *Patent Act* dealing with double-patenting, the Supreme Court of Canada has indicated that the statutory basis for double-patenting is subsection 36(1) of the *Patent Act* which indicates, in the singular, that "a patent shall be granted for one invention only": Whirlpool at para 63. The courts have also considered double-patenting to be a proper basis for the Commissioner of Patents to refuse an application: Bayer Schering Pharma Aktiengesellschaft v Canada (Attorney General), 2010 FCA 275, affirming 2009 FC 1249.

[29] In Whirlpool, the Supreme Court noted that the doctrine of double-patenting has two branches. The first is "same-invention" double-patenting, which occurs when the claims of a first and second patent, both of which are owned by the same party, are "identical" or "conterminous" to one another. The second branch of the test for double-patenting, known as "obviousness double-patenting" is a "more flexible and less literal test" which prohibits the issuance of the second patent unless its claims are "patentably distinct" and exhibit "novelty or ingenuity" over those of the first patent: Whirlpool at paras 66 to 67.

[30] Obviousness double-patenting is assessed from the perspective of the person skilled in the art, taking into account their common general knowledge. The analysis compares the claims in the subject application to the claims of the issued patent: Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc, 2016 FCA 119 at paras 28 to 29. Double-patenting exists where there is no patentable distinction between the subject application and the issued patent such that the claims of the subject application are obvious in view of the claims of the issued patent: Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research, 2020 FCA 30 at para 99; Hoffman LaRoche Limited v Sandoz Canada Inc, 2021 FC 384, para 151.

Analysis

[31] The approach used in the second branch of the test for double-patenting is the same assessment used to determine whether the claims of a divisional application

are directed to a different invention than the claims of its parent patent, in cases where the filing of a divisional application was not directed by the Patent Office: Manual of Patent Office Practice (CIPO) at 21.10, revised October 2022.

[32] The Preliminary Review letter, on page 13, explained that in our preliminary view claims 1 to 15 of the present application are not patentably distinct from claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting, for the same reasons provided above that claims 1 to 15 of the present application do not define an “other” invention relative to claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957.

[33] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claims 1 to 15 of the present application are not patentably distinct from claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting.

INDEFINITENESS

Legal Background

[34] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define the subject-matter of the invention:

> 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.

[35] 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 scope of the monopoly sought, as well as 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.

Analysis

[36] The Preliminary Review letter, on page 14, explained why in our preliminary view claims 4 and 8 are indefinite:

> Claim 4 refers to the insect cell according to either claims 2 or 3. However, the term "the second nucleic acid construct" has no antecedent in claim 2. Therefore, it is our preliminary view that claim 4 is indefinite when it refers to claim 2 contrary to subsection 27(4) of the *Patent Act*.
>
> Claim 8 refers to an expression control sequence comprising a nucleotide sequence with at least 60% identity to SEQ. ID NO: 7. However, the nucleotide sequence is not defined as having the same expression control function as SEQ. ID NO:7 and thus claim 8 encompasses sequences having undefined function(s) and its exact scope cannot be readily determined. Therefore, it is our preliminary view that claim 8 is indefinite contrary to subsection 27(4) of the *Patent Act*.
>
> In light of the above, it is our preliminary view that claims 4 and 8 on file are indefinite contrary to subsection 27(4) of the *Patent Act*.

[37] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claims 4 and 8 on file are indefinite, contrary to subsection 27(4) of the *Patent Act*.

THE PROPOSED CLAIMS DO NOT REMEDY THE DEFECTS

[38] As indicated above, with the Response to the Final Action the Applicant submitted proposed claims 1 to 15. A review of the proposed claims indicates that claim 1 on file has been amended to remove the reference to partial exon skipping and to add that the nucleotide sequence comprises an expression control sequence for expression in an insect cell comprising a nine nucleotide sequence of SEQ ID NO:7 or a nucleotide sequence which has at least 60% identity to SEQ ID NO:7 and which has the same expression control function as a sequence with SEQ ID NO: 7, which control sequence is upstream and operably linked to the initiation codon of the nucleotide sequence encoding the AAV Rep78 protein.

[39] According to pages 2 to 3 of the Summary of Reasons, proposed claim 1 defines the same invention as claim 1 of the parent patent. In addition, proposed claim 1 does not define an "other" invention relative to claim 9 when it depends on claim 8,

claim 6, claim 5 and claim 3 of the parent patent. Further, proposed dependent claims 2 to 15 directly parallel claims 10 to 12, 14 to 21 and 23 to 25 of the parent patent. Finally, the amendments to proposed claim 1 introduce a lack of antecedent defect in proposed claim 3.

[40] The Preliminary Review letter, on pages 15 to 18, explained our preliminary view that proposed claims 1 to 15 would not overcome the improper divisional and double-patenting defects and that proposed claims 3 and 8 would be indefinite:

> Having reviewed proposed claim 1, we preliminarily agree with the Summary of Reasons that it does not define an “other” invention than the one claimed in the combination of claim 9 when it depends on claims 8, 6, 5 and 3 of the granted parent patent 2,655,957.

Claim comparison

Proposed claim 1	Claim 9 when it depends on claims 8, 6, 5 and 3 of the parent patent
An insect cell	An insect cell
Comprising a first nucleic acid construct comprising a first nucleic acid sequence which encodes both parvoviral Rep78 and Rep52 proteins from a Rep78 nucleotide sequence	Comprising a nucleic acid construct comprising a nucleotide sequence comprising a single open reading frame encoding parvoviral Rep78 and Rep52 proteins, wherein the insect cell comprises a first nucleic acid construct comprising a single open reading frame comprising nucleotide sequences encoding parvoviral Rep78 and Rep 52 proteins
Wherein the initiation codon for translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG	Wherein the initiation codon for translation of the parvoviral Rep78 protein is selected from ACG, TTG, CTG, and GTG
And wherein the nucleotide sequence comprises an expression control sequence for expression in an insect cell comprising a nine nucleotide sequence of SEQ ID NO:7 or a nucleotide sequence which has at least 60% identity to SEQ ID NO: 7 and which has the same expression control function as a sequence with SEQ ID NO:7, which expression control sequence is upstream and operably linked to the initiation codon of the nucleotide sequence encoding the AAV Rep78 protein	Wherein the nucleotide sequence is operably linked to expression control sequences for expression in an insect cell, wherein the nucleic acid construct is an insect compatible vector, wherein the insect compatible vector is a baculoviral vector, the nucleic acid construct further comprising an expression control sequence that comprises nucleotide sequence SEQ ID NO:7 upstream of the initiation codon of the nucleotide sequence encoding the Rep78 protein

With respect to proposed claim 1, there are two possible differences over the combination of claim 9 when it depends on claims 8, 6, 5 and 3

of the parent patent, as illustrated in the claim comparison table. The first is that proposed claim 1 specifies that the expression control sequence can comprise a nucleotide sequence which has at least 60% identity to SEQ ID NO: 7 and which has the same expression control function as a sequence with SEQ ID NO:7. In our view, the inclusion of this feature does not create a claim that is patentably distinct from the patent such that an “other” invention is present. Although it results in proposed claim 1 being broader in scope than the combination of claim 9 when it depends on claims 8, 6, 5 and 3 of the parent patent, we note that the variant is an alternative and the feature that the expression control sequence can comprise a nucleotide sequence of SEQ ID NO:7 is present in both proposed claim 1 and the combination of claim 9 when it depends on claims 8, 6, 5 and 3 of the parent patent. Further, in our view a structural variant having the same functional activity as a nucleotide sequence of SEQ ID NO:7 would have been obvious to the person skilled in the art.

The second possible difference is that proposed claim 1 does not specify that the nucleic acid construct is an insect compatible vector that is a baculoviral vector. In our preliminary view, the omission of the specific mention that the nucleic acid construct is an insect compatible vector that is a baculoviral vector does not create a claim that is patentably distinct from the patent such that an “other” invention is present. In our view the omission does not significantly change the scope of proposed claim 1 in comparison with the combination of claim 9 when it depends on claims 8, 6, 5 and 3 of the parent patent since it would have been obvious to the person skilled in the art that baculoviral vectors are a type of insect-compatible vector used for expression in insect cells: page 10 of the present description.

In light of the above, it is our preliminary view that the scope of the combination of claim 9 when it depends on claims 8, 6, 5 and 3 of the parent patent is encompassed by proposed claim 1. It follows that proposed claim 1 does not define an “other” invention relative to the combination of claim 9 when it depends on claims 8, 6, 5 and 3 of the parent patent.

Given that there is no meaningful difference between proposed claims 2 to 15 and the corresponding claims on file, it is our preliminary view that proposed claims 1 to 15 do not define an “other” invention relative to claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957 and the application would not comply with subsection 36(2) of the *Patent Act*. In addition, it is our preliminary view that proposed claims 1 to 15 are not patentably distinct from claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957 and would not comply with the doctrine of obviousness double-patenting.

> We also preliminarily agree with the Summary of Reasons that the term "the first nucleic acid construct" in proposed claim 3 has no antecedent in proposed claim 2 (which depends on proposed claim 1). Therefore, it is our preliminary view that proposed claim 3 would not comply with subsection 27(4) of the *Patent Act*. In addition, we note that proposed claim 8 has not been amended and therefore it is our preliminary view that proposed claim 8 would not comply with subsection 27(4) of the *Patent Act* for the same reasons provided above for claim 8 on file.
>
> **Conclusion on proposed claims**
>
> Our preliminary view is therefore that proposed claims 1 to 15 do not define an "other" invention relative to claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957 and the application would not comply with subsection 36(2) of the *Patent Act*. In addition, proposed claims 1 to 15 are not patentably distinct from claims 9 to 12, 14 to 21 and 23 to 25 of parent patent CA 2,655,957 and would not comply with the doctrine of obviousness double-patenting. Finally, proposed claims 3 and 8 would be indefinite contrary to subsection 27(4) of the *Patent Act*. Accordingly, it is our preliminary view that the proposed amendments do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

[41] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that the proposed amendments do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS

[42] We have determined that claims 1 to 15 do not define an "other" invention relative to the claims of parent patent CA 2,655,957, contrary to subsection 36(2) of the *Patent Act*, that claims 1 to 15 are not patentably distinct from the claims of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting and that claims 4 and 8 are indefinite contrary to subsection 27(4) of the *Patent Act*.

[43] In our view, proposed claims 1 to 15 submitted with the Response to the Final Action would not overcome the improper divisional and obviousness double-patenting defects and proposed claims 3 and 8 would be indefinite. Therefore, proposed claims 1 to 15 are not considered a necessary amendment for compliance with the *Patent Act* and *Patent Rules* as required by subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[44] In view of the above, the Panel recommends that the application be refused on the grounds that:

- claims 1 to 15 do not define an “other” invention relative to the claims of parent patent CA 2,655,957, contrary to subsection 36(2) of the *Patent Act*;
- claims 1 to 15 are not patentably distinct from the claims of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting; and
- claims 4 and 8 on file are indefinite contrary to subsection 27(4) of the *Patent Act*.

Christine Teixeira	Marcel Brisebois	Michael O’Hare
Member	Member	Member

DECISION OF THE COMMISSIONER

[45] I concur with the findings of the Board and its recommendation to refuse the application on the grounds that:

- claims 1 to 15 do not define an “other” invention relative to the claims of parent patent CA 2,655,957, contrary to subsection 36(2) of the *Patent Act*;
- claims 1 to 15 are not patentably distinct from the claims of parent patent CA 2,655,957, contrary to the doctrine of obviousness double-patenting; and
- claims 4 and 8 on file are indefinite contrary to subsection 27(4) of the *Patent Act*.

[46] Therefore, in accordance with section 40 of the *Patent Act*, I refuse to grant a patent for this application. Under section 41 of the *Patent Act*, the Applicant has six months to appeal my decision to the Federal Court of Canada.

Konstantinos Georgaras

Commissioner of Patents
Dated at Gatineau, Quebec
this 19 day of October, 2023