Citation: Glutagen PTY Ltd, 2023 CACP 15

Commissioner's Decision #1648
Décision du commissaire nº 1648
Date: 2023-04-17

TOPIC:	F00	Novelty
	O00	Obviousness
	C00	Ambiguity or indefiniteness
SUJET:	F00	Nouveauté
	O00	Évidence
	C00	Caractère ambigu ou indéfini

Application No. : 2,749,690

Demande nº 2 749 690

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,749,690 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 to refuse the application.

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,749,690, which is entitled “Compositions for the treatment of gluten intolerance and uses thereof”. Glutagen PTY Ltd 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 application was filed under the *Patent Cooperation Treaty* and has an effective filing date in Canada of January 6, 2010. It was laid open to public inspection on July 22, 2010.

[4] The rejected application relates to the use of compositions comprising caricain to prevent or treat a condition arising from gluten intolerance. Caricain is one of several known cysteine proteases, enzymes which can hydrolyze peptide bonds, that is naturally expressed in the papaya plant, *Carica papaya*. The present description demonstrates that caricain was able to modify toxic oligopeptides that are produced following gluten ingestion to produce non-toxic peptides. The use of compositions comprising caricain offers an improved method for preventing or at least partly alleviating the toxic effect of gluten in gluten intolerant individuals over imposing a gluten-free diet.

[5] The application has 13 claims on file that were received at the Patent Office on November 28, 2019.

Prosecution History

[6] On November 6, 2020, a Final Action was written under subsection 86(5) of the *Patent Rules*. The Final Action states that the subject-matter of claims 1 to 13 on file at the time of the Final Action is anticipated contrary to paragraph 28.2(1)(a) of

the *Patent Act*. The Final Action also indicates that claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite and therefore non-compliant with subsection 27(4) of the *Patent Act*.

[7] In the Response to the Final Action dated March 8, 2021, the Applicant did not contest the anticipation assessment but did address the indefiniteness defects. In addition, the Response to the Final Action includes a first set of proposed claims that the Applicant submits addresses both the anticipation and indefiniteness defects.

[8] On April 12, 2021, the application was forwarded to the Patent Appeal Board for review under subsection 86(7)(c) of the *Patent Rules* along with a Summary of Reasons explaining that although the first set of proposed claims submitted with the Response to the Final Action were considered to overcome the defects of anticipation and indefiniteness raised against the claims on file, they introduce new defects in relation to indefiniteness and improper dependency.

[9] In a letter dated April 14, 2021, 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 June 22, 2021, 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 December 14, 2022, the Panel sent a Preliminary Review letter detailing our preliminary analysis and opinion that claims 1 to 13 on file are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act* and that claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite contrary to subsection 27(4) of the *Patent Act*. The Preliminary Review letter also expresses the preliminary opinion that the first set of proposed claims overcome the defects of anticipation and indefiniteness raised against the claims on file but they introduce new defects in relation to indefiniteness and improper dependency. In addition, the Preliminary Review letter explains why, in our preliminary view, the claims on file, as well as the first set of proposed claims are obvious contrary to section 28.3 of the *Patent Act* and notifies the Applicant of this defect under subsection 86(9) of the *Patent Rules*. The Preliminary Review letter also provided the Applicant with an

opportunity to make oral and/or written submissions.

[12] The Response to the Preliminary Review letter dated February 9, 2023 included a second set of proposed claims and provided written submissions in support of their patentability. On February 21, 2023, the Applicant declined the opportunity for an oral hearing.

Issues

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

- whether the claims on file are anticipated contrary to subsection 28.2(1)(a) of the *Patent Act*;
- whether the claims on file are obvious contrary to section 28.3 of the *Patent Act*; and
- whether claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite contrary to subsection 27(4) of the *Patent Act*.

[14] In addition to the claims on file, the second set of proposed claims submitted with the Response to the Preliminary Review letter has also been considered.

FOLLOWING A PURPOSIVE CONSTRUCTION, WHICH CLAIMED ELEMENTS ARE ESSENTIAL?

[15] In our view, all of the elements of the claims on file are essential.

Legal Background

[16] According to *Free World Trust v Électro Santé* Inc, 2000 SCC 66 and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, 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.

[17] 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.

All of the claimed elements are essential

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

[18] The Preliminary Review letter, on pages 3 to 5, states the following with regard to the identity of the person skilled in the art and their expected common general knowledge:

> [**Bolding** indicates added text] Neither the Final Action nor the Response to the Final Action identify the person skilled in the art and the relevant common general knowledge. As indicated above, a purposive construction of the claims 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 and the subject-matter of the claims, our preliminary view is that the person skilled in the art would be a team comprising a protein chemist, pharmaceutical chemist and a medical practitioner familiar with treating gluten intolerance and its causes.
>
> Further, in our preliminary view, the common general knowledge of this team would include the following:
>
> - Patients with gluten intolerance have symptoms which include abdominal pain, bloating and diarrhoea (page 1 of the description);
>
> - In severe and long term cases, such as coeliac disease, there are inflammatory changes to the intestinal mucosa, resulting in malabsorption of nutrients, fatigue, chronic diarrhoea, weight loss, abdominal distension, anaemia, increasing tendency to haemorrhage, as well as increased risk of gastrointestinal malignancies (page 1 of the description);
>
> - Patients with gluten intolerance characteristically have T cells present in the intestinal mucosa which recognize certain sequences present in toxic gluten

peptides and evidence suggests that these T cells play a crucial role in the immunopathogenesis of the disease by recognizing peptides containing specific sequences of amino acids associated with toxicity (page 1 of the description);

- Gluten is a protein fraction found in most grains and can be subdivided into glutenins and prolamins (page 2 of the description);
- Prolamins may be subclassified by origin as gliadins, secalins, hordeins and avenins from wheat, rye, barley and oat, respectively (page 2 of the description);
- Gluten intolerant individuals lack enzymes normally present in the small bowel that are necessary for the digestion of gluten (page 2 of the description);
- Peptide fragments produced by incomplete digestion of grain protein are toxic to gluten intolerant individuals (page 2 of the description);
- The most toxic peptides are those derived from gliadin (page 2 of the description);
- Serine containing peptides and tyrosine containing peptides, such as those found in gliadin, are associated with toxicity (page 3 of the description);
- Caricain has been structurally and functionally characterized as a cysteine protease typically found in the latex of plants such as *Carica papaya* (see Groves *et al*., 1996, *Structure*, 4(10):1193-1203) (page 7 of the description);
- Caricain can be at least partially purified from a natural source using conventional methods, including as described in Azarkan M. *et al.* ("Fractionation and purification of the enzymes stored in the latex of *Carica papaya*", *J. Chromatogr B Analyt Technol Biomed Life Sci.* 2003 790(1-2):229-38) **[Azarkan et al.]** and Buttle D.J. (Caricain in *Handbook of Proteolytic Enzymes*, 2 edition, p.1130-1132, Elsevier, London) (page 8 of the description) **[Buttle]**; and
- The ability of caricain to inactivate a toxic gluten peptide can be determined by many methods known in the art, for example, by using a Rat Liver Lysosome assay, as described, for example in WO 2003/100051 and Cornell and Townley (1974; *Gut*, 15(11): 862-869) (page 11 of the description).

[19] The Response to the Preliminary Review letter, on pages 3 to 6, did not disagree with these characterizations of the person skilled in the art and the relevant common general knowledge, however it submits that the common general knowledge would further include an awareness of the field of enzyme therapy for celiac disease. Specifically, knowledge that the field was focussed on prolyl endopeptidases that were believed to cleave toxic gluten oligopeptides and an

awareness that the field taught away from caricain as the enzyme of papaya latex responsible for detoxification.

[20] In support of what was known in the field of enzyme therapy for celiac disease, the Response to the Preliminary Review letter lists the following five references as evidence that the field was focussed on prolyl endopeptidases as candidate enzymes that might help digest and detoxify gliadin peptides: Sina Koch et al., "On the Role of Dipeptidyl Peptidase IV in the Digestion of an Immunodominant Epitope in Celiac Disease" In Nathan Back, Irun R. Cohen, David Kritchevsky, Abel Lajtha & Rodolfo Paoletti, eds, 524 *Dipeptidyl Aminopeptidases in Health and Disease. Advances in Experimental Medicine and Biology* (Boston, MA: Springer, 2004) pages 181 to 187; Lu Shan et al., "Structural basis for gluten intolerance in celiac sprue" (2002) 297:5590 Science pages 2275 to 2279; Nadine Cerf-Bensussan et al., "Oral proteases: a new approach to managing coeliac disease" (2007) 56 Gut pages 157 to 160; Jonathan Gass et al., "Enhancement of dietary protein digestion by conjugated bile acids" (2007) 133 Gastroenterology pages 16 to 23; and Michael Bethune and Chaitan Khosla, "Oral enzyme therapy for celiac sprue" (2012) 502 Methods Enzymol., pages 241 to 271 [Bethune and Khosla].

[21] Having reviewed the above-mentioned references, we agree that it was generally known and accepted without question by the bulk of those in the field that prolyl endopeptidases had been identified as promising candidates for oral enzyme therapy of celiac disease. Further, as explained on page 3 of Bethune and Khosla, in addition to the focus on prolyl endopeptidases, the field was also investigating substrate-directed strategies to identify enzymes that have evolved to digest gluten as their natural substrate. This approach screens for glutenase candidates *in vitro*, based on activity in complex biological mixtures, or *in silico*, based on sequence homology with known glutenases.

[22] Although Bethune and Khosla is a review article that was published after the publication date of the present application, as explained in the Manual of Patent Office Practice (CIPO) at 12.02.02c, revised October 2019, it is possible to consider references that were published after the relevant date if, for example, they can confirm that certain knowledge had been accepted in the field at the relevant date. In our view, Bethune and Khosla establishes that it was common general knowledge that the field was focussed on identifying prolyl

endopeptidases, as well as identifying naturally occurring glutenases as candidate enzymes that might help digest and detoxify gliadin peptides.

[23] With regard to the field as it related to the possibility of Papaya latex being useful for cleaving toxic peptides, the Response to the Preliminary Review letter refers to the following article as teaching away from caricain as the enzyme responsible: M. Messer et al., “Studies on the mechanism of destruction of the toxic action of wheat gluten in coeliac disease by crude papain” (1964) 5 Gut pages 295 to 303 [Messer et al.]. In our view, the person skilled in the art reading Messer et al. in view of their common general knowledge would understand that any teaching away was now in the past. Not only was Messer et al. published 45 years before the claim date but it was well known by the claim date that papaya latex was a rich source of the cysteine endopeptidases papain, chymopapain, glycyl endopeptidase and caricain, as well as containing small amounts of a glutaminyl cyclotransferase: see Azarkan et al.

[24] In this view, the person skilled in the art would consider evaluating all of the various proteolytic enzymes present in papaya latex for their ability to detoxify gluten, notwithstanding the hypothesis in Messer et al. that the detoxifying factor in crude papain may be an enzyme with glutamine cyclotransferase activity. This is consistent with one of the well known strategies in the field—screening for candidate proteases *in vitro*, based on activity in complex biological mixtures: Bethune and Khosla, page 3.

[25] Therefore, we do not agree that the person skilled in the art would consider that the field taught away from caricain. As such, we have not included this as part of the common general knowledge.

The claims on file

[26] There are 13 claims on file. Claims 1, 6, 12 and 13 are independent claims. The Preliminary Review letter, on pages 5 to 6, expresses the preliminary view that claim 1 is representative of the independent claims. Independent claim 1 reads as follows:

> 1. A composition for the prophylaxis or treatment of a condition related to gluten intolerance, the composition including a first component comprising from 5%

> w/w to 95% w/w partially purified caricain or a biologically active fragment or a or variant thereof, of total weight of the first component, said biologically active fragment or variant comprising an amino acid sequence which is at least 80% identical to SEQ ID NO:1 or SEQ ID NO:2, and a second component comprising at least one pharmaceutically acceptable carrier**.**

[27] Independent claims 6 and 12 are Swiss-style use claims directed to the same use as claim 1, however claim 6 specifies that caricain is purified and claim 12 further includes a pig intestinal enzyme extract in the composition used in the manufacture of a medicament. Independent claim 13 is directed to the same use as claim 1 but is written in the structure of a German-style use claim.

[28] The dependent claims 2 to 5 and 7 to 11 define further limitations regarding the source of caricain (claims 2 and 7), the amino acid sequence of caricain (claims 3 and 8), the inclusion of additional enzymes (claims 4, 5 and 9), the form of the composition (claim 10) and the amount of caricain (claim 11).

[29] In the absence of submissions from the Applicant, we adopt the above identification of claim 1 as being representative of the independent claims. Likewise, we adopt the above characterization of dependent claims 2 to 5 and 7 to 11 as providing further limitations with regard to: the source of caricain, the amino acid sequence of caricain, the inclusion of additional enzymes, the form of the composition and the amount of caricain.

Essential elements

[30] The Preliminary Review letter, on page 6, states 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 13 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, or a preferred embodiment. Although some claims recite a list of alternatives, we consider that the person skilled in the art would understand that the element represented by one of said alternatives is essential. In addition, there is no indication on the record before us that any claim elements are 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.

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

ARE THE CLAIMS ANTICIPATED?

[32] In our view, claims 1 to 13 on file define subject-matter that was publicly available before the claim date.

Legal Background

[33] Subsection 28.2(1) of the *Patent Act* requires claimed subject-matter to be new:

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

[34] In *Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 at paras 24 to 29 [Sanofi], the Supreme Court of Canada clarifies that there are two separate requirements that must be satisfied in order to show that a prior art document anticipates a claimed invention: prior disclosure and enablement.

[35] The prior disclosure requirement means that the prior art must disclose subject-matter which, if performed, would necessarily result in infringement of the invention as claimed. It is not necessary for the person performing the subject-matter to know they are infringing: Sanofi at para 25, citing a reference from *Synthon B.V. v SmithKline Beecham plc*, [2006] 1 All ER 685, [2005] UKHL 59 [Synthon] at para 22:

> [W]hether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such

> that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied.

[36] Further, at this stage, there is no room for trial and error or experimentation by the person skilled in the art. The prior art is simply read "for the purposes of understanding it": see Sanofi at para 25, citing Synthon.

[37] The enablement requirement means that the person skilled in the art would have been able to perform the invention as claimed without undue burden. Unlike the prior disclosure stage, at this stage the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work: see Sanofi at paras 26 to 27.

The claims on file are anticipated

[38] The Preliminary Review letter, on page 7, identifies the sole prior art document that was cited in the Final Action:

> On page 1, the Final Action cites the following document as relevant art:
>
> D1: Cornell and Stelmasiak AU 2008100719 A4 4 September 2008 (04-09-2008)

D1, Disclosure and Enablement

[39] The Preliminary Review letter, on pages 8 to 11, explains why in our preliminary view claims 1 to 13 are disclosed and enabled by D1:

> D1, Disclosure requirement
>
> On pages 2 to 3, the Final Action submits that claims 1 to 13 on file encompass subject-matter that was disclosed in D1, before the claim date, contrary to paragraph 28.2(1)(a) of the *Patent Act*. In particular, the Final Action disputes the arguments presented in the response dated November 28, 2019 regarding the presence of caricain in the composition of D1:
>
> > [Emphasis in original] In the correspondence of 28 November 2019, Applicant argues that the purification methods of Example 1 of the present application and Example 1 of D1 are different and result in preparations with different protection indices. Applicant argues that it "<u>cannot be said that the composition of D1 necessarily comprises caricain</u>, and (…)<u>D1 discloses no information concerning the amount of caricain in the composition as is recited in the present claims</u>" (page 4 of

10 in Applicant's correspondence of 28 November 2019). These arguments have been carefully considered but are not persuasive.

(…)

The fact that example 1 in D1 uses a different method of purification than example 1 of the present application is not relevant, because the present claims do not define any particular method by which the caricain is to be "partially purified". D1 states that "crude caricain" was prepared by dissolving papaya latex extract in water, adjusting the concentration of ammonium sulphate to 60%, collecting the resulting precipitate by filtration, dialyzing it, and freeze drying. This material was further enriched by chromatography on CM Sephadex™ using phosphate buffers with elution of the crude caricain with 0.7 M sodium chloride, followed by dialysis and freeze-drying, and assessed at a concentration of 6 mg/ml, resulting in a protection index of 71% using the RLL assay. These are all purification techniques, as acknowledged in the present application. Therefore, the "crude caricain" composition of D1 is partially purified.

(…)

The composition comprising caricain in D1 is protective in the RLL assay, and therefore, comprises an amount of caricain encompassed in the composition defined in present claims 1-3, 12, and 13.

(…)

Since the present application discloses the activity of caricain at levels as low as 4 μg, the composition comprising caricain disclosed in D1 comprises at least 4 μg of caricain. Therefore, the use of a purified caricain up to 15 mg in a composition of unknown total weight does not confer novelty on the use in any one of present claims 6-8 and 11.

D1 discloses a synergistic effect when using a 1:1 (6 mg/ml) ratio of pig intestinal extract to crude caricain, as compared to use of either pig intestinal extract (6 mg/ml) or crude caricain (6 mg/ml) alone in the RLL assay. These results are identical to those disclosed on page 30 of the present application. The use of bromelain for prophylaxis or treatment of a condition related to gluten intolerance is disclosed in D1. Therefore, the use of caricain, bromelain and/or an intestinal extract for prophylaxis or treatment of a condition associated with gluten intolerance, as defined in present claims 4, 5, and 9, is known in view of D1.

> Finally, D1 discloses that the composition comprising caricain is in the form of an enterically coated tablet or capsule, as defined in present claim 10.

The Response to the Final Action, on pages 2 to 3, did not contest the lack of novelty assessment and instead proposed an amended claim set that they submit is not anticipated by the D1 reference. We will consider the proposed claims in a separate section below.

We agree with the assessment in the Final Action that the crude caricain referred to in D1 is encompassed by the partially purified caricain defined in claims 1 to 5, 12 and 13.

Further, having reviewed D1, it is our preliminary view that D1 also describes on pages 11 and 17 to 18 embodiments of compositions comprising purified caricain for the prophylaxis or treatment of a condition related to gluten intolerance in a subject that are encompassed by claims 6 to 11.

Although D1 does not indicate that caricain is purified, in our preliminary view, the person skilled in the art would understand the reference to caricain to mean the protein in isolation. This view is supported, for example, by page 12 of D1 which refers to biologically active fragments of caricain, which may comprise “up to the complete protein, and may extend further to include additional sequences.” As explained in D1, “In each case, the key criterion is whether the fragment retains the ability to modify the toxic oligopeptides that contribute to a condition related to gluten intolerance.”

Likewise, analogues of caricain are said to denote a peptidase “that has an amino acid sequence that is substantially identical to the amino acid sequence of the respective naturally occurring enzyme and has at least part of the biologically activity of naturally-occurring caricain”. In our preliminary view, these statements in the description all suggest that the reference to caricain, absent any qualification, means the protein in isolation.

Regarding the amino acid sequence recited in the claims, we note that although D1 does not reference an amino acid sequence for caricain, this is an inherent feature of the protein which, in our preliminary view, would have formed part of the common general knowledge of the person skilled in the art. We base this view on the statements in D1, identified above, which refer to biologically active fragments and analogues of caricain in the context of their amino acid sequence.

We also agree with the submissions in the Final Action that D1 discloses the additional features recited in claims 2, 4, 5, 7, 9, 10 and 12. As explained on page 6 of D1, crude caricain can be purified from an extract derived from the species *Carica papaya*. In addition, D1 describes on pages 11 to 12 and 17 to 18 embodiments of compositions comprising caricain and bromelain and/or a pig intestinal enzyme

extract for prophylaxis or treatment of a condition associated with gluten intolerance. Likewise, D1 describes on pages 5 and 16, oral formulations comprising enteric coatings.

Finally, it is our preliminary view that D1 also describes embodiments of these compositions that can encompass partially purified caricain or purified caricain in percent by weight of the total weight of the compositions and amounts as defined in the claims. For example, page 8 of D1 describes compositions that can include papaya resin in an amount at least about one or a few percent to at least about ninety-five percent or more by weight of the total weight of the composition. Further, as explained on page 11 of D1, such compositions "may include papaya resin in combination with other enzymes capable of inactivating toxin gluten oligopeptides, including, but not limited to caricain". There are no indications as to the amount of caricain that can be included in the compositions. This means that the caricain present in the compositions can include five to ninety-five percent by weight of the total weight of the composition and in amounts including at least 15 mg.

Therefore, it is our preliminary view that D1 discloses subject-matter which, if performed by the person skilled in the art, would necessarily result in the infringement of claims 1 to 13 if a patent were to issue for the claimed subject-matter.

D1, Enablement requirement

D1 discloses compositions comprising partially purified caricain or purified caricain for the prophylaxis or treatment of a condition related to gluten intolerance. In our preliminary view, these teachings would enable the person skilled in the art to put into practice the subject-matter of claims 1 to 13 without difficulty or the need for undue experimentation.

Conclusion on anticipation

In light of the above analysis, it is our preliminary view that claims 1 to 13 are anticipated by D1 contrary to paragraph 28.2(1)(a) of the *Patent Act*.

[40] The Response to the Preliminary Review letter, on pages 6 to 10, disagrees that the person skilled in the art would read D1 as disclosing that purified caricain can be used to detoxify wheat gliadin. Although these submissions were made in the context of the obviousness inquiry, they are also relevant to our preliminary findings on anticipation above and will be addressed here.

[41] In particular, the Response to the Preliminary Review letter submits that the focus of D1 relates primarily to the use of a papaya oleoresin extract to detoxify a toxic digest of wheat gliadin. It further submits that, although D1 compares the

detoxifying effect of papaya oleoresin against crude caricain, it was not clear from D1 which enzymes in crude caricain are responsible for the detoxifying effect. Finally, it argues that the reference to “crude caricain” in the Example of D1 refers to crude preparations of a mixture of enzymes, and the term “caricain” was used throughout D1 in that context by the inventors of D1 (who are also the inventors of the present application). The Response to the Preliminary Review letter concludes that if D1 is read with this frame of reference, there is simply no teaching that caricain the enzyme can be used to detoxify already digested wheat gliadin.

[42] We agree that the focus of D1 is on demonstrating that papaya oleoresin extracts are capable of inactivating toxic oligopeptides that are produced following gluten ingestion. Further, we agree non-purified caricain is used in Example 1 of D1. However, we do not agree that this would exclude caricain as the enzyme responsible for the observed detoxify effect. Nor do we agree that the person skilled in the art would consider that the term “caricain” is synonymous with “crude caricain” in D1.

[43] As we indicated above in the Preliminary Review letter, the person skilled in the art would understand the reference to the term caricain to mean the protein in isolation. This view is supported, for example, by page 12 of D1 which refers to biologically active fragments of caricain, which may comprise “up to the complete protein, and may extend further to include additional sequences.” As explained in D1, “In each case, the key criterion is whether the fragment retains the ability to modify the toxic oligopeptides that contribute to a condition related to gluten intolerance.”

[44] Likewise, analogues of caricain are said to denote a peptidase “that has an amino acid sequence that is substantially identical to the amino acid sequence of the respective naturally occurring enzyme and has at least part of the biological activity of naturally-occurring caricain”. In our view, these statements in the description all suggest that the reference to caricain, absent any qualification, means the protein in isolation.

[45] Therefore, we also disagree with the conclusion from the Response to the Preliminary Review letter that there is no teaching in D1 that caricain the enzyme can be used to detoxify already digested wheat gliadin. Although Example 1 of D1

only compares the detoxifying effect of papaya oleoresin against crude caricain, this does not contradict the references throughout D1 which identify caricain as an enzyme that is capable of inactivating toxic gluten oligopeptides.

[46] Likewise, the reference in D1 that caricain can be used together with papaya oleoresin does not contradict the teaching that caricain alone is capable of detoxifying gluten peptides, nor does it mean that caricain should not be used alone. On the contrary, in our view, the following passage on page 18 of D1 contemplates the administration of caricain as a separate dosage:

> [Emphasis added] Caricain, bromelain and the intestinal extract may be administered together with papaya resin (or an analogue thereof) **or as separate dosages, as required**.

[47] In view of the above, we maintain that D1 discloses and enables the subject-matter of claims 1 to 13 on file.

[48] Therefore, we conclude that claims 1 to 13 are anticipated by D1 contrary to paragraph 28.2(1)(a) of *the Patent Act*.

ARE THE CLAIMS OBVIOUS?

[49] In our view, the claims on file define subject-matter that would have been obvious to the person skilled in the art in view of information that was publicly available before the claim date.

Legal Background

[50] Section 28.3 of the *Patent Act* requires that the subject-matter of a claim not be obvious to the person skilled in the art:

> 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 before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim 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.

[51] In Sanofi, the Supreme Court of Canada states 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?

The claims on file are obvious

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

[52] The person skilled in the art and the relevant common general knowledge have been identified as part of the purposive construction of the claims. Although in this context the information forming the relevant common general knowledge is identified using the publication date, this information is also considered common general knowledge at the claim date and is therefore relevant for assessing obviousness.

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

[53] The Preliminary Review letter, on page 12, identifies the inventive concepts of claims 1 to 13:

> In this assessment, we take into account all of the essential elements of the claims. In our preliminary view, the combination of essential elements of independent claims 1, 6 12 and 13 represents their inventive concepts as well.
>
> Our preliminary view is also that the elements of the dependent claims relating to the source of caricain, the amino acid sequence of caricain, the inclusion of additional enzymes, the form of the composition and the amount of caricain, as set out above, are part of the respective inventive concepts of dependent claims 2 to 5 and 7 to 11.

[54] In the absence of submissions from the Applicant, we adopt the above identification of the inventive concepts of the claims in this recommendation.

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

[55] The Preliminary Review letter, on page 12, identifies the differences between the inventive concepts of the claims and D1:

> For the purpose of anticipation we have already determined what has been disclosed and taught by D1.
>
> In our preliminary view the main difference between the inventive concept of the claims and D1 is that D1 does not explicitly disclose the amino acid sequence of caricain or a working embodiment wherein caricain has been purified.

[56] As explained above in the anticipation assessment, we do not agree with the position in the Response to the Preliminary Review letter regarding how the person skilled in the art would interpret D1. In our view, the person skilled in the art would consider that D1 discloses that caricain the enzyme can be used to detoxify already digested wheat gliadin and further contemplates the administration of caricain as a separate dosage.

[57] Therefore, we maintain that the main difference between the inventive concept of the claims and D1 is that D1 does not explicitly disclose the amino acid sequence of caricain or a working embodiment wherein caricain has been purified.

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?

[58] Although the Court in Sanofi provides a four-step approach for addressing the issue of obviousness, it is important to remember that the obviousness analysis is concerned with whether bridging the difference between the prior art and a second point constitutes steps that require any degree of invention: *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA 76 at para 65

> It may be helpful to keep in mind that the obviousness analysis asks whether the distance between two points in the development of the art can be bridged by the Skilled Person using only the common general knowledge available to such a person. If so, it is obvious. The first of those points is the state of the prior art at the relevant date. References in the jurisprudence to "the inventive concept", "the solution taught by the patent", "what is claimed" or simply "the invention" are attempts to define the second point.

[59] In the present case, what must be considered is whether it would have required any degree of invention from the person skilled in the art, based on the disclosure of D1 and the relevant common general knowledge, to use purified caricain, having the amino acid sequence of SEQ ID NO:1 or 2, in the prophylaxis or treatment of a condition related to gluten intolerance.

[60] The Response to the Preliminary Review letter, on pages 10 to 13, submits that D1, alone or in combination with the common general knowledge, would not lead the person skilled in the art directly and without difficulty to the subject-matter of the claims. The submissions are based on a characterization of D1 as teaching that the term "caricain" is synonymous with "crude caricain" and the papaya literature teaching that a mixture of enzymes being responsible for detoxifying gluten—not a single enzyme. In that context, the Response to the Preliminary Review letter submits the person skilled in the art would first need to believe, contrary to the thinking at the time, a single enzyme may be able to detoxify toxic oligopeptides. "Then an extensive research project would be required that purified and characterized every component of the "crude caricain" extract of D1."

[61] As indicated above, we do not agree that the person skilled in the art would consider that the term "caricain" is synonymous with "crude caricain" in D1. In our

view, the person skilled in the art would understand that the references to the term caricain, absent any qualification, mean the protein in isolation.

[62] Therefore, contrary to the characterization of D1 in the Response to the Preliminary Review letter, in our view, the person skilled in the art would consider that D1 specifically identifies caricain as an enzyme capable of inactivating toxic gluten oligopeptides that contribute to a condition related to gluten intolerance (pages 11, 12 and 17 to 18).

[63] Further, the person skilled in the art knows that caricain can be purified using conventional methods: Azarkan et al. and Buttle (page 8 of the instant description). Although the instant description refers to caricain that is at least partially purified using these methods, a review of each of these references discloses caricain has been “purified to apparent homogeneity” (page 230 of Azarkan et al.) and “isolation of fully active caricain” has been achieved (page 1131 of Buttle).

[64] Alternatively, as explained on pages 12 to 13 of D1, analogues of caricain “may be naturally occurring, such as an allelic variant or an mRNA splice variant, or they may be constructed using synthetic or recombinant techniques available to one skilled in the art.” In our view, this statement indicates that the amino acid sequence of caricain is part of the common general knowledge of the person skilled in the art. This is consistent with page 1131 of Buttle which discloses the recombinant expression and purification of caricain having the amino acid sequence of SEQ ID Nos: 1 and 2 was already known from Revell D.F. et al. (“Nucleotide sequence and expression in *Escherichia coli* of cDNAs encoding papaya proteinase omega from *Carica papaya*”, Gene 1993 127(2): 221 to 225).

[65] Therefore, it is our view that it would not have required any degree of invention from the person skilled in the art to use purified caricain, having the amino acid sequence of SEQ ID NO: 1 or 2, in the prophylaxis or treatment of a condition of gluten intolerance.

[66] Further, even if we were to accept that D1 only discloses the use of crude caricain, which we don’t, it remains that the person skilled in the art would have been motivated to use purified caricain instead of a crude extract on the basis of promising results of Example 1 and/or the disclosure of D1 as a whole. As

explained above, the common general knowledge includes screening for candidate proteases *in vitro*, based on activity in complex biological mixtures: Bethune and Khosla, page 3. In this view, the person skilled in the art would consider evaluating all of the various proteolytic enzymes present in crude caricain for their ability to detoxify gluten.

[67] With respect to the remaining dependent claims, as indicated above, the additional features relating to the source of caricain, the inclusion of additional enzymes, the form of the composition and the amount of caricain are all known from D1. Therefore, in our view, none of the features from the dependent claims would have required any degree of invention from the person skilled in the art.

Conclusion on obviousness

[68] In light of the above considerations, it is our view that the claims on file define subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to D1 in view of their common general knowledge, contrary to paragraph 28.3(a) of the *Patent Act*.

ARE CLAIMS 1, 3, 5, 6, 8 AND 10 TO 13 INDEFINITE?

[69] In our view, claims 1, 3, 5, 6, 8 and 10 to 13 on file are indefinite.

Legal Background

[70] 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.

[71] 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.

Claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite

[72] The Preliminary Review letter, on pages 15 to 17, explains why in our preliminary view claims 1, 3, 5, 6, 8 and 10 to 13 on file are indefinite:

> The Final Action, on pages 3 to 4, indicates that claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite in view of several clarity defects and also identifies various clerical errors:
>
> > [Emphasis in original] Claims 1, 6, and 13 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The composition is specified as “including” a first and second component, meaning additional components can be present, and the amount of partially purified caricain in the composition can be negligible. The first component **comprising** from 5% w/w to 95% w/w partially purified caricain (claims 1 and 13) or purified caricain (claim 6), or a biologically active fragment or a variant thereof, causes ambiguity as to the amount of caricain in the composition. In particular, because the caricain is partially purified, the first component inevitably comprises undefined compounds or contaminants ranging from 95% w/w to 5% w/w of the total weight of the first component. Therefore, reference to a composition comprising a **partially purified** caricain causes a lack of clarity. In claims 1, 6, and 13, it is unclear from the claim language if the “variant thereof” refers to caricain or the biologically active fragment of caricain. In claims 1, 6, and 13, a variant that is at least 80% identical to SEQ ID NO: 1 or 2 should be defined as having the same biological activity as SEQ ID NO: 1 or 2. In claims 1 and 13, the phrase “or a or variant” should be amended to “or a variant”
> >
> > Claims 3 and 8 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. It is unclear if the phrase “variant thereof” refers to caricain or the biologically active fragment of caricain. In claims 3 and 8, the variant that is at least 80% identical to SEQ ID NO: 1 or 2 should be defined as having the same biological activity as SEQ ID NO: 1 or 2. In claim 3, the phrase “a biologically active fragment or SEQ ID NO: 2, 1, or 2, or biologically active fragment or variant thereof” causes a lack of clarity. It appears that said phrase should be amended to “SEQ ID NO: 1 or 2, or the biologically active fragment or the variant thereof”. In claim 8, the elements “biologically active fragment” (first occurrence) and

> "variant" (first occurrence), are defined with indefinite articles, causing a lack of clarity as to whether they are intended to refer to the same elements defined in the claims or an additional element thereto.
>
> Claim 5 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The analogue or variant of bromelain must be defined as having the same activity as bromelain.
>
> In claims 6 and 13, the phrase "variant comprising an amino acid sequence" should be amended to "variant comprises an amino acid sequence".
>
> Claim 10 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The phrase "composition **includes** an enterically coated tablet or capsule" causes a lack of clarity. It is unclear if said phrase is intended to refer to a composition that is formulated as an enterically coated tablet or capsule, or the composition additionally comprises an enterically coated tablet or capsule.
>
> Claim 11 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. It is unclear if the composition defined in claims 6-10, upon which claim 11 depends, is a unit dose composition. Since the total weight of the composition is not defined in any one of claims 6-10, upon which claim 11 depends, the use of the composition comprising 15 mg of caricain lacks clarity as to the amount of caricain that is used in the medicament that is used to treat the subject having the condition related to gluten intolerance.
>
> Claim 12 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The element "condition related to gluten tolerance", is defined with an indefinite article, causing a lack of clarity as to whether it was intended to refer to the same element "condition related to gluten tolerance" as was previously defined in the claims or an additional element thereto. The phrase "the manufacture of a medicament **or** the prophylaxis" should probably read "the manufacture of a medicament **for** the prophylaxis".

The Response to the Final Action on pages 6 to 7 proposes the cancellation of claims 3, 5, 8 and 10 to 12 to render the clarity defects in respect of these claims moot. In addition, amendments to claims 1, 6 and 13 are proposed to address the ambiguity as to the amount of caricain in the composition. However, the Response to the Final Action disagrees that there is a lack of clarity regarding the identity of the "variant thereof" referred to in these claims. As worded, the claims require that the variant comprises an amino acid sequence which is at least 80% identical to SEQ ID NO: 1 or SEQ ID NO:2. Accordingly, a protein will qualify as a variant if it meets the sequence requirement, which could include variants of caricain or

> variants of biologically active fragments of caricain. The Summary of Reasons agrees that the lack of clarity defects are overcome in view of the arguments in the Response to the Final Action and the proposed amendments.
>
> Having reviewed claims 1, 3, 5, 6, 8 and 10 to 13, we agree that the clarity defects identified in the Final Action are present with the exception of the alleged ambiguity in claims 1, 3, 6, 8 and 13 regarding the variant referred to therein. In this instance, we agree with the submissions in the Response to the Final Action that a person skilled in the art would know that as long as the sequence requirement is met, the variant could be a variant of either caricain or a biologically active fragment of caricain. However, each of these claims suffers from other clarity defects as identified in the Final Action, therefore, it is our preliminary view that claims 1, 3, 5, 6, 8 and 10 to 13 do not comply with subsection 27(4) of the *Patent Act*.

[73] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claims 1, 3, 5, 6, 8 and 10 to 13 do not comply with subsection 27(4) of the *Patent Act*.

THE PROPOSED CLAIMS DO NOT REMEDY THE DEFECTS

[74] As indicated above, with the Response to the Preliminary Review letter the Applicant submitted a second set of proposed claims. According to pages 1 and 14 of the Response to the Preliminary Review letter, the second set of proposed claims substantially reflect the first set of proposed claims submitted with the Response to the Final Action and further address the indefiniteness and improper claim dependency defects noted in the Summary of Reasons and Preliminary Review letter, as well as the clerical errors noted in the Preliminary Review letter.

[75] Second proposed independent claims 1, 5, 9, 13, 16 and 19 recite a composition comprising, as the active ingredient, at least 15 mg of caricain and in an oral unit dose form. Second proposed dependent claims 2 to 4, 6 to 8, 10 to 12, 14, 15, 17, 18 and 20 to 22 define further limitations with regard to the first component of the composition, the timing of the administration of the composition and the activity of caricain.

[76] Having reviewed the second set of proposed claims submitted with the Response to the Preliminary Review letter, we consider that the subject-matter of the second set of proposed claims would comply with paragraph 28.2(1)(a) of the *Patent Act*. We also consider that the subject-matter of second proposed claims 1, 5, and 9

(corresponding to claims 1, 6 and 13 on file) would comply with subsection 27(4) of the *Patent Act*. Further, we agree that the second set of proposed claims no longer contain the indefiniteness or claim dependency defects or clerical errors that were present in the first set of proposed claims.

[77] However, for the reasons that follow we do not consider that the second set of proposed claims overcome the obviousness defect.

ARE THE SECOND SET OF PROPOSED CLAIMS OBVIOUS?

[78] In our view, the second set of proposed claims define subject-matter that would have been obvious to the person skilled in the art in view of information that was publicly available before the claim date.

The second set of proposed claims are obvious

[79] The limitations in the second set of proposed claims were also present in the first set of proposed claims, for which we provided the following analysis in the Preliminary Review letter on pages 19 to 21:

> As indicated above, the proposed amendments would introduce the following claim amendments:
>
> - specifying the composition is an oral unit dose form;
> - specifying the oral unit dose form is for administration at the start of each meal;
> - specifying the composition comprises at least 15 mg of caricain; and
> - specifying an activity of 7512 U caricain per mg of composition.
>
> With respect to the form of the composition and the timing of administration, we note that D1 refers to pharmaceutical compositions that are formulated to be compatible with their intended route of administration. Typically, the route of administration is oral because, as explained on page 14 of D1, “[i]t is advantageous to formulate oral compositions in dosage unit form for ease of administration and uniformity of dosage.” On page 18 of D1, administration with meals is given as an example of oral administration.
>
> With regard to determining a therapeutic dose of caricain for the prophylaxis or treatment of a condition related to gluten intolerance, D1 explains that oral

compositions in dosage unit form can be readily determined through standard pharmaceutical procedures for a person skilled in the art (pages 14 to 18):

> "Dosage unit form", as used herein, refers to physically discrete units suited as unitary dosages for the subject to be treated; each unit containing a predetermined quantity of active compound calculated to produce the desired therapeutic effect in association with the required pharmaceutical carrier. The toxicity and therapeutic efficacy of such compounds can be determined by standard pharmaceutical procedures including *in vitro* assays, cell cultures or experimental animals, e.g., for determining the LD_{50} (the dose lethal to 50% of the population) and the ED_{50} (the dose therapeutically effective in 50% of the population) depending on the compound studied.
>
> (…)
>
> Dosages for a given composition can be readily determined by those of skill in the art by a variety of means, such as measuring the biological activity of a given composition required to overcome the symptoms of gluten intolerance.
>
> The skilled artisan will appreciate that certain factors may influence the dosage and timing required to effectively treat a subject, including the activity of the specific compound employed, the age, body weight, general health, gender, and diet of the subject, the time of administration, the route of administration, the rate of excretion, any drug combination, the degree of expression or activity to be modulated, sensitivity to gluten, previous treatments and other diseases present.
>
> (…)
>
> The therapeutic effect can be measured in terms of clinical outcome or can be determined by immunological or biochemical tests. (…) Alternatively, one can look for a reduction in the severity of symptoms.

In light of the above, it is our preliminary view that the person skilled in the art would not have required any degree of invention to determine with routine experimentation a therapeutic dosage of caricain, as recited in the proposed claims, for preventing or treating conditions arising from gluten intolerance.

Further, the person skilled in the art knows that the specific activity of caricain is an inherent feature related to the purity of the enzyme, and as indicated above, methods of producing purified caricain, having the amino acid sequence of SEQ ID NO: 1 or 2, were part of the common general knowledge.

> It follows that the determination of a therapeutic dosage of caricain, having a specific activity as defined in the proposed claims, would not require any degree of invention from the person skilled in the art in view of their common general knowledge.
>
> Further, considering the above elements together with the subject-matter of the claims on file, it is our preliminary view that our reasoning and preliminary conclusions concerning the obviousness of the claims on file also apply to the proposed claims.
>
> Therefore, it is our preliminary view that it would not have required any degree of invention from the person skilled in the art to use a composition, comprising at least 15 mg of purified caricain, having the amino acid sequence of SEQ ID NO: 1 or 2 and a specific activity of at least 7512 U caricain per mg of composition, in the prophylaxis or treatment of a condition of gluten intolerance.
>
> Conclusion on obviousness
>
> In light of the above considerations, it is our preliminary view that the proposed claims define subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to D1 in view of their common general knowledge, contrary to section 28.3 of the *Patent Act*.

[80] The Response to the Preliminary Review letter did not address these claim elements. Therefore, considering the substantial similarity between the first set and second set of proposed claims and our conclusions concerning the obviousness of the claims on file, we adopt the foregoing reasoning and conclude that the second set of proposed claims define subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to D1 in view of their common general knowledge, contrary to paragraph 28.3(a) of the *Patent Act*. It follows that the second set of proposed claims do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS

[81] We have determined that claims 1 to 13 are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act* and that claims 1 to 13 are obvious contrary to paragraph 28.3(a) of the *Patent Act*.

[82] We have also determined that claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite contrary to subsection 27(4) of the *Patent Act*.

[83] In our view, the second set of proposed claims submitted with the Response to the Preliminary Review letter would not overcome the obviousness defect and are therefore 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

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

- claims 1 to 13 are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act*;
- claims 1 to 13 are obvious contrary to paragraph 28.3(a) of the *Patent Act*; and
- claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite contrary to subsection 27(4) of the *Patent Act*.

Christine Teixeira	Marcel Brisebois	Kerry Ferguson
Member	Member	Member

DECISION OF THE COMMISSIONER

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

- claims 1 to 13 are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act*;
- claims 1 to 13 are obvious contrary to paragraph 28.3(a) of the *Patent Act*; and
- claims 1, 3, 5, 6, 8 and 10 to 13 are indefinite contrary to subsection 27(4) of the *Patent Act*.

[86] 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 17 day of April, 2023.