Citation: Emmanuel E Egom (Re), 2024 CACP 5
Commissioner's Decision #1664
Décision du commissaire n^{o} 1664
Date: 2024-03-18

TOPIC:	B00	Ambiguity or Indefiniteness (incomplete)
	C00	Adequacy or Deficiency of Description

SUJET :	B00	Caractère ambigu ou indéfini (incomplet)
	C00	Caractère adéquat ou inadéquat de la description

Application No. 2889826
Demande nº 2 889 826

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,889,826 having been rejected under subsection 199(1) of the *Patent Rules*, has subsequently 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 unless necessary amendments are made.

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,889,826 which is entitled “Methods of treating pulmonary hypertension by administration of natriuretic peptide receptor C signaling pathway activators”. Emmanuel E. Egom 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 inform the Applicant by notice pursuant to subsection 86(11) of the *Patent Rules* that certain amendments to the claims are necessary to make the application allowable.

BACKGROUND

The application

[3] Canadian patent application 2,889,826 has a filing date of April 30, 2015 and has been open to public inspection since December 20, 2015.

[4] The rejected application relates to the use of an activator of natriuretic peptide receptor C (NPR-C) signaling for treating or preventing pulmonary hypertension in a human subject. In particular, the contemplated activator is a synthetic ring-deleted atrial natriuretic factor, c-ANF$_{4\text{-}23}$, that binds NPR-C and reduces intracardiac and/or pulmonary pressure.

[5] The application has 18 claims on file that were received in the Patent Office on March 21, 2022.

Prosecution history

[6] On January 31, 2023 a Final Action was written under subsection 86(5) of the *Patent Rules*. The Final Action indicated that the specification does not comply with subsection 27(3) of the *Patent Act* insofar as it relates to the subject-matter

of claims 1, 2, 4 to 10 and 12 to 17. The Final Action also indicated that claims 1 to 18 are indefinite and do not comply with subsection 27(4) of the *Patent Act* and that the description and claims are not numbered consecutively and do not comply with subsection 73(1) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019 (the former *Patent Rules*).

[7] The Response to the Final Action dated March 7, 2023 did not contest the insufficient disclosure, lack of clarity, or page numbering defects, and instead proposed an amended claim set, containing proposed claims 1 to 16 (proposed claims set-1), that was submitted to address the defects raised in the Final Action. However, following a telephone interview with the Examiner, which indicated that proposed claims set-1 does not overcome all of the defects raised in the Final Action, a voluntary amendment containing proposed claims 1 to 24 (proposed claims set-2) was submitted on May 26, 2023.

[8] On July 4, 2023 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 that explained that the rejection is maintained as proposed claims set-2 does not overcome all of the defects identified in the Final Action.

[9] In a letter dated July 5, 2023, 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 October 4, 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 February 14, 2024, the Panel sent a Preliminary Review letter which detailed our preliminary analysis and opinion that the specification, insofar as it relates to claims 1, 2, 4 to 10 and 12 to 17 on file, does not comply with subsection 27(3) of the *Patent Act*, that claims 1 to 18 on file are indefinite and do not comply with subsection 27(4) of the *Patent Act,* and that the specification does not comply with subsection 73(1) of the former *Patent Rules*.

[12] In addition, the Preliminary Review letter notified the Applicant that, in accordance with subsection 86(9) of the *Patent Rules*, an additional question arose as to whether claims 1, 2, 4 to 10 and 12 to 17 on file suffer from overbreadth. The Preliminary Review letter expressed our preliminary analysis and opinion that claims 1, 2, 4 to 10 and 12 to 17 on file suffer from overbreadth.

[13] The Preliminary Review letter also expressed the preliminary opinion that proposed claims set-2 would overcome the insufficient disclosure, overbreadth, clarity and page numbering defects but that there was a lack of clear differentiation in the scope of claims 3, 4, 14 and 23 and claims 5, 6, 15 and 24, respectively, of proposed claims set-2 and so these claims would not comply with subsection 27(4) of the *Patent Act*.

[14] Finally, the Preliminary Review letter provided the Applicant with an opportunity to make oral and/or written submissions.

[15] The Response to the Preliminary Review letter dated February 29, 2024 declined the opportunity for an oral hearing and further proposed another amended claim set, containing proposed claims 1 to 20 (proposed claims set-3), to address the defects raised in the Preliminary Review letter with respect to proposed claims set-2.

THE ISSUES

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

- whether the specification, insofar as it relates to claims 1, 2, 4 to 10 and 12 to 17 on file, is insufficient contrary to subsection 27(3) of the *Patent Act*;
- whether claims 1, 2, 4 to 10 and 12 to 17 on file suffer from overbreadth;
- whether claims 1 to 18 on file lack clarity contrary to subsection 27(4) of the *Patent Act*; and
- whether the pages of the specification are not numbered consecutively contrary to subsection 73(1) of the former *Patent Rules*.

[17] In addition, proposed claims set-3, submitted with the Response to the Preliminary Review letter, has also been considered.

PURPOSIVE CONSTRUCTION

Legal Background

[18] 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.

[19] 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

[20] The Preliminary Review letter, on pages 4 to 7, stated the following with regard to the identity of the person skilled in the art and their expected common general knowledge:

> *The person skilled in the art and the relevant common general knowledge*
>
> On page 3, the Final Action identifies the person skilled in the art and the relevant common general knowledge:
>
> > The posita to whom the application is directed can be characterized as a team practicing in the field of molecular biology of natriuretic

peptides, protein chemistry and a clinical vascular medicine specialist.

Said team possesses the following cgk at the filing date (April 30, 2015) of the present application:

1) Natriuretic peptides are a family of three polypeptide hormones termed atrial natriuretic peptide (ANP), brain natriuretic peptide (BNP), and C-type natriuretic peptide (CNP),

2) The three peptides are structurally related,

3) There are three Natriuretic peptide receptors: NPR-A, NPR-B and NPR-C,

4) NPR-C binds to all three natriuretic peptides,

5) NPR-C is coupled to adenylyl cyclase inhibition through inhibitory guanine nucleotide regulatory protein (Gi), and

6) CNP can interact with NPR-C and inhibit adenylyl cyclase activity through an inhibitory guanine nucleotide regulatory protein.

Neither the Response to the Final Action nor the voluntary amendment letter dated May 26, 2023 contest or comment on these characterizations of the person skilled in the art and their relevant common general knowledge. Further, the Applicant does not propose any additional considerations with regard to either the person skilled in the art or the relevant common general knowledge in these responses.

Regarding the person skilled in the art, we note that several court decisions have provided additional context for their identification. For example, the Supreme Court of Canada explained that although the person skilled in the art is deemed to have no scintilla of inventiveness or imagination, a patent specification is addressed to “skilled individuals sufficiently versed in the art to which the patent relates to enable them on a technical level to appreciate

the nature and description of the invention": Whirlpool at para 53. Moreover, "in the case of patents of a highly technical and scientific nature, that person may be someone possessing a high degree of expert scientific knowledge and skill in the particular branch of science to which the patent relates": Consolboard v MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504 at page 525.

In addition, the person skilled in the art can represent a composite of scientists—highly skilled and trained persons who conduct scientific research to advance knowledge in an area of interest—and researchers: Bayer Aktiengesellschaft v Apotex Inc [1995] 60 CPR (3d) 58 at page 79

> The notional skilled technician can be a composite of scientists, researchers and technicians bringing their combined expertise to bear on the problem at hand: "This is particularly true where the invention relates to a science or art that transcends several scientific disciplines." (Per Wetston J. in Mobil Oil Corp. v. Hercules Canada Inc. (unreported, September 21, 1994, F.C.T.D., at p. 5 [now reported 57 C.P.R. (3d) 488 at p. 494, 82 F.T.R. 211].)

With the above considerations in mind and having reviewed the specification as a whole, we consider that the characterization of the person skilled in the art presented in the Final Action is reasonable. For example, para [0001] of the present description identifies the field of the invention as relating to "methods of treating P[ulmonary] H[ypertension] and disorders related to vasculopathy by administration of NPR-C signaling pathway activators." Further, the subject-matter of the claims on file relates to the use of an activator of NPR-C signaling for treating pulmonary hypertension in a human subject, wherein the activator is C-type atrial natriuretic factor (cANF) or a functional analog thereof.

However, given the technical field to which the present patent application relates and the subject-matter of the claims on file, we would further add that, in our preliminary view, this team is familiar with the diagnosis and

treatment of pulmonary hypertension as well as the underlying conditions that can lead to pulmonary hypertension.

Regarding the identification of the common general knowledge, it is well established that the common general knowledge is limited to knowledge which is generally known by persons skilled in the field of art or science to which a patent relates: Apotex Inc v Sanofi–Synthelabo Canada Inc, 2008 SCC 61 at para 37 [Sanofi]; Free World Trust at para 31. Accordingly, the common general knowledge is with respect to the subset of patents, journal articles and technical information which is generally acknowledged by persons skilled in the art as forming part of the common general knowledge in the field to which a patent relates.

Established reference works (such as textbooks, review articles, handbooks, etc.) or demonstrated commonality of certain knowledge in a number of disclosures in the field are relevant to the inquiry: see the Manual of Patent Office Practice (CIPO) at 12.02.02c, revised October 2019.

Furthermore, it is our preliminary view that information in the present specification may be evidence of the common general knowledge as it could be reasonable to consider general or broadly worded assertions of conventional practice or knowledge as common general knowledge (see Corning Cable Systems LLC v Canada (Attorney General), 2019 FC 1065 and Newco Tank Corp v Canada (Attorney General), 2015 FCA 47).

Having reviewed the specification, as well as the references cited therein, we are of the preliminary view that the information regarding natriuretic peptides and their receptors as set out in the Final Action would have been generally known by the person skilled in the art as defined above who is “sufficiently versed in the art to which the patent relates to enable them on a technical level to appreciate the nature and description of the invention”: Whirlpool at para 53.

Further, based on certain points in the background of the description and the relevant scientific literature, in our preliminary view, the common general knowledge of the person skilled in the art would also include the following:

- Pulmonary arterial hypertension is a progressive lung disorder which is characterized by sustained elevation of pulmonary artery pressure (para [0002] of the description);
- Patients can be sub categorized into three groups: those with idiopathic, familial and associated pulmonary arterial hypertension (para [0004] of the description);
- Despite advances in therapy of pulmonary arterial hypertension there is no cure and the majority of patients continue to progress to right ventricular failure (para [0006] of the description);
- Studies with the ring deleted ANP analogue, $cANF_{4-23}$ (cANF), which demonstrated its ability to function as a specific and selective agonist of NPR-C appear to be the basis for the classification of NPR-C as a "clearance receptor" of atrial natriuretic factor (paras [0008] and [0014] of the description, Maack et al., Science, Volume 238, pages 675 to 678, 1987 [Maack 1987] cited in para [0008] of the description); and
- In addition to $cANF_{4-23}$, other ring-deleted analogs of atrial natriuretic factor which only interact with NPR-C are known (reviewed in Bovy, Medicinal Research Reviews, Volume 10, Issue 1, pages 115 to 142, 1990 [Bovy]; Maack, Annual Review of Physiology, Volume 54, pages 11 to 27, 1992 [Maack 1992]; and von Geldern, Current Opinion on Therapeutic Patents, Volume 2, Issue 12, pages 2087 to 2101, 1992 [von Geldern]).

[21] The Response to the Preliminary Review letter did not contest or comment on these characterizations of the person skilled in the art and the relevant common general knowledge. Accordingly, we adopt the above characterizations for our final review.

The claims on file

[22] There are 18 claims on file. Claims 1, 2, 10, 11 and 18 are the independent claims and read as follows:

> 1. A use of a therapeutically effective amount of an activator of Natriuretic Peptide Receptor-C (NPR-C) signaling for treating or preventing pulmonary hypertension in a human subject, wherein the activator of NPR-C signaling is C-type atrial natriuretic factor (cANF) or a functional analog thereof, and wherein cANF or the functional analog thereof binds the NPR-C and binding of cANF or the functional analog thereof to the NPR-C reduces intercardiac and/or pulmonary pressure.
>
> 2. A use of a therapeutically effective amount of an activator of Natriuretic Peptide Receptor-C (NPR-C) signaling in the manufacture of a medicament for treating or preventing pulmonary hypertension in a human subject, wherein the activator of NPR-C signaling is C-type atrial natriuretic factor (cANF) or a functional analog thereof, and wherein cANF or the functional analog thereof binds the NPR-C and binding of cANF or the functional analog thereof to the NPR-C reduces intercardiac and/or pulmonary pressure.
>
> 10. A pharmaceutical composition comprising an activator of Natriuretic Peptide Receptor-C (NPR-C) signaling and a pharmaceutically acceptable diluent for use in the treatment or prevention of pulmonary hypertension in a human subject, wherein the activator of NPR-C signaling binds the NPR-C and wherein binding of cANF or the functional analog thereof to the NPR-C reduces intercardiac and/or pulmonary pressure.
>
> 11. A pharmaceutical composition comprising C-type atrial natriuretic factor (cANF) and a pharmaceutically acceptable diluent for use in the treatment or prevention of pulmonary hypertension in a human subject.

18. A commercial package comprising C-type atrial natriuretic factor (cANF) and instructions for its use in the treatment or prevention of pulmonary hypertension in a human subject.

[23] The dependent claims 3 to 9 and 12 to 17 define further limitations regarding the activator (claim 3), the condition pulmonary hypertension is associated with (claims 4 and 12) and the type of pulmonary hypertension (claims 5 to 9 and 13 to 17).

Terms requiring clarification

[24] The Preliminary Review letter, on page 9, stated the following with regard to the meaning of the expression “C-type atrial natriuretic factor (cANF)” and the term “cANF” as used in the claims:

> As indicated above, purposive construction is used to interpret the meaning of the terms and expressions of a claim. In our preliminary view, the meaning of the expression “C-type atrial natriuretic factor (cANF)” and the term “cANF” as used in the claims requires clarification as a proper understanding of their meaning impacts our analyses. The expression “C-type atrial natriuretic factor” is not explicitly defined in the description as being an acronym for “cANF”. However, consistent with the common general knowledge identified above, the description indicates that the term “cANF” refers to the ring-deleted ANP analogue $cANF_{4\text{-}23}$ (see para [0008] of the description and review article by Rose and Giles). Further, the description identifies “**the** synthetic C-type atrial natriuretic factor (cANF)” [Emphasis added] as a synthetic analog of the NPR-C signaling pathway (see para [00016]). Taking these two references to “cANF” into account and the lack of an indefinite article preceding the expression “C-type atrial natriuretic factor (cANF)”, in our preliminary view, the person skilled in the art would readily understand the expression “C-type atrial natriuretic factor (cANF)” and the term “cANF” are meant to be synonymous with the ring-deleted ANP analogue $cANF_{4\text{-}23}$.

[25] The Response to the Preliminary Review did not contest or comment on the above preliminary views regarding the meaning of the expression “C-type atrial natriuretic factor (cANF)” and the term “cANF”. Accordingly, we adopt the above interpretation of said expression and term for our final review.

Essential Elements

[26] 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.

[27] The Preliminary Review letter, on pages 9 to 10, 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 18 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. Although some of the claims express a list of alternatives, it is our view that the person skilled in the art would understand that, when any one of these alternatives is chosen they are essential for that particular embodiment. Therefore, our preliminary view is that the person skilled in the art would consider all of the elements in the claims to be essential.

[28] The Response to the Preliminary Review did not contest or comment on the above identification of the essential elements of the claims on file. Accordingly, we adopt the above identification of the claim elements that are essential for our final review.

SUFFICIENCY OF DISCLOSURE AND OVERBREADTH

Legal Background

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

> 27(3) The specification of an invention must:
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it.

[30] A determination of whether the specification complies with paragraphs 27(3)(a) and 27(3)(b) of the *Patent Act* requires that three questions be answered: What is the invention? How does it work? Having only the specification, can the person skilled in the art produce the invention using only the instructions contained in the disclosure?: Teva Canada Ltd v Novartis AG, 2013 FC 141 citing Teva Canada Ltd v Pfizer Canada Inc, 2012 SCC 60 [Teva] and Consolboard v MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504 at 520 [Consolboard].

[31] With respect to this third question, “it is necessary that no additional inventive ingenuity be required in order to make the patent work”: Aventis Pharma Inc v Apotex Inc, 2005 FC 1283 at para 172. A patent will not be invalid for insufficient disclosure where routine experimentation is required of the person skilled in the art, but the Supreme Court of Canada has held that a disclosure is insufficient if the specification “necessitates the working out of a problem”: Idenix Pharmaceuticals, Inc v Gilead Pharmasset LLC, 2017 FCA 161 at para 19, citing Pioneer Hi-Bred v Canada [1989] 1 SCR 1623 at 1641.

[32] The principles and authorities laid out above primarily relate to the concept of sufficiency (or insufficiency) of disclosure.

[33] Another related concept is overbreadth (or overclaiming). The concept of overbreadth stems from subsections 27(3) and 27(4) of the *Patent Act*, and is a consequence of the bargain theory: Western Oilfield Equipment Rentals Ltd v M-I LLC, 2021 FCA 24, at paras 129 and 130. Overbreadth may overlap with other grounds of invalidity but overbreadth is a distinct ground of invalidity. Where a claim is broader than the description, it may fail for overbreadth, but it may also fail because the description does not adequately describe how to put it into practice.

[34] Overbreadth could be found because a claim is broader than the invention disclosed in the specification or it is broader than the invention made. To determine whether a claim is overbroad, it must be assessed whether the claim reads fairly on what the patent application discloses in the description and the drawings and whether the claim is too wide and claims more than what was invented. In this regard, this determination does not require that the patent application describe all possible embodiments of the claims as the claims may be broader than the embodiments disclosed in the description, which are considered examples of what is protected by the patent's monopoly: Angelcare Canada Inc v Munchkin Inc, 2022 FC 507 at para 452. However, there is a limit to how much broader the claims can be relative to the described embodiments: Les Laboratoires Servier v Apotex Inc, 2019 FC 616 at para 209.

[35] Considerations such as what exactly is encompassed by the scope of the claims and what is disclosed in the description are relevant to both overbreadth and insufficiency. If the claims do not read fairly on what the patent application discloses in the description and the drawings, then the claims may encompass subject-matter that is more than what was invented or adequately disclosed.

[36] Further, it is not enough for the disclosure to teach how to make the preferred embodiment. The disclosure must teach the person skilled in the art how to put into practice all the claimed embodiments of the invention, and without exercising

inventive ingenuity or undue experimentation: Seedlings Life Science Ventures, LLC v Pfizer Canada ULC, 2021 FCA 154 at para 68.

Analysis

[37] The Preliminary Review letter, on pages 12 to 16, explained that in our preliminary view the specification fails to provide an enabling disclosure for all cANF functional analogs encompassed by claims 1, 2, 4 to 10 and 12 to 17 on file and, independently of this view, claims 1, 2, 4 to 10 and 12 to 17 on file suffer from overbreadth:

> *Correct and full description, enablement and overbreadth of a cANF functional analog*
>
> The Final Action indicates on pages 3 to 7 that the subject-matter of claims 1, 2, 4 to 10 and 12 to 17 is not sufficiently disclosed:
>
> > The description does not correctly and fully describe the invention, and its operation or use, and does not comply with subsection 27(3) of the *Patent Act*. Specifically, the structural nature that encompasses the genus of macromolecules defined as “activator of NPR-C signaling”, more specifically “cANF analog”, is not sufficiently disclosed over the entire scope in the originally filed application. The description teaches a single representative species with any structural particularity, cANF, that may be effective to treat PH. No cANF analogs are disclosed. Therefore subsection 27(3)(a) of the *Patent Act* is not complied with. Furthermore, undue experimentation would be required by a posita to identify a product within said genus of macromolecules that would be effective for the treatment of a pulmonary hypertension in a subject, contrary to subsection 27(3)(b) of the *Patent Act*. As a consequence, the subject matter of claims 1, 2, 4–10 and 12–17 is not sufficiently disclosed in the originally filed application in contravention of subsection 27(3) of the *Patent Act*.

It should be noted that reference to the broad “activator of NPR-C signaling” made above as opposed to only a functional analog of the specific product cANF is because of the lack of clear definition for what said activation is in independent claim 10 versus independent claims 1, 2, 11 and 18. Based on the claim language of the other independent claims and the second paragraph on page 3 of the Applicant’s correspondence dated 21 Marc[h] 2022, the Examiner would surmise that “cANF or analog thereof” was intended.

[…]

The Examiner does not believe his assertion, based on the *Teva* and sufficiency of disclosure vis a vis subsection 27(3) of the *Patent Act*, is out of line with the facts as presented with the originally filed application currently under examination as suggested by the Applicant. Superficially, the *Teva* case and the instant application can be differentiated because they concern different subject matter e.g. different products with different purported mechanisms of action. Where the two are not differentiated is that both failed to properly disclose the claimed invention. In the *Teva*, the Court deemed undue experimentation was required to determine which of the few exemplified embodiments were effective at treating erectile dysfunction. In the present application, no actual cANF analogs are described beyond a mere desired result (i.e. no structural particularity). In this respect, undue experimentation would be required to identify a cANF functional analog that can bind NPR-C and reduce intracardiac pressure and/or pulmonary pressure. It is not clear how *Teva* differs from the circumstances of the present application.

As summarized by the Applicant above with respect to Teva, because the disclosure did not identify which compound was effective, the public would have to complete a research project in order to determine which compound was actually effective to treat erectile dysfunction. This is no different than the case at hand. No cANF functional analog is disclosed in the present application. No

guidance is given with respect to specific changes to cANF that can be made to produce a functional analog of cANF that can bind NPR-C and reduce intracardiac pressure and/or pulmonary pressure.

Turning to *Consolboard*, which the Applicant believes is the authoritative case with respect to sufficiency of disclosure, the Examiner believes his argument is consistent with *Consolboard*. Specifically, the originally filed application fails to sufficiently disclose what the invention is with respect to cANF analogs. Said analogs are merely defined by a desired result, namely, a compound that can bind NPR-C and reduce intracardiac pressure and/or pulmonary pressure. No analogs are described with any structural particularity. No guidance is disclosed with respect to, for example, how cANF can be modified such that the resultant modified product can bind NPR-C and reduce intracardiac pressure and/or pulmonary pressure. This necessitates the Applicant's stated "research project" to identify what modifications are effective.

The present description provides an assay to test whether binding of a cANF functional analog candidate reduces intracardiac pressure and/or pulmonary pressure. As well, NPR-C binding assays are known in the art. Furthermore, standard procedures to modify compounds are known. However, these points do not overcome the fact that what the invention is (cANF functional analog) is not disclosed with sufficient structural particularity and that undue experimentation would be required to make the invention. *Teva* clearly indicates that experimentation that may be allowed to satisfy subsection 27(3) is very limited.

In view of the Examiner's arguments above, the subject matter of claims 1, 2, 4–10 and 12–17 does not comply with subsection 27(3) of the *Patent Act*.

The Response to the Final Action and the voluntary amendment dated May 26, 2023 do not contest the above views and instead indicate that the proposed claims have been amended to refer to "a ring deleted atrial

natriuretic peptide analog", support for which is found in the specification at page 4 and 5 and in Examples 1 and 2.

Having reviewed the specification as a whole from the perspective of the person skilled in the art identified above, we understand that the description teaches that NPR-C knockout (NPR-$C^{-/-}$) mice are prone to pulmonary arterial hypertension and, therefore, represent an experimental model for pulmonary arterial hypertension (para [00036]). As in the Final Action, we also note that the description discloses relevant exemplary embodiments wherein the ring-deleted atrial natriuretic factor, cANF, a known selective agonist NPR-C, was demonstrated to reduce intracardiac and/or pulmonary pressure in NPR-$C^{+/+}$ mice. On this basis, the description proposes that activators of the NPR-C signaling pathway, such as cANF, can be used to prevent or treat NPR-C related pulmonary arterial hypertension.

Although the specification teaches that the NPR-$C^{-/-}$ mice can be used to screen for candidate agents for use in treating or relieving the symptoms of pulmonary hypertension (paras [00018] and [00036]), these candidate agents are necessarily outside the scope of the claims which require a functional analog that can bind NPR-C and reduce intracardiac pressure and/or pulmonary pressure. The specification does not provide any details or specific guidance to the person skilled in the art as to how to obtain the contemplated cANF functional analogs and no cANF functional analogs possessing the functional characteristics defined in the claims are described with any structural particularity.

Further, as noted in the Final Action, said analogs are merely defined by a desired result, namely a compound that can bind NPR-C and reduce intracardiac pressure and/or pulmonary pressure. In the absence of any structural features, the cANF functional analog is broadly defined by a functional description of its activity i.e. binding to NPR-C and reducing intracardiac and/or pulmonary pressure. Notably, the only activator of NPR-C signaling which the description discloses with particularity is cANF. However, the description leaves open the possibility that any cANF functional analog, regardless of structure, could be encompassed within the

scope of the invention. In our preliminary view, the level of experimentation and testing, as detailed in the Final Action, that would be required to put into practice all of the claimed embodiments of the invention and identify all cANF functional analogs goes beyond routine experimentation. These gaps with respect to the identification of the encompassed cANF functional analogs are not filled by the common general knowledge.

In view of the foregoing, it is our preliminary view that the specification fails to provide a correct and full description of all cANF functional analogs which exhibit these particular functional characteristics. Further, it is our preliminary view that the specification fails to enable the person skilled in the art to practice the invention without exercising undue experimentation to identify all cANF functional analogs that possesses the functional characteristics defined in the claims.

Further, and on the basis of the same considerations, it is our preliminary view that claims 1, 2, 4 to 10 and 12 to 17 do not read fairly on what the application discloses in the description and drawings with respect to any activator of NPR-C signaling, other than cANF, that could bind NPR-C and reduce intracardiac and/or pulmonary pressure.

Conclusion on sufficiency of disclosure and overbreadth

In view of the above analyses, it is our preliminary view that the specification fails to provide an enabling disclosure for all cANF functional analogs encompassed by claims 1, 2, 4 to 10 and 12 to 17 and does not comply with subsection 27(3) of the *Patent Act* in respect of this subject-matter and, independently of this view, claims 1, 2, 4 to 10 and 12 to 17 suffer from overbreadth.

[38] The Response to the Preliminary Review did not contest or comment on the above preliminary determinations that the specification fails to provide an enabling disclosure for all cANF functional analogs encompassed by claims 1, 2, 4 to 10 and 12 to 17 on file and, independently of this view, that claims 1, 2, 4 to 10 and 12 to 17 on file suffer from overbreadth.

[39] Therefore, we maintain the foregoing reasoning and conclude that the specification fails to provide an enabling disclosure for all cANF functional analogs encompassed by claims 1, 2, 4 to 10 and 12 to 17 on file and does not comply with subsection 27(3) of the *Patent Act* in respect of this subject-matter and, independently of this view, claims 1, 2, 4 to 10 and 12 to 17 on file suffer from overbreadth.

INDEFINITENESS

Legal Background

[40] 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.

[41] 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

[42] The Preliminary Review letter, on pages 17 to 20, explained that in our preliminary view we agreed with the analysis presented in the Final Action that claims 1 to 18 on file suffer from ambiguity and indefiniteness:

> The Final Action, on pages 7 to 9, indicates that claims 1 to 18 are indefinite and do not comply with subsection 27(4) of the *Patent Act*:
>
> > Claims 1, 2, 4–10 and 12–17 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. An activator of NPR-C signaling, including a cANF functional analog, is a type of chemical compound and therefore should be defined in the same manner as any other chemical compound, i.e. in terms of its structural formula, in terms of the process by which it is made, or in terms of physical or chemical properties, which serve to uniquely and unambiguously distinguish the activator from all other chemical compounds.
> >
> > It should be noted that the above explanation broadly includes “an activator of NPR-C signaling” and is not restricted merely to a “cANF functional analog” because the expression “wherein the activator of NPR-C signaling binds the NPR-C and wherein binding of cANF or the functional analog thereof…” in claim 10 does not explicitly and unambiguous recite that an activator of NPR-C signaling is cANF or a functional analog thereof. Judging by the wording of independent claims 1, 2 and 11 and the second paragraph on page 3 of the Applicant’s correspondence dated 21 March 2022, it seems that the activator recited in claim 10 was meant to be restricted to cANF or a functional analog thereof, however, this must be clarified.
> >
> > This defect was part of the Office action dated 2 February 2022.
> >
> > The Applicant submits in the correspondence dated 21 March 2022 the Examiner acknowledges that cANF is clearly and unambiguously defined and contends that a functional analog of cANF is not defined as there are no structural limitations. Furthermore, the amended independent claims define the functional analog as being able to

bind the NPR-C, and that binding of the functional analog of cANF to NPR-C results in reduction of intercardiac and/or interpulmonary pressure. Thus, there are limitations included in the amended claims that clearly define the functional properties of the cANF functional analog and exclude products such as CNP which can bind NPR-C.

The Applicant further submits that the person of skill in the art would understand what is encompassed by “a functional analog of cANF” and would understand that a functional analog of cANF is a molecule that shares the functional properties of cANF. The required functional properties are clearly recited in the amended claims and include the ability of the functional analog of cANF to bind the NPR-C wherein binding of the functional analog of cANF to the NPR-C reduces intercardiac and/or pulmonary pressure. As outlined above with respect to sufficiency of description, the Applicant submits that the person of skill in the art would know how to test whether a cANF analog binds the NPR-C and reduces intercardiac and/or pulmonary pressure using assays that are known in the art and/or disclosed in the specification. Accordingly, the scope of the claim is clear.

The Examiner has considered these arguments but does not find them persuasive.

In Free World Trust v. Électro Santé Inc. 2000 SCC 66 (“Free World Trust”) and Whirlpool Corp. v. Camco Inc. 2000 SCC 67 (“Whirlpool”), the Supreme Court outlined that purposive construction is performed by the court to objectively determine what the person skilled in the art would, as of the date of publication of the patent application and on the basis of the particular words or phrases used in the claim, have understood the applicant to have intended to be the scope of protection sought for the disclosed invention. Furthermore, Free World states “[B]y 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 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."

In this respect, when one turns to the description to construe subject matter defined by an activator of NPR-C signaling, one finds that a single structurally distinguishable product, cANF is clearly and unambiguously defined. However, no functional cANF analogs, which fall under the broader category of activators of NPR-C signaling, are clearly and unambiguously defined. In fact, there is no definition for what the scope of cANF analogs should be, in terms of structure and function. A comprehensive patent application contains a "Definitions" section so as to put "fences around the fields of his monopoly" that are defined by words or phrases of a claim. In this respect, the same words or phrases found in different patent applications are not universally defined for all patent applications. The Applicant gets to define his "fenced-in monopoly". Although the posita may have an idea of an embodiment that falls within the "fenced-in monopoly", the posita would not be able to know the boundaries of said monopoly, particularly without a clear and unambiguous definition disclosed in the originally filed application.

Patent applications exist whereby subject matter disclosed in the description and that falls under a phrase such as "functional analog" are described as any product, including a product without any structural restriction or particularity, a product having structural similarity of varying degrees to an exemplified embodiment and/or derivatized products (e.g. pegylated product) that have a particular function. Without a clear demarcation of what such "functional analogs" look and function like, the posited cannot determine where to place the "fence" to define the patent monopoly being sought. The reader would not know what the product looks like. Such a "functional analog" may already exist in the art but cannot be deciphered unless further experimentation was done to test whether it falls within the scope intended for said product. The reader must

unduly determine whether a give product falls within the intended fenced-in monopoly.

Turning to the present independent claims (excluding claim 10 which is ambiguous as described above), they recite cANF analogs that are not defined by any distinguishing structural feature. If the description does not adequately define the “fence” in a distinguishing structural manner to put around subject matter encompassed by a functional analog of cANF, a reader would not know whether he is trespassing without further undue ingenuity and effort.

For these reasons, claims 1, 2, 4–10 and 12–17 are ambiguous and do not satisfy subsection 27(4) of the *Patent Act*.

Claims 1–3, 11 and 18 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. Subject matter defined by the phrase “C-type atrial natriuretic factor (cANF) lacks clarity. The designation “cANF” according to page 4 lines 16–24 and cgk teaches that cANF is a specific compound, that is, a ring deleted atrial natriuretic peptide analog. “C-type atrial natriuretic factor” is not full name of cANF. This creates ambiguity. It should also be noted that the expression “C-type atrial natriuretic factor” is neither defined in the originally filed application or has a universal meaning in the general field of the invention.

Claims 1, 2 and 10 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The word “intercardiac” lacks clarity and appears to be a typographical error as such a word does not appear to exist upon a simple google search, nor is it defined in the originally filed application. Given that support in the application appears to be derived from right ventricular systolic pressure studies, it seems that the word “intracardiac” was intended.

The Response to the Final Action and the voluntary amendment letter dated May 26, 2023 do not contest the above views and instead indicate that the proposed claims contain amendments that address the identified clarity issues.

> Having reviewed claims 1 to 18, we agree with the Final Action that these claims suffer from ambiguity and indefiniteness for the reasons reproduced above. Therefore, it is our preliminary view that claims 1 to 18 do not comply with subsection 27(4) of the *Patent Act*.

[43] The Response to the Preliminary Review did not contest or comment on the above preliminary views that claims 1 to 18 on file suffer from ambiguity and indefiniteness.

[44] Therefore, we maintain the foregoing reasoning and conclude that claims 1 to 18 on file suffer from ambiguity and indefiniteness and do not comply with subsection 27(4) of the *Patent Act*.

PAGE NUMBERING

Legal Background

[45] Subsection 50(1) of the *Patent Rules* requires that:

> The pages of the specification must be numbered consecutively.

[46] Section 193 of the *Patent Rules* provides an exception: where an application was filed between October 1, 1996 and October 30, 2019, the Applicant may meet the requirements of subsection 73(1) of *the Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019 (the former *Patent Rules*) instead of subsection 50(1) of the current *Patent Rules*. Nonetheless, this alternative would still require the pages of the description and claims to be numbered consecutively.

Analysis

[47] The Preliminary Review letter, on pages 17 to 18, explained that in our preliminary view we agreed with the analysis presented in the Final Action that

the specification does not comply with subsection 73(1) of the former *Patent Rules*:

> The Final Action, on page 9, indicates that the present claim pages are not numbered and do not comply with subsection 73(1) of the former *Patent Rules*:
>
> > Pursuant to section 193 of the *Patent Rules*, the pages of the description and claims are not numbered consecutively and do not comply with subsection 73(1) of the former *Patent Rules*. The description pages are numbered 1 through 19. The pages containing present claims 1–18 submitted with the Applicant's correspondence dated March 21, 2002 are not numbered. These claim pages should be numbered pages 20 and 21, respectively.
>
> The Response to the Final Action and the voluntary amendment letter dated May 26, 2023 do not contest the above views and instead indicate that the proposed claim pages have been numbered consecutively with the pages of the description.
>
> Having reviewed the page numbering of the specification, we preliminarily agree for the same reasons as outlined in the Final Action. Therefore, it is our preliminary view that the specification does not comply with subsection 73(1) of the former *Patent Rules*.

[48] The Response to the Preliminary Review did not contest or comment on the above preliminary views that the pages of the description and claims are not numbered consecutively.

[49] Therefore, we maintain the foregoing reasoning and conclude that the specification does not comply with subsection 73(1) of the former *Patent Rules*.

DO THE PROPOSED CLAIMS REMEDY THE DEFECTS?

[50] During the review, the Panel may consider a set of proposed amendments.

[51] As indicated above, with the Response to the Final Action the Applicant submitted proposed claims set-1 wherein the proposed independent claims were amended to replace the reference to “C-type atrial natriuretic factor” with “a ring deleted atrial natriuretic peptide analog”. In addition, claims 3 and 11 on file were deleted and the claim pages were numbered consecutively with the pages of the description.

[52] However, following a telephone interview with the Examiner, a voluntary amendment containing proposed claims set-2 was submitted on May 26, 2023. According to page 1 of the voluntary amendment letter, new claims 3 to 6, 14, 15, 23 and 24 in proposed claims set-2 relate to uses of and compositions and commercial packages comprising C-type atrial natriuretic factor (cANF) or $cANF_{4-23}$.

[53] In the Preliminary Review letter, on pages 19 to 20, we explained why we were of the preliminary view that the subject-matter of claims 1 to 4, 7 to 14 and 16 to 23 of proposed claims set-2 is sufficiently disclosed and fully supported by the description, that claims 1 to 4, 7 to 14 and 16 to 23 of proposed claims set-2 are not overly broad, that claims 1, 2, 13 and 23 of proposed claims set-2 do not lack clarity but that there was a lack of clear differentiation in the scope of claims 3, 4, 14 and 23 and claims 5, 6, 15 and 24, respectively, of proposed claims set-2:

> According to pages 2 to 3 of the Summary of Reasons, proposed claims 1 to 4, 7 to 14 and 16 to 23 lack clarity. In proposed claims 3, 4, 14 and 23 the association of the expression “C-type atrial natriuretic factor” as the full name for “cANF” contradicts the meaning of cANF in view of common general knowledge or Maack 1987 which recognize cANF to be the compound cANF4-23. In proposed claims 1, 2, 13 and 22 the scope of the phrase “a ring-deleted atrial natriuretic peptide analog” is unclear. Proposed claims 7 to 12 and 16 to 21 are said to be ambiguous because of their dependencies on proposed claims 1 to 4 and 13.
>
> In addition, page 3 of the Summary of Reasons indicates that the subject-matter of proposed claims 1 to 4, 7 to 14 and 16 to 23 is not sufficiently disclosed contrary to subsection 27(3) of the Patent Act and lack support in

the description contrary to section 60 of the Patent Rules as the scope of the expressions “C-type atrial natriuretic factor” and “a ring-deleted atrial natriuretic peptide analog” goes beyond the compound $cANF_{4-23}$.

With regard to the clarity defect in proposed claims 1 to 4, 7 to 14 and 16 to 23, it is our preliminary view that the use of the expression “C-type atrial natriuretic factor (cANF)” in proposed claims 3, 4, 14 and 23 causes a lack of clarity in view of proposed claims 5, 6, 15 and 24, respectively. As indicated in our purposive construction analysis above, based on the teachings of the description and in view of the common general knowledge, the person skilled in the art would consider that the expression “C-type atrial natriuretic factor (cANF)” and the term “cANF” are meant to be synonymous with the ring-deleted ANP analogue $cANF_{4-23}$. Given that the only difference between proposed claims 3, 4, 14 and 23 and proposed claims 5, 6, 15 and 24, respectively, is that the expression “C-type atrial natriuretic factor (cANF)” has been replaced by the term “$cANF_{4-23}$”, in our preliminary view, the person skilled in the art would see no practical distinction in scope of these claims.

With regard to the use of the expression “ring-deleted atrial natriuretic peptide analog” in proposed claims 1, 2, 13 and 22, we do not agree that the scope of this expression is unclear. As indicated above, the structure of atrial natriuretic peptide was part of the common general knowledge as was the identification of many atrial natriuretic peptide analogs, some of which, like $cANF_{4-23}$ are specific and selective agonists of NPR-C (reviewed in Bovy, Maack 1992 and von Geldern). Therefore, it is our preliminary view that the person skilled in the art would understand a “ring-deleted atrial natriuretic analog” to define a structural analog of ANP where the 17 amino acid ring structure that is formed between Cys7 and Cys23 (in hANP) is shortened.

With regard to the insufficient disclosure and lack of support defects in proposed claims 1, 2, 13 and 22, given our preliminary view that the person skilled in the art would understand the scope encompassed by a ring-deleted atrial natriuretic peptide, our preliminary view is that the subject-

matter of proposed claims 1, 2, 13 and 22 would comply with subsection 27(3) of the *Patent Act* and would be fully supported by the description. Similarly, with respect to proposed claims 3, 4, 7 to 12, 14, 16 to 21 and 23, in our preliminary view, the person skilled in the art would understand the expression “C-type atrial natriuretic factor (cANF)” in proposed independent claims 3, 4, 14 and 21 to be synonymous with the ring-deleted atrial natriuretic peptide $cANF_{4-23}$. Therefore, in our preliminary view the subject-matter of proposed claims 3, 4, 7 to 12, 14, 16 to 21 and 23 would also comply with subsection 27(3) of the Patent Act and would be fully supported by the description.

Conclusion on proposed claims

Our preliminary view is therefore that the subject-matter of proposed claims 1 to 4, 7 to 14 and 16 to 23 is sufficiently disclosed and fully supported by the description and would comply with subsection 27(3) of the *Patent Act* and section 60 of the *Patent Rules*, respectively. In addition, proposed claims 1, 2, 13 and 22 are definite and would comply with subsection 27(4) of the Patent Act. However, due to the lack of clear differentiation in the scope of proposed claims 3, 4, 14 and 23 and proposed claims 5, 6, 15 and 24, respectively, these claims would not comply with 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*.

[54] The Response to the Preliminary Review letter did not contest or comment on the above preliminary determinations regarding proposed claims set-2 and instead submitted proposed claims set-3 containing proposed claims 1 to 20.

[55] The Response to the Preliminary Review letter further submitted that proposed claims set-3 would address the outstanding issues raised with respect to proposed claims set-2. More specifically, claims 3, 4, 14 and 23 of proposed claims set-2 have been deleted to address the lack of clear differentiation identified between claims 3, 4, 14 and 23 and claims 5, 6, 15 and 24, respectively of proposed claims set-2.

[56] We agree that proposed claims set-3 addresses the clarity issue and would comply with subsection 27(4) of the *Patent Act* and is otherwise compliant with *Patent Act* and *Patent Rules*.

RECOMMENDATION OF THE BOARD

[57] In view of the above, the Panel recommends that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the replacement of the claims on file with proposed claims 1 to 20 as presented in the Applicant's letter of February 29, 2024, are necessary for compliance with the *Patent Act* and *Patent Rules*.

Christine Teixeira	Marcel Brisebois	Michael O'Hare
Member	Member	Member

DECISION OF THE COMMISSIONER

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

- replace the claims on file with proposed claims 1 to 20 as presented in the Applicant's letter dated February 29, 2024.

Konstantinos Georgaras

Commissioner of Patents
Dated at Gatineau, Quebec
this 18th day of March, 2024.