Citation: Nakao, Kazuwa (Re), 2022 CACP 21

Commissioner's Decision #1628
Décision du commissaire nº 1628
Date: 2022-10-19

TOPIC:	F00	Novelty
	C00	Adequacy or Deficiency of Description
	B00	Ambiguity or Indefiniteness
SUJET:	F00	Nouveauté
	C00	Caractère Adéquat ou Inadéquat de la Description
	B00	Caractère ambigu ou indéfini

Application No. : 2,918,219

Demande nº 2 918 219

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,918,219 having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Patent Rules*), has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,918,219, which is entitled “Therapeutic agents for achondroplasia” and owned by Kazuwa Nakao. A review of the rejected application has been conducted by a Panel of the Patent Appeal Board pursuant to paragraph 199(3)(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 is a divisional application of parent application number CA2398030 [parent application] and has an effective filing date of August 14, 2002. The parent application was laid open to public inspection on March 28, 2003.

[4] The rejected application generally relates to the use of a C-type Natriuretic Peptide (CNP) for the treatment of achondroplasia caused by the cartilage growth inhibition resulting from mutations in the gene for fibroblast growth factor receptor 3 (FGFR3).

[5] The claims under review are claims 1 to 6 dated May 22, 2018 and claims 7 to 11 dated June 15, 2018 that were rejected in the Final Action [the claims on file].

Prosecution History

[6] On February 5, 2019, a Final Action was written under subsection 30(4) of the former *Patent Rules*. The Final Action states that the present application is defective on the ground that the claims on file are anticipated and do not comply with paragraph 28.2(1)(d) of the *Patent Act*. The Final Action further states that the specification does not comply with subsection 27(3) of the *Patent Act* because it fails to correctly and fully describe all possible contemplated therapeutic agents, and is therefore not enabling in that respect. Finally, the Final Action states that

claims 1, 6 and 7 are indefinite because the contemplated therapeutic agent is only defined by a desired result and a negative limitation.

[7] The response to the Final Action dated July 31, 2019 included an amended claims set containing proposed claims 1 to 9 [proposed claims set-1].

[8] On June 2, 2020, the application was forwarded to the Patent Appeal Board for review under subsection 86(7) of the *Patent Rules* along with a Summary of Reasons explaining that the proposed amendments presented in the response to the Final Action do not overcome all the defects identified in the Final Action and stating that the rejection is therefore maintained.

[9] In a letter dated June 5, 2020, 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 August 12, 2020, the Applicant confirmed their interest in having the review proceed.

[11] The present Panel was formed to review the rejected application under paragraph 199(3)(c) of the *Patent Rules*. On May 26, 2022, the Panel sent a Preliminary Review letter detailing our preliminary analysis and opinion that all the claims on file, as well as all the claims of proposed claims set-1, are anticipated and do not comply with paragraph 28.2(1)(d) and 28.2(1)(c), respectively, of the *Patent Act*. In that letter, the Panel further expressed the preliminary opinion that the claims on file, as well as all the claims of proposed claims set-1, suffer from overbreadth and, independently of this view, the specification does not comply with the requirements of subsection 27(3) of the *Patent Act*. Finally, the Panel expressed the preliminary opinion that the subject-matter of claims 1, 6 and 7 on file and of claims 1, 5 and 6 of proposed claims set-1 complies with subsection 27(4) of the *Patent Act*. The Preliminary Review letter also provided the Applicant with an opportunity to make oral and/or written submissions.

[12] The Applicant submitted a written response to the Preliminary Review letter on June 23, 2022 but ultimately declined the opportunity for an oral hearing in a

subsequent electronic correspondence dated July 19, 2022. The Applicant's response to the Preliminary Review letter does not argue for the patentability of the claims on file but rather proposes a second amended claims set containing claims 1 to 5 [proposed claims set-2]. The response to the Preliminary Review letter further submits that the description is fully and correctly describing the subject-matter as defined in the proposed claims set-2 in accordance with subsection 27(3) of the *Patent Act*.

ISSUES

[13] The following issues are considered in this review:

- whether the subject-matter of claims 1 to 11 on file is anticipated, contrary to paragraph 28.2(1)(d) of the *Patent Act*;
- whether the specification does not comply with subsection 27(3) of the *Patent Act*; and
- whether claims 1, 6 and 7 are indefinite and do not comply with subsection 27(4) of the *Patent Act*.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Purposive construction

[14] 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 of ordinary skill in the art (POSITA) in light of the relevant common general knowledge (CGK) 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.

[15] We consider that all elements set out in a claim are presumed essential unless it is

established otherwise or such presumption is contrary to the claim language.

Anticipation

[16] Paragraph 28.2(1)(d) of the *Patent Act* requires that a claim must not define subject-matter disclosed in a co-pending Canadian application that is based on a previously filed priority application filed before the claim date of the pending application and which is disclosing the subject-matter defined by the claim:

> 28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> (d) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if
>
> (i) the co-pending application is filed by
>
> (A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or
>
> (B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,
>
> (ii) the filing date of the previously regularly filed application is before the claim date of the pending application,
>
> (iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and
>
> (iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.

[17] Therefore, a co-pending Canadian application is citable under paragraph

28.2(1)(d) of the *Patent Act* if the filing date of the previously regularly filed application [priority application] is before the claim date of the pending application and if the priority application also discloses the subject-matter defined by the claims at issue in the pending application.

[18] There are two separate requirements to show that prior art anticipates a claimed invention: there must be a prior disclosure of the claimed subject-matter as recited above in 28.2(1)(d) of the *Patent Act* and the prior disclosure must enable the claimed subject-matter to be practised by the POSITA (*Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 [Sanofi] at paras 24 to 29 and 49).

[19] Regarding the claim date of the pending application, the legal test governing priority claims to an earlier filed priority application is set out in subsection 28.1(1) of the *Patent Act*, which requires that the priority application disclose the subject-matter defined by the asserted claims in order to benefit from the filing date of the priority application as the claim date:

> 28.1 (1) The date of a claim in an application for a patent in Canada (the “pending application”) is the filing date of the application, unless
>
> (a) the pending application is filed by
>
> (i) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or
>
> (ii) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim;
>
> (b) the filing date of the pending application is within twelve months after the filing date of the previously regularly filed application; and
>
> (c) the applicant has made a request for priority on the basis of the previously regularly filed application In the context of the fourth step, the Court in Sanofi states that it may be appropriate in some cases to consider an “obvious to try” analysis.

[20] In *Paid Search Engine Tools, LLC v Google Canada Corporation,* 2021 FC 1435,

at para 221, Justice McDonald held that the phrase “disclosing the subject-matter defined by the claim” has the same meaning in both the novelty and claim date provisions of the *Patent Act* cited above. In both provisions, the priority application must disclose the subject-matter at issue and such disclosure is not achieved merely if an inference can be drawn from the priority application. This position differs from *Pfizer Canada Inc v Ratiopharm Inc*, 2010 FC 612 at para 87, referring to *AstraZeneca AB v Apotex Inc*, 2007 FC 688, paras 62 to 65 [AstraZeneca], according to which in the absence of an explicit disclosure “the subject matter of the Canadian patent may nevertheless be inferable from the language of the priority document”. We note that Justice McDonald has considered the reasons of AstraZeneca but stated that “[i]t is clear that the Court was looking for an actual disclosure”.

[21] We therefore considered in the Preliminary Review letter that prior disclosure means the same in both provisions, that the relevant priority application must disclose subject-matter which, if performed, would necessarily result in infringement of the pending patent application claims if granted.

[22] The response to the Preliminary Review letter did not contest or comment on the above characterizations of the relevant legal principles regarding anticipation.

Insufficiency of description and enablement under subsection 27(3) of the *Patent Act* and the judicially-created doctrine of overbreadth

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

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

[24] 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 POSITA produce the invention using only the instructions contained in the disclosure? see: *Teva Canada Ltd v Novartis AG*, 2013 FC 141 citing *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 and *Consolboard v MacMillan Bloedel* [1981], 56 CPR 2d 145 (SCC) [Consolboard]. Although the CGK can be relied upon, an affirmative answer to the third question requires that the POSITA not be called upon to display inventive ingenuity or undertake undue experimentation: *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283; *Mobil Oil Corp v Hercules Canada Inc*, [1995] FCJ No 1243; *Merck & Co v Apotex Inc*, [1995] 2 FC 723.

[25] In Consolboard, at pages 154-155, the Supreme Court referred to the textbook *Canadian Law and Practice Relating to Letters Patent for Inventions* (1969, 4th ed.) from which it quoted H.G. Fox as saying “the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired”.

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

[27] 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 (see *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. For example, it has often been said that overbreadth and insufficiency are the two sides of the same coin. 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.

[28] 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 (see *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 (see *Les Laboratoires Servier v Apotex Inc,* 2019 FC 616, para 209).

[29] As mentioned above, overbreadth and insufficiency are often compared to the two sides of the same coin and therefore considerations such as what is exactly encompassed by the scope of the claims and what is disclosed in the description are relevant to both inquiries. 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.

[30] Further, it is not enough for the disclosure to teach how to make the preferred embodiment. The disclosure must teach the POSITA how to put into practice all the claimed embodiments of the invention, and without exercising inventive ingenuity or undue experimentation (see *Seedlings Life Science Ventures, LLC v Pfizer Canada ULC*, 2021 FCA 154, at para 68).

[31] The response to the Preliminary Review letter did not contest or comment on the above characterizations of the relevant legal principles and authorities regarding insufficiency of description, enablement and overbreadth.

Indefiniteness

[32] Subsection 27(4) of the *Patent Act* states that "[t]he 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".

[33] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized the obligation of an applicant to make clear in the claims the ambit of the monopoly sought and the requirement

that the terms used in the claims be clear and precise:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

[34] A claim is not indefinite simply because it has broad scope; an applicant is the "master of his claims, within the breadth of his invention, and entitled to draft the[m] 'in words wide enough to secure the protection desired'": *Riddell v Patrick Harrison & Co*, [1956-57] ExCR 213, 28 CPR 85 at para 66.

[35] The response to the Preliminary Review letter did not contest or comment on the above characterizations of the relevant legal principles and authorities regarding indefiniteness.

ANALYSIS OF THE CLAIMS ON FILE

Purposive construction

The claims on file

[36] There are 11 claims on file. Claims 1, 6 and 7 are independent claims and read as follows:

1. A therapeutic agent for treating achondroplasia caused by the cartilage growth inhibition resulting from mutations in the gene for fibroblast growth factor receptor 3 (FGFR3), said therapeutic agent activating guanylyl cyclase B (GC-B) and provided that C-type natriuretic peptide-53 (CNP-53) is not the therapeutic agent.

6. Use of a therapeutic agent for treating achondroplasia caused by a cartilage growth inhibition resulting from mutations in the gene for fibroblast growth factor receptor 3 (FGFR3), wherein said therapeutic agent activates guanylyl cyclase B (GC-B) and provided that c-type natriuretic peptide-53 (CNP-53) is not the therapeutic agent.

7. Use of a therapeutic agent for the manufacture of a medicament for treating achondroplasia caused by a cartilage growth inhibition resulting from mutations in the gene for fibroblast growth factor receptor 3 (FGFR3), wherein said therapeutic agent activates guanylyl cyclase B (GC-B) and provided that C-type natriuretic peptide-53 (CNP-53) is not the therapeutic agent.

[37] The dependent claims 2 to 5 and 8 to 11 define further limitations with regard to: how the cartilage growth inhibition is rescued (claims 2 and 8); and the therapeutic agent (claims 3 to 5 and 8 to 11).

The POSITA and the relevant CGK

[38] The Preliminary Review letter, on pages 4 to 6, stated the following with regard to the identity of the POSITA and their expected CGK:

> The FA does not explicitly define either the POSITA or their CGK. However, the FA refers to the prosecution of the parent application and, in our view, adopts the findings of *Re Kazuwa Nakao's Patent Application 2398030* (2015), CD 1389 (Pat App Bd & Pat Commr) [CD 1389] in that regard.
>
> CD 1389 at paras 22 to 24 defines the POSITA and their CGK:
>
> > In our letter of February 3, 2015, we proposed characterizing the skilled person as someone with research interests in the field of skeletal dysplasia, having significant and extensive knowledge of experimental medicine and treatment options for the various types of dwarfisms, including achondroplasia. In the letter of April 7, 2015, the Applicant substantially agreed with our proposed characterization, adding that the skilled person would also be knowledgeable in the field of skeletal dysplasia diagnostics, including genetic testing of skeletal dysplasia. Based on the teachings of the description, we are in agreement with this characterization.
> >
> > Thus, the person skilled in the art would have research interests in the field of skeletal dysplasia, including achondroplasia, knowledge of the diagnosis of skeletal dysplasia, including by genetic testing, and knowledge of the treatment options, including experimental treatment options.
> >
> > To aid in our understanding of the state of the common general knowledge of the skilled person, the panel considered two review articles that were published in 1995, Hagiwara and McDowell. In our letter of February 3, 2015, we proposed several teachings from these

> review articles as being part of the common general knowledge. The Applicant agreed, in the letter of April 7, 2015, that the common general knowledge would at least include these points from Hagiwara and McDowell (page 2). Accordingly, the points considered as common general knowledge of the skilled person are the following:
>
> ▪ achondroplasia is caused by gain-of-function mutations in the FGFR3 gene;
>
> ▪ natriuretic peptides including CNP play a role in bone development, and CNP and its receptor GC-B (NPR-B) were known to be expressed in chondrocytes;
>
> ▪ the CNP gene produces a CNP precursor polypeptide of 126-amino acid residues (termed “pre-pro-CNP”), which is processed to give a CNP precursor of 103 residues (termed “pro-CNP”), which is further processed to provide two peptide forms: CNP-53 and CNP-22;
>
> ▪ CNP-53 and CNP-22 are identical except for an extension of 31 amino acids at the amino-terminal end of CNP-53; and
>
> ▪ the abbreviation “CNP” was generally understood by the skilled person as referring to CNP-22. [footnote references omitted]
>
> The RFA did not comment on either the identity of the POSITA or their CGK.
>
> Having reviewed the specification as whole, as well as the review articles Hagiwara et al., “Natriuretic Peptides and Their Receptors”, Zool. Sci., 1995, vol. 12, no. 2, pages 141-149 [Hagiwara] and McDowell et al., “The natriuretic peptide family”, Eur. J. Clin. Invest., 1995, vol. 25, no. 5, pages 291-298 [McDowell], we consider that the characterizations of the POSITA and the points of CGK as cited above are reasonable and we adopt both of them for the purposes of this preliminary review.
>
> We further consider that the disclosures of Hagiwara and McDowell as well as the instant description on pages 2 and 3 support that it was CGK that guanylyl cyclase B is highly specific for CNP and that guanylyl cyclase B activation is associated with increased cGMP levels.

[39] The response to the Preliminary Review letter did not contest or otherwise comment on the Panel’s characterization of the POSITA and the relevant CGK cited above. We therefore adopt the above identification of the POSITA and elements of CGK.

[40] However and with respect to the proposed claims set-2, the response to the

Preliminary Review letter on page 2 submits that CNP analog peptides are also part of the CGK. Given that we considered that CNP and its encoding sequences were CGK and otherwise are of the view that polypeptide sequences that possess some modified structural property of the native sequence (e.g., analogs, variants, mutants, derivatives, etc.) were also CGK, we agree that the general concept of a structurally modified CNP was CGK. That is not to say that we consider each and every specific analog or variant of CNP as being CGK.

Essential elements

[41] The Preliminary Review letter, on page 11, expresses the preliminary view that the person skilled in the art would consider all of the elements in the claims to be essential:

> [W]e consider that the POSITA reading claims 1 to 11 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. Further, there is no indication on the record before us that any claim elements are non-essential. It is therefore our preliminary view that the POSITA would consider all of the elements of claims 1 to 11 as essential.

[42] The response to the Preliminary Review letter did not contest or comment on this preliminary identification of the essential elements. Therefore, we adopt the above identification of the essential elements for the purposes of this final review.

Meaning of terms

[43] In the Preliminary Review letter on pages 6 to 7, we determined what is exactly encompassed by the phrases “said therapeutic agent activating guanylyl cyclase B” found in independent claim 1 and “said therapeutic agent activates guanylyl cyclase B” found in independent claims 6 and 7:

> The phrases “said therapeutic agent activating guanylyl cyclase B” found in independent claim 1 and “said therapeutic agent activates guanylyl cyclase B” found in independent claims 6 and 7 merit further consideration to determine what is exactly encompassed by these words. Given their similarities and for the sake of convenience, we will refer to both phrases using the unitary phrase “said therapeutic agent activating/activates guanylyl cyclase B” in the analysis below.

More specifically, we will determine whether this phrase could reasonably be construed as encompassing all possible therapeutic agents which activate guanylyl cyclase B (with the exception of CNP-53 which is excluded) as suggested in the FA on page 3.

As introduced above, purposive construction is performed from the point of view of the POSITA in light of the relevant CGK, considering the whole of the disclosure including the specification and drawings. One may look to the disclosure and drawings to understand what was meant by the phrase “therapeutic agent activating/activates guanylyl cyclase B” in the claims but not to “enlarge or contract the scope of the claim as written” (Whirlpool at para 52).

Given that any construction given to the words in a claim will affect the scope of the claim (Whirlpool at para 49(h)), we share the view expressed in *Guest Tek Interactive Entertainment Ltd v Nomadix, Inc*, 2021 FC 276, at para 42 and understand the rule against using the disclosure to “enlarge or contract” the claim as written to “preclude adding words, elements, or limitations not found in the claim, or giving the words a meaning they cannot reasonably bear when interpreted in the context of the patent as a whole”.

We have considered the application as a whole and more particularly the following passage found on page 5, lines 16 to 28 of the description:

> As used herein, the expression “substance activating guanylyl cyclase B” means a substance (peptide or low molecular compound) capable of binding to GC-B known as a receptor for CNP (C-type natriuretic peptide) to activate it, preferably a substance (peptide or low molecular compound) having CNP (C-type natriuretic peptide)-like activity, such as mammalian CNP (CNP-22 (Biochem. Biophys. Res. Commun. 168: 863-870, 1990, W091/16342), CNP-53 (Biochem. Biophys. Res. Commun. 170: 973-979, 1990, JPA 1992-74198, JPA 1992-139199), avian CNP (JPA 1992-120094), amphibian CNP (JPA 1992-120095) and CNP analog peptides (JPA 1994-9688), preferably mammalian CNP, more preferably CNP-22.

It is therefore our preliminary view that the POSITA would understand that the phrase “said therapeutic agent activating/activates guanylyl cyclase B” in the context of the claims on file means to include any peptide or low molecular weight compound capable of binding to guanylyl cyclase B and activating it (with the exception of CNP-53), i.e., not limited to C-type natriuretic peptides.

We also note that dependent claims 3 and 9 explicitly state that the contemplated therapeutic agent activating guanylyl cyclase B is a peptide.

[44] The response to the Preliminary Review letter did not contest or comment on the above characterizations of the phrases “said therapeutic agent activating guanylyl

cyclase B" and "said therapeutic agent activates guanylyl cyclase B". Therefore, we adopt those for the purposes of this final review.

Anticipation

[45] All 11 claims on file were rejected in the Final Action for lack of novelty.

Claim date

[46] The Preliminary Review letter expressed the preliminary view on page 10 that September 28, 2001 is the claim date of claims 1 to 11 on file:

> The claim date of claims 1 to 11 on file must first be ascertained. The present application claims priority on the basis of two Japanese patent applications: JP301586/2001 filed on September 28, 2001 and JP310322/2001 filed on October 5, 2001.
>
> We retrieved and reviewed translated versions of both documents from the USPTO Global Dossier of the parent application CA2398030[1]. In our preliminary view, both documents recite the use of CNP-22 as therapeutic agent that activates guanylyl cyclase B (GC-B) for treating achondroplasia caused by cartilage growth inhibition resulting from mutations in FGFR3. Therefore and according to subsection 28.1(1) of the *Patent Act*, September 28, 2001 is considered the claim date of claims 1 to 11 on file for the purposes of this preliminary review. [footnote omitted]

[47] The response to the Preliminary Review letter did not contest or comment on the above determination of the claim date. Therefore, we adopt September 28, 2001 as the claim date of claims 1 to 11 on file for the purposes of this final review.

The prior art and corresponding priority document disclosure

[48] The co-pending application CA2441815A1 (D1) was cited in the Final Action.

[49] On pages 11 to 12, the Preliminary Review letter determined whether the subject-matter of claims 1 to 11 on file is disclosed in D1 and whether D1 is entitled to a priority date based on the filing date of Israeli application IL14211801A and US application US60/276,939, both filed on March 20, 2001:

Next, we must determine if the subject-matter of claims 1 to 11 on file is disclosed in the following co-pending application cited in the FA:

D1: CA2441815A1 Golembo and Yayon priority date: March 20, 2001

We must also determine if the subject-matter in the co-pending application is entitled to priority based on the filing date of Israeli application IL14211801A and US application US60/276,939, both filed on March 20, 2001. We consider that both documents essentially contain the same information and although we will refer only to the Israeli application [the priority application], our statements equally apply to both documents.

D1 discloses that achondroplasia (which is a type of skeletal dysplasia) is the most common form of short-limbed dwarfism and is mainly caused by the mutation G380R in the transmembrane domain of FGFR3 and discloses the use of CNP for treating achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3. Femora derived from achondroplasia model mice were incubated with CNP. CNP is disclosed to induce longitudinal growth of achondroplasia-derived bones. D1 discloses that the active form of CNP is CNP-22 (Example 6, on page 21) and consists of the amino acid sequence recited in SEQ ID NO:1 (see also Figure 3). D1 further teaches the use of functional CNP variants to induce bone elongation and treating skeletal dysplasias.

Unlike D1, the priority application does not disclose that the active form of CNP is CNP-22 or otherwise discloses the term CNP-22 or related identifiers. However, we have expressed the preliminary view above in the “The POSITA and the relevant CGK” section that the POSITA would have understood that the abbreviation “CNP” in the priority application is referring to the CGK active form of CNP, i.e., CNP-22. Therefore, we consider that the POSITA, looking at the disclosure of the priority application and trying to understand what the author of the description in the priority application meant, would have understood that the priority application discloses the use of CNP-22 for treating achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3. Therefore, it is our preliminary view that this subject-matter benefits from the earlier priority date of March 20, 2001.

Further, it is our preliminary view that D1 and the priority application enable the POSITA to use CNP-22 to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

With regard to the feature “said therapeutic agent activating/activates guanylyl cyclase B” found in the independent claims on file and the feature “wherein the cartilage growth inhibition is rescued by enlarging hypertrophic chondrocytes and increasing the extracellular matrix of the proliferative chondrocyte layer” found in dependent claims 2 and 8, it is our preliminary view that these features are inherent features of using CNP-22 to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

> For the reasons above, it is our preliminary view that the subject-matter of the claims on file is anticipated by D1 and therefore non-compliant with paragraph 28.2(1)(d) of the *Patent Act*.

[50] The response to the Preliminary Review letter did not contest or comment on the above preliminary determination with respect to the lack of novelty of the subject-matter of the claims on file and instead submitted proposed claims set-2.

Conclusion

[51] Therefore, for the cited reasons above, it is our view that the subject-matter of the claims on file is anticipated by D1 and therefore non-compliant with paragraph 28.2(1)(d) of the *Patent Act*.

Insufficiency of description and enablement under subsection 27(3) of the *Patent Act* and the judicially-created doctrine of overbreadth

[52] The Final Action on pages 2 and 3 submitted that the specification, insofar as it relates to the claimed use of any therapeutic agent which activates guanylyl cyclase B to treat achondroplasia caused by the cartilage growth inhibition resulting from mutations in the FGFR3 gene (with the exception of CNP-53), does not comply with subsection 27(3) of the *Patent Act* because it fails to correctly and fully describe all possible contemplated therapeutic agents, and is therefore not enabling in that respect.

[53] In the response to the Final Action, the Applicant expressed general disagreement with the position presented in the Final Action with respect to the claims on file but submitted that the proposed claims set-1 would be considered enabling to the POSITA.

[54] Taking into account the herein adopted view that the contemplated therapeutic agent activating guanylyl cyclase B recited in the independent claims includes any peptide or low molecular weight compound capable of binding to guanylyl cyclase B and activating it (with the exception of CNP-53), the Preliminary Review Letter expressed the preliminary views that; i) the claims on file suffer from overbreadth and, independently of this view, ii) the specification does not comply with the requirements of subsection 27(3) of the *Patent Act*:

> Having reviewed the description and the drawings, we are of the preliminary view that the application discloses separate exemplary embodiments wherein mouse CNP-22 is used in the context of treating achondroplasia and activating guanylyl cyclase B, discloses that different C-type natriuretic peptides are known to activate guanylyl cyclase B but is otherwise silent with regard to what other peptides or low molecular weight compounds other than C-type natriuretic peptides could successfully be used to activate guanylyl cyclase B. On the basis of the record before us, it is also our preliminary view that the CGK regarding activating peptides of guanylyl cyclase B is limited to C-type natriuretic peptides and that the POSITA would not be aware of any low molecular weight compound capable of activating guanylyl cyclase B.
>
> In light of the above considerations, it is our preliminary view that the claims on file do not read fairly on what the patent application discloses in the description and the drawings with respect to peptides or low molecular weight compounds other than C-type natriuretic peptides that could activate guanylyl cyclase B.
>
> Further, and on the basis of the same considerations, it is our preliminary view that the specification fails to teach the POSITA how to put into practice all the claimed embodiments of the invention without exercising undue experimentation to identify peptides or low molecular weight compounds other than C-type natriuretic peptides. These gaps with respect to the identification of the encompassed therapeutic agents activating guanylyl cyclase B are not filled by the CGK.
>
> Accordingly, our preliminary conclusions are that; i) the claims on file suffer from overbreadth and, independently of this view, ii) the specification does not comply with the requirements of subsection 27(3) of the *Patent Act*.

[55] In the Response to the Preliminary Review letter, the Applicant expressed general disagreement with our preliminary position but submitted that the proposed claims set-2 would be considered enabling to the POSITA and that the application is fully and correctly describing the subject-matter as now defined in the proposed claims set-2.

Conclusions

[56] Therefore, for the reasons laid out in the Preliminary Review letter and cited

above, our conclusions are that; i) the claims on file suffer from overbreadth and, independently of this view, ii) the specification does not comply with the requirements of subsection 27(3) of the *Patent Act* insofar as the claims on file encompass peptides or low molecular weight compounds other than C-type natriuretic peptides.

Indefiniteness

[57] According to the Final Action on page 3, claims 1, 6 and 7 are indefinite because "[t]he therapeutic agent is only defined by a desired result and a negative limitation".

[58] The response to the Final Action on pages 2 and 3 submitted that the expression "agent which activates guanyl cyclase B" is clearly defined in the present application but nevertheless proposed amendments to further specify the extent of guanyl cyclase B activity required to achieve the desired therapeutic effect.

[59] In the Preliminary Review letter on page 16, we expressed the preliminary view that the subject-matter of claims 1, 6 and 7 on file complies with subsection 27(4) of the *Patent Act*:

> As stated above in the "The POSITA and the relevant CGK" section, we consider that guanyl cyclase B and its activity are CGK elements. It is our preliminary view that the POSITA with a mind willing to understand would readily comprehend that the intended therapeutic agent for treating achondroplasia is one which activates guanyl cyclase B. The agent is being defined in functional terms and thus such definition has a broad scope but it nevertheless serves to distinctly, explicitly and clearly define the contemplated therapeutic agent.
>
> Therefore, it is our preliminary view that the subject-matter of claims 1, 6 and 7 on file complies with subsection 27(4) of the *Patent Act*.

[60] The response to the Preliminary Review letter did not contest or comment on the above preliminary determination.

Conclusion

[61] Therefore, for the reasons laid out in the Preliminary Review letter and cited

above, it is our view that the subject-matter of claims 1, 6 and 7 on file complies with subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED AMENDMENTS

[62] During the review, the Panel may consider proposed amendments. With the response to the Final Action, the Applicant submitted the proposed claims set-1 comprising proposed claims 1 to 9 wherein new independent claims 1, 5 and 6 (corresponding to independent claims 1, 6 and 7 on file) have been amended to indicate that the therapeutic agent activates guanylyl cyclase B by at least 9 times compared to a control and to further specify that the therapeutic agent is not CNP-22. New claims 4 and 6 have been amended to exclude both CNP-53 and CNP-22 and former claims 5 and 11 have been cancelled.

[63] In the Preliminary Review letter on pages 16 to 19, we explained why we were of the preliminary view that the subject-matter of the proposed claims set-1 is anticipated by D1 and therefore non-compliant with paragraph 28.2(1)(c) of the *Patent Act*, that the proposed claims set-1 suffers from overbreadth, that the specification does not comply with the requirements of subsection 27(3) of the *Patent Act* insofar as it relates to the subject-matter of the proposed claims set-1 and that the subject-matter of proposed claims 1, 5 and 6 complies with subsection 27(4) of the *Patent Act*:

> Claim date
>
> The claim date of proposed claims 1 to 9 must first be ascertained.
>
> As mentioned above, we retrieved and reviewed translated versions of the two priority Japanese patent applications JP301586/2001 and JP310322/2001. In our preliminary view, neither JP301586/2001 nor JP310322/2001 disclose the use of an agent that is not CNP-22 or CNP-53 and that activates guanylyl cyclase B by at least 9 times compared to a control. Therefore and according to subsection 28.1(1) of the *Patent Act*, August 14, 2002, the filing date of the instant application, is considered the claim date of proposed claims 1 to 9 for the purposes of this preliminary review.
>
> Prior art disclosure

Paragraph 28.2(1)(c) of the *Patent Act* requires that a claim must not define subject-matter disclosed in a co-pending Canadian application that has a filing date that is before the claim date and which is disclosing the subject-matter defined by the claim:

> 28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> (c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date.

Therefore, co-pending Canadian application D1 having a filing date of March 20, 2002 is citable under paragraph 28.2(1)(c) of the *Patent Act* if it discloses the subject-matter defined by the proposed claims.

As stated above, we consider that D1 discloses the use of the active form of CNP (i.e., CNP-22) for treating achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3. Further, and more relevant to the subject-matter of the proposed claims, we also consider that D1 discloses on pages 21 to 24 functional CNP variants eliciting the same or higher level of CNP receptor (guanylyl cyclase B) activation than CNP-22. Finally, D1 teaches the use of said CNP analogs to induce bone elongation and to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

The instant application discloses that CNP-22 activates guanylyl cyclase by at least 9 times compared to a control. It follows that functional CNP variants eliciting the same or higher level of guanylyl cyclase B activation than CNP-22 would also inherently activate guanylyl cyclase by at least 9 times compared to a control.

With regard to the feature "said therapeutic agent activating/activates guanylyl cyclase B" found in the independent proposed claims and the feature "wherein the cartilage growth inhibition is rescued by enlarging hypertrophic chondrocytes and increasing the extracellular matrix of the proliferative chondrocyte layer" found in dependent proposed claims 2 and 7, it is our preliminary view that these features are inherent features of using CNP-22 and functional variants thereof to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

For the reasons above, it is our preliminary view that the subject-matter of the proposed claims is anticipated by D1 and therefore non-compliant with paragraph 28.2(1)(c) of the *Patent Act*.

Insufficiency of description and enablement under subsection 27(3) of the *Patent Act* and the judicially-created doctrine of overbreadth

To parallel our analysis above with respect to the claims on file, we will first consider what is exactly encompassed by the scope of the proposed claims and what is disclosed in the description. Again, if the proposed claims do not read fairly on what the patent application discloses in the description and the drawings, then the proposed claims may encompass subject-matter that is more than what was invented or adequately disclosed and/or encompass subject-matter that the POSITA could not put into practice without exercising inventive ingenuity or undue experimentation.

We are of the preliminary view that the POSITA would understand that the contemplated therapeutic agent activating guanylyl cyclase B by at least 9 times compared to a control is any peptide or low molecular weight compound capable of activating guanylyl cyclase B by at least 9 times compared to a control with the exception of CNP-22 and CNP-53 that are expressly excluded from the scope of the proposed claims.

Having reviewed the description and the drawings, we are of the preliminary view that the application discloses one exemplary embodiment wherein mouse CNP-22 is showed to activate guanylyl cyclase B by at least 9 times compared to a control but is otherwise silent with regard to what other peptides or low molecular weight compounds other than CNP-22 could successfully be used to activate guanylyl cyclase B by at least 9 times compared to a control. It is also our preliminary view that the knowledge of peptides or low molecular weight compounds capable of activating guanylyl cyclase B by at least 9 times compared to a control is not part of the CGK.

In light of the above considerations and further noting that the sole exemplary embodiment of a therapeutic agent activating guanylyl cyclase B by at least 9 times compared to a control is expressly excluded from the scope of the proposed claims, it is our preliminary view that the proposed claims do not read fairly on what the patent application discloses in the description and the drawings with respect to peptides or low molecular weight compounds capable of activating guanylyl cyclase B by at least 9 times compared to a control. Further, and on the basis of the same considerations, it is our preliminary view that the specification fails to teach the POSITA how to put into practice all the claimed embodiments of the invention without undue experimentation. These gaps with respect to the identification of the encompassed therapeutic agents capable of activating guanylyl cyclase B by at least 9 times compared to a control are not filled by the CGK.

Accordingly, our preliminary conclusions are that; i) the proposed claims suffer from overbreadth and, independently of this view, ii) the specification does not comply with the requirements of subsection 27(3) of the *Patent Act*.

Indefiniteness

> Our considerations and preliminary conclusions recited above with respect to the clarity and definiteness of the expression “agent which activates guanyl cyclase B” generally apply to the corresponding expression “therapeutic agent activating guanylyl cyclase B (GC-B) by at least 9 times compared to a control” found in the proposed claims.
>
> According to the SOR on page 3, the term “control” in proposed claims 1, 5 and 6 lacks clarity because a specific reference for which the undefined therapeutic agent is contemplated to activate guanylyl cyclase B by at least 9 times in comparison to must be defined.
>
> It is our preliminary view that the POSITA with a mind willing to understand would readily comprehend that the term “control” refers to an element that won’t affect the measured variable as it is used as a point of comparison against which other test results are measured and we consider that not specifying the exact nature of the control does not create ambiguity or render the scope of the claims unclear.
>
> Therefore, it is our preliminary view that the subject-matter of proposed claims 1, 5 and 6 complies with subsection 27(4) of the *Patent Act*.

[64] The response to the Preliminary Review letter did not contest or comment on the above preliminary determinations regarding proposed claims set-1 and instead submitted proposed claims set-2 comprising proposed claims 1 to 5 wherein proposed independent claims 1, 3 and 4 (corresponding to claims 1, 6 and 7 on file respectively) have been amended to indicate that the therapeutic agent is an analog of C-type natriuretic peptide (CNP) and is not CNP-53. Proposed dependent claims 2 and 5 correspond to dependent claims 2 and 8 on file respectively.

[65] The response to the Preliminary Review letter submits that proposed claims set-2 would address the defects of insufficiency of description and enablement under subsection 27(3) of the *Patent Act* and that the indefiniteness defect is now moot in view of the proposed claims set-2. We agree.

[66] The response to the Preliminary Review letter further submits that given that the subject-matter of the proposed claims set-2 now excludes both CNP-53 and CNP-22, the proposed claims set-2 clearly exclude the teachings of D1. We respectfully

disagree.

[67] In the Preliminary Review letter we stated on page 11 that “D1 further teaches the use of functional CNP variants”. On page 17 of the same letter, we further stated the following with respect to the teachings of D1:

> Further, and more relevant to the subject-matter of the proposed claims, we also consider that D1 discloses on pages 21 to 24 functional CNP variants eliciting the same or higher level of CNP receptor (guanylyl cyclase B) activation than CNP-22. Finally, D1 teaches the use of said CNP analogs to induce bone elongation and to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

[68] It is our view that the POSITA would understand that “analogs” of CNP can also be referred to as peptide “variants” or “derivatives” and therefore it is our view that the teachings of D1 encompass the disclosure of CNP analogs and uses thereof to induce bone elongation and to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

[69] We therefore need to determine if D1 is citable under any provision under subsection 28.2(1) of the *Patent Act*.

Claim date of the proposed claims set-2

[70] We reviewed translated versions of both priority documents JP301586/2001 filed on September 28, 2001 and JP310322/2001 filed on October 5, 2001. In our view, both documents recite the use of CNP analog peptides as therapeutic agents that activate guanylyl cyclase B (GC-B) for treating achondroplasia caused by cartilage growth inhibition resulting from mutations in FGFR3 as an alternative to CNP-22, although no working exemplary embodiment is disclosed.

[71] As mentioned above at para 40, we consider that the native sequence of CNP-22 was CGK and that the general concept of a structurally modified CNP was also CGK.

[72] We consider that both priority documents disclose subject-matter that a POSITA willing to make trial and error experiments would have been able to perform without an undue burden and, if performed, would be encompassed by the claims

of proposed claims set-2. Therefore and according to subsection 28.1(1) of the *Patent Act*, September 28, 2001 is considered the claim date of proposed claims set-2 for the purposes of this review.

The prior art and corresponding priority document disclosure

[73] Given the claim date September 28, 2001, we must now determine if the subject-matter in the co-pending application D1 is entitled to a priority date based on the filing date of Israeli application IL14211801A or US application US60/276,939, both filed on March 20, 2001. As mentioned in the Preliminary Review letter, we consider that both documents essentially contain the same information and although we will refer only to the Israeli application, our statements equally apply to both documents.

[74] We consider that the POSITA, looking at the disclosure of the Israeli application and trying to understand what is meant in the description, would have understood that it discloses the use of natriuretic peptides, including CNP-22 (see examples and experiments), for treating achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3. Further, it is also disclosed that "[t]he term 'natriuretic peptides' or 'NP' as referred to herein relates to any of the three isoforms, atrial natriuretic peptide (ANP), brain natriuretic peptide (BNP) and C-type natriuretic peptide (CNP) and to any functional derivatives thereof" [emphasis added].

[75] We already expressed our view above that the POSITA would understand that "analogs" of CNP can also be referred to as peptide "variants" or "derivatives" (see para 68), and that both the native sequence of CNP-22 and the general concept of a structurally modified CNP was also CGK (see para 40).

[76] We consider that both D1 and the Israeli application disclose the use of CNP derivatives/analogs to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3. Such disclosure, in the same way we considered the disclosure of the instant application and its corresponding priority applications, is considered subject-matter that a POSITA willing to make trial and error experiments would have been able to perform without an undue burden and, if performed, would be encompassed by the claims of proposed claims set-2.

[77] With regard to the feature “wherein the cartilage growth inhibition is rescued by enlarging hypertrophic chondrocytes and increasing the extracellular matrix of the proliferative chondrocyte layer” found in dependent claims 2 and 5 of the proposed claims set-2, it is our view that this feature is an inherent feature of using CNP derivatives/analogs to treat achondroplasia caused by cartilage growth inhibition resulting from mutations in the gene for FGFR3.

[78] For the reasons above, it is our view that the subject-matter of the proposed claims set-2 is non-compliant with paragraph 28.2(1)(d) of the *Patent Act*.

Conclusion

[79] Therefore, it is our view that the proposed amendments do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*

RECOMMENDATION OF THE BOARD

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

- Claims 1 to 11 on file lack novelty and are therefore non-compliant with paragraph 28.2(1)(d) of the *Patent Act*;
- Claims 1 to 11 on file suffer from overbreadth as they do not read fairly on what the patent application discloses in the description and the drawings; and
- The specification does not comply with the requirements of subsection 27(3) of the *Patent Act* insofar as the specification fails to teach the POSITA how to put into practice all the embodiments encompassed by the claims on file without exercising undue experimentation.

[81] Further, we found above that proposed claims set-1 and claims set-2 lack novelty and that otherwise the specification does not comply with the requirements of subsection 27(3) of the *Patent Act* insofar as the specification fails to teach the POSITA how to put into practice all the embodiments encompassed by claims set-1. We therefore consider that they do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

Marcel Brisebois Ryan Jaecques Christine Teixeira

Member Member Member

DECISION OF THE COMMISSIONER

[82] I concur with the findings of the Board and its recommendation to refuse the application because the claims on file do not comply with paragraph 28.2(1)(d) of the *Patent Act*, the claims on file suffer from overbreadth and the specification does not comply with the requirements of subsection 27(3) of the *Patent Act*.

[83] Therefore, I refuse to grant a patent for this application in accordance with section 40 of the *Patent Act*. 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 19th day of October 2022.