Citation: Amgen Research (Munich) GmbH (Re), 2021 CACP 2
Commissioner's Decision #1555
Décision du Commissaire #1555
Date: 2021-01-06

TOPIC:	J80	Professional or Artistic Skill
	K11	Treatment
	B00	Ambiguity or Indefiniteness
SUJET:	J80	Aptitudes professionnelles (artistiques)
	K11	Traitement
	B00	Caractère ambigu ou indéfini

Application No. : 2,633,594

Demande n^{o} 2 633 594

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,633,594 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 unless necessary amendments are made.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,633,594, which is entitled "Means and Methods for the Treatment of Tumorous Diseases" and is owned by Amgen Research (Munich) GmbH (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the 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 notify the Applicant that specific claim amendments are considered necessary amendments under subsection 86(11) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules* and that the patent application be allowed if amended accordingly.

BACKGROUND

The Application

[3] The application was filed under the provisions of the Patent Cooperation Treaty and has an effective filing date in Canada of November 29, 2006. It was laid open to public inspection on June 21, 2007.

[4] The application relates to the use of an anti-CD19 x anti-CD3 bispecific single chain antibody in the treatment or amelioration of indolent or aggressive B cell non-Hodgkin lymphoma (B NHL) or B cell leukemia. The description discloses that administering the antibody construct by continuous infusion over a longer period of time was therapeutic and well tolerated with no significant adverse side effects observed.

[5] The application has 19 claims on file, which were received at the Patent Office on March 21, 2017.

Prosecution History

[6] On December 13, 2017, a Final Action (FA) was written pursuant to subsection 30(4) of the former *Patent Rules*. The FA stated that the instant application was defective on the grounds that:

- claims 1 to 19 (all claims on file) encompass a method of medical treatment and do not comply with section 2 of the *Patent Act;* and

- claims 1, 6, 17 and 18 are indefinite and do not comply with subsection 27(4) of the *Patent Act.*

[7] In a response to the FA (RFA) dated June 13, 2018, the Applicant proposed an amended set of 19 claims (the proposed claims) and submitted arguments addressing the statutory subject-matter defect raised in the FA.

[8] As the Examiner still considered the application not to comply with the *Patent Act*, pursuant to paragraph 30(6)(c) of the former *Patent Rules*, the application was forwarded to the Board for review along with an explanation outlined in a Summary of Reasons (SOR). The SOR indicated that the proposed claims were considered to overcome the indefiniteness defects, but were not considered to overcome the defect for non-statutory subject-matter.

[9] In a letter dated September 13, 2018, the Board forwarded to the Applicant a copy of the SOR and requested that the Applicant confirm its continued interest in having the application reviewed.

[10] In a letter dated November 22, 2018, the Applicant confirmed its interest in having the review proceed.

[11] The present panel (the Panel) was formed to review the instant application under paragraph 199(3)(c) of the *Patent Rules*. The Panel sent a preliminary review letter (PR letter) dated August 7, 2020, which set out our preliminary opinion that the claims on file do not encompass a method of medical treatment and comply with section 2 of the *Patent Act*, and that claims 1, 6, 17 and 18 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. Further, we expressed the view that the proposed claims constitute a necessary amendment in accordance with subsection 86(11) of the *Patent Rules*. The PR letter also provided the Applicant with an opportunity to make oral and/or written submissions.

[12] The Applicant responded to the PR letter on September 4, 2020 (RPR), providing written submissions, as well as the same proposed claim set that had been submitted with the RFA. In a subsequent letter dated September 18, 2020, the Applicant indicated that a hearing was not necessary.

ISSUES

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

- whether or not claims 1–19 on file encompass a method of medical treatment and are therefore non-compliant with section 2 of the *Patent Act;* and
- whether claims 1, 6, 17 and 18 on file are indefinite and are therefore non-compliant with subsection 27(4) of the *Patent Act*.

[14] After considering the claims on file, we will consider the proposed claims.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICES

Purposive construction

[15] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66, essential elements are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings (see also *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49(f) and (g) and 52). This is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK).

Statutory subject-matter and methods of medical treatment

[16] The definition of invention is set out in section 2 of the *Patent Act*:

> invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter

[17] It is well established that methods of medical treatment and surgery are not statutory subject-matter and are excluded from the definition of invention as defined in section 2 of the *Patent Act* (see *Tennessee Eastman Co v Commissioner of Patents* (1970), 62 CPR 117 (Ex Ct), aff'd [1974] SCR. 111).

[18] However, medical "use" claims have been considered to be directed to patentable subject-matter (see *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 (*AZT*)). In *AZT*, the Supreme Court suggested that a complication might arise in a case where a claim, although drafted as a medical use, nonetheless attempts to "fence in" an area of medical treatment by indicating "how and when" (e.g., by indicating a dosage range or treatment regime) a

pharmaceutical composition is to be used. In that decision the Supreme Court considered a claim directed to a pharmaceutical composition comprising an old compound (AZT) for a new use in treating AIDS and found that the patentee had not attempted to fence in a method of medical treatment:

> The AZT patent does not seek to "fence in" an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession. (para 50)

[19] A number of lower court decisions have considered the validity of medical use claims that indicate "how and when" a drug is to be used (*Axcan Pharma Inc v Pharmascience Inc*, 2006 FC 527 (*Axcan*); *Merck & Co, Inc v Pharmascience Inc*, 2010 FC 510; *Janssen Inc v Mylan Pharmaceuticals ULC*, 2010 FC 1123; *AbbVie Biotechnology Ltd v Canada (Attorney General)*, 2014 FC 1251 (*AbbVie*)). Upon reviewing prior decisions, the Federal Court in *AbbVie* concluded that the jurisprudence is consistent; Federal Court jurisprudence has developed the principle that:

> [A] claim directed to the exercise of professional skill or judgment is not patentable. However, a claim which does not restrict, or interfere with, or otherwise engage professional skill or judgment – including a claim for a fixed dosage or a fixed dosage schedule or interval – is not impermissible subject matter where there is no evidence to contradict that claimed dosage. (para 114)

[20] Subsequent to *AbbVie*, the Office clarified its approach to determining if a medical use claim is statutory subject-matter in the following Patent Notice: *Revised Examination Practice Respecting Medical Uses* (*PN 2015-01*). According to *PN 2015-01*, the determination of whether the subject-matter of a claim is statutory considers whether an essential element prevents, interferes with or requires the professional skill of a physician. If the answer is "yes", this will lead to the conclusion that the claimed use encompasses a method of medical treatment that does not comply with section 2 of the *Patent Act*. Notably, *PN 2015*-01 also recognizes that there may be instances where essential elements serve to instruct a medical professional "how" to treat a patient but are not considered to prevent, interfere with or require professional skill.

Indefiniteness

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

> 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.

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

ANALYSIS OF THE CLAIMS ON FILE

Purposive construction

The claims on file

[23] There are 19 claims on file. Claims 1–3 are the only independent claims:

> 1. A bispecific single chain antibody construct for use in a method for the prevention, treatment or amelioration of indolent or aggressive B cell non-Hodgkin lymphoma (B NHL) or B cell leukemia, said bispecific single chain antibody construct being for administration to a subject in need thereof, said bispecific single chain antibody construct comprising binding domains specific for human CD3 and human CD19, wherein the corresponding variable heavy chain regions (V_H) and the corresponding variable light chain regions (V_L) regions are arranged, from N-terminus to C- terminus, in the order,
>
> V_L(CD19)-V_H(CD19)-V_H(CD3)-V_L(CD3),
>
> V_H(CD19)-V_L(CD19)-V_H(CD3)-V_L(CD3),
>
> V_H(CD3)-V_L(CD3)-V_H(CD19)-V_L(CD19) or
>
> V_H(CD3)-V_L(CD3)-V_L(CD19)-V_H(CD19),
>
> wherein the bispecific single chain antibody construct is for administration for at least 1 week in a daily dose of 10μg to 80μg per square meter patient body surface area and wherein the daily dose is for administration over at least 6h.

2. Use of a bispecific single chain antibody construct for the preparation of a pharmaceutical composition for the prevention, treatment or amelioration of indolent or aggressive B cell non-Hodgkin lymphoma (B NHL) or B cell leukemia, said bispecific single chain antibody construct comprising binding domains specific for human CD3 and human CD19, wherein the corresponding variable heavy chain regions (V_H) and the corresponding variable light chain regions (V_L) regions are arranged, from N-terminus to C- terminus, in the order,

VL(CD19)-VH(CD19)-VH(CD3)-VL(CD3),

VH(CD19)-VL(CD19)-VH(CD3)-VL(CD3),

VH(CD3)-VL(CD3)-VH(CD19)-VL(CD19) or

VH(CD3)-VL(CD3)-VL(CD19)-VH(CD19)

and wherein said bispecific single chain antibody construct is for administration for at least 1 week in a daily dose of 10μg to 80μg per square meter patient body surface area and whereby said daily dose is for administration over at least 6h.

3. A kit for use in the prevention, treatment or amelioration of indolent or aggressive B cell non-Hodgkin lymphoma (B NHL) or B cell leukemia in humans, according to a regimen of at least one week comprising the administration of a bispecific single chain antibody construct comprising binding domains specific for human CD3 and human CD19, wherein the corresponding variable heavy chain regions (V_H) and the corresponding variable light chain regions (V_L) regions are arranged, from N-terminus to C- terminus, in the order,

V_L(CD19)-V_H(CD19)-V_H(CD3)-V_L(CD3),

V_H(CD19)-V_L(CD19)-V_H(CD3)-V_L(CD3),

V_H(CD3)-V_L(CD3)-V_H(CD19)-V_L(CD19) or

V_H(CD3)-V_L(CD3)-V_L(CD19)-V_H(CD19),

wherein said bispecific single chain antibody construct is for administration for at least 1 week in a daily dose of 10μg to 80μg per square meter patient body surface area and wherein the daily dose is to be administered over at least 6h, and wherein said kit contains the following components:

at least 7 individual daily doses of from 140μg to 320μg of said pharmaceutical active bispecific single chain antibody construct; and

a means for having the components arranged in a way to facilitate compliance with the regimen.

[24] In the RPR, the Applicant did not contest the Panel's consideration in the PR letter of

claims 1–3 as being representative of the claims on file for the purposes of our analysis. Likewise, the Applicant did not contest our characterization of the dependent claims 4–19 as providing further limitations with regard to: the daily administration time interval (claims 4–6), the bispecific antibody construct (claims 7–15), the overall duration of the treatment regimen (claim 16), the use of an additional pharmaceutical agent (claim 17), the subject to be treated (claim 18) and the administration of an initial dose prior to the start of the treatment regimen (claim 19).

The skilled person and the relevant CGK

[25] In the RPR, the Applicant did not contest or comment on the Panel's agreement with characterization of the skilled person and their relevant CGK from the FA as set out on page 5 of our PR letter. Accordingly, we adopt those characterizations for this review:

> In view of statements in the description which refer to "immunological, medical interventions" (page 1, first paragraph) and the "attending physician" (page 13, second paragraph), the person skilled in the art to whom the application is directed can be characterized as a team of a clinician and an immunologist.
>
> The person skilled in the art would possess the following CGK: knowledge of antibody therapies, cytokine release syndrome or first-dose effects, and the design of clinical trials to determine safety and efficacy of therapeutic agents.

Meaning of the terms

[26] The RPR, on page 2, expressed disagreement with the claim construction put forth in the PR letter. However, the RPR did not explicitly address or comment on the meaning of any of the terms in the claims or suggest any alternative interpretations of the claims on file. Therefore, in view of the analysis put forth in the PR letter (page 8), we adopt the construction of the following terms in claims 1 and 2:

> Independent claim 1 refers to "a product for use in a method". As explained in the FA on page 4, the claim as formulated was deemed indefinite: "It is unclear if the use of a product or the use of a method is being claimed."
>
> (…)
>
> [I]t is our view that the skilled person would construe this as a product for use. There are no active steps defined in the claim, which are the hallmark of a method, as indicated in the *MOPOP* §16.10.01: "A method is the series of steps to be followed either alone or in conjunction within a process in order to achieve a desired result."

> Independent claim 2 is a "Swiss" style use claim. The form of this type of claim is typically, "the use of compound X in the manufacture of a medicament for the treatment of Y". A literal interpretation may suggest that the contemplated use is simply for the manufacture of a medicament but the format also permits an interpretation of the claim as relating to a therapeutic use for the compound (see for example, see *GD Searle & Co v Canada (Minister of Health)*, 2008 FC 437, aff'd 2009 FCA 35; *Eli Lilly Canada Inc v Apotex Inc*, 2008 FC 142; and *Pfizer Canada Inc v Apotex Inc*, 2007 FC 971, aff'd 2009 FCA 8). Although the use recited in the preamble of claim 2 relates to the preparation of a pharmaceutical composition, the claim specifies a therapeutic use. In our view, the claimed use goes beyond the use of the antibody construct to prepare a pharmaceutical composition; it further requires the actual delivery of that pharmaceutical composition according to a defined dosage regimen, to treat or ameliorate indolent or aggressive B cell non-Hodgkin lymphoma (B NHL) or B cell leukemia. Therefore, we consider that although claim 2 is worded in the "Swiss" format, it essentially claims the same subject-matter as claim 1.

Essential elements

[27] On page 9 of the PR letter, we expressed our preliminary agreement with the FA regarding the identification of the essential elements. At page 2 of the RPR the Applicant maintained their disagreement with the construction of the claims:

> Applicant does not acquiesce to the construction put forth by the Examiner or the Board.

[28] In the present case, an agreement as to the essential elements is not necessary for the statutory subject-matter analysis and so our analysis will therefore proceed on the basis that all of the claim elements are essential.

<u>Statutory subject-matter and methods of medical treatment</u>

[29] Our preliminary analysis was put forth on pages 9-12 of the PR letter as follows:

> According to the FA and the SOR, the claims on file all encompass an unpatentable method of medical treatment. As acknowledged on page 3 of the FA, the essential elements include a dosage regimen that involves a range. According to the FA determining the duration of treatment (at least one week) and selecting a dosage from within the recited range (10 to 80 μg) were not considered to require the skill and judgment of a physician. As explained in the FA (page 3):
>
> > Although the specification states that the physician will determine the dosage regimen (page 13, second and third paragraphs), and provide monitoring of the duration (pages 58–60), there is no indication that a particular duration or fixed dose would not work for all subjects (even if not a preferred embodiment).

Nonetheless, the FA and the SOR considered that calculating the specific dose for administration based on the square metre body surface area of a patient does require the skill and judgment of a physician. The FA and SOR both refer to Example 4 of the Examples of purposive construction analysis of medical use claims for statutory subject-matter evaluation (referenced in *PN 2015*-01) which states:

> Even if the dosage claimed was a specific value e.g. 14 mg/kg/day, the physician still has to determine for each patient what the specific dose to administer is.

On page 2 of the RFA, the Applicant disagreed with this assessment, arguing that:

> [T]he calculations needed to assess a particular dosage needed for a patient are within the skill of a technician and not a physician, and Applicant submits that the claims do not prevent, interfere with or require the professional skill of a physician. The determination of a patient's body surface area is not a determination that requires professional skill, but is rather a standard test that can be carried out by any suitable technician or physician with the basic level of training using the proper equipment. A mere mathematical calculation is needed in order to determine the correct amount to administer based on the patient's body surface area once that surface area has been determined.

We note that Example 4 is based on *Axcan* and *Re Allergan's Patent Application 2,300,723* (2009) Commissioner's Decision CD 1292 (Pat App Bd & Pat Commr) (*Re Allergan*) which were decided before *AbbVie*. In both *Axcan* and *Re Allergan*, claims involving a dosage range based on a patient's weight were considered to require the skill and judgment of a physician, based on their knowledge of a patient's physiology, to determine an appropriate dosage. In our view the skill and judgment referred to in those cases was in respect of selecting a safe and effective dosage for a given patient from within the range. Further, the evidence in *Axcan* was that the limits of the range were not really fixed:

> [I]t is up to the physician based on his or her knowledge of the patient's rate of metabolism and other factors to determine the appropriate daily dosage. I cannot, for a moment, contemplate that Axcan could claim exclusive property in the dosage and sue a physician for prescribing Ursodiol for the treatment of PBC at a dosage less than 13 mg/kg/day or greater than 15 mg/kg/day. In fact, Dr. Shaffer, who was called by Axcan, stated during cross-examination that he has at times prescribed Ursodiol at dosages greater than those set out in the patent. (para 46)

Subsequent to *Axcan*, the Federal Court in *AbbVie* similarly explained that this may also arise in claims involving a fixed dosage and schedule "where there is evidence to contradict that claimed dosage"; i.e. where adjustments are needed which require a physician to exercise their skill and judgment.

> In view of the above context, we are of the preliminary view that Example 4 should not be relied on to mean that calculating a dose *per se* would in all cases require the skill and judgment of a physician or restrict prescribing practices. We consider that Example 4 relates to cases where there is a requirement for a physician to exercise their skill and judgment, for example, in selecting an appropriate dosage for a given patient. In such cases, to the extent that the calculation of the specific dose would necessarily be dependent on the selected patient-specific dosage, that calculation may also be considered as being associated with skill and judgment. The evidence in this case indicates that any dosage falling within the claimed range would be appropriate for all those to whom it is administered and merely converting to a specific dose based on a patient's body surface area does not require skill and judgment.
>
> In our view, the present application is distinguishable from the facts of *Axcan*, *Re Allergan* and Example 4. As reasoned in the FA, there is no skill and judgment required in relation to determining an appropriate dosage based on body surface area. The evidence in the description is that any dosage falling within the claimed range would be safe and effective and, based on the examples, the selection from within the range does not appear to depend on any patient-specific factors. Likewise, there is no evidence that a physician requires any skill and judgment to determine a patient's body surface area. Therefore, in our preliminary view, the skilled person would consider that no skill and judgment is associated with calculating the daily dose to administer based on the dosage and the patient's body surface area.
>
> Further, there is no evidence that the skill and judgment of the physician would be required to determine either the duration of the daily administration (at least 6h) or the overall duration of treatment regimen (at least one week). As well, there is no evidence contradicting the dosage regimen as it is recited in the claim. Indeed, the description teaches on page 17 that administration of the antibody construct for at least 1 week in a daily dose of 10 μg to 80 μg per square metre patient body surface area, whereby said daily dose is administered over at least 6h achieved the desirable biological effects, and this is supported by the examples in the description.
>
> In addition, once the physician has determined that a particular treatment regimen within the scope of the claim is appropriate for a patient, no further skill and judgment is expected or necessary. All dosages in the range are safe and effective, and based on the teachings in the description no adjustments are needed before or during treatment.
>
> Therefore, we are of the preliminary view that the claims on file do not require, restrict, prevent or interfere with the skill and judgment of a physician and do not amount to a method of medical treatment. Our preliminary view is therefore that the claims on file are directed to subject-matter that falls within the definition of an invention as set out in section 2 of the *Patent Act*.

[30] In the RPR, the Applicant expressed general agreement with the preliminary conclusions reached in the PR, although its comments were confined to the proposed claims. Our conclusion is therefore that the claims on file do not require, restrict, prevent or interfere with the skill and judgment of a physician and do not amount to a method of medical

treatment. It is our view therefore that the claims on file are directed to subject-matter that falls within the definition of an invention as set out in section 2 of the *Patent Act.*

Indefiniteness of claims 1, 6, 17 and 18 on file

[31] On pages 3–4, the FA explained that the subject-matter of claim 1 was indefinite because: "Claim 1 relates to a product for use in a method. It is unclear if the use of a product or the use of a method is being claimed."

[32] In that regard, the FA elaborated that the concern was that the claim could be interpreted to encompass a non-statutory method of medical treatment. In the RFA, the Applicant did not argue that claim 1 was compliant with subsection 27(4) of the *Patent Act*. Instead, the Applicant submitted new proposed claim 1 which does not contain the expression "in a method" as suggested in the FA.

[33] It is our view that the skilled person would consider that the expression "in a method" introduces a lack of clarity because, as mentioned above, the claim does not recite any active method steps that are consistent with a method.

[34] In the absence of any method steps, this introduces ambiguity that can be avoided by simply omitting the expression "in a method" as the Applicant has done in proposed claim 1.

[35] On page 4, the FA also identified minor clarity defects in claims 6, 17 and 18. Specifically, it is unclear from the expression "the kit for use according to claims 3–5" whether claim 6 depends on each of claims 3–5 individually or in combination. Further, in claims 17 and 18 the expression "the pharmaceutical composition" was considered to be indefinite because it has no antecedent basis in claims 1 or 3.

[36] In the RFA, the Applicant did not express disagreement and submitted new proposed claims 6, 17 and 18 wherein the identified defects are addressed.

[37] Having reviewed claims 6, 17 and 18 on file, we agree that these defects render the claims unclear.

[38] Therefore, it is our view that claims 1, 6, 17 and 18 on file do not comply with subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

[39] With the RFA the Applicant submitted proposed claims 1–19 which would amend claim 1 on file by omitting the expression "in a method", claim 6 on file to refer to dependent claims in the alternative and claims 17 and 18 on file to replace the expression "the pharmaceutical composition" with "the bispecific antibody construct". In the RPR, the Applicant did not express any disagreement with the analysis of the proposed claims set out in the PR. Rather, the Applicant indicated on page 1 its agreement to replace the claims on file with the proposed claims, and re-submitted the same proposed claim set provided previously with the RFA.

[40] With regard to the proposed claims, the SOR expressed the view that the proposed amendments would overcome the defects of indefiniteness raised against claims 1, 6, 17 and 18 on file, but that the subject-matter of the proposed claims would still be considered to not comply with section 2 of the *Patent Act*.

[41] We agree that the proposed amendments to former claims 1, 6, 17 and 18 would overcome the clarity defects raised in the FA.

[42] Further, we have already expressed above our view that the analogous claims on file do not require, restrict, prevent or interfere with the skill and judgment of a physician. Once the physician has decided to prescribe the antibody construct in accordance with a treatment regimen for the use stated in the claims, no further skill and judgment is required.

[43] In light of the above, it is our view that the proposed claims meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS

[44] We conclude that the claims on file do not encompass a method of medical treatment and therefore comply with section 2 of the *Patent Act*. We also conclude that claims 1, 6, 17 and 18 on file are indefinite and do not comply with subsection 27(4) of the *Patent Act*.

[45] Further, we conclude that the proposed claims meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[46] For the reasons set out above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the deletion of the claims on file and the insertion of proposed claims 1–19 as presented in the Applicant's letter of June 13, 2018 are necessary for compliance with the *Patent Act* and *Patent Rules*.

Christine Teixeira	Ryan Jaecques	Cara Weir
Member	Member	Member

DECISION OF THE COMMISSIONER

[47] I concur with the conclusion and recommendation of the Board. In accordance with subsection 86(11) of the *Patent Rules*, I hereby notify the Applicant that the following amendments and only the following amendments 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:

- the deletion of the claims on file; and
- the insertion of proposed claims 1–19 as presented in the Applicant's letter dated June 13, 2018.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 6th day of January, 2021.