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Commissioner's Decision #1588
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TOPICS: J–40 Mental Steps

SUJETS: J–40 Étapes mentales

Application No. : 2,591,113
Demande nº 2 591 113

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,591,113, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *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 that the application be refused 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 2,591,113, which is entitled "DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) AS A DIAGNOSTIC MARKER FOR RENAL DISORDERS" and is owned by ANTIBODYSHOP A/S. (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*. As explained below, our recommendation is to 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

[2] Canadian patent application 2,591,113 was filed under the provisions of the Patent Cooperation Treaty and has an effective filing date in Canada of December 20, 2005. It was laid open to public inspection on June 29, 2006.

[3] The instant application relates to methods for diagnosing renal disorders resulting from a renal insult by measuring the concentration of human neutrophil gelatinase-associated lipocalin (NGAL).

[4] The claims under review are claims 1 to 15 which were received at the Patent Office on August 15, 2018 (claims on file).

Prosecution history

[5] On June 17, 2019, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA rejected the application and noted the following defects: i) claims 1 to 15 are directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*; ii) claims 1 to 15 are anticipated and do not comply with paragraph 28.2(1)(b) of the *Patent Act*; iii) claims 1 to 15 are obvious and do not comply with section 28.3 of the *Patent Act*; and iv) claim 15 suffers from minor clarity defects contrary to subsection 27(4) of the *Patent Act*.

[6] Following the mailing of the FA, an Office notice entitled "Patentable subject-matter under the *Patent Act*" (CIPO, November 2020) [*PN2020–04*] was published. Said notice was

drafted in response to *Choueifaty v Canada (Attorney General)* 2020 FC 837 [*Choueifaty*]. This notice addressed the Office's current approach to both claim construction and to the determination of patentable subject-matter.

[7] In a December 8, 2020 response to the FA (RFA), the Applicant submitted arguments addressing the defects raised in the FA with regard to the claims on file with the exception of the minor clarity defect that was not addressed.

[8] As the Examiner still considered the application not to comply with the *Patent Act*, pursuant to paragraph 30(6)(c) of the former *Rules*, the application was forwarded to the Board for review along with an explanation outlined in a Summary of Reasons (SOR). Specifically, the SOR indicated that in view of changes to the Office practice relating to diagnostic methods since the mailing of the FA: i) only claims 1 to 11 are now considered directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*; ii) claims 1 to 15 are now considered novel and compliant with paragraph 28.2(1)(b) of the *Patent Act*; iii) claims 1 to 15 are now considered non-obvious and compliant with section 28.3 of the *Patent Act*; and iv) claim 15 still suffers from minor clarity defects contrary to subsection 27(4) of the *Patent Act*. In a letter dated April 19, 2021, the Board forwarded a copy of the SOR to the Applicant.

[9] In a May 5, 2021 response to the Board letter and the SOR (RSOR), the Applicant submitted an amended claim set containing 15 claims (proposed claims set-1) and related arguments as to why the proposed claims addressed the remaining defects identified in the SOR.

[10] 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 (PR) Letter to the Applicant on July 2, 2021.

[11] In a written response to the PR letter (RPR Letter) dated July 13, 2021, the Applicant accepted the invitation to a hearing and provided written submissions as well as a second proposed set of claims (proposed claims set-2).

[12] Because the submissions and accompanying proposed claims set-2 received in response to the PR Letter addressed all the outstanding issues, the Panel suggested in a communication dated July 13, 2021 that a hearing on the matter was possibly unnecessary. In a response received on the same day, the Applicant agreed that given the Panel's inclination to

recommend that the Commissioner require these proposed amendments in accordance with subsection 86(11) of the *Patent Rules* a hearing did not appear necessary at that stage of the review. Therefore, a hearing was not held.

ISSUES

[13] In view of the foregoing, the issues to be addressed in the present review are whether:

- claims 1 to 11 on file are directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*; and
- claim 15 suffers from a clarity defect contrary to subsection 27(4) of the *Patent Act*.

[14] In addition to the claims on file, the proposed claims set-2 has also been considered.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Purposive construction

[15] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust*] and *Whirlpool Corp v Camco Inc*, 2000 SCC 67 [*Whirlpool*] purposive construction is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK), considering the whole of the disclosure including 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 of ordinary skill in the art (POSITA) that a variant has a material effect upon the way the invention works.

[16] *PN2020–04* also discusses the application of these principles, pointing out 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.

Patentable subject-matter and diagnostic methods

[17] Once the subject-matter defined by a claim has been determined through a purposive construction, it is necessary to determine whether the subject-matter defined by a claim is

patentable subject-matter having regard to both the definition of "invention" in section 2 of the *Patent Act*:

> [I]nvention 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.

and in accordance with subsection 27(8) of the *Patent Act*:

> No patent shall be granted for any mere scientific principle or abstract theorem.

[18] *PN2020–04* explains the Patent Office's approach to assess whether the subject-matter defined by a claim is patentable and not prohibited under subsection 27(8) of the *Patent Act*. According to *PN2020-04*, the assessment of patentable subject-matter requires the identification of the actual invention defined by the subject-matter of the claim be grounded in a purposive construction of the claim: *Free World Trust* para 46. Further, *PN2020-04* also considers the guidance in *Canada (Attorney General) v Amazon.com Inc*, 2011 FCA 328 at paras 66-69 stating:

> To be both patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*, the subject-matter defined by a claim must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change and that relates to the manual or productive arts, meaning those arts involving or concerned with applied and industrial sciences as distinguished in particular from the fine arts or works of art that are inventive only in an artistic or aesthetic sense.
>
> […]
>
> Where an actual invention consists of a combination of elements cooperating together, all of the elements of the combination must be considered as a whole when considering whether there is patentable subject-matter and whether the prohibition under subsection 27(8) of the *Patent Act* is applicable.

[19] With particular reference to the determination of patentable subject-matter in respect of diagnostic method claims, *PN2020-04* states that:

> A claim to a medical diagnostic method often includes an element correlating a specific analyte or the result of a medical test to a disease. A correlation, on its own, would generally be considered an abstract or disembodied idea. In many cases, a claim to a medical diagnostic method further includes one or more physical steps that comprise carrying out a medical test or determining the presence or quantity of the analyte in a sample. Such steps may include, for example, means for identifying, detecting, measuring, etc. the presence or quantity of an analyte.

> An abstract idea that is an element of a claim that cooperates with other elements of the claim becomes part of a combination of elements making up a single actual invention. In such cases, all of the elements of the combination are considered as a whole and may constitute patentable subject-matter if the actual invention either has physical existence or manifests a discernible physical effect or change.
>
> Thus, a diagnostic method claim that defines a combination of elements that cooperate together so as to form a single actual invention that includes physical means for testing or for identifying, detecting, measuring, etc. the presence or quantity of an analyte in a sample would be considered to be patentable subject-matter and not to be prohibited under subsection 27(8) of the *Patent Act*.

Indefiniteness

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

[21] 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.

ANALYSIS

Purposive construction

The claims on file

[22] Claim 1 is the sole independent claim on file:

> 1. A method of determining the likelihood of a renal disorder resulting from a renal insult selected from acute renal failure, acute tubular necrosis and acute tubule-interstitial nephropathy in a human being, wherein said method discriminates between the renal disorder and a condition that is not affecting the kidney, said method comprising the steps of

> i) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being, wherein the sample is obtained from the human being within 24 hours of the renal insult,
>
> ii) comparing said concentration with a predetermined cutoff value of between 250 ng/mL and 525 ng/mL, chosen to exclude lower concentrations of NGAL associated with conditions that do not affect the kidney, wherein a concentration above the cutoff value is indicative of the likelihood of the renal disorder.

[23] Dependent claims 2 to 15 provide further limitations relating to the condition not affecting the kidney and how the corresponding cutoff value is chosen (claims 2 to 4), the recitation of further repetition of steps i) and ii) under further defined circumstances (claims 5 to 7), the type of renal insult (claims 8 and 9), the recitation of a further step of comparing the concentration of NGAL with a second cutoff value indicative of a renal disorder requiring treatment by dialysis or not (claims 10 and 11), and the recitation of the measuring/determining means (claims 12 to 15).

The POSITA and their CGK

[24] In the PR Letter, we preliminarily adopted the identification of the POSITA and their CGK as found in the FA and reproduced here:

> The person skilled in the art is a team comprising at least a person in the field of nephrology, such as a nephrologist or medical research scientist, as well as a person in the field of detection assays development for biological analytes in biological samples, such as a biochemist or medical technologist.
>
> The common general knowledge (CGK) possessed by such a person skilled in the art includes the systems and methods commonly used in the art for the detection of analytes in biological samples. This person would also be familiar with standard and conventional methods of diagnosing renal disorders, particularly diagnostic assays using protein diagnostic markers. Methods of measuring NGAL in urine, plasma or serum would have been well known to the skilled person. This is supported by the current description, which explicitly teaches that NGAL was measured in blood or urine (see page 2, line 29 to page 4, line 4), that the measurement of NGAL according to the invention can be accomplished using any known techniques in the common general knowledge of the art (see page 12, lines 12-15), and specifically wherein a well-established ELISA antibody method in the common general knowledge of the art was used to detect NGAL within the claimed method (see Example 4, page 15, lines 25-29). This is further supported by documents D1, D2 and D3 which are used to exemplify the common general knowledge. D1, D2 and D3 specifically disclose the use of an ELISA-based method for the measurement of NGAL in urine, serum or plasma in the diagnosis of diseases including renal disorders, using a monoclonal or polyclonal antibody for NGAL. Furthermore, it was well established in the CGK to measure NGAL repeatedly in samples taken at various time points (within 24h) to monitor the

> progression of diseases, as exemplified by D1 and D2, and to monitor the effectiveness/progression of the disease following treatment for the disease, as further disclosed in D1. Likewise, it was well established in the CGK to measure NGAL in patients that suffered an ischemic renal injury caused by exposure to a nephrotoxic agent, as further disclosed in D1.

[25] In the RPR Letter, the Applicant did not contest or comment on these characterizations, and so we adopt them for the purposes of this final review.

The essential elements

[26] With regard to the assessment of the essential elements, *PN2020-04* states that:

> In carrying out this identification of essential and non-essential elements, all elements set out in a claim are presumed essential, unless it is established otherwise or is contrary to the language used in the claim.

[27] With respect to the claims on file, we expressed in the PR Letter our preliminary view that the POSITA reading claims 1 to 15 would understand that there is no use of language in any of the claims indicating that any of the elements are optional, a preferred embodiment or one of a list of alternatives. Although claims 1 and 15 list a number of types of renal insult (claim 1), types of sample (claim 1) and types of immunochemical method (claim 15), where at least one of them is contemplated, those are considered essential elements of the claims. Further, there is no indication on the record before us that any claim elements are non-essential. It was therefore our preliminary view that the POSITA would consider all of the elements of claims 1 to 15 as essential.

[28] In the RPR Letter, the Applicant did not contest or comment on the essentiality of the elements. We therefore consider all of the elements of claims 1 to 15 as essential for the purposes of this final review.

Meaning of terms

[29] In the PR Letter, we gave further consideration to the phrase “determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being” recited in claim 1. Having reviewed the prosecution record and the relevant jurisprudence, we expressed the preliminary view that construing said phrase as encompassing an embodiment of the claimed method with no physical measuring step, as submitted in the SOR, would be giving the words a meaning

they cannot reasonably bear when interpreted in the context of the patent application as a whole and the record before us. The POSITA would rather understand that determining the concentration of NGAL includes a physical step of measuring:

> The phrase "determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being" recited in claim 1 merits further consideration to determine what is exactly meant by these words.
>
> More specifically, we will determine whether this phrase could reasonably be construed as encompassing reading a report containing the concentration values, and thus encompassing an embodiment of the claimed method with no physical measuring step (the concentrations would have presumably been measured in a prior step outside the scope of the claim) as submitted in the SOR on page 2:
>
> > The step of "determining" the concentration of NGAL could encompass reading a report containing the values (i.e. a mental step), and thus comprises an embodiment of the claimed method with no physical measuring step for the biomarker…
>
> 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 word "determining" 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".
>
> Having considered the application as a whole, it is our preliminary view that the POSITA would understand that the word "determining" in the context of the claims on file means to include a physical step of measuring, and thus does not encompass an embodiment of the claimed method with only mental steps for the following reasons.
>
> Focusing on the claims on file first, we note that the subject-matter of dependent claims 5 to 7 imply that an embodiment of the recited method step i) includes a physical measurement of NGAL concentration that is repeated. We also note that the subject-matter of dependent claims 12 to 15 explicitly relate to an embodiment wherein step i) includes a physical measuring step. On the other hand, but not determinative on the issue, an explicit or implicit indication that step i) of claim 1 could be only a mental step is not found in any dependent claims.
>
> Following a review of the rest of the specification and drawings, it appears that the phrase "determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being" is not expressly discussed or further defined in the disclosure.

In our preliminary view, the most relevant portions of the description that could be of assistance to construe the intended meaning of "determining" in the context of the phrase "determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being" as recited in step i) of claim 1 are the following ones:

> The present invention relates to methods for diagnosis and monitoring of human disease by means of measurement in a bodily fluid of human neutrophil gelatinase-associated lipocalin (NGAL)… [page 1]
>
> …
>
> Accordingly, the present invention provides methods for the diagnosis and/or monitoring of renal injury in humans, comprising measuring a level of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid, preferably urine, obtained from the patient. [pages 4 to 5]
>
> …
>
> Levels of NGAL are preferably determined by an immunochemical method. Examples of such methods include, but are in no way limited to a sandwich ELISA (enzyme-linked immunosorbent assay), a lateral flow method, or a dipstick. [page 6]
>
> …
>
> Accordingly, the present invention relates to measurement of NGAL in a sample of bodily fluid, preferably human urine from which any neutrophils have been removed, as a diagnostic marker of renal disorders, especially those due to renal ischemia or nephrotoxic agents. [page 8]
>
> …
>
> The method of the present invention in one embodiment comprises the steps of measuring the concentration of human NGAL in a sample of urine, preferably centrifuged to remove any neutrophils, from the individual to be diagnosed, and comparing the measured concentration with a selected cutoff value determined to exceed those urinary concentrations found in humans that have no renal disorder, but may either be apparently healthy or have other disorders including inflammatory conditions, bacterial infections or carcinomas. [page 9]
>
> …
>
> In another embodiment, the present invention comprises the steps of measuring the concentration of human NGAL in a sample of plasma or serum from the individual to be diagnosed, and comparing the measured

> concentration with a selected cutoff value determined to exceed those plasma or serum concentrations found in humans that have no renal disorder, but may either be apparently healthy or have other disorders including inflammatory conditions, bacterial infections or carcinomas. [pages 9 to 10]
>
> …
>
> Measurement of human NGAL in a sample of bodily fluid, such as a urine sample, can be performed by any method that provides satisfactory analytical specificity, sensitivity and precision. Preferred methods are binding assays using one or more binding molecules specific to human NGAL. Such binding molecules include, but are not limited to, polyclonal or monoclonal antibodies against NGAL or specific NGAL binding molecules generated by other means. [page 12]
>
> …
>
> A preferred means for measuring NGAL in accordance with the present invention in a sample of human urine comprises a dipstick, lateral flow or minicolumn test, which allows for the rapid, near-patient analysis of a sample. As will be understood by those of skill in the art upon reading this disclosure, however, other means for measuring NGAL can be used. [page 13]

All the above passages relate to an embodiment of the disclosed invention wherein the determination of the concentration of NGAL is achieved with a physical measuring step and it is our preliminary view that no passage of the description discloses or suggests that determining the concentration of NGAL in the context of the described invention encompasses an embodiment of the claimed method wherein determining the concentration of NGAL is achieved with only a mental step.

It is therefore our preliminary view that construing the phrase "determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being" as encompassing an embodiment of the claimed method with no physical measuring step would be giving the words a meaning they cannot reasonably bear when interpreted in the context of the patent application as a whole and the record before us. The POSITA would rather understand that determining the concentration of NGAL includes a physical step of measuring.

[30] In the RPR Letter, the Applicant did not contest or comment on our purposive construction of the phrase and the related preliminary view that the subject-matter recited in claim 1 includes a physical step of measuring the concentration of NGAL. We therefore adopt this construction for the purposes of the following analysis of the patentability of the subject-matter of claims 1 to 11 on file.

Patentable subject-matter and diagnostic methods

[31] Independent claim 1, set out above, primarily relates to the steps of a diagnostic method for determining the likelihood of a renal disorder resulting from a renal insult. The description, on page 4, explains the discovery that NGAL levels due to renal injury are higher than levels of NGAL that result from a condition that is not affecting the kidney:

> It has now surprisingly been found that NGAL levels due to renal injury are generally higher than levels of NGAL that result from inflammatory, infective or cancerous conditions that do not affect renal function. This has allowed the establishment of methods for the diagnosis and/or monitoring of a renal disorder in a patient which distinguish renal disorders from other disorders that do not affect the kidney.

[32] According to the FA, the essential elements of the diagnostic methods of claims 1 to 15 are limited to disembodied mental conclusions. However, this assessment was based on guidance that has since been rescinded. As explained above, the Office's revised position *vis-à-vis* diagnostic methods considers whether the actual invention is a combination of elements that has physical existence or manifests a discernible physical effect or change.

[33] In the RFA, the applicant submitted that, according to its interpretation of the new guidance found in *PN2020-04*, the subject-matter of the claims on file meets the requirements to be considered patentable subject-matter as all elements of the claims on file should be considered essential elements, all elements should be considered together to form a single actual invention and the claimed invention includes the physical step of "determining the concentration" of NGAL.

[34] The position expressed in the SOR with regard to the claims on file is based on the revised guidance. The SOR stated that since claims 12 to 15 clearly define a measuring step by using an immunochemical method these claims are now allowable according to the new practice. However, and as mentioned above in the "Meaning of terms" section, the SOR on page 2 disagreed with the Applicant's submission that the claimed invention includes a physical step and expressed the view that the step of "determining" the concentration of NGAL encompassed by the methods defined in claims 1 to 11 is not limited to a physical step of measuring that has physical existence or manifests a discernible physical effect or change and could encompass acquiring the pertinent information through other means, such as reading a report containing the values (i.e. a mental step):

> Since the practice on diagnostic methods has changed since the mailing of the Final Action, the purposive construction and analysis of the claims expressed in the Final Action are no

> longer applicable. Following the new Practice Notice released on November 3, 2020 for patentable subject-matter under the Patent Act, all elements of claims 1-15 are considered essential features of the claimed invention.
>
> Claims 1-11 still encompass an embodiment that lies outside the definition of "invention" and do not comply with Section 2 of the Patent Act. Independent claim 1 defines a diagnostic method with no physical method step. The step of "determining" the concentration of NGAL could encompass reading a report containing the values (i.e. a mental step), and thus comprises an embodiment of the claimed method with no physical measuring step for the biomarker, which is considered non-patentable subject matter. It is suggested that the term "determining" be changed to "measuring" to make it clear that such step of the claimed method is a physical active step.

[35] In the RSOR, the Applicant did not contest or comment on the construction of the term "determining" as found in the SOR and instead submitted proposed claims wherein claim 1 is amended to change the step of "determining" the concentration of NGAL to "measuring" the concentration of NGAL.

[36] In the PR Letter, we expressed the preliminary view that the data acquisition elements of step i) and the data analysis elements of step ii) cooperate to form a single actual invention that allows for the determination of the likelihood of a renal disorder resulting from a renal insult. Given our view with respect to the purposive construction of the phrase "determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a urine, plasma or serum sample from the human being", a view that we adopted for the purposes of this final review, it was also our view that step i) includes a physical step, and thus the actual invention of claim 1 on file manifests a discernable effect or change. In comprising the use of a physical step of data acquisition, it was our preliminary view that the actual invention of claim 1 on file also relates to the manual or productive arts and is not prohibited subject-matter under subsection 27(8) of the *Patent Act*.

[37] We further considered that dependent claims 2 to 11, being ultimately dependent on independent claim 1, also comprise actual inventions that manifest a discernable effect or change, are related to the manual or productive arts and that are not prohibited subject-matter under subsection 27(8) of the *Patent Act*.

[38] In the RPR Letter, the Applicant did not contest or comment on our preliminary conclusions regarding the patentability of the claimed subject-matter.

[39] In light of the above, our conclusion is therefore that claims 1 to 11 are directed to

patentable subject-matter and therefore comply with section 2 of the *Patent Act.*

Indefiniteness

[40] According to the FA, claim 15 on file is indefinite because of a clarity defect:

> Claim 15 is indefinite and does not comply with subsection 27(4) of the *Patent Act.* The term "the immunochemical method" (claim 15, lines 21-22) has no antecedent with respect to claims 1-13.

[41] Having reviewed the claims on file, we agreed in the PR Letter that the clarity defect identified in the FA with regard to claim 15 is present.

[42] Furthermore, pursuant to subsection 86(9) of the *Patent Rules*, we identified that claim 12 may suffer from a clarity defect contrary to subsection 27(4) of the *Patent Act* because the phrase "is measured" in claim 12 is not consistent with the phrase "is determined" in claim 1.

[43] In the RPR Letter, the Applicant did not contest or comment on the clarity defects identified by the Panel and instead submitted proposed claims set-2 to correct the identified antecedence defects.

[44] Therefore, it is our view that claims 12 and 15 on file do not comply with subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

[45] As indicated above, the Applicant submitted proposed claims set-1 with the RSOR. According to the RSOR, the claims were amended to address the alleged defect relating to non-patentable subject-matter with regard to claims 1 to 11 (i.e., "determining" was changed to "measuring" in claim 1) and the antecedence defect of claim 15.

[46] We indicated in the PR Letter that the subject-matter of the proposed claims would comply with section 2 and subsection 27(4) of the *Patent Act*. However, given our opinion to the effect that the subject-matter of claims 1 to 11 on file complies with section 2 of the *Patent Act*, we were of the preliminary view that the proposed amendment to claim 1 on file goes beyond an amendment that is necessary in order to make the application allowable and thus it is not all of the proposed claim amendments found in the proposed claims that qualify as certain necessary amendments under subsection 86(11) of the *Patent Rules*.

[47] In response, the Applicant submitted proposed claims set-2 with the RPR Letter. According to the RPR Letter, the claims on file were amended to address the antecedence defects identified in claims 12 and 15.

[48] We agree that the proposed claims set-2 addresses the clarity issues and would comply with subsection 27(4) of the *Patent Act*.

CONCLUSIONS

[49] With regard to the claims on file, we have determined that:

- Claims 1 to 11 define patentable subject-matter that complies with section 2 of the *Patent Act*; and
- claims 12 and 15 on file do not comply with subsection 27(4) of the *Patent Act*.

[50] With regard to the proposed claims, we are of the view that the proposed claims set-2 qualify as amendments that are necessary in order to make the application allowable under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[51] In view of the above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the following amendments are necessary for compliance of the application with the *Patent Act* and *Patent Rules*:

- the deletion of the claims of file; and
- the insertion of proposed claims set-2 submitted on July 13, 2021.

Marcel Brisebois	Ryan Jaecques	Christine Teixeira
Member	Member	Member

DECISION OF THE COMMISSIONER

[52] I concur with the conclusions and recommendation of the Board. 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:

- the deletion of the claims on file; and
- the insertion of proposed claims set-2 submitted on July 13, 2021.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 20th day of July, 2021