Citation: BIO-RAD LABORATORIES, INC. (Re), 2022 CACP4

Commissioner's Decision#1611

Décision du Commissaire nº 1611

Date: 2022-01-27

TOPIC:	J00	Meaning of Art
	B00	Ambiguity or Indefiniteness
	C00	Disclosure - Adequacy or Deficiency of Description
SUJET:	J00	Signification de la technique
	B00	Caractère ambigu ou indéfini
	C00	Divulgation - Caractère adéquat ou inadéquat de la description

Application No. : 2,759,416

Demande nº 2 759 416

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,759,416, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019, has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019–251). The recommendation of the Board and the decision of the Commissioner are to require the Applicant to make necessary amendments to the application, failing which the application would be refused.

Agent for the Applicant:

MARKS & CLERK
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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,759,416 which is entitled “SYSTEM AND METHOD FOR DETERMINING SIGMA OF A CLINICAL DIAGNOSTIC PROCESS” and is owned by BIO-RAD LABORATORIES, INC. (“the Applicant”).

[2] 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* (SOR/2019-251) (“the *Patent Rules*”). As explained in more detail below, our recommendation to the Commissioner of Patents is to require the Applicant to make necessary amendments to the application, failing which the application would be refused.

BACKGROUND

The application

[3] The application, based on a previously filed *Patent Cooperation Treaty* application, was filed on April 12, 2010, and was laid open to public inspection on January 27, 2011.

[4] The application relates to clinical diagnostic processes, and more particularly to a method of determining a sigma-metric for such processes.

[5] The claims under review are claims 1 to 34 on file (“claims on file”), which were received at the Patent Office on January 11, 2016.

Prosecution history

[6] On August 14, 2018, a Final Action (“FA”) was issued pursuant to subsection 30(4) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019 (“the former *Rules*”), in which the application was rejected on the basis of non-statutory subject-matter and incorporation by reference. Accordingly, the FA considered that the application did not comply with section 2 of the *Patent Act*, and did not comply with subsection 81(1) of the former *Rules* (now subsection 57(1) of the *Patent Rules* (SOR/2019–251)).

[7] On February 14, 2019, a response to the FA (“R-FA”) was filed by the Applicant. In the R-FA, the Applicant submitted a proposed amendment of the description, removing the first paragraph that incorporated by reference a U.S. patent application. The Applicant further argued that the claims complied with section 2 of the *Patent Act*, and that the amended description complied with the *Patent Rules*.

[8] After considering the R-FA, the Examiner maintained the position that the application did not overcome the non-statutory subject-matter defect. Additionally, the Examiner considered that claim 14 on file was indefinite and thus did not comply with subsection 27(4) of the *Patent Act*. The application was forwarded to the Board on October 2, 2019, along with a Summary of Reasons (SOR), explaining the Examiner’s rationale for identifying the defects.

[9] In a letter dated December 10, 2019, the Applicant expressed continued interest in having the application reviewed by the Board.

[10] *Choueifaty v Canada (AG)* 2020 FC 837, issued on August 21, 2020, prompted a review of Patent Office Practice, and the subsequent issuance of “Patentable Subject-Matter under the *Patent Act*” (CIPO, November 2020) [*PN2020–04*]. *PN2020–04* provides guidance on the current understanding by the Patent Office of the legal principles applicable in purposive construction and patentable subject-matter.

[11] In view of the latest Office Practice, the Examiner further provided a Supplemental Summary of Reasons (“SSOR”), dated March 26, 2021, stating that the claims complied with section 2 of the *Patent Act*, and that the amended description complied with the *Patent Rules*.

[12] The present panel (“the Panel”) was formed to review the application under paragraph 199(3)(c) of the *Patent Rules*.

[13] In a preliminary review letter dated December 7, 2021 (“PR letter”), the Panel presented its preliminary analysis and rationale, and was of the preliminary view that:

- claims 1 to 34 on file are directed to non-patentable subject-matter, which is prohibited under subsection 27(8) of the *Patent Act* and falls outside the definition of “invention” in section 2 of the *Patent Act*;

- the description of the present application incorporates by reference another document and does not comply with subsection 57(1) of the *Patent Rules*;
- claim 14 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act*; and
- the proposed amendment in the R-FA does not overcome the non-patentable subject-matter and indefinite defects and cannot be considered a “necessary” amendment under subsection 86(11) of the *Patent Rules*.

[14] The PR letter also offered the Applicant the opportunities to make written submissions and to attend an oral hearing.

[15] In letters dated January 4 and January 13, 2022, the Applicant submitted further proposed amendments to the claims and the description, and stated that if the amendments were acceptable, the hearing would not be necessary.

ISSUES

[16] This review will address the following issues:

- whether claims 1 to 34 on file are directed to patentable subject-matter, as required by section 2 of the *Patent Act*;
- whether the description of the application complies with subsection 57(1) of the *Patent Rules*; and
- whether claim 14 on file is definite, as required by subsection 27(4) of the *Patent Act*.

[17] In this review, we will first consider the issues that pertain to the claims on file. We will then consider whether the proposed amendments constitute amendments necessary for compliance with the *Patent Act* and *Patent Rules*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive construction

[18] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66, and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, 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 skilled person that a variant has a material effect upon the way the invention works.

[19] *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

[20] 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.

[21] Subsection 27(8) of the *Patent Act* also prescribes that:

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

[22] *PN2020–04* describes the Patent Office's approach to determining if a claim is directed to patentable subject-matter:

> 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.

[23] *PN2020–04* further describes the Patent Office's approach to determining if a computer-related invention is patentable subject-matter. For example, the mere fact that a computer is among the essential elements of the claimed invention does

not necessarily mean that the claimed invention is patentable subject-matter. An algorithm itself is abstract and unpatentable subject-matter. A claim to a computer programmed to merely process the algorithm in a well-known manner without solving any problem in the functioning of the computer will not be patentable subject-matter because the computer and the algorithm do not form part of a single actual invention that solves a problem related to the manual or productive arts. On the other hand, if processing the algorithm improves the functionality of the computer, then the computer and the algorithm would together form a single actual invention that solves a problem related to the manual or productive arts and the subject-matter defined by the claim would be patentable.

[24] In *Schlumberger Canada Ltd v Commissioner of Patents*, [1982] 1 FC 845 (CA) [*Schlumberger*], the court concluded that, although computers were necessary for the invention to be put into practice, the computer did not form part of "what has been discovered" and thus was not relevant in determining whether the claimed invention was patentable subject-matter; the computer was merely being used to make the kind of calculations it was invented to make.

Description

[25] Subsection 57(1) of the *Patent Rules* states:

> The description must not incorporate any document by reference.

Indefiniteness

[26] Subsection 27(4) of the *Patent Act* requires that a claim 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.

[27] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306, 12 CPR 99, at page 146, 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

Purposive construction

The person skilled in the art and their common general knowledge

[28] The PR letter provided our preliminary identifications of the skilled person and their CGK. The Applicant did not dispute or comment on these identifications and we adopt them in this review.

> The FA (page 2) identified the skilled person and their CGK as:
>
> > The skilled person, who may be a team of people, is skilled in the fields of computer programming, quality control, statistics, data analysis, and laboratory instruments.
> >
> > The person skilled in the art would possess the following CGK:
> >
> > > The sigma-metric defines how many sigmas (i.e., standard deviations) of deviation or variation a process can experience and still be within its allowable tolerance limits. The higher the sigma, the more robust a process is in the presence of error. By definition, a six sigma process is still within specification even with six standard deviations of variation (see page 1, lines 16–18);
> > >
> > > six sigma concepts are used in clinical diagnostics (see page 1, lines 21–28);
> > >
> > > computers are used to determine sigma-metrics; and
> > >
> > > how to acquire specimen data from laboratory instruments and to use computers to process this data.
>
> The Applicant did not contest or comment on the identifications above and they are adopted for this preliminary review.

The essential elements

[29] There are 34 claims in the claims on file, including independent claims 1, 12, 16, and 24, and dependent claims 2 to 11, 13 to 15, 17 to 23, and 25 to 34.

[30] Claim 1 is representative of the independent claims and reads:

> 1. A computer-implemented method of determining sigma of a clinical diagnostic process, comprising:
>
> acquiring specimen data from a plurality of laboratory instruments;
>
> evaluating said specimen data and determining an analytical standard deviation for a plurality of said specimen data, wherein said analytical deviation corresponds to analytical imprecision in said evaluation;
>
> acquiring patient analyte values;
>
> assigning a standard deviation to said patient analyte values based on said specimen data analytical standard deviations;
>
> computing a single sigma-metric from said assigned standard deviations, wherein said single sigma-metric defines a number of process standard deviations said clinical diagnostic process can experience while remaining within allowable tolerance limits, said sigma-metric representing a sigma for said clinical diagnostic process; and
>
> reporting said sigma-metric to a user of at least one of said plurality of laboratory instruments.

[31] Claims 12, 16, and 24 recite similar features as claim 1. The dependent claims define further limitations regarding computation of the single sigma-metric.

[32] The FA considered some of the claimed elements as non-essential, based on the Office Practice at the time. However, in view of the change in Office Practice (*PN2020–04*), the PR letter undertook anew the analysis of the essential elements.

[33] As explained in the PR letter, according to *PN2020–04*, purposive construction is conducted by considering where the skilled person would have understood the Applicant to have intended to place the fences around the monopoly being claimed.

[34] Considering the whole of the specification, we consider that the skilled person would understand that there is no use of language in the claims indicating that any of the elements are optional, a preferred embodiment, one of a list of alternatives, or otherwise non-essential. Therefore, we presume that all claimed elements are essential.

Meaning of expression

[35] The PR letter provided our estimation of the expression “acquiring specimen data from a plurality of laboratory instruments.” The Applicant did not dispute or comment on this estimation and we adopt it in this review.

> The meaning of the following expression, which is used in the claims on file, is significant to our analysis of patentable subject-matter: “acquiring specimen data from a plurality of laboratory instruments.”
>
> The description of the present application recites (pages 7 to 8):
>
> > It should be appreciated that application module 20, or portions thereof, as well as appropriate data can be downloaded to and executed on client system 10.
> >
> > …
> >
> > The specimens may be commercial control materials or may be pooled patient specimens, in either case the sample volumes of the specimens are preferably large enough to allow a precision evaluation to be conducted. Because the accuracy of the calculated sigma is related to the number of samples of each specimen and the range of the specimen concentrations evaluated, most preferably the specimen concentrations cover the entire analytical range of the process being evaluated, and the specimens are repeatedly measured over an extended period of time.
>
> In our preliminary view, the specimen data may be obtained via active measurements using laboratory instruments, or simply via data retrieval from certain apparatus.
>
> After considering the specification as a whole, in view of the nature of the skilled person with their CGK, we provide our estimation of the skilled person’s understanding of this expression:
>
> - “acquiring specimen data from a plurality of laboratory instruments”: means obtaining specimen data through performing measurements using the laboratory instruments, or receiving specimen data from the laboratory instruments.

<u>Patentable subject-matter</u>

[36] The PR letter explained why the Panel preliminarily determined that the claims on file define non-patentable subject-matter. The Applicant did not dispute this analysis and we adopt it in this review.

> In the FA (pages 3 to 5), the Examiner stated that the computerized features as claimed were not essential, and that the “the claims [are]

directed to a mere scheme which is not considered to be an invention under section 2 of the *Patent Act"*. Notably, this assessment was based on an Office Practice that has since been rescinded.

The Applicant disagreed. In the R-FA (pages 3 to 7), the Applicant argued that the computer elements are essential, and that the claims defined a method of practical application:

> Applicant respectfully submits that the claimed invention has a method of practical application and provides a technical solution to a technical problem. As such, the claimed invention does not lack physicality, and is not directed towards a mere idea, scheme, plan or set of rules.
>
> In view of the above, Applicant respectfully submits that the claims do, in fact, relate to patentable subject matter as defined by Section 2 of the *Patent Act* and requests that the Examiner's rejection be withdrawn [emphases in the original].

In view of the new guidance in *PN2020–04*, the Examiner stated in the SSOR that all the claimed elements were considered to be essential, and that the data acquisition step as claimed provided the required physicality to the claimed subject-matter. Accordingly, the SSOR concluded that the claims were directed to patentable subject-matter.

After considering the R-FA, SOR, SSOR, and the specification as a whole, we are of the preliminary view that the claims are not directed to patentable subject-matter, for the reasons stated below.

Although all the claimed elements, including the computer elements, are presumed to be essential, as noted in *PN2020–04*, the mere fact that a computer is identified to be an essential element of a claimed invention for the purpose of determining the fences of the monopoly under purposive construction does not necessarily mean that the subject-matter defined by the claim is patentable subject-matter and outside of the prohibition under subsection 27(8) of the *Patent Act*.

Further, as stated in *PN2020–04*, "[t]o 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," referencing, in part, *Canada (Attorney General) v Amazon.com, Inc*, 2011 FCA 328 [*Amazon*] paras 42 and 66 to 69.

Regarding the argument that the claimed invention defines a method of "practical application," as explained in *Amazon*, a disembodied idea cannot be rendered patentable merely because it has a practical embodiment or a practical application (*Amazon*, para. 61). *Amazon* also noted that this was the situation in *Schlumberger*, where the computer

was merely being used to make the kind of calculations it was invented to make. Therefore, the fact that the claimed method generates a single-sigma metric which allows evaluation of laboratory instruments and multiple clinical diagnostic processes would not render the claimed subject-matter patentable.

For the present application, the claimed computer elements, such as “computer system,” “processor,” and “computer-readable medium,” are directed to generic computer components that are used in a well-known manner to input and process data. Further, although claims 1 to 15 are directed to “a computer-implemented method”, the method steps do not refer to any computer elements. Therefore, the mere presence of computer elements in some of the claims would not render an abstract algorithm patentable, in accordance with *PN2020–04*. In our preliminary view, the skilled person, when reading the specification as a whole, would understand how these elements might be implemented and used conventionally by the claimed method, without any improvement to the functioning of the computer. Therefore, the computer elements as claimed are merely being used to make the kind of generic calculations and data processing they are known to make (see *Schlumberger*) and do not form part of the actual invention.

Further, although the independent claims recite that the specimen data is “acquired” or “received” from a plurality of laboratory instruments, they do not specify that the specimen data is acquired through measurements using the laboratory instruments. As indicated above, in our preliminary view, the skilled person would consider that the step of “acquiring specimen data from a plurality of laboratory instruments” is broad enough to encompass embodiments wherein measurements are not performed. In this case, receiving data from an apparatus as an input to an abstract algorithm would not provide the required physicality to the claimed subject-matter. In our preliminary view, the claims must include steps of performing measurements, and acquiring specimen data through the measurements, to impart the required physicality to the claimed subject-matter.

All other method steps of the independent claims are directed to data manipulations without the involvement of any physical elements. Therefore, it is our preliminary view that the actual invention is directed to the abstract algorithm of computing a single sigma-metric. This subject-matter is directed to an abstract algorithm, is prohibited under subsection 27(8) of the *Patent Act*, and is not considered to be patentable subject-matter under section 2 of the *Patent Act*.

The dependent claims recite further data manipulation rules concerning how the single sigma-metric is computed. These claims are directed to abstract rules and do not comply with subsection 27(8) and section 2 of the *Patent Act* for the same reasons above.

> Accordingly, it is our preliminary view that claims 1 to 34 on file are directed to non-patentable subject-matter and are therefore non-compliant with section 2 and subsection 27(8) of the *Patent Act*.

[37] We therefore conclude that claims 1 to 34 on file define non-patentable subject-matter, and do not comply with section 2 and subsection 27(8) of the *Patent Act*.

Description

[38] The PR letter explained why the Panel preliminarily determined that the description did not comply with subsection 57(1) of the *Patent Rules*. The Applicant did not dispute or comment on this analysis and we adopt it in this review.

> The first paragraph of the description recites:
>
> > This application is based on and claims priority to U.S. Non-Provisional Application Serial No. 12/508,718 filed on July 24, 2009, which is hereby incorporated herein by reference.
>
> Since this paragraph incorporates by reference a U.S. patent application, it is our preliminary view that the description does not comply with subsection 57(1) of the *Patent Rules*.

[39] We therefore conclude that the description does not comply with subsection 57(1) of the *Patent Rules*.

Indefiniteness

[40] The PR letter preliminarily agreed with the identification in the SOR that claim 14 on file was indefinite. The Applicant did not dispute or comment on this analysis and we adopt it in this review.

> The SOR identified a clarity defect in claim 14:
>
> > Claim 14 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The term “said patient value assigned stand deviations” (claim 14, line 3) has no antecedent when claim 14 is dependent on claim 12.
>
> Claim 14 recites:
>
> > 14. The computer-implemented method of claim 12 or 13, wherein said computing a single sigma-metric comprises:
> >
> > applying an averaging function to said patient value assigned standard deviations to determine an estimated standard deviation for said clinical process; and

> dividing a total allowable error for said clinical process by said estimated standard deviation to determine a sigma-metric (emphases added).
>
> We preliminarily agree with the clarity defect identified in the SOR. Therefore, it is our preliminary view that claim 14 does not comply with subsection 27(4) of the *Patent Act* [emphases in the original].

[41] We therefore conclude that claim 14 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act*.

Proposed Amendments

[42] In the letter dated January 4, 2022, the Applicant submitted proposed amendments to the claims and the description, and stated:

> Applicant proposes to amend independent claims 1, 13 (formerly claim 12), and 27 (formerly claim 24) to recite "performing measurements using laboratory instruments to obtain specimen data". Claim 18 (formerly claim 16) has been similarly amended to recite a "plurality of laboratory instruments implementing a clinical diagnostic process and operable to measure data related to that process". Thus, Applicant submits that the claims now recite the steps of performing measurements and acquiring specimen data through the measurements sufficient to impart the required physicality to the claimed-subject matter.

[43] Further, new dependent claims 12, 17, 26, and 38 were introduced, which recite implementing the computed single sigma-metric into the laboratory instruments, and testing patient specimens using the laboratory instruments having the newly-calculated sigma-metric.

[44] In the letter dated January 13, 2022, the Applicant submitted further proposed amendments to address a typographical error, the amendments being otherwise identical to those submitted on January 4, 2022. For this analysis, we only consider the proposed amendments dated January 13, 2022.

Patentable subject-matter

[45] We consider that the step of performing measurements, which is present in all of the proposed independent claims, is part of the actual invention, and is sufficient to impart the required physicality to the claimed subject-matter. Therefore, the actual invention is directed to "something with physical existence, or something that

manifests a discernible effect of change” (*Amazon*, at para. 66). Accordingly, the subject-matter of the proposed independent claims is physical, solves a problem related to the manual or productive arts, and is not prohibited under subsection 27(8) of the *Patent Act*.

[46] All dependent claims, including the newly introduced dependent claims, are also directed to patentable subject-matter based on their dependency on the independent claims.

[47] We therefore conclude that the proposed claims 1 to 38 define patentable subject-matter, comply with section 2 of the *Patent Act*, and are not prohibited under subsection 27(8) of the *Patent Act*.

Description

[48] In the proposed amendments to the description (page 1), the sentence that incorporates a document by reference has been removed. Therefore, we conclude that the amended description complies with subsection 57(1) of the *Patent Rules*.

Indefiniteness

[49] In the proposed amendments, claim 13 on file becomes claim 14, and claim 14 on file becomes claim 15, with only claim number and dependency changes. Since claim 15 only depends on claim 14 in the proposed amendments, the indefiniteness defect of claim 14 on file is overcome.

[50] Therefore, we conclude that the proposed claims comply with subsection 27(4) of the *Patent Act*.

[51] Accordingly, since the proposed amendments, submitted with the letter of January 13, 2022, overcome the non-patentable subject-matter, incorporation by reference, and indefiniteness defects as identified by the PR letter, they are considered “necessary” amendments under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS

[52] We are of the view that:

- claims 1 to 34 on file are directed to non-patentable subject-matter, which is prohibited under subsection 27(8) of the *Patent Act* and falls outside the definition of “invention” in section 2 of the *Patent Act*;

- the description of the present application incorporates by reference another document and does not comply with subsection 57(1) of the *Patent Rules*;

- claim 14 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act*; and

- the proposed amendments, submitted with the letter of January 13, 2022, overcome the non-patentable subject-matter, incorporation by reference, and indefinite defects, and thus are considered “necessary” amendments under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[53] In view of the above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the amendments proposed in the letter of January 13, 2022, namely the deletion of claims 1 to 34 on file, the insertion of proposed claims 1 to 38, the deletion of page 1 of the original description, and the insertion of the proposed page 1 of the description, are necessary for compliance with the *Patent Act* and *Patent Rules*.

Liang Ji	Christine Teixeira	Christian Workman
Member	Member	Member

DECISION OF THE COMMISSIONER

[54] I concur with the conclusions and recommendation of the Patent Appeal 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 within three (3) months of the date of this decision, failing which I intend to refuse the application:

i) the deletion of claims 1 to 34 on file;

ii) the insertion of claims 1 to 38 proposed in the letter of January 13, 2022;

iii) the deletion of page 1 of the description on file; and

iv) the insertion of page 1 of the description proposed in the letter of January 13, 2022.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec,

This 27th day of January 2022