

Citation: BIO-RAD LABORATORIES, INC. (Re), 2021 CACP 37

Commissioner's Decision 1590

Décision du Commissaire n°1590

Date: 2021-08-05

TOPIC: J00 Meaning of Art
 J10 Computer Programs

SUJET: J00 Signification de la technique
 J10 Programmes d'ordinateur

Application No. 2,837,728

Demande n° 2 837 728

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,837,728 having been rejected under subsection 30(3) of the *Patent Rules* 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 Patent Appeal Board and the decision of the Commissioner are to refuse the application unless necessary amendments are made.

Agent for the Applicant:

MARKS & CLERK

100 Simcoe Street, Suite 200
Toronto, Ontario
M5H 3G2

INTRODUCTION

- [1] This recommendation concerns the review of rejected Canadian patent application number 2,837,728 (“the instant application”), which is entitled “SYSTEM AND METHOD FOR DETERMINING AN OPTIMUM QC STRATEGY FOR IMMEDIATE RELEASE RESULTS ” and is owned by BIO-RAD LABORATORIES, INC. (“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* (SOR/2019-251) (“the *Patent Rules*”). As explained in more detail below, the Board’s recommendation is that the Commissioner of Patents refuse the application, unless necessary amendments are made.

BACKGROUND

The Application

- [2] The application relates generally to methods and systems for determining an optimum quality control schedule for testing reference samples and patient samples subject to certain constraints. The application has 65 claims on file, which were received at the Patent Office on May 10, 2018.

Prosecution History

- [3] On June 29, 2018, a Final Action (“FA”) was written pursuant to subsection 30(4) of the *Patent Rules* (SOR 96-423) as they read immediately before October 30, 2019. The FA stated that the instant application is defective because all of the claims on file are directed to subject-matter outside of the definition of invention and therefore are not compliant with section 2 of the *Patent Act*. (We note an error in the FA which referred to section 28.3 of the *Patent Act*, rather than section 2.) The FA also indicated that claims 38-52 are indefinite with respect to subsection 27(4) of the *Patent Act*.
- [4] In a December 12, 2018 response to the FA (“R-FA”), the Applicant submitted arguments in favour of the patentability of the claims on file, as well as proposed claims (“proposed claim set-1”).
- [5] As the Examiner still considered the application not to comply with the *Patent Act*, pursuant to paragraph 30(6)(c) of the *Patent Rules* (SOR 96-423) as they read immediately before October 30, 2019, the application was forwarded to the Board for review on February 15, 2019 along with an explanation outlined in a Summary of Reasons (SOR).

The SOR set out the position that the claims on file were still considered to be defective and that proposed claim set-1 did not cure the subject-matter defect.

- [6] In a letter dated February 18, 2019 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.
- [7] In a letter dated April 30, 2019, the Applicant confirmed its interest in having the review proceed.
- [8] A Panel of the Board (“The Panel”) comprised of the undersigned members reviewed the instant application under paragraph 199(3)(c) of the *Patent Rules*.
- [9] In a preliminary review letter (“PR letter”) dated May 28 2021, we set out our preliminary analysis of the issues with respect to the claims on file and proposed claim set-1. We also provided the Applicant with an opportunity to make oral and/or written submissions.
- [10] In a reply to the PR letter (“R-PR”) received on June 18, 2021 the Applicant declined the opportunity for a hearing and submitted another proposed claim set (“proposed claim set-2”).

ISSUES

[11] The issues to be addressed by the present review are:

- whether the claims on file are directed to subject-matter which meets the definition of invention found at section 2 of the *Patent Act*; and
- whether claims 38-52 on file are clear and comply with subsection 27(4) of the *Patent Act*.

[12] We also consider proposed claim set-2.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Purposive Construction

[13] 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 both 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.

- [14] “Patentable Subject-Matter under the *Patent Act*” (CIPO, November 2020) [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

- [15] 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.

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

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

- [17] PN2020-04 describes the Patent Office’s approach to determining if a claim is 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.

This references, in part, *Canada (Attorney General) v Amazon.com, Inc*, 2011 FCA 328 paras 42 and 66-69.

- [18] 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 computer programmed to merely process the algorithm in a well-known manner without solving any problem in the functioning of the computer will not make it 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.

- [19] 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.

Indefiniteness

- [20] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define the 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.

- [21] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306, 12 CPR 99 at para 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

[22] The FA characterized the skilled person and CGK as follows:

The person who may be a team skilled in the art would be a person skilled in the field of analysing test results from diagnostic devices (page 1, “Background”). The person skilled in the art is also skilled in the field of general purpose computing technologies.

The skilled person or team is also familiar with general purpose computer hardware and general purpose computer programming techniques.

[23] In the R-FA and R-PR, the Applicant did not dispute these characterizations. We adopt them for this analysis, as we did in the PR letter.

[24] The FA performed a purposive construction that resulted in a set of essential elements for certain claims according to a previous Patent Office practice, now superseded by *PN2020-04*. We undertake anew the identification of essential elements.

[25] Independent claim 1 is representative and reads:

A method of operating a diagnostic device comprising an analyte measurement module, the method comprising:

causing the analyte measurement module to measure analyte responses in at least one physical reference sample and in a plurality of physical patient samples in a ratio according to a quality control utilization rate of a candidate quality control rule, wherein the candidate quality control rule is selected from a set of candidate quality control rules according to a method comprising:

for each candidate rule:

computing a control limit that meets a false rejection criteria;

computing, using the control limit, a correctible maximum by calculating how many patient samples can be tested between quality control events while keeping the number of correctible results with an error exceeding a predetermined threshold below a predetermined value;

computing, using the control limit, a final maximum by calculating how many patient samples that can be tested between quality control events while keeping the number of final results with an error exceeding a predetermined threshold below a predetermined value;

selecting a quality control interval size, the quality control interval being a smallest value of the correctible maximum and the final maximum; and

computing a quality control utilization rate by dividing the number of reference samples tested at each quality control event by the quality control interval size; and

selecting the candidate quality control rule based on the quality control utilization rates of the set of candidate quality control rules.

[26] According to *PN2020-04*, a purposive construction considers where the skilled person would have understood the applicant to have intended to place the fences around the monopoly being claimed.

[27] Considering the whole of the specification, the skilled person would understand that there is no use of language indicating that any of the elements in the claim are optional or one of a list of alternatives. Therefore, we maintain the view, as expressed in the PR letter, that all elements recited in claim 1 are considered to be essential, including the computer-implemented components.

Patentable Subject-Matter

[28] Given that our view of essential elements differs from that of the FA, and in view of the updated Patent Office practice, we undertake anew the assessment of patentable subject-matter according to *PN2020-04*.

[29] As described above in the section “Legal Principles and Office Practice” we assess for each claim whether the subject-matter it defines forms a single actual invention having physical existence or causing a discernible physical effect or change.

[30] Our view remains as per our preliminary view as expressed in the PR letter:

Claim 1 recites the elements “an analyte measurement module” and “causing the analyte measurement module to measure...”. These elements are physical and cause a discernible physical effect (measurements are physically made by a physical device). In our preliminary view, the skilled person would see the actual invention as the analyte measurement module cooperating with the computer to take measurements, provide the

measured results to the computer to calculate an optimum quality control interval size according to an algorithm. The actual invention of claim 1 has physicality and relates to the manual and productive arts. We therefore consider that claim 1 is directed to subject-matter which meets the definition of invention at section 2 of the *Patent Act* and is not prohibited under subsection 27(8) of the *Patent Act*.

Independent claims 11, 12, and 19 similarly recite an analyte measurement module making measurements and therefore are also considered to be directed to patentable subject-matter.

Dependent claims 2-10, 13-18 and 20-26 depend on independent claims 1, 11, 12 or 19 and are also considered to be directed to patentable subject-matter.

Referencing claims 53 and 65 and dependent claim 64 recite an analyte measurement module. This element cooperates with the algorithm and computer and is considered part of the actual invention of these claims. Therefore, in our preliminary view, these claims are directed to patentable subject-matter.

Dependent claim 55 positively recites using the output information to physically carry out testing of samples. This element cooperates with the algorithm and computer to provide a discernible effect and the testing driven by the algorithmic output is part of the actual invention of this claim. Therefore, in our preliminary view, this claim is directed to patentable subject-matter.

Independent claims 27, 37, 38, 45, 54 and 63 are different in that they do not recite an analyte measurement module or making measurements. Purposive construction must be based on the claim language. The understanding that the input data came from measurements using an analyte measurement module or that the output data is to be used to guide measurements is of intellectual significance only. To have physicality, actual testing or an analyte testing module would have to be positively recited in the claims. The only physical element of these claims is the computer for executing the algorithm to determine an optimum test interval from provided data. These claims do not distinguish from the case in *Schlumberger*, in which the Court determined that a computer merely carrying out calculations on data in a well-known manner does not render an otherwise abstract algorithm patentable subject-matter. In our preliminary view, the actual invention in these claims is only the algorithm. These claims are therefore not directed to subject-matter meeting the definition of invention at section 2 of the *Patent Act* and they are directed to subject-matter prohibited under subsection 27(8) of the *Patent Act*.

Dependent claims 28-36, 39-44, 46-52 and 56-62 do not add any physical essential elements that would render them as directed to patentable subject-matter.

[31] In summary, our view remains that claims 1-26, 53, 55 and 64-65 are directed to patentable subject-matter, and claims 27-52, 54 and 56-63 are not directed to patentable subject-matter.

Indefiniteness

[32] The FA noted with respect to the claims on file:

Claims 38-52 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. For example, claim 28 recites:

A system for optimizing a quality control strategy comprising:

- a processor;
- a quality control rule generator operable to generate a set of candidate quality control rules;
- a quality control rule assessment module operable to, using the processor, compute a maximum number of patient specimens that can be tested between quality control events while keeping the expected number of correctible unacceptable results below a predetermined threshold for correctible results and keeping the expected number of final unacceptable results below a predetermined threshold for final unacceptable results for a candidate quality control rule; and
- a quality control rule section module operable to, using the processor: select a candidate rule for which a best quality control utilization rate was computed.

More specifically, it is not clear

- (1) if the selected “candidate rule” is selected from the “set of candidate quality control rules” generated by the quality control rule generator;
- (2) how the machine component “a quality control rule assessment module” interact with other machine parts apart from “using the processor”; and
- (3) how the computed “maximum number of patient specimens” is used.

[33] Our view remains as expressed in the PR letter:

In our preliminary view, the skilled person would understand that

1. the selected “candidate rule” is selected from the “set of candidate quality control rules”;
2. the “quality control rule assessment module” interacts with the “set of candidate quality control rules” by determining the performance of each; and

3. the “maximum number of patient specimens” is an output value that guides how often patient testing is to be interrupted for control testing.

We note that claim 38 introduces an element “a quality control rule section module”. The Applicant appears to have intended “a quality control rule *selection* module”.

[34] In summary, in our view, the claims are not indefinite and meet the requirements of subsection 27(4) of the *Patent Act*. Claim 38 contains a typographic error in that “section” should be “selection”.

PROPOSED CLAIMS

[35] Having found some of the claims on file to be defective in terms of unpatentable subject-matter, we now consider proposed claim set-2, submitted with the R-PR.

Patentable Subject-Matter

[36] Regarding proposed claim set-2, in the R-PR, the Applicant wrote:

In the Preliminary Review, it was concluded that claims 1-26, 53, 55 and 64-65 are directed to patentable subject-matter, but claims 27-52, 54 and 56-63 are not directed to patentable subject-matter.

As noted above, Applicant proposes amending independent claims 27 and 37 to include the recitation of claim 53, which is considered to be directed to patentable subject matter. Thus, the objection to claims 27 to 37 is moot.

Further, Applicant proposes amending claim 38 to include the recitation of claim 39. Specifically, Applicant proposes amending claim 38 to recite a test apparatus operable to:

test at least two reference specimens to obtain a test value for each specimen in accordance with at least one of the candidate quality control rules, wherein each specimen has a corresponding reference value, and

determine whether the differences between the test values and the reference-values is due to a systematic error.

Applicant submits that the test apparatus recited in the proposed amendment to claim 38 is physical and cause a discernible physical effect (physical specimens are physically tested by a physical device). Thus, the skilled person would see the actual invention as the test apparatus cooperating with the computer to test at least two reference specimens to calculate an optimum quality control interval size according to an

algorithm. Thus, the actual invention of claim 38 has physicality and relates to the manual and productive arts.

Similarly, Applicant proposes amending claim 45 to include the recitation of claim 46. Specifically, Applicant proposes amending claim 45 (proposed claim 44) to recite:

testing at least two reference specimens to obtain a test value for each specimen in accordance with at least one of the candidate quality control rules, wherein each specimen has a corresponding reference value, and

determining whether the differences between the test values and the reference-values is due to a systematic error.

Applicant submits that the testing step recited in the proposed amendment to claim 45 is physical and cause a discernible physical effect (physical specimens are physically tested by a physical device). Thus, the skilled person would see the actual invention as the test apparatus cooperating with the computer program product to test at least two reference specimens to calculate an optimum quality control interval size according to an algorithm. Thus, the actual invention of claim 45 has physicality and relates to the manual and productive arts.

For at least these reasons, claim 38-52 (proposed claim 38-50) are directed to subject-matter which meets the definition of invention at section 2 of the Patent Act and is not prohibited under subsection 27(8) of the Patent Act.

Yet further, Applicant proposes amending claim 54 to include the recitation of claim 55 which is considered to be directed to patentable subject matter. Claims 56 to 62 depend from amended claim 54. Thus, the objection to claims 54-62 is moot. Yet further, Applicant proposes amending claim 63 to include the recitation of claim 64 which is considered to be directed to patentable subject matter. Thus, the objection to claim 63 is moot.

[37] We agree that the proposed amendments add physicality to the claims in that all independent claims recite either the physical testing apparatus, or physically performing an analytical test.

[38] The subject-matter of proposed claim set-2 would therefore comply with section 2 of the *Patent Act* and is not prohibited subject-matter under subsection 27(8) of the *Patent Act*.

Conclusion Regarding Proposed Claim Set-2

[39] In our view, proposed claim set-2 would meet all requirements of the *Patent Act* and *Patent Rules*.

CONCLUSION AND RECOMMENDATION OF THE BOARD

[40] 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 following amendments are necessary for compliance of the application with the *Patent Act* and *Patent Rules*:

- the deletion of the claims on file;
- the insertion of claims corresponding to proposed claim set-2.

Howard Sandler

Member

Alison Canteenwalla

Member

Leigh Matheson

Member

DECISION OF THE COMMISSIONER

[41] 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 claims corresponding to proposed claim set-2.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 5th day of August, 2021