

Citation: F. Hoffmann-La Roche AG (Re), 2021 CACP 21

Commissioner's Decision #1574

Décision du commissaire n°1574

Date: 2021-05-04

TOPIC: J00 Meaning of Art

J10 Computer Programs

J40 Mental Steps

SUJET: J00 Signification de la technique

J10 Programmes d'ordinateur

J40 Processus psychologique

Application No. : 2,675,564

Demande n° 2 675 564

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,675,564 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 2,675,564 (“the instant application”), which is entitled “SYSTEM AND METHOD FOR QUALITY ASSURED ANALYTICAL TESTING” and is owned by F. HOFFMANN-LA ROCHE AG (“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 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 instant application was filed on August 14, 2009. It was laid open to public inspection on February 20, 2010.
- [3] The instant application relates generally to a system and method to ensure that users of an analytical instrument are qualified to use it. The application has 25 claims on file as of the date of the Final Action (“FA”). These were received at the Patent Office on February 22, 2016.

Prosecution History

- [4] On November 30, 2017, an FA was written pursuant to subsection 30(4) of the *former Patent Rules*. 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*.
- [5] In a May 28, 2018 response to the FA (“R-FA”), the Applicant submitted arguments in favour of the patentability of the claims on file, and did not submit any proposed claims.
- [6] 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 on November 30, 2018 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.

- [7] In a letter dated December 4, 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.
- [8] In a letter dated January 10, 2019, the Applicant confirmed its interest in having the review proceed.
- [9] The undersigned was assigned to review the application on behalf of the Board under paragraph 199(3)(c) of the *Patent Rules*. In a preliminary review letter (“PR letter”) dated March 9, 2021, I set out my preliminary analysis of the issues with respect to the claims on file. I also provided the Applicant with an opportunity to make oral and/or written submissions.
- [10] In a letter dated March 23, 2021 the Applicant declined the opportunity for an oral hearing.
- [11] The Applicant submitted a reply to the PR letter (“R-PR”) on April 7, 2021, accompanied by a set of proposed claims (“the proposed claims”).

ISSUES

- [12] The issue to be addressed by the present review is whether the claims on file are directed to subject-matter which meets the definition of invention found at section 2 of the *Patent Act*.
- [13] In reviewing the claims on file, I noticed a claim dependency defect with respect to subsection 63(2) of the *Patent Rules*. This is discussed below.
- [14] I also consider the proposed claims.

LEGAL PRINCIPLES

Purposive Construction

- [15] 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.

- [16] “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

- [17] 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.

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

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

- [19] PN2020-04 clarifies examination practice with respect to the Patent Office’s understanding of the legal principles applicable in determining whether the subject-matter defined by 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.

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

- [20] 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 processes 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.

Claim Dependency

[21] Subsection 63(2) of the *Patent Rules* requires: “A dependent claim may only refer to a preceding claim or claims.”

ANALYSIS

Purposive Construction

[22] The FA at page 2 characterized the skilled person and CGK as follows:

The skilled person or persons may consist of engineers familiar with the design of analytical instruments. The skilled person also has knowledge of the requirements, the procedures and the design of software tools for performing an analytical test.

The claims have to be purposively construed to determine what the invention is. As described in the background of the invention, it is well known in the art to have a certain degree of quality assurance of analytical testing which is mostly based on self-training by users or by an administrator/supervisor who trains users in person so that the quality of diagnostics tests they perform will be sufficient and reliable.

It is also well known that testing instruments allow control of who is allowed to do testing using the instrument. For this purpose, a list of users is stored in the instrument and only these users can log in and do testing. Registering of the users is being done by a supervisor based on his personal decision (page 1, lines 16-22).

[23] In the R-PR, R-FA and previous correspondence, the Applicant did not dispute these characterizations, and I adopt them for this review as I did in the PR letter.

[24] The FA at pages 2-4 performed a purposive construction that resulted in a set of essential

elements for the claims according to a previous Patent Office practice, now superseded by *PN2020-04*. I undertake anew the identification of essential elements.

[25] 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.

[26] The independent claims on file are claim 1, directed to a system, and claim 15, directed to a method. Both claims recite similar subject-matter. Claim 1 is representative and reads:

A system for administering an examination for quality assured analytical testing by an actual user and for managing an analytical instrument by an administrator comprising:

the analytical instrument comprising a microprocessor programmed to conduct an analytical testing routine, and an input section to determine the actual user of the instrument, the microprocessor being further programmed to check if the actual user is a certified user permitted to conduct the testing routine; and

a server connected to the analytical instrument and which runs an Instrument Management System (IMS) program which provides an examination module that is at least hosted on the server and programmed to:

conduct the examination during which the examination module prompts questions to the actual user which relate to at least one of the analytical instrument and a diagnostic test to be conducted therewith,

receive answers from the actual user to the questions, evaluate the answers,

determine if the actual user has passed the exam, and

transmit a user certificate directly from the examination module to the analytical instrument if the actual user passed the exam, wherein the microprocessor of the analytical instrument is programmed to check if the user certificate for the actual user is available and grant access to the analytical testing routine by the actual user for conducting an analytical test only if the user certificate is available for the actual user; and

a Learning Management System (LMS) workstation connected to the server, the LMS workstation being a different component in the system from the analytical instrument and which is configured to permit the administrator to log into the server:

to manage the analytical instrument and decide which users of the analytical instrument need training; and

to set a time frame via the LMS workstation for which the user certificate is valid;

the IMS program is configured to delete a user certificate if the actual user fails the examination or if the time frame for which the user certificate is valid has expired by deleting the user certificate from a list of certified users; and

the microprocessor of the analytical instrument is programmed to download program data or content data to the analytical instrument via the LMS workstation to check if the user certificate for the actual user is available by determining if the actual user is on the list of certified users, and deny access to the analytical testing routine if the actual user is not on the list of certified users.

[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, in my view, all elements recited in the claim are considered to be essential, including the computer-implemented components.

Patentable subject-matter

[28] As I stated in the PR letter:

The actual invention appears to be the computerized elements of the claim cooperating together to administer an examination and produce a digital certificate which is sent to the analytical instrument to allow a user to access the instrument.

[29] In the R-PR, the Applicant did not take issue with this view, which remains unchanged.

[30] As I stated in the PR letter:

As noted in *PN2020-04*, the fact that a computer is necessary to put a disembodied idea, scientific principle or abstract theorem into practice does not necessarily mean that there is patentable subject-matter even if the computer cooperates together with other elements of the claimed invention. In *Amazon* (paras 61–63, 66, 69) the court stated that a computer cannot necessarily be used to give an abstract idea a practical application satisfying the physicality requirement implicit in the definition of invention in section 2 of the *Patent Act* simply by programming the idea into the computer by means of an algorithm. *Amazon* notes that this was the situation in *Schlumberger Canada Ltd v Commissioner of Patents*, [1982] 1 FC 845 (FCA) at 205-206, where the computer was merely being used to make the kind of calculations it was invented to make.

The subject-matter of claim 1 can be distinguished from the case in *Schlumberger* in that the physical analytical instrument that is an essential element of the claim is not part of a generic computer system in this context. In *Schlumberger*, the only physical element of the actual invention was a generic computer merely executing calculations. In the instant case, the result of the examination administered by the other elements of the claim cooperating together with the analytical instrument which receives the digital certificate is that the user of the analytical instrument is either allowed or prevented from using the physical analytical instrument. This is a discernible effect. Together, the analytical instrument and the allowance or prevention of its use provide physicality and are part of the manual and productive arts. Therefore, in my preliminary view, the claim is directed to patentable subject-matter meeting the definition of invention found at section 2 of the *Patent Act*.

[31] In the R-PR the Applicant did not disagree with this analysis, which I maintain.

[32] Independent claim 15 includes the same actual invention as claim 1.

[33] The dependent claims are all directed to patentable subject-matter by virtue of their dependence on claim 1 or claim 15.

[34] In my view, all claims on file meet the physicality requirement for patentable subject-matter according to *PN2020-04*, relate to the manual and productive arts, and comply with the definition of “invention” according to section 2 of the Patent Act. Further, the claims are not directed to a mere scientific principle or abstract theorem and therefore are not excluded subject-matter under subsection 27(8) of the *Patent Act*.

Claim Dependency

[35] In reviewing the claims on file I noted a claim dependency error in claim 23. As I wrote in the PR letter:

Claim 23 refers to claims 15 to 33; however, there are no claims beyond claim 25, and in addition, claims 24 and 25 are not preceding claims to claim 23. This does not comply with subsection 63(2) of the *Patent Rules*.

[36] In the R-PR, the Applicant did not dispute this, and I maintain that this constitutes a defect.

[37] The Applicant submitted the proposed claims to address this defect.

PROPOSED CLAIMS

[38] In response to the PR letter, the Applicant submitted a set of 25 proposed claims. These are identical to those on file, except for the claim dependency of claim 23, which was changed to refer to preceding claims 15 to 22. In my view, this proposed claim set would cure the claim dependency defect, and the proposed claims would comply with all requirements of the *Patent Act* and *Patent Rules*.

CONCLUSION AND RECOMMENDATION OF THE BOARD

[39] For the reasons set out above, I 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*:

- delete the claims on file; and
- insert the proposed claims.

Howard Sandler

Member

DECISION OF THE COMMISSIONER

[40] 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:

- delete the claims on file; and
- insert the proposed claims.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 4th day of May 2021