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Commissioner's Decision #1527  
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TOPIC: J00 (Meaning of Art)

J50 (Mere Plan)

SUJET: J00 (Meaning of Art)

J50 (Mere Plan)

Application No. : 2,678,235  
Demande n° 2 678 235

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,678,235, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019, has 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.

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## INTRODUCTION

- [1] This recommendation concerns the review of rejected patent application number 2,678,235, which is entitled “REAL-TIME PCR ELBOW CALLING BY EQUATION-LESS ALGORITHM” and is owned by F. Hoffmann-La Roche AG. The outstanding defect to be considered is whether the subject-matter of the claims on file lies outside the definition of “invention” in section 2 of the *Patent Act*. 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). As explained in more detail below, the recommendation of the Board is to refuse the application.

## BACKGROUND

### The application

- [2] Patent application 2,678,235 has been filed in Canada on September 8, 2009 and was laid open to the public on March 12, 2010.
- [3] The claimed subject-matter of the application relates to methods and systems for determining a transition value in a sigmoid or growth curve, such as the cycle threshold (Ct) value of a Polymerase Chain Reaction (PCR) amplification curve or elbow values in other growth curves.

### Prosecution history

- [4] On March 8, 2017, a Final Action (the FA) was written pursuant to subsection 30(4) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Rules*). The FA explained that the essential elements of the claims on file amount to an abstract and disembodied idea, and thus are directed to subject-matter that lies outside the definition of “invention” in section 2 of the *Patent Act*.
- [5] In a response to the FA (the RFA) dated September 7, 2017, the Applicant submitted arguments as to why the subject-matter of the claims on file was not open to objection for the reasons outlined in the FA.
- [6] As the Examiner was not persuaded by the Applicant’s arguments, the application and an accompanying Summary of Reasons (the SOR) were forwarded to the Board for review. The SOR maintained that the claims on file are directed to subject-matter that lies outside

the definition of “invention” in section 2 of the *Patent Act*. In a letter dated February 1, 2018, the Board sent the Applicant a copy of the SOR.

- [7] The present Panel was formed to review the application under paragraph 199(3)(c) of the *Patent Rules* and to make a recommendation to the Commissioner as to its disposition. In a preliminary review letter dated January 10, 2020 (the PR Letter), we provided the preliminary opinion that the claims on file are directed to subject-matter excluded from the definition of “invention” as set out in section 2 of the *Patent Act*.
- [8] The PR Letter also offered the Applicant the opportunity to make further written submissions and to attend an oral hearing in response to the Panel’s preliminary review, if desired.
- [9] In a response letter dated January 24, 2020, the Applicant stated that they did not wish to participate in a hearing and that no written submissions would be provided.

## **ISSUES**

[10] In view of the above, the following issue is considered in this review:

- whether claims 1 to 31 on file dated December 20, 2016 are directed to subject-matter that lies outside the definition of “invention” in section 2 of the *Patent Act*.

## **LEGAL PRINCIPLES AND OFFICE PRACTICES**

### Purposive construction

[11] Essential elements are identified through a purposive construction of the claims. The exercise is conducted from the standpoint of a person of ordinary skill in the art (POSITA) by considering the whole of the disclosure, including the specification and drawings: *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World*]; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49(f) and (g) and 52 [*Whirlpool*]. According to the *Manual of Patent Office Practice* [MOPOP] §12.02, the first step in the construction of the claims of a patent application is to identify the POSITA and their relevant common general knowledge (CGK). The next step is to identify the problem addressed by the inventors and the solution disclosed in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution

Statutory subject-matter

[12] The definition of “invention” is set out 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.

[13] Following the Federal Court of Appeal decision in *Canada (Attorney General) v Amazon.com Inc*, 2011 FCA 328 [*Amazon.com*], the Patent Office released an examination memo “Examination Practice Respecting Computer-Implemented Inventions” PN 2013-03 (CIPO, March 2013) [*PN 2013-03*] that clarified the Patent Office’s approach to determining if a computer-related invention is statutory subject-matter.

[14] As stated in *PN 2013-03*, Patent Office practice considers that where a computer is found to be an essential element of a construed claim, the claimed subject-matter will generally be statutory. Where, on the other hand, it is determined that the essential elements of a construed claim are limited to matter excluded from the definition of invention (for example, mere ideas, schemes or rules), the claimed subject-matter will not be compliant with section 2 of the *Patent Act*

*Applicant’s submissions on Patent Office practice relating to purposive construction and non-statutory subject-matter*

[15] The Applicant submitted in the RFA that the purposive claim construction carried out in accordance with Patent Office practice does not accord with Canadian jurisprudence. In summary, the Applicant submitted that:

- the fundamental principle of claims construction as per *Free World* and *Whirlpool* is the inventor’s intention regarding the meaning of claim terms and the resulting scope of protection;
- the analysis of the essential elements presented in the FA determines patent-eligibility on the basis of what was contributed over the CGK, which amounts to a forbidden “contribution analysis”;
- the decision in *Schlumberger Canada Ltd v Canada (Commissioner of Patents)* [1981] FC 845, 38 NR 299, 56 CPR (2d) 204 (FCA) [1982] [*Schlumberger*] antedates the Supreme Court’s decisions in *Free World* and *Whirlpool* by almost 20 years, and to the

extent that the principles applied in *Schlumberger* are inconsistent with the principles set forth in *Free World* and *Whirlpool*, they must now be considered as overruled;

- the proposition that the principles of claims construction to be applied by the Patent Office during prosecution are somehow different from those which a court would apply would surely be in error; and
- *MOPOP* has no effect in law and neither the Examiner nor Commissioner is bound by *MOPOP* or the guidelines found in *PN 2013-03* because they are inconsistent with or fail to apply the governing relevant jurisprudence.

[16] The guidance of *MOPOP* at §12.02 outlines the Patent Office's interpretation of Canadian patent law in respect of purposive claim construction as applied to the examination of a patent application. The Patent Office practice specifies that a properly informed purposive claim construction must consider the specification as a whole, as read through the eyes of POSITA, against the background of the CGK in the field or fields relevant to the invention, so as to identify the problem and solution addressed by the application. The identification of the problem is guided by the examiner's understanding of the CGK in the art and by the teachings of the description. The solution to that problem informs the identification of the essential elements.

[17] As explained in *MOPOP* at §12.02.02e, not every element having a material effect on the operation of a given practical embodiment is essential to the solution; some recited elements define the context or environment of the embodiment but do not actually change the nature of the solution.

[18] Strict adherence to a literal interpretation of claim language as used by the inventor cannot be an overriding factor in claim assessment of patentable subject-matter. In *Amazon.com* at paras 43, 44, 62 and 63, the Federal Court of Appeal mandated the assessment of patentable subject-matter on the basis of purposive construction which "will necessarily ensure that the Commissioner is alive to the possibility that a patent claim may be expressed in language that is deliberately or inadvertently deceptive." The Court gave the situation in *Schlumberger* as an example, saying that on a proper construction, the claimed invention was "for a mathematical formula and therefore not patentable subject matter" despite its appearance as "an 'art' or 'process'" and the fact that the mathematical formula was programmed into a computer.

## ANALYSIS

Purposive construction

*The POSITA and the relevant CGK*

[19] The FA identified the POSITA and the relevant CGK as follows:

[T]he person skilled in the art to whom the application is directed can be characterized as a team consisting of molecular biologists familiar with real time polymerase chain reactions and computer programmers with software development abilities.

The person skilled in the art would possess the following CGK knowledge of real-time kinetic polymerase chain reaction (PCR) process comprising enzymatically synthesizing or amplifying nucleic acid sequences, thermocyclers, generating growth curves and PCR analysis devices that generate PCR datasets.

[20] In the PR Letter, we adopted these characterizations for the purposes of our preliminary review. As no further submissions were provided by the Applicant, we therefore also adopt them for the purposes of this final review.

*The problem to be solved and the proposed solution*

[21] The FA identified the problem to be solved and the proposed solution as follows:

The person skilled in the art, having read the specification and in light of their CGK, would consider that the problem addressed by the claimed invention is analysing and calculating Ct values from PCR curves having untypical curve shapes [Description: page 2, line 14-page 3, line 3].

The person skilled in the art, having read the specification and in light of their CGK, would consider that the description provides the following solution: a generic, yet robust method to determine PCR elbow values using mathematical/numerical steps [Description: page 3, lines 8-14].

[22] In the RFA at page 13, the Applicant submitted that a particular problem addressed by the inventors “concerned the need to provide a real-time system, and the difficulty in doing so given the complexity of the calculation required in order to generate the needed Ct value with useful precision”. Given such computational complexity and the need to generate Ct values in real-time, the Applicant further submitted that the solution necessarily relies on the use of the defined physical computer as the defined practical results would not

otherwise be achievable.

- [23] In the PR Letter, we stated the following with respect to the Applicant's submissions and our preliminary view regarding the problem to be solved and the proposed solution:

We respectfully disagree. Having reviewed the specification as a whole, notably pages 1 to 18 of the description, we are of the preliminary view that the problem to be solved is a need of a more generic method for determining the transition value in growth curves, including curves that have a geometry that does not fit the typical double sigmoid type shape and for which the existing methods may no longer be applicable (see page 2, lines 14 to 30).

With respect to the "real-time" aspect of the disclosed methods and systems, it is our preliminary view that the expression "real-time" only relates to the acquisition step of the data set via a real-time PCR apparatus rather than to the processing of the data set to determine the Ct value in the context of a PCR process. In the context of a PCR process, the specification discloses that the data manipulation steps are to be performed on a data set representing a PCR amplification curve, i.e., performed after the data set representing the growth curve has been obtained rather than calculated during the data set acquisition step (see for example page 14, lines 4 to 25). Therefore, it is our preliminary view that such a problem does not relate to how a data set representing a PCR amplification curve has been acquired (i.e., real-time or not) or wherein the means to accurately perform complex real-time calculations would be relevant in addressing the problem.

Turning now to the corresponding solution, it is our preliminary view that the proposed solution embodied by the claimed subject-matter is to provide a generic but robust method to determine Ct values of PCR amplification curves using a particular scheme of mathematical manipulation steps (i.e., an algorithm workflow) (see page 3, lines 5 to 14).

- [24] As no further submissions were provided by the Applicant, we therefore retain our preliminary views regarding the problem to be solved and the corresponding solution for the purposes of this final review.

*The essential elements that solve the identified problem*

- [25] There are 31 claims on file. Methods claim 1 and 7, computer readable storage medium claim 15 and system claims 16 and 17 are the independent claims. It is our preliminary view that independent claim 1 is representative of the subject-matter of all the independent claims on file, as they all recite subject-matter generally similar to the subject-matter recited in claim 1. Claim 1 reads as follows:



1. A method of carrying out a real-time kinetic Polymerase Chain Reaction (PCR) process comprising:

(a) using a kinetic thermocycler device enzymatically to synthesize or amplify at least one target nucleic acid sequence and to generate and output in real time a dataset representing a growth curve of synthesis or amplification of said at least one target nucleic acid sequence;

(b) using a computer system to determine a defined signal threshold value and to determine a cycle threshold (Ct) value being a number of cycles required to reach the signal threshold value for the reaction to be analyzed, wherein the cycle threshold (Ct) value is determined by data manipulation steps performed by the computer system; and

(c) using the computer system to determine at least one of: the efficiency of the polymerase chain reaction amplification on the basis of the cycle threshold value obtained from the target nucleic acid; and, the absolute or relative copy number of the target molecule on the basis of the cycle threshold values obtained from the target nucleic acid and a reference nucleic acid;

said data manipulation steps comprising:

determining a point at the end of a baseline region of the growth curve, comprising the steps, implemented in the computer system having a processor, of:

receiving in real time from the kinetic thermocycler device the dataset representing the growth curve for the real-time kinetic Polymerase Chain Reaction (PCR) process, said dataset comprising a plurality of data points each having a pair of coordinate values;

numerically determining second derivative values for data points along the growth curve;

determining a maximum value of the determined second derivative values;

calculating an approximation of a curve that fits the determined second derivative values by applying a regression process to a Gaussian Mixture Model function to determine one or more parameters of the function, wherein said parameters comprise initial conditions, and wherein the maximum value is used as an initial condition for a first parameter; and

outputting the first parameter, wherein the first parameter represents the end of the baseline region of the growth curve, and wherein the point at the end of the baseline region represents the cycle threshold (Ct) value of the growth curve.

- [26] In the FA at pages 2 to 3, the essential elements were identified as specific data analysis steps, without the physical computer elements.
- [27] In the RFA at page 13, the Applicant argued that the physical computer elements as recited in the claims are essential because the defined practical results in real-time applications would not otherwise be achievable. Such methods are too computationally complex to dispense with computing technology and any substituted means would have a material effect on the claimed invention and would not produce a solution which performs substantially the same function, in substantially the same way, to produce substantially the same result, thus the claimed computing technology is essential according to *Free World*.
- [28] In the PR Letter, we disagreed with the Applicant's submissions and expressed the following with regard to the essential elements of the claims on file:

As expressed above, our preliminary view is that the identified problem is a need of a more generic method for determining the transition value in growth curves. The application does not propose to solve a problem of quickly processing and computing data accurately. This is not a problem that needed to be solved in order to implement and practice the claimed subject matter as any conventional computer system or data processing device may be used (see, for example, page 25 of the description as well as Fig. 15 and Fig. 16). Therefore, use of the referenced computer elements may be part of the context or working environment of the invention, as it is the case for the kinetic thermocycler device used to produce the data set, but are not essential elements of the claimed invention itself. As stated in MOPOP at §12.02.02e, not every element that has a material effect on the operation of a given embodiment is necessarily essential to the solution provided by the claimed invention.

Given the solution identified above, our preliminary view is that the POSITA would understand that the computer elements and the kinetic thermocycler device recited in representative claim 1 are not essential elements to the identified solution as they are not necessary for the successful resolution of the identified problem.

Therefore, our preliminary view is that the essential elements of the claims on file, as purposively construed, are the data manipulation steps for determining a point at the end of a baseline region of the growth curve:

- receiving a dataset representing the growth curve for a real-time kinetic PCR process, said dataset comprising a plurality of data points, each having a pair of coordinate values;
- numerically determining from the dataset the second derivative values for data points along the growth curve;
- determining a maximum value of the determined second derivative values;
- calculating an approximation of a curve that fits the determined second derivative values by applying a regression process to a Gaussian Mixture Model function to determine one or more parameters of the function, wherein said parameters comprise initial conditions, and wherein the maximum value is used as an initial condition for a first parameter; and
- outputting the first parameter, wherein the first parameter represents the end of the baseline region of the growth curve, and wherein the point at the end of the baseline region represents the Ct value of the growth curve.

[29] As no further submissions were provided by the Applicant, we therefore retain our preliminary views regarding the essential elements of the claims on file for the purposes of this final review.

Statutory subject-matter

[30] The Applicant's position that the claims are directed to statutory subject-matter is based on the submissions that the use of physical computer elements and the production of physical effects through the use of a kinetic thermocycler device are essential claimed elements to solve the problem faced by the inventors (see RFA on pages 13 to 14).

[31] As mentioned above, no further submissions were provided by the Applicant and we retain the view expressed in the PR Letter that the computer elements and the kinetic thermocycler device are not essential; what is essential is the use of a particular scheme involving mathematical manipulation steps (i.e., an algorithm workflow) to determine Ct values of PCR amplification curves.

[32] Therefore, our view is that the claims on file are directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act*.

### **RECOMMENDATION OF THE BOARD**

[33] For the reasons set out above, the Panel recommends that the application be refused on the basis that the claims on file define subject-matter that is non-statutory and thus does not comply with section 2 of the *Patent Act*.

Marcel Brisebois

Leigh Matheson

Lewis Robart

Member

Member

Member

### **DECISION OF THE COMMISSIONER**

[34] I concur with the findings of the Board and its recommendation to refuse the application as the claims on file do not comply with section 2 of the *Patent Act*.

[35] Accordingly, I refuse to grant a patent for this application. Under section 41 of the *Patent Act*, the Applicant has six months to appeal my decision to the Federal Court of Canada.

Johanne Bélisle  
Commissioner of Patents

Dated at Gatineau, Quebec

this 5th day of May, 2020