

Citation: F. Hoffmann-La Roche AG (Re), 2020 CACP 13
Commissioner's Decision no 1533
Décision du Commissaire #1533
Date: 2020-05-06

TOPIC: J00 (Meaning of Art)
J50 (Mere Plan)
SUJET: J00 (Meaning of Art)
J50 (Mere Plan)

Application No. : 2,571,446

Demande n° 2 571 446

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,571,446, 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 2,571,446, which is entitled “PCR ELBOW DETERMINATION BY USE OF A DOUBLE SIGMOID FUNCTION CURVE FIT WITH THE LEVENBERG-MARQUARDT ALGORITHM AND NORMALIZATION” 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 2,571,446 has been filed December 18, 2006 and was laid open to the public on June 20, 2007.
- [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 February 19, 2019, 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 July 29, 2019, 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 October 1, 2019, 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 13 on file dated September 20, 2018 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:

- Computer programming
- Knowledge of how to carry out polymerase chain reaction (PCR) processes, specifically the use of kinetic PCR thermocyclers to perform PCR growth processes by enzymatically synthesizing or amplifying nucleic acid sequences in order to generate PCR datasets representing growth curves [Description: page 1, lines 17-24].

- [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 the CGK, would consider that the problem addressed by the claimed invention is how to interpret the data produced during a polymerase chain reaction (PCR) to determine the Ct value in growth curves. Current methods of determining the elbow value in a PCR curve have severe drawbacks. For example, some methods are very sensitive to outlier (noisy) data, and the arbitrary fluorescence value (AFL) value approach does not work well for data sets with high baselines. Traditional methods to determine the baseline stop (or end of the baseline) for some growth curves may not work satisfactorily, especially in a high titer situation.

Furthermore, these algorithms typically have many parameters (e.g., 50 or more) that are poorly defined, linearly dependent, and often very difficult, if not impossible, to optimize [Description: page 2, lines 1-10].

The person skilled in the art, having read the specification, would consider that the description provides the following solution: an algorithm for determining the elbow value in PCR curves using improved mathematical/numerical steps [Description: page 2, lines 19-26].

- [22] In the RFA at page 2, the Applicant referred to reasons presented in its submissions dated April 29, 2016, April 6, 2017 and September 20, 2018. In the submissions dated April 6, 2017 at pages 12 to 13, the Applicant submitted that the problem addressed by the inventors “concerned how to perform real-time determination of the elbow value Ct in PCR growth curves, which allows for more precise determination of the efficiency of the PCR reaction and/or for more precise determination of the absolute or relative amount of a target nucleic acid in the PCR reaction”. The corresponding 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 7 of the description, we are of the preliminary view that the problem to be solved is a need of a method for determining the transition value in sigmoid or growth-type curves, such as Ct values in PCR amplification curves, that overcomes the drawbacks of known methods (see page 2, lines 1 to 10).

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 pages 6 to 7, Fig. 2 and Fig. 9). Therefore, it is our preliminary view that such problem is not a problem wherein 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 use a method for determining the C_t value in PCR amplification curves. Such a method entails using a particular scheme of mathematical manipulation steps (i.e., an algorithm workflow) that is recited in the claims (see page 3, lines 19 to 26).

- [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 13 claims on file. Method claim 1, computer readable storage medium claim 11 and system claim 12 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:

using a kinetic PCR thermocycler device:

to perform a PCR growth process by enzymatically synthesizing or amplifying at least one defined nucleic acid sequence;

to detect intensity values of signals generated using the at least one defined nucleic acid sequence undergoing the PCR growth process at a plurality of growth cycles of the PCR growth process; and

to generate a PCR dataset representing a growth curve of the synthesis or amplification of said at least one defined nucleic acid sequence, the dataset including a plurality of data points, each data point having a pair of coordinate values, each pair of coordinate values corresponding to a different one of the cycle numbers of the PCR growth process and the intensity value of the signal generated using the at least one defined nucleic acid sequence undergoing the PCR growth process after a growth cycle corresponding to the cycle number;

receiving the dataset at a computer system from the kinetic PCR thermocycler device; and using the computer system comprising a processor:

to determine a defined signal threshold value and a number of cycle

required to reach the threshold value for a reaction to be analyzed, wherein the cycle threshold (Ct) value is determined by data manipulation steps; and

to determine the efficiency of the polymerase chain reaction amplification or to determine the absolute or relative copy number of the target molecule on the basis of the cycle threshold value obtained from the target nucleic acid or 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 performed by the processor of:
- receiving the dataset representing the growth curve;
- calculating an approximation of a curve that fits the dataset by applying a Levenberg-Marquardt (LM) regression process to a double sigmoid function to determine parameters of the function;
- normalizing the curve using the determined parameters to produce a normalized curve; and
- processing the normalized curve to determine a coordinate value of a point at the end of the baseline region of the growth curve, wherein said processing includes applying a root-finding process to the normalized curve, and

wherein the point at the end of the baseline region represents the elbow or cycle threshold (Ct) 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 submissions dated April 6, 2017 at pages 12 to 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 be 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 method for determining the transition value in sigmoid or growth-type curves, such as Ct values in PCR amplification curves, that overcomes the drawbacks of known methods. 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 pages 6 to 7 and 21 of the description and Fig. 14). 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 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. This view equally applies to the rest of the claims.

Therefore, our preliminary view is that the essential elements of the claims on file, as purposively construed, are the data manipulation steps for determining whether the data for a PCR amplification curve represent or exhibit valid or significant growth, and if so determining the Ct value of the PCR amplification curve:

- receiving the dataset representing the growth curve;
- calculating an approximation of a curve that fits the dataset by applying a Levenberg-Marquardt (LM) regression process to a double sigmoid function to determine parameters of the function;
- normalizing the curve using the determined parameters to produce a normalized curve; and
- processing the normalized curve to determine a coordinate value of a point at the end of the baseline region of the growth curve, wherein said processing includes applying a root-finding process to the normalized curve, and wherein the point at the end of the baseline region represents the elbow or cycle threshold (Ct) 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 submissions dated April 6, 2017 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 the Ct value of the PCR amplification curve.

[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 6th day of May, 2020