Citation: F. Hoffmann-La Roche AG (Re), 2020 CACP 8
Commissioner's Decision #1528
Décision du Commissaire #1528
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TOPIC:	J00	(Meaning of Art)
	J50	(Mere Plan)
	B00	(Indefiniteness)
SUJET:	J00	(Meaning of Art)
	J50	(Mere Plan)
	B00	(Caractère indéfini)

Application No. : 2,561,458

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,561,458, 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.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,561,458, which is entitled "CT DETERMINATION BY CLUSTER ANALYSIS WITH VARIABLE CLUSTER ENDPOINT" and is owned by F. Hoffmann-La Roche AG. The outstanding defects 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* and whether claims 1 and 18 on file suffer from lack of clarity contrary to subsection 27(4) 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 2,561,458 has been filed in Canada on September 28, 2006 and was laid open to the public on March 29, 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 March 10, 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*. Further, the FA stated that claims 1 and 18 on file are indefinite and do not comply with subsection 27(4) of the *Patent Act*.

[5] In a response to the FA (the RFA) dated September 8, 2017, the Applicant submitted an amended claims set (the proposed claims) and arguments as to why the subject-matter of the claims on file and the proposed claims was not open to objection for the reasons outlined in the FA.

[6] As the Examiner considered the application still did not comply with the *Patent Act*, 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*. However, the SOR considered that the proposed claims would overcome the indefiniteness defect. 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 and the proposed claims are directed to subject-matter excluded from the definition of "invention" as set out in section 2 of the *Patent Act* and that claims 1 and 18 on file comply with subsection 27(4) 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 41 on file dated July 12, 2016 are directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*; and
- whether claims 1 and 18 on file suffer from lack of clarity contrary to subsection 27(4) of the *Patent Act*.

[11] After considering the claims on file, we will consider the proposed claims.

LEGAL PRINCIPLES AND OFFICE PRACTICES

Purposive construction

[12] 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

[13] 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.

[14] 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.

[15] 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

[16] 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.

[17] 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.

[18] 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.

[19] 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.

Indefiniteness and lack of clarity

[20] Subsection 27(4) of the *Patent Act* states that "[t]he 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 146, the Court emphasized 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 POSITA and the relevant CGK

[22] 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 of molecular biologists and computer scientists who are familiar with PCR and analysis of measurements obtained from PCR.
>
> The person skilled in the art would possess the following CGK: knowledge of PCR and how to identify transition points in kinetic PCR growth curves.

[23] 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

[24] 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 providing new systems and methods for determining the elbow value in curves such as sigmoid-type curves, and kinetic PCR curves [Description: page 2, lines 22-24].
>
> 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 mathematically manipulating a dataset to determine a specific point of interest in a data curve.

[25] In the RFA at pages 13 and 14, 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.

[26] 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 9 of the description, we are of the preliminary view that the problem to be solved is a need of a method for determining the Ct value in PCR amplification curves that overcomes the drawbacks of known methods (see page 2, lines 10 to 24).
>
> 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 9, lines 4 to page 10, line 26). 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 use a variable cluster endpoint method to determine Ct values of PCR amplification curves, a method that entails using a particular scheme of mathematical manipulation steps (i.e., an algorithm workflow) (see page 3, lines 1 to 19).

[27] 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

[28] There are 41 claims on file. Method claim 1, computer readable storage medium claim 18 and system claim 23 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 computer-implemented method of determining a cycle threshold (Ct) value in a real-time kinetic Polymerase Chain Reaction (PCR) amplification curve implemented in a computer system having a processor, the method performed by the processor comprising:

- receiving in real time a data set representing a data curve, said data set including a plurality of first data points, each first data point having a pair of coordinate values (x,y), wherein if viewed in a two-dimensional coordinate system the data set has a region of interest;

- applying a transformation to at least a portion of the data set including the region of interest to produce a transformed data set, wherein the transformed data set includes a plurality of second data points, each second data point having a pair of coordinate values (y',y*), where the y' coordinate value of a second data point is the y coordinate value of a corresponding first data point, and the y* coordinate value of said second data point is the y coordinate value of a subsequent first data point;

- identifying a plurality of clusters of second data points in the transformed data set;

- determining a linear slope of each of said clusters;

- determining, for each cluster, a ratio of the slope of that cluster with the slope of an adjacent cluster; and

- comparing the ratios, wherein an end point of a cluster having the largest or smallest ratio represents a specific point of interest in the data curve and wherein the data curve is a curve for a kinetic PCR process, and wherein the specific point of interest represents the elbow or Ct value for the kinetic PCR curve; and storing the Ct value or transmitting the Ct value for display.

[29] In the FA at pages 2 to 3, the essential elements were identified as specific data analysis steps, without the physical computer elements.

[30] In the RFA at pages 13 to 14, 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*.

[31] 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 Ct value 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, for example, pages 9 to 10 and 28 of the description and Fig. 18). 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.
>
> Although the dependent claims recite additional features, our preliminary view for representative claim 1 applies equally to the dependent claims: the computer elements are not considered to be essential for the dependent claims since they do not form part of the identified solution to 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 data set representing a data curve, said data set including a plurality of first data points, each first data point having a pair of coordinate values (x,y), wherein if viewed in a two-dimensional coordinate system the data set has a region of interest;
>
> • applying a transformation to at least a portion of the data set including the region of interest to produce a transformed data set, wherein the transformed data set includes a plurality of second data points, each second data point having a pair of coordinate values (y',y*), where the y' coordinate value of a second data point is the y coordinate value of a corresponding first data point, and the y* coordinate value of said second data point is the y coordinate value of a subsequent first data point;
>
> • identifying a plurality of clusters of second data points in the transformed data set;
>
> • determining a linear slope of each of said clusters;

> • determining, for each cluster, a ratio of the slope of that cluster with the slope of an adjacent cluster;
>
> • comparing the ratios, wherein an end point of a cluster having the largest or smallest ratio represents a specific point of interest in the data curve and wherein the data curve is a curve for a kinetic PCR process, and wherein the specific point of interest represents the elbow or Ct value for the kinetic PCR curve; and
>
> • storing the Ct value or transmitting the Ct value for display.

[32] 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

[33] 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 14 to 15).

[34] 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.

[35] 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*.

Indefiniteness and lack of clarity

[36] The FA stated that claims 1 and 18, line 4 are indefinite because it is not clear what the expression "real-time" references. The FA further stated that the language used in lines 7 and 8 of claim 23 would be suitable to address the defect.

[37] In the RFA, the Applicant did not express disagreement and submitted a set of proposed claims wherein claims 1 and 18 were amended in accordance with the Examiner's suggestion.

[38] Lines 4 and 5 of claim 1 on file reads as follows:

> receiving in real time a data set representing a data curve, said data set including a plurality of first data points, each first data point having a pair of coordinate values (x,y)

[39] In the PR Letter, we expressed the preliminary view that the POSITA, defined above as familiar with PCR and analysis of measurements obtained from PCR, would readily understand the meaning of the expression "real-time" in the context of claims 1 and 18, i.e., that the referred PCR data set representing a data curve is received by the processor in real time as the PCR data set is being collected.

[40] Our conclusion is therefore that claims 1 and 18 on file comply with subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED AMENDMENTS

[41] As this review has determined 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*, we consider the Applicant's proposed claims set. The proposed claims set contains claims 1 to 41 wherein former claim 1 and 18 have been amended to address the indefiniteness issue identified in the FA with respect to the expression "real-time" in line 4 of claims 1 and 18.

[42] With regard to the proposed claims, the SOR expressed the view that the proposed amendments overcome the defects of indefiniteness, but that the subject-matter of the proposed claims is still considered to not comply with section 2 of the *Patent Act*.

[43] We already expressed our view above that the claims on file comply with subsection 27(4) of the *Patent Act* but 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*.

[44] In the PR Letter, we stated that given that the proposed amendments do not address the subject-matter defect, we were of the preliminary view that the proposed claims are directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act* for the same reasons given with respect to claims on file.

[45] In view of the above and as no further submissions were provided by the Applicant, our conclusion is that the proposed claims are directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act*. The proposed amendments are therefore not considered a necessary specific amendment under subsection 86(11) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules*.

RECOMMENDATION OF THE BOARD

[46] 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*.

[47] We do not consider the claims proposed on September 8, 2017 to constitute amendments necessary to comply with the *Patent Act* and *Patent Rules*. Accordingly, we decline to recommend that the Applicant be notified under subsection 86(11) of the *Patent Rules* that said proposed claims are necessary.

Marcel Brisebois	Leigh Matheson	Lewis Robart
Member	Member	Member

DECISION OF THE COMMISSIONER

[48] 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*.

[49] 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