Citation: F. Hoffmann-La Roche AG (Re), 2020 CACP 9 Commissioner's Decision #1529 Décision du Commissaire #1529 Date: 2020-05-05

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

Application No. : 2,701,078 Demande nº 2,701,078

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,701,078, 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 2,701,078, which is entitled "DETERMINATION OF SINGLE PEAK MELTING TEMPERATURE BY PCR ANALOGY AND DOUBLE SIGMOID EQUATION" 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 2,701,078 has been filed in Canada on April 15, 2010 and was laid open to the public on October 17, 2010.
- [3] The claimed subject-matter of the application relates to methods for determining the melting temperature (Tm) of DNA based on melt curve data derived from a Polymerase Chain Reaction (PCR) amplification reaction.

Prosecution history

- [4] On October 20, 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 April 18, 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 August 7, 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 11 on file dated October 6, 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 nonstatutory 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 a molecular biologist, a technician, a programmer and a statistician.

The person skilled in the art would possess common general knowledge of the generation of a melt curve dataset for a DNA sample by enzymatically synthesizing or amplifying defined nucleic acid sequences, the use of an automated apparatus for such data generation, the data generated by same, methods for statistical data processing and correction, as well as computer programming.

[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 common general knowledge (CGK), would consider that the problem addressed by the claimed invention is a need for an improved method of determining a melting temperature of DNA.

The person skilled in the art, having read the specification and in light of their CGK, would consider that the description provides the solution by numerically determining an analytical expression that fits a melt-curve dataset wherein the analytical expression is determined by calculating an approximation of a curve that fits the dataset by applying a regression process to a double sigmoid function, determining a derivative curve, and determining a maximum value of the derivative curve as the melting temperature of the DNA sample.

[22] In the RFA at page 2, the Applicant referred to reasons presented in previous submissions, particularly the Applicant's submissions dated July 10, 2017. In those July 10, 2017 submissions at pages 12 to 13, the Applicant submitted that the problem addressed by the inventors was how to provide a practical, viable technology to determine the melting

temperature of an oligonucleotide sample. According to the Applicant, the corresponding solution lies in the specific, concrete configuration of the computer technology to enable real-time, accurate and efficient determination of the melting temperature of an oligonucleotide sample. Such a solution necessarily relies on the use of the physical computer as the defined results would not otherwise be practical and other means to achieve the defined results are certain to introduce inefficiency and error.

[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 review the specification as a whole, we are of the preliminary view that the problem to be solved is a need of an improved method for determining the melting temperature of an oligonucleotide sample from melt curve data.

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 melting temperature. In the context where the process of producing a melt curve data set is conducted with a PCR apparatus, the specification discloses that the data manipulation steps are to be performed on a data set representing a melt 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 page 9 to 10). Therefore, it is our preliminary view that such problem is not a problem wherein how a data set representing a melt 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 determine an analytical expression that fits the data set and to take advantage of previous algorithms designed to process and analyze PCR curve data set to determine the melting temperature of an oligonucleotide sample, a method that entails using a particular scheme of mathematical manipulation steps (i.e., an algorithm workflow) (see page 3, first and second paragraphs).

[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 11 claims on file. Method claim 1 is the sole independent claim. Claim 1 reads as follows:

1. A computer-implemented method of determining a melting temperature, T_m , of DNA, the method comprising:

(a) enzymatically synthesizing or amplifying defined nucleic acid sequences, and

(b) generating, with a computer system comprising a processor, a melt curve of synthesis or amplification of said defined nucleic acid sequence by:

- altering the temperature of said synthesized or amplified defined nucleic acid over a temperature range in the presence of at least one double strand-specific DNA dye or at least one labeled oligonucleotide and measuring the change in fluorescence; determining the melting temperature, T_m , of the defined nucleic acid sequence by computer-implemented data manipulation steps, said computer-implemented data manipulation steps comprising:

o receiving on the computer system a dataset representing a melt curve for a DNA sample, the dataset including a plurality of data points represented as a sequence of data values {(X1,Y1), (X2,Y2)...(X_{n-1}, Y_{n-1}), (X_n, Y_n)}, where X represents a temperature (T) value and Y represents a fluorescence intensity value;

o determining with the computer system an analytical expression that fits the dataset, wherein the analytical expression is determined by the computer system by calculating an approximation of a curve that fits the dataset by applying a regression process to a double sigmoid function to determine parameters of the double sigmoid function, the double sigmoid function having the form wherein a, b, c, d, e, f, and g are the parameters;

$$a + bx + \frac{c}{(1 + \exp^{-d(x-e)})(1 + \exp^{-f(x-g)})}$$

o determining with the computer system a derivative curve by taking the derivative of the analytical expression with respect to X;

o determining with the computer system a value X_{max} corresponding to a maximum derivative (dY/dX) value of the derivative curve; and - recording or displaying the value X_{max}, wherein the value X_{max} represents a melting temperature, T_m, of the DNA sample.

- [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 July 10, 2017 at pages 12 to 13, the Applicant argued that the physical computer elements as recited in the claims are essential because practical results in real-time applications would not be otherwise be achievable and the omission of the claimed physical agents and entities would necessarily cause the claimed invention not to work in the same way, thus the claimed physical entities are essential according to *Free World*. Further, the Applicant argued that performance of determination of the melting temperature of an oligonucleotide sample by human minds would be not only impractical, but also certain to introduce inefficiency and error.
- [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 an improved method for determining the melting temperature of an oligonucleotide sample from melt curve data. 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 page 14 to 15 of the description as well as Fig. 10 and Fig. 11). 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. 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 the melting temperature of an oligonucleotide sample from melt curve data:

• receiving a dataset representing a melt curve for a DNA sample, the dataset including a plurality of data points represented as a sequence of data values $\{(X1,Y1), (X2,Y2)...(X_{n-1},Y_{n-1}), (X_n,Y_n)\}$, where X represents a temperature (T) value and Y represents a fluorescence intensity value;

• determining an analytical expression that fits the data set, wherein the analytical expression is determined by the computer system by calculating an approximation of a curve that fits the data set by applying a regression process to a double sigmoid function to determine parameters of the double sigmoid function, the double sigmoid function having the form wherein a, b, c, d, e, f, and g are the parameters;

$$a+bx+\frac{c}{(1+\exp^{-d(x-e)})(1+\exp^{-f(x-g)})}$$

• determining with the computer system a derivative curve by taking the derivative of the analytical expression with respect to X;

• determining with the computer system a value X_{max} corresponding to a maximum derivative (dY/dX) value of the derivative curve; and

• determining, for each cluster, a ratio of the slope of that cluster with the slope of an adjacent cluster; and recording or displaying the value X_{max} , wherein the value X_{max} represents a melting temperature, T_m , of the DNA sample.

[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 July 10, 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 melting temperature of an oligonucleotide sample from melt curve data.
- [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