

Citation: Qiagen Redwood City, Inc. (Re), 2021 CACP 30
Commissioner's Decision #1583
Décision du commissaire n° 1583
Date: 2021-06-09

TOPICS: J-00 Meaning of Art

J-50 Mere Plan

J-10 Computer Programs

SUJETS: J-00 Signification de la technique

J-50 Simple plan

J-10 Programmes d'ordinateur

Application No. : 2,474,754

Demande n° 2 474 754

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,474,754, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Rules*) has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are that the application be refused unless necessary amendments are made.

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INTRODUCTION

- [1] This recommendation concerns the review of rejected Canadian patent application number 2,474,754, which is entitled “SYSTEMS FOR EVALUATING GENOMICS DATA” and is owned by QIAGEN REDWOOD CITY, INC. (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 199(3)(c) of the *Patent Rules*. As explained below, our recommendation is to inform the Applicant by notice pursuant to subsection 86(11) of the *Patent Rules* that certain amendments to the claims are necessary to make the application allowable.

BACKGROUND

The Application

- [2] Canadian patent application 2,474,754 was filed under the provisions of the Patent Cooperation Treaty and has an effective filing date in Canada of February 3, 2003. It was laid open to public inspection on August 14, 2003.
- [3] The instant application relates to systems for evaluating genomics data using a built library of biological pathway profiles generated from an ontology database, a knowledge database and profile generation criteria.
- [4] The claims under review are claims 1 to 19 which were received at the Patent Office on July 11, 2013 (claims on file).

Prosecution History

- [5] On June 11, 2015, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA rejected the application and noted the following defects: i) claims 1 to 19 on file are directed to subject-matter that lies outside the definition of “invention” in section 2 of the *Patent Act*; and ii) claims 6, 14 and 16 on file suffer from minor clarity defects contrary to subsection 27(4) of the *Patent Act*.
- [6] In a November 29, 2016 response to the FA (RFA), the Applicant submitted arguments addressing the defects raised in the FA with regard to the claims on file and proposed an amended set of 18 claims (proposed claims set-1).
- [7] As the Examiner still considered the application not to comply with the *Patent Act*,

pursuant to paragraph 30(6)(c) of the former *Rules*, the application was forwarded to the Board for review along with an explanation outlined in a Summary of Reasons (SOR). Specifically, the SOR indicated that proposed claims set-1 would overcome the defect raised under subsection 27(4) of the *Patent Act* but would not overcome the defect raised under section 2 of the *Patent Act*. In a letter dated July 5, 2017, the Board forwarded a copy of the SOR to the Applicant.

- [8] The present panel (the Panel) was formed to review the instant application under paragraph 199(3)(c) of the *Patent Rules*. The Panel sent a Preliminary Review (PR) Letter to the Applicant on February 4, 2020. The PR Letter also provided the Applicant with an opportunity to make oral and/or written submissions.
- [9] The Applicant declined the opportunity for a hearing in a communication dated February 19, 2020 but informed the Panel that written submissions would be provided in due course. In a written response to the PR Letter (RPR Letter) dated March 17, 2020, the Applicant provided written submissions with regard to the claims on file and a second proposed set of claims (proposed claims set-2).
- [10] During the review, an Office notice entitled “Patentable subject-matter under the *Patent Act*” (CIPO, November 2020) [PN2020-04] was published. Said notice was drafted in response to *Choueifaty v Canada (AG)* 2020 FC 837 [*Choueifaty*]. This notice addressed the Office’s current approach to both claim construction and to the determination of patentable subject-matter.
- [11] A Supplementary Preliminary Review (SPR) Letter that reconsidered the Panel’s preliminary opinion in view of the latest guidance from *Choueifaty* and PN2020-04 was sent on April 30, 2021. The SPR letter also provided the Applicant with an additional opportunity to make oral and/or written submissions. In a written response to the SPR Letter dated May 12, 2021 (RSPR Letter), the Applicant provided written submissions with regard to the claims on file and a third proposed set of claims (proposed claims set-3) and stated that no hearing was desired pending favorable consideration of the written submissions and proposed claim amendments.
- [12] Given the considerations and recommendation that follows, a hearing was not required.

ISSUES

[13] In view of the foregoing, the issues to be addressed in the present review are whether:

- claims 1 to 19 on file are directed to subject-matter that lies outside the definition of “invention” in section 2 of the *Patent Act*; and
- claims 6, 14 and 16 on file suffer from minor clarity defects contrary to subsection 27(4) of the *Patent Act*.

[14] In addition to the claims on file, proposed claims set-3 has also been considered..

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Purposive construction

[15] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, purposive construction is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK), considering the whole of the disclosure including the specification and drawings. In addition to interpreting the meaning of the terms of a claim, purposive construction distinguishes the essential elements of the claim from the non-essential elements. Whether or not an element is essential depends on the intent expressed in or inferred from the claim, and on whether it would have been obvious to the person of ordinary skill in the art (POSITA) that a variant has a material effect upon the way the invention works.

[16] *PN2020-04* also discusses the application of these principles, pointing out that all elements set out in a claim are presumed essential unless it is established otherwise or such presumption is contrary to the claim language.

Patentable subject-matter

[17] The definition of invention is set out in section 2 of the *Patent Act*:

[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.

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

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

[19] *PN2020-04* explains the Patent Office's approach to determining if a computer-related invention is patentable subject matter:

To be both patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*, the subject-matter defined by a claim must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change and that relates to the manual or productive arts, meaning those arts involving or concerned with applied and industrial sciences as distinguished in particular from the fine arts or works of art that are inventive only in an artistic or aesthetic sense.

...

The mere fact that a computer is identified to be an essential element of a claimed invention for the purpose of determining the fences of the monopoly under purposive construction does not necessarily mean that the subject-matter defined by the claim is patentable subject-matter and outside of the prohibition under subsection 27(8) of the *Patent Act*.

...

If a computer is merely used in a well-known manner, the use of the computer will not be sufficient to render the disembodied idea, scientific principle or abstract theorem patentable subject-matter and outside the prohibition under subsection 27(8) of the *Patent Act*.

In the case of a claim to a computer programmed to run a mathematical algorithm, if the computer merely processes the algorithm in a well-known manner and the processing of the algorithm on the computer does not solve any problem in the functioning of the computer, the computer and the algorithm do not form part of a single actual invention that solves a problem related to the manual or productive arts. If the algorithm by itself is considered to be the actual invention, the subject-matter defined by the claim is not patentable subject-matter or is prohibited under subsection 27(8) of the *Patent Act*.

On the other hand, if running the algorithm on the computer improves the functioning of the computer, then the computer and the algorithm would together form a single actual invention that solves a problem related to the manual or productive arts and the subject-matter defined by the claim would be patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*.

Indefiniteness

[20] Subsection 27(4) of the *Patent Act* states that "The 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 at 352, 12 CPR 99, 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 their CGK

- [22] On page 5 of the PR Letter, we identified the POSITA as a team that comprises a bioinformatician with experience in functional genomics analysis and computer scientists or other computer related technologists familiar with general purpose computer hardware and general purpose computer programming techniques.
- [23] With respect to the relevant CGK, we expressed the preliminary view that it should include the following elements:
- analysis of genomics data, i.e., data mining;
 - the use of gene ontology databases;
 - the use of algorithms that perform comparisons of genomics information to a library of biological pathway profiles generated from databases of ontology data, that perform the scoring of results and calculation of statistics that rank biological pathway profiles against genomics data, and that perform the graphical presentation of scored results;
 - knowledge of general purpose computer hardware including processors, memory, servers, and data communications; and
 - knowledge of general purpose software including user interfaces, databases, and mathematical calculations.
- [24] In the PR Letter we noted that the RFA did not express disagreement with the definitions of the POSITA and the CGK as recited in the FA. In that regard, the RPR on page 4 stated that “[t]he Applicant did not express disagreement for the sake of expediency. This does not mean that the Applicant in the RFA conceded or agreed with the definition of the POSITA and CGK put forth by the Examiner”.

[25] Although the RPR offered the view that “to the extent the Panel is relegating any and all ‘computer system elements’ to the common general knowledge of a person skilled in the art, this could represent a tautology that would preclude any and all computer-implemented inventions from being considered statutory subject matter”, it did not provide further submissions or comments with respect to the identity of the POSITA or the relevant CGK. We therefore adopted the characterizations of both the POSITA and the CGK as defined in the PR Letter for the purposes of our supplemental preliminary review and we also adopt it for the purpose of this final review.

The essential elements

[26] There are 19 claims on file. System claim 1 is the only independent claim. Claim 1 reads as follows:

1. A computerized system for evaluating genomics data, comprising:
 - a computer comprising:
 - a knowledge representation system for storing and accessing a first database storing an ontology and a second database storing first genomics information structured according to the ontology, and
 - a graphical user interface;
 - wherein the first genomics information comprises structured facts entered into a template, and
 - wherein the ontology is organized so that:
 - said ontology comprises genes, gene products, and biological effects;
 - each gene, gene product, and biological effect is categorized by class, wherein a class includes genes, gene products, and biological effects sharing similar properties; and
 - the relationship of each gene or gene product and any disease state is defined by slots and facets, wherein a slot identifies a relationship between classes and a facet identifies a restriction on a slot for a specific gene, gene product, or biological effect within a class; and wherein the computer further comprises hardware and software components configured to:
 - generate a library of biological pathway profiles from the structured genomics information by receiving profile generation criteria, and extracting a subset of the stored

structured genomics information that fits the profile generation criteria from the knowledge representation system:

receive second genomics information as input; and
generate a scoring result from the profiles by comparing the second
genomics information with the library of
biological pathway profiles, and computing a statistic that ranks the profiles against the
second genomics information, wherein the scoring result is presented to the user in an
interactive form of the graphical user interface.

[27] In view of the change in the Office practice, we undertook anew the analysis of essential elements and presented it to the Applicant in the SPR Letter. We stated that there is no claim language in independent claim 1 indicating any of the elements to be optional, preferred embodiments or one of a list of alternatives. Nor is there any indication in the record before us that would lead to a determination of any claimed elements being non-essential. We therefore presumed all the claimed elements to be essential.

[28] The Applicant did not contest or comment on our supplemental analysis regarding essential elements of independent claim 1 in the RSPR Letter. Accordingly, we adopt the above characterization for the purpose of this final review.

Patentable subject-matter

[29] In view of the change in the Office practice, we also undertook anew the analysis of patentable subject-matter. When directing the Commissioner to reconsider the patent application at issue in *Choueifaty*, the Federal Court offered the following observations regarding a set of proposed claims (*Choueifaty* at para 42):

The Appellant submits that the Commissioner mischaracterised the purpose (or solution) of the claimed invention to be simply the creation of a new financial portfolio. However, he notes that another purpose of the invention was to improve computer processing. The Commissioner failed to address this adequately in her decision. Specifically, she found that the problem and solution of the claims centred on financial management (yielding a new financial product), but did not explain why she excluded computer processing as a solution. This aspect of the invention requires closer examination.

[30] In the SPR Letter, we considered these observations relevant to the instant case because:

- The Applicant submitted in the RFA on page 5 and RPR on page 6 that the recited database structure (i.e., the class, slots, and facet structures defining the ontology) improves the computer's processing efficiency as well as the quality of the analysis in order to generate a useful "scoring result";
- We acknowledged in the PR Letter on page 8 that the class, slots, and facet structures defining the ontology enables the computer to process genomics data differently and arguably improve the speed and quality of the analysis and further agreed that the organization of the database is essential to the computer in performing the recited algorithms for generating a useful scoring result; and
- We did not specifically address this submission under the former "problem and solution" approach as we had expressed the preliminary view that the computer elements are not essential. We took this view because we considered at the time that the main problem addressed by the subject-matter of the claims on file was the shortcomings in the content of the known databases and how the data was structured within it and thus we did not consider computer-related shortcomings potentially addressed by the new database structure.

[31] Having reconsidered the specification as a whole as well as the Applicant's submissions on record in light of *Choueifaty* and *PN2020-04*, it was our supplemental preliminary view that although the description does not expressly identify specific computer shortcomings to be addressed, the POSITA would understand that the relationship between the recited new database structure and the computer is that the database structure improves the recited computer's processing efficiency within the context of the claimed system as well as the quality of the analysis in order to generate a useful "scoring result" when the computer is used within the claimed computerized system for evaluating genomics data. In that regard, the description on page 3 states the following:

A great deal of such information is available from public sources, e.g., scientific publications. However, the sheer volume of such data is overwhelming such that the data cannot be accessed and correlated in an efficient and effective manner.

...

Another partial solution is databases of genomics data. One example is GenBank, which is maintained by NCBI. Gene sequences entered in such databases are usually annotated with information that may include, e.g., the type of cell in which a given gene sequence is expressed, the probable function of the sequence, etc.

While these databases are enormously helpful, they miss some data that appear in scientific publications and, more problematically, they cannot readily be used to determine disease pathways because the data are not structured in a way that allows computer analysis of complex relations between different genes and gene products.

- [32] We also noted that the RFA on page 5 states “[t]hus, the claimed system provides a computer improved by the claimed database, and not merely a computer executing a database as a matter of convenience without any benefit to the computer”.
- [33] We agreed with this assessment. It was our supplementary preliminary view that it would have been apparent to the POSITA reading the description that the new database structure permits the analysis of complex interactions occurring within complex biological pathways and optimizes the production of a library of biological pathway profiles, as recited in independent claim 1, with significantly less processing and greater speed than if the genomics data were obtained from public sources.
- [34] Accordingly, as a result of the improved efficiency in data storage and retrieval, we considered that the new database structure improves the functioning of the computer used to interact with it is akin to what is described in *PN2020-04*: the computer and the new database together form a single actual invention that has physicality, solves a problem related to the manual or productive arts and is not prohibited subject-matter under subsection 27(8) of the *Patent Act*.
- [35] The Applicant did not contest or comment on our supplemental analysis of patentable subject-matter. Therefore, our view is that the claims on file define patentable subject-matter that complies with section 2 of the *Patent Act*.

Indefiniteness

- [36] According to the FA on page 4, claims 6, 14 and 16 are indefinite because of minor clarity defects:
- Claims 6, 14 and 16 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. There are minor clarity defects in said claims: the expressions “user supplied genomics information” (claims 6 and 14) and “user provided genomic information” (claim 16) have no antecedent.
- [37] Having reviewed claims 6, 14 and 16 on file, we agreed in the PR and SPR Letters that the clarity defects identified in the FA are present and expressed the preliminary view that claims 6, 14 and 16 on file do not comply with subsection 27(4) of the *Patent Act*.
- [38] The Applicant did not contest or comment our preliminary view and instead submitted proposed claim set-3 with the RSPR wherein the identified defects are addressed.

[39] Therefore, it is our view that claims 6, 14 and 16 do not comply with subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

[40] As indicated above, with the RSPR the Applicant submitted proposed claims set-3. According to the RSPR, the claims of proposed claims set-3 were amended to address the minor clarity defects. We agree. Therefore, it is our view that proposed claims set-3 is directed to subject-matter which complies with subsection 27(4) of the *Patent Act*.

CONCLUSIONS

[41] With regard to the claims on file, we have determined that:

- the claims on file define patentable subject-matter that complies with section 2 of the *Patent Act*; and
- claims 6, 14 and 16 do not comply with subsection 27(4) of the *Patent Act*.

[42] With regard to the proposed claims, we are of the view that proposed claims set-3 qualifies as amendments that are necessary in order to make the application allowable under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[43] In view of the above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the deletion of the claims on file and the insertion of the proposed claims set-3 submitted on May 12, 2021 as the amended claims are necessary for compliance with the *Patent Act* and *Patent Rules*.

Marcel Brisebois

Howard Sandler

Christine Teixeira

Member

Member

Member

DECISION OF THE COMMISSIONER

[44] I concur with the conclusions and recommendation of the Board. In accordance with subsection 86(11) of the *Patent Rules*, I hereby notify the Applicant that the following amendment, and only this amendment, must be made in accordance with paragraph 200(b) of the *Patent Rules* within three (3) months of the date of this decision, failing which I intend to refuse the application:

- Delete the claims on file; and
- Insert proposed claims set-3 submitted on May 12, 2021.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 9th day of June, 2021