Citation: Becton, Dickinson and Company (Re), 2021 CACP 46

Commissioner's Decision 1599

Décision du commissaire n^{o}1599

Date: 2021-11-02

TOPIC:	J00	Meaning of Art
	J10	Computer Programs
	O00	Obviousness
	B00	Ambiguity or Indefiniteness

SUJET:	J00	Signification de la technique
	J10	Programmes d'ordinateur
	O00	Évidence
	B00	Indéfini

Application No. : 2,429,405
Demande nº 2 429 405

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,429,405 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 is to notify the Applicant that specific amendments are necessary for compliance with the *Patent Act* and *Patent Rules*.

Agent for the Applicant:

Gowling WLG (CANADA) LLP
2600-160 Elgin St.
OTTAWA Ontario
K1P 1C3

INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,429,405 (“the instant application”), which is entitled “SYSTEM AND METHOD FOR ASSESSMENT AND CORRECTIVE ACTION BASED ON GUIDELINES” and is owned by Becton, Dickinson and Company (“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 in more detail below, our recommendation is to notify the Applicant that specific amendments are necessary for compliance with the *Patent Act* and *Patent Rules*.

BACKGROUND

The Application

[2] The instant application generally relates to a system and method for assessment and corrective action based on guidelines. The application refers to the Staged Diabetes Management (SDM) system that assists medical practitioners to manage a patient’s diabetes by comparing patient data with SDM guidelines. The system includes self-assessment steps to inform patients of ways to take corrective action in order to return to therapy targets. The addition of these immediate self-assessment steps provides feedback to the patient and assists the patient in maintaining and recording pre-set clinical values.

Prosecution History

[3] On March 19, 2018, a Final Action (“FA”) was written pursuant to subsection 30(4) of the former *Rules*. The FA stated that the instant application was defective because all the application claims 1-15 received at the Patent Office May 04, 2015 (“claims on file”) were directed to subject matter that was both non-patentable and obvious and therefore did not comply with section 2 and section 28.3 of the *Patent Act*. The FA also stated that there were indefiniteness and incorporation by reference defects, as per subsection 27(4) of the *Patent Act* and subsection 81(1) of the former *Rules* (currently subsection 57(1) of the *Patent Rules*).

[4] In the September 13, 2018 response to the FA (“RFA”), the Applicant submitted

new claims (“first proposed claims”) with proposed claims 1-15 enclosed and a new page 3 to remove the incorporation by reference statements and also enclosed arguments in favour of the patentability of these claims.

[5] 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 on January 22, 2019 along with an explanation outlined in a Summary of Reasons (“SOR”). The SOR set out the position that even with the proposed amendments the application would still be considered to be non-compliant with the *Patent Act.*

[6] In a letter dated January 28, 2019, the Board forwarded to the Applicant a copy of the SOR and requested that the Applicant confirm its continued interest in having the application reviewed.

[7] In a letter dated April 04, 2019, the Applicant confirmed its interest in having the review proceed.

[8] A Panel of the Board (“the Panel”), comprised of the undersigned members, was formed to review the instant application under paragraph 199(3)(c) of the *Patent Rules*. A Preliminary Review (PR) letter was sent on June 18, 2021 which set out the preliminary view that claims 1, 2 and 5-15 do not comply with section 2 of the *Patent Act*. Furthermore, claim 4 was also considered obvious and therefore does not comply with section 28.3 of the *Patent Act*. It was noted in the PR letter that claim 3 was considered to be compliant with both sections 2 and 28.3 of the *Patent Act,* in that the claim was preliminarily viewed to be directed to patentable subject matter as well as being preliminarily viewed as being non-obvious to the skilled person.

[9] The PR letter further provided a preliminary analysis of first proposed claims 1-15 and provided the Applicant with an opportunity to make oral and/or written submissions. The PR letter also addressed the indefiniteness and incorporation by reference defects mentioned in the FA.

[10] The Applicant responded to the PR letter on July 20, 2021 (RPR) and did not dispute, contest or comment on the positions taken in the PR letter. We adopt them in this review.

[11] The RPR proposed a new claim set, consisting of a single claim ("newly proposed claim 1"). Newly proposed claim 1 is identical to claim 3 on file. The RPR also maintained the proposal to amend page 3 to address the incorporation by reference defects.

[12] Given the preliminary indication in the PR letter that claim 3 on file was patentable and that the proposed amendments to the description would remedy the incorporation by reference defect, coupled with the Applicant's proposed amendments in the RPR, and after a conversation via email with the Applicant's agent on July 28, 2021 to finalize a hearing date and to confirm that only newly proposed claim 1 was to be entered, we agreed that no further written or oral submissions would be necessary. The Panel proceeded to prepare the instant recommendation.

ISSUE

[13] The issues to be addressed are whether:

- Claims 1-15 on file are directed to patentable subject-matter;
- Claims 1-15 on file would have been obvious;
- Claims 3, 4 and 11 are indefinite; and
- Paragraphs 0006 and 0008 of the description contain impermissible "incorporation by reference" statements.

[14] After addressing the above issues, we review the proposed amendments submitted with the RPR to determine if they are considered a necessary amendment under subsection 86(11) of the *Patent Rules*.

LEGAL PRINCIPLES

<u>Purposive Construction</u>

[15] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust*] and *Whirlpool Corp v Camco Inc*, 2000 SCC 67 [*Whirlpool*], 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 skilled person that a variant has a material effect upon the way the invention works.

[16] "Patentable Subject-Matter under the *Patent Act*" (CIPO, November 2020) [*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*:

> ***Invention*** 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* describes the Patent Office's approach to determining if a claim 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.

[20] *PN2020–04* further describes the Patent Office's approach to determining if a computer-related invention is patentable subject matter. For example, the mere fact that a computer is among the essential elements of the claimed invention does not necessarily mean that the claimed invention is patentable subject matter. An

algorithm itself is abstract and unpatentable subject matter. A computer programmed to merely process the algorithm in a well-known manner without solving any problem in the functioning of the computer will not make it patentable subject matter because 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. On the other hand, if processing the algorithm improves the functionality 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.

Obviousness

[21] The *Patent Act* requires that the subject-matter of a claim not be obvious to a person skilled in the art. Section 28.3 of the *Patent Act* states:

> 28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
>
> (a) information disclosed before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[22] In *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, at paragraph 67, the Supreme Court of Canada stated that it is useful in an obviousness inquiry to follow the following four-step approach:

> (1)(a) Identify the notional “person skilled in the art”;
>
> (1)(b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;

> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Indefiniteness

[23] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define subject matter:

> 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.

[24] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized both 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.

Incorporation By Reference

[25] Subsection 57(1) of the *Patent Rules* is worded slightly differently from subsection 81(1) of the former *Rules* but it has the same effect. It states:

> The description must not incorporate any document by reference.

ANALYSIS

Purposive Construction

[26] In our analysis, the Panel construes the claims first, according to a purposive construction, and identifies the essential elements. The Panel then considers the questions of patentable subject-matter, obviousness, indefiniteness, and incorporation by reference. Finally, the Panel analyzes the proposed claims.

[27] In the PR letter at pages 6-8, we introduce D6 as citable prior art and then set out

our preliminary views as to the person skilled in the art (POSITA) and the relevant CGK:

The Skilled Person and the relevant CGK

The FA at page 2 identified the POSITA and the relevant CGK:

> …who may be a team of people, would be skilled in the fields of databases, graphic user interfaces, networking technology, pharmacology, and diabetes management.

The Applicant disputed the examiner's purposive construction analysis in the RFA, but did not contest these POSITA characterizations in the RFA.

After reviewing the specification and the references cited therein, we agree that the characterization of the skilled person presented in the FA is reasonable, and therefore we adopt it in this review.

With regard to the CGK, page 2 of the FA remarks that:

> It is well known in the art that computers can receive input data via a graphical user interface by dragging icons, selecting items from drop down menus, typing information into textboxes, etc.
>
> It is also well known in the art to use data received from a user either by manual or automated entry pertaining to a patient's glucose levels, diet, exercise, and to determine compliance with a diabetes treatment regime (see paragraphs [0003] - [0014]).

Again the Applicant, in the RFA, disputed the examiner's purposive construction analysis, but did not contest these CGK characterizations.

In addition to the above, the Panel preliminarily identifies additional relevant CGK, which includes points taken from the following prior art documents.

…

D1:	WO2002005702	MAULT et al.	24 January 2002 (24-01-2002)
D6:	WO2002025529	OLSON et al.	28 March 2002 (28-03-2002)

The additional points of CGK are as follows:

- Lancets (paragraph 0034)
- Electronic medication delivery pens (paragraphs 0010 and 0033)
- Glucose level monitors (paragraphs 0011 and 0035)

- Portable electronic diabetes monitoring kits (paragraphs 0009, 0012 and 0014)

- Wireless communications (paragraphs 0042 and 0045)

- Diabetes treatment programs such as Staged Diabetes Management (instant application paragraphs 0006 and 0007)

- Knowledge of portable glucose delivery systems that consist of a housing with a lancet, an insulin delivery pen and a glucose monitor. (instant application, paragraphs 0013 and 0014)

- Knowledge of healthcare data manipulation and analysis systems that allows a healthcare provider to obtain patient data during a visit with the patient at the patient's home, where patient data is entered into a database that compares the data to treatment guidelines for the patient's particular disease, and then provides a recommended course of action for the patient. (instant application, paragraph 0004)

- Knowledge that glucose monitoring user interaction modules may take various configurations, including personal computers, hand-held devices, multiprocessor systems, microprocessor-based or programmable consumer electronic devices, telephones, pagers, pocket PCs, network PCs, minicomputers, mainframe computers, and the like. Such devices may be considered mobile information devices and may be a personal digital assistant (PDA). (D6 WO2002025529 page 12 lines 1-10)

- Knowledge that graphical user interfaces (GUIs) designed for portable glucose monitors can include keyboard-style keys to assist the user to enter data, and further that those skilled in the art will recognize that the keys may be replaced by other user controls, such as switches, buttons, or graphic controls implemented on a touch sensitive screen. (Worthington et al., US5822715, incorporated by reference in D1, page 3 lines 10-14)

- Knowledge that there are various other GUI interfaces that are capable of performing the desired function of allowing a clinician and/or patient to gather and subsequently view medical information, such as a textual, interactive, drop-down menu, voice activated, and the like interface. User interfaces may allow a user to select choices through pushing buttons, selecting icons, scanning bar codes, vocalization of procedure codes or medical treatments, or through some other method, system, hardware device, and/or software application known to one skilled in the art. (D6, WO2002025529 page 23 lines 18-27)

- Knowledge that various icons or indicators may be used in a glucose monitoring device GUIs, such as syringe icons, blood glucose icons, thumbs-

up icons and low battery icons (Olsen US6188648 column 5 lines 42-53, incorporated by reference into D1 page 3 lines 3-9)

[28] None of the above from the PR letter was disputed by the Applicant in the RPR and we adopt it for the purposes of this review.

The Essential Elements of the Claims

There are 15 claims on file. Claims 1, 3, 4, 5, 8 and 11 are independent claims and are listed below:

1. A system for assessment and corrective action based on guidelines, comprising:

a data storage component, adapted to store guideline data representing at least one of guidelines for assessing a condition of an entity and guidelines for taking action on said entity, and to store qualitative user data representing self-assessment of one or more entity performance factors,

said qualitative user data being generated by a user interaction with a user interface wherein a position on the user interface is representative of the user's self-assessment of entity performance ranging from good to poor, and quantitative data;

and an output device, adapted to display a representation of a relationship of at least a portion of said user data to at least a portion of said guideline data;

wherein said user interface comprises a graphical user interface comprising a target image and at least one icon associated with a factor, said at least one icon adapted to be dragged onto a position on said target image, said position representing a user's self-assessment of performance related to one of said factors.

3. A method of assessment and corrective action based on guidelines comprising:

storing guidelines data comprising guidelines for assessing a condition of an entity and guidelines for taking action on said entity in a memory;

setting acceptable range and plan values in a device adapted to measure a property in an entity;

measuring said property;

inputting qualitative data representing self-assessment of user performance relative to at least one factor, said qualitative user data being generated by a user interaction with a user interface wherein a position on the user interface is representative of the user's self-assessment of said user performance relative to said at least one factor ranging from good to poor;

storing measured property data and said qualitative data in said memory, said property data comprising at least one of data representing the value of the property measured and data representing the time said measurement was taken;

comparing at least one of said measured property data and said qualitative data to a subset of said guidelines data, said subset being identified by said acceptable range and therapy plan values; and

based on said comparison, alerting an operator of said device if said measured property data values and/or said qualitative data are not within said acceptable range, or are in danger of falling outside of said acceptable range;

wherein said inputting step comprises the steps of:

displaying a target image and at least one factor icon in a graphical user interface; and

moving said icon to a position on said target image representative of user performance relative to said factor.

4. A method of assessment and corrective action based on guidelines comprising:

storing guidelines data comprising guidelines for assessing a condition of an entity and guidelines for taking action on said entity in a memory;

setting acceptable range and plan values in a device adapted to measure a property in an entity;

measuring said property;

inputting qualitative data representing self-assessment of user performance relative to at least one factor, said qualitative user data being generated by a user interaction with a user interface wherein a position on the user interface is representative of the user's self-assessment of said user performance relative to said at least one factor ranging from good to poor;

storing measured property data and said qualitative data in said memory, said property data comprising at least one of data representing the value of the property measured and data representing the time said measurement was taken;

comparing at least one of said measured property data and said qualitative data to a subset of said guidelines data, said subset being identified by said acceptable range and therapy plan values; and

based on said comparison, alerting an operator of said device if said measured property data values and/or said qualitative data are not within said acceptable range, or are in danger of falling outside of said acceptable range; wherein said

factor is selected from the group consisting of compliance with a diet plan, compliance with an exercise plan, level of stress at home, and level of stress at work.

5. A device for assessment and corrective action based on guidelines comprising:

a graphical user interface including a target image and at least one factor icon representing a factor relevant to glucose control that a user moves to a position on said target image, said position being representative of the user's self assessment of user performance relative to said factor, said user performance ranging from good to poor;

a memory adapted to store self-assessment values based on said position on said target image and a plurality of actionable alternatives that are presentable to the user;

a processor adapted to select a subset among said plurality of actionable alternatives stored in said memory based on said stored self assessment values; and a display adapted to display said subset of suggestion data.

8. A method of assessment and corrective action based on guidelines comprising the steps of:

in a graphical user interface comprising a target image and at least one factor icon representing a factor relevant to glucose control, moving said factor icon to a position on said target image, said position being representative of a user's self assessment of user performance related to said factor, said user performance ranging from good to poor; and

based on said position, selecting a subset from a plurality of actionable alternatives and displaying said selected subset of actionable alternatives on a display.

11. A computer readable medium of instructions adapted to control a system for assessment of disease management comprising:

a first set of instruction adapted to control a graphical user interface to display a target image and at least one factor icon;

a second set of instructions adapted to control the system to allow a user to move the at least one factor icon representing a factor relevant to glucose control to a position on said target image, said position being representative of the user's self assessment of user performance relative to said factor, said user performance ranging from good to poor;

a third set of instructions adapted to select, based on said self-assessment, a subset from a plurality of actionable alternatives for performance improvement; and

> a fourth set of instructions adapted to display said selected subset among said plurality of actionable alternatives.

[29] We said the following in relation to the essential elements in the PR letter:

> The FA at pages 2, 3 and 4 performed a purposive construction that resulted in a set of essential elements for certain claims according to a previous Patent Office practice, now superseded by PN2020-04. The Panel undertakes anew the identification of essential elements.
>
> According to PN2020-04, purposive construction is conducted in accordance with the principles set out by the Supreme Court of Canada in Free World Trust and Whirlpool. The objective determination considers where the person skilled in the art would have understood the applicant to have intended to place the fences around the monopoly being claimed.
>
> Considering the claims and the whole of the specification, the person skilled in the art would understand that there is no use of language indicating that any of the steps in each claim are optional, a preferred embodiment 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. Therefore, in our preliminary view, all the elements of the claims are considered to be essential, including the computer-implemented method steps identified in the claims and the computer-implemented components that are used for carrying out these method steps as recited in the corresponding system claims.

[30] The Applicant did not dispute, contest or comment on this identification of the essential elements and we adopt it in this review.

Patentable Subject Matter

[31] In the PR letter, the Panel stated, with respect to the claims on file:

> Page 4 of the FA states that claims 1-15 relate to a scheme to determine corrective action needed for a therapy regime and do not fall within the scope of section 2 of the *Patent Act*,
>
> Given that our preliminary view of the essential elements differs from that of the FA, we undertake anew the assessment of patentable subject-matter according to *PN2020-04*.
>
> As described above in the section in “LEGAL PRINCIPLES” we will assess the claims on whether the subject-matter they define forms a single actual invention having physical existence or a discernible physical effect or change.

…

Claims 1 and 2 are system claims.

Claims 3, 4, 8, 9 and 10 are method claims.

Claims 5, 6 and 7 are device claims.

Claims 11, 12, 13, 14 and 15 are computer readable medium claims.

We begin with method claims 3, 4, 8, 9, and 10.

Method claim 3 is a method of assessment and corrective action. Several method steps are claimed including storing data, setting ranges in a device adapted to measure properties such as blood glucose, measuring these properties, inputting qualitative data with a target image and factor icon GUI and alerting an operator if measured properties are out of range.

Claim 3 is considered to have physical existence or manifest a discernable physical effect or change relating to the manual or productive arts according to *PN2020-04*. The method stores inputted data, measures this data and alerts based on the results. It is evident from the claim and the rest of the specification that the physical measurement of the property cooperates with the other steps of the method to provide an assessment of an individual with recommended corrective action, through the use of the computer elements set out in the claim. There is a discernable physical effect. It is the Panel's preliminary view that claim 3 is considered to comply with section 2 of the *Patent Act*.

Method claim 4 is similar to claim 3 but without the specific GUI claimed. Claim 4 also includes method steps that are considered patentable. Again there is cooperation between the elements, the method steps and the computer algorithm , with the measurement of the property providing a discernable physical effect. It is the Panel's preliminary view that claim 4 is also considered to comply with section 2 of the *Patent Act*.

Method claim 8 is also a method of assessment and corrective action that claims a moving step of a factor icon onto a target image GUI based on a user's self-assessment, and displaying actionable alternatives based on the position of the factor icon onto the target image GUI. Graphical user interfaces (GUIs) are CGK in the art. Claim 8 refers to a GUI only and its use. The ability to select icons and/or use graphic controls on a touch sensitive screen on a glucose monitoring system is considered CGK. Moving icons or controls on a touchscreen GUI is also considered CGK. The POSITA possessing ordinary skill in the art would understand from the specification and their CGK that this method utilizes a generic computer that functions in a conventional manner.

According to *PN2020-04*, “[i]f 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 Panel’s preliminary view, this is the situation for claim 8, where the GUI alone is considered to be an abstract scheme implemented on a computer, but the computer is merely used in a well known manner. The computer does not form a single actual invention with the abstract scheme and thus does not render the scheme patentable subject-matter. The computer is merely being used to perform the kind of processing; in this case the new location of icons on a screen, that the computer was invented to make.

Accordingly, the actual invention is the abstract scheme to select and provide a subset of data based on the self-assessment of a user, which has no physical existence itself and does not manifest a physical effect or change. Nor does the use of the computer in this case cause it to meet the physicality requirement.

Dependent claims 9 and 10 specify the factors considered for the user’s self assessment and the specific indication of self-assessment level, both of which are part of the abstract self-assessment scheme and do not lend patentability to the claims.

Device claim 5 claims a device with a graphical user interface with a target image and a factor icon, a memory, a processor and a display.

Glucose monitoring devices with a memory and a processor that contain memory storing medical instructions are considered CGK. Again the POSITA possessing ordinary skill in the art would understand from the specification and their CGK that this device utilizes a generic computer that functions in a conventional manner.

The algorithm claimed in claim 5 is a graphical user interface (GUI) on the device that can determine the location of an icon on the GUI. Running this algorithm is considered to be within the well-established manner of a generic computer running an algorithm, as opposed to an improvement in computer functioning. Claim 5 is therefore not compliant with section 2 of the *Patent Act* for the same reasons as those for claim 8. It is also the Panel’s preliminary view that dependent claims 6 and 7 are not compliant with section 2 of the *Patent Act* for the same reasons as those for dependent claims 9 and 10.

The same reasoning applies to computer readable medium claims 11 to 15.

Finally, claim 1 is a system claim for assessment and corrective action that comprises a data storage component “adapted to store” guideline data, qualitative user data representing self-assessment and quantitative data, with a graphical user interface comprising a target that is “adapted to be dragged” to a target image to represent a user’s self-assessment.

> It appears that the actual invention, like that of other independent claims 5, 8 and 11, is directed to the abstract scheme to select and provide a subset of data based on the self-assessment of a user.
>
> Running the algorithm set out by claim 1 is not considered to be an improvement in computer functioning, the generic computer is running an algorithm in a well-established manner.
>
> In view of the requirements set out in *PN2020-04*, it is the Panel's preliminary view that the actual invention of claim 1 does not "manifest a discernible physical effect or change and that relates to the manual or productive arts". The actual invention contains no physical effect or change. Unlike claims 3 and 4, claim 1 does not include any physical step of measuring a property. Thus, in our preliminary view, the actual invention of claim 1 is prohibited under subsection 27(8) of the *Patent Act* and the subject-matter of claim 1 is not patentable subject-matter and therefore falls outside the definition of "invention" in section 2 of the *Patent Act*.
>
> Dependent claim 2 would also not be patentable, for the same reasons set out in relation to dependent claim 6.

[32] None of the above has been disputed by the Applicant in the RPR. As noted earlier, the Applicant proposed replacing the claims on file with a single claim identical to claim 3 on file, indicated above as being compliant with section 2 and subsection 27(8) of the *Patent Act*.

[33] We conclude that claims 1-2 and 5-15 are not directed to patentable subject-matter and are non-compliant with section 2 and subsection 27(8) of the *Patent Act*. Claims 3 and 4 on the other hand, are directed to patentable subject-matter and are compliant with section 2 and subsection 27(8) of the *Patent Act*.

Obviousness

(1) Identify the notional "person skilled in the art" and the relevant common general knowledge (CGK) of that person

[34] The person skilled in the art and the relevant CGK have been identified above under *Purposive Construction*. We consider the above identifications of the notional skilled person and the relevant CGK to be applicable for the purpose of assessing obviousness.

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

[35] We consider all the claim elements to be essential and to form the inventive concept, consistent with the PR letter on page 15. The Applicant did not dispute, contest or comment on this identification and we adopt it in this review.

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed

[36] In addition to D1, the FA cited:

D4:	WO200150330	AHMED	12 July 2001 (12-07-2001)
D5:	US20020055855	CULE et al.	09 May 2002 (09-05-2002)

[37] In the PR letter, the Panel stated, with respect to the claims on file:

> Previously introduced above in the *Purposive Construction* section, D1 discloses a closed loop glycemic index system. The system consists of an electronic device and a software program adapted to receive nutritional data of food consumed and then calculate the blood glucose level for the person using the nutritional data and a glycemic response model that presents the blood glucose level to the person on the device display.
>
> D4 discloses a medical self-assessment decision making system that uses both information and expert system theories such as fuzzy logic and AI to assist in making a medical diagnosis.
>
> D5 discloses a system and method for graphically indicating patient information, including a representative image of the patient with icons to indicate or inform a healthcare worker of the condition of the patient. This image can then be placed near the patient for visual conveyance of the patient's condition.
>
> The Panel has retrieved an additional prior art document D6 that it considers to be pertinent to the assessment of obviousness of the claims on file and in accordance with subsection 86(9) of the *Patent Rules* now gives the Applicant notice of the document and its applicability in relation to the defect of obviousness.
>
> Previously introduced above in the *Purposive Construction* section, D6 discloses a clinician decision-support system that communicated with mobile information devices. As best depicted in figures 2 and 3 of D6, a decision-support module 210 is configured to generate decision-supported patient data specific to each patient for a clinician to examine. A knowledge module 228 and a patient module 220 communicate with an inference engine 232 and generates decision-supported patient data. Users submit patient data via modules 214 to the network that are then

analyzed via the decision-support module 210. Modules 214 may take various configurations, including personal computers, hand-held devices, multiprocessor systems, microprocessor-based or programmable consumer electronic devices, telephones, pagers, pocket PCs, network PCs, minicomputers, mainframe computers, and the like.

D6 further teaches from page 21 line 29 to page 22 line 7 that diabetes can be supported by this system and teaches “if the patient has diabetes the medical information received from decision-support module 210 will be directed to the pertinent medical conditions associated with the patient's diabetes and control module 244 will summarize the decision-supported patient data to recite the most recently acquired pulse rate, blood pressure, blood sugar level, critical warnings and alerts, and the like. Alternatively, when a therapeutic regimen is suggested, the summarized decision-supported patient data includes drug name and type, dose, route, interval and duration of therapy, critical alerts and warnings specific to the patient and the drug, patient demographics, and the like.” Furthermore from the bottom of page 3 line 31 to line 2 of page 4 of D6 it is taught that “such current patient data may include general health information like blood pressure and heart rate and/or medical condition specific data such as blood sugar level for a diabetes patient.”

D6 further discloses that patient data may optionally be in the form of a decision-supported progress note that assists a clinician in making a decision. These notes “represent a qualitative and quantitative analysis of the patient assessment process” as disclosed at the bottom of page 9 line 28 to the top of page 10 line 6 of D6. Patient data is disclosed on page 11 lines 7-18 as including any data regarding the patient's general health, such as exercise, eating, smoking, drinking, and drug habits, if any, and the like, while the clinician may view current and past medical conditions, treatments, medications prescribed, family history, genetic predispositions and microbial susceptibilities, and the like. In response to patient data, D6 further discloses on page 13 lines 5-20 that “education materials” such as educational literature may be delivered to the patient that the decision-support module 210 identifies as appropriate. An example of preventing heart disease is disclosed as an example.

In our preliminary view, the difference between claims 1-3 and 5-15 and the state of the art is:

> the ability of the user to perform self-assessment of his or her management of a therapy regime by dragging an icon on a graphical user interface to a position ranging between good and poor on a target image.

This difference is less specific in claim 4:

> inputting qualitative data representing self-assessment of user performance relative to at least one factor, said qualitative user data being generated by a user interaction with a user interface wherein a position on the user interface is representative of the user's self-

assessment of said user performance relative to said at least one factor ranging from good to poor;

D6 discloses both qualitative and quantitative data being entered by a patient via a user interface and analyzed by a clinician. Information can be provided to the patient based on patient data to treat the medical condition or prevent the onset of other medical conditions. Page 9 lines 22-27 of D6 teach that “a patient or clinician may input information regarding the patient's health, medical conditions, billing information, and past and current medical care, termed "patient data".” This is depicted in D6 figure 2. Further on page 9 line 22 to page 10 line 5 of D6 it is disclosed that “system 200 may evaluate this patient data to create data that assists the clinician in making a medical diagnosis or medical care decision. Such data is termed ''decision-supported patient data.'' A patient data configuration option that assists the clinician in making a medical diagnosis or medical care decision is disclosed from page 9 line 28 to page 10 line 5 of D6. Configuring this patient data in the form of a “decision-supported progress note” that “represents a qualitative and quantitative analysis of the patient assessment process performed by the decision-support module 210 and the clinician and the recommended plan of medical care suggested by decision-support module 210. Such qualitative and quantitative analysis may extend over a long period, such as with an outpatient situation, or over a shorter period, such as with an inpatient situation.”

In our preliminary view, the state of the art is represented by prior art document D6. D1 is considered as another relevant document.

D1 discloses blood glucose management systems that allow a person to view projected future levels of blood glucose, so as to assist the person to keep blood glucose levels within a predetermined range, such as a medically advisable healthy range. Systems are provided by which a person can view future projections of blood glucose levels based on actions or planned actions, receive advance warnings of possible excursions of blood glucose from the predetermined range, and receive advice on diet, exercise, behavior modification, or medical treatments that can help the person prevent the blood glucose level excursions into unhealthy ranges. D1 discloses the use of a personal computing device such as a PDA or “wireless phone with computational portability” (D1 page 17 lines 12-26) to run calorie management software with glycemic modeling capability, and depicts a GUI with a “stylus entry” option 364 in figure 13 of D1. Other device options include portable Internet access devices and wristwatches. Wireless Bluetooth™ data transmission from the glucose sensor to the PDA is also disclosed on page 18 line 28 of D1.

D4 discloses fuzzy logic and AI to make suggestions to a patient on diabetes treatment.

D5 discloses an image system but the image system is saved, printed and displayed. This image system is not sent to a physician to comment on and reply to the patient.

[38] The Applicant did not dispute, contest or comment on this identification and we adopt it in this review.

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[39] In the PR letter, the Panel stated, with respect to the claims on file:

> In almost all the claims on file, the GUI allows a user/patient to place an icon on a bullseye GUI to represent a self-assessment on a specific factor, specifically food, diet and stress as best depicted in figures 11, 12 and 13 of the instant application. This is not specifically disclosed but inferred that once the user/patient places each icon on the bullseye GUI the GUI is "saved" and the program then reads the location of each icon and processes the locations of each.
>
> D6 teaches that patient data entered by either the patient or a clinician can be converted to a decision-supported progress note by module 210 to "represent a qualitative and quantitative analysis of the patient assessment process".
>
> Touch screen GUIs designed for portable glucose monitors with user controls such as switches, buttons, or graphic controls are considered CGK. Other interactive GUI interfaces that are capable of performing the desired function of allowing a clinician and/or patient to gather and subsequently view medical information are also considered CGK. Furthermore choice of icon such as syringe icons, blood glucose icons and "thumbs-up" icons is also considered CGK.
>
> D4 discloses the use of fuzzy logic algorithms to assist with medical decision making. Interfaces are disclosed but consist mostly of check boxes that are not considered "qualitative". No icon and target GUIS are disclosed.
>
> D5 discloses a method of graphically indicating patient information in which a user can graphically represent the condition of a patient so that hospital staff can view a printout of the graphical representation at the patient's bedside for "visual conveyance of the patient's condition" (D5 abstract).
>
> It is the Panel's preliminary view that D4 and D5 do not disclose or suggest combining fuzzy logic with reading graphical representations of a patient in some sort of "feedback" form as claimed by the applicant in the pending application. Additionally, this combination is not considered to be CGK.
>
> D1 and D6 combined do not disclose or suggest a glucose monitoring icon and target GUI that represents a user's self-assessment of qualitative user data as claimed.

> Claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 15 each claim an icon/target GUI which was not found or suggested in the prior art or CGK.
>
> Therefore, in our preliminary opinion, some degree of invention is required for adding a "qualitative input" GUI in the form of moving icons onto a target; to a blood glucose management system that allows for results to be interpreted based on the representation of the icons placed on the GUI. This is regarded as a technological feature providing new functionality to solve a practical problem as noted in MOPOP 22.09.01.
>
> Claim 4 claims a comparison step of qualitative data and an alerting step if the qualitative data is not within a selected range, or is in danger of falling outside of said acceptable range, where the ranges can be based on a diet plan, an exercise plan or level of stress. Claim 4 does not recite a specific icon/target self-assessment embodiment.
>
> The comparison step of claim 4 is performed by the decision-support module 210 taught in D6.
>
> Adding this comparison step to a blood glucose management system as disclosed in D1 is not considered inventive.
>
> In light of the above considerations, it is our preliminary view that claim 4 defines subject-matter that would have been obvious to the POSITA, as of the relevant date, in view of D1, D6 and their CGK, contrary to section 28.3 of the *Patent Act*.

[40] None of the above was disputed by the Applicant in the RPR. We conclude that claim 4 on file would have been obvious and is non-compliant with section 28.3 of the *Patent Act*. However, claims 1-3 and 5-15 would not have been obvious and are compliant with section 28.3 of the *Patent Act*.

Indefiniteness

[41] In the PR letter, the Panel stated, with respect to the claims on file:

> The FA states that claims 3, 4 and 11 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. Page 7 of the FA states that claims 3 and 4 recite a "device adapted to measure a property" and "measuring the property." According to the FA, it is not clear what property is measured. It is also not clear as to who, or what, performs the methods of claims 3 and 4.
>
> Also on page 7 of the FA, a defect is noted in claim 11, specifically claim 11 is directed to a computer readable medium of instructions, however, this expression is ambiguous. The claim must specify the that computer readable medium is storing

> the instructions, which, when executed, cause a computer to control a system for assessment of disease management.
>
> Pages 5 and 6 of the RFA disputes the 27(4) defect stating that the Examiner has failed to acknowledge the previously submitted arguments related to this objection. The Applicant submits that the claims must be read along with the specification as a whole when construing elements or terms. Nevertheless amendments were proposed to claims 3 and 4 in the RFA, which now form part of the proposed claims.
>
> The SOR states that proposed claims 3 and 4 address the subsection 27(4) of the *Patent Act* defect but a subsection 27(4) defect still remains in the preamble of claim 11. Specifically the SOR states that claim 11 should read "when executed by a computer" to comply with subsection 27(4).
>
> The description dated May 22, 2003 disclosed a "property" in paragraph 0018 as well as "property data values". Furthermore in the same description paragraph 0027 discloses that figure 1 depicts a screen shot of a display "generated by a system upon receiving data from a medication delivery and property measurement device". The "properties" depicted in figure 10 are glucose readings.
>
> In view of the description, claims 3 and 4 are considered to claim the term "property" distinctly and in explicit terms.
>
> The preamble of claim 11 claims "(A) computer readable medium of instructions adapted to…". In the FA the Examiner remarked that the preamble was ambiguous and must specify that the computer readable medium stores the instructions. The Panel agrees. A claim comprising a "readable means of instructions" may be a device or a simply a computer program; which is not, by itself, patentable subject matter as per MOPOP 22.03.02.
>
> Therefore, it is our preliminary view that claims 3 and 4 on file do comply with subsection 27(4) of the *Patent Act* and that a subsection 27(4) defect still remains in the preamble of claim 11.

[42] The Applicant did not dispute any of the above in the RPR. We conclude that claims 3 and 4 on file do comply with subsection 27(4) of the *Patent Act* and that the preamble of claim 11 is defective under subsection 27(4) of the *Patent Act*.

Incorporation By Reference

[43] In the PR letter, the Panel stated, with respect to paragraphs 0006 and 0008 of the description:

> In the FA there are two incorporation by reference defects found in paragraphs 0006 and 0008. We preliminarily agree that these two paragraphs contravene subsection 57(1) of the *Patent Rules*.

[44] The Applicant did not dispute the above in the RPR. We conclude that the incorporation by references found in paragraphs 0006 and 0008 contravene subsection 57(1) of the *Patent Rules*.

Conclusions on Patentable Subject Matter

[45] In light of the above, we conclude that independent method claims 3 and 4 on file are considered to be directed to patentable subject-matter .

[46] However, we also conclude that independent system claim 1, independent device claim 5, independent method claim 8, independent computer readable medium claim 11, as well as dependent claim 2 which depends directly on claim 1, dependent claims 6 and 7 which depend directly or indirectly on claim 5, dependent claims 9 and 10 which depend directly or indirectly on claim 8, and dependent claims 12, 13, 14 and 15 which depend directly or indirectly on claim 11; would not be considered patentable subject matter. Therefore only claims 3 and 4 on file are compliant with section 2 of the *Patent Act*.

Conclusions on Obviousness

[47] In light of the above, we conclude that claims 1-3 and 5-15 on file would not have been obvious in view of D1 or D6 taken individually or in combination. However, we also conclude that claim 4 on file would have been obvious.

Conclusions on Indefiniteness

[48] In light of our analysis above, in our view that claims 3 and 4 on file do comply with subsection 27(4) of the *Patent Act* and that a subsection 27(4) defect still remains in the preamble of claim 11 on file.

Conclusions on Incorporation By Reference

[49] In light of our analysis above, in our view, the description on file includes incorporations by reference. Proposed amended page 3 (specifically paragraphs 6 and 8) would remedy the incorporation by reference defects.

PROPOSED CLAIMS

[50] As noted above, newly proposed claim 1 is the same as claim 3 on file. The PR letter stated that claim 3 was considered to be compliant with both sections 2 and 28.3 of the *Patent Act*, in that the claim was preliminarily viewed to be directed to patentable subject matter as well as being preliminarily viewed as being non-obvious to the skilled person. The Applicant did not dispute, contest or comment on this preliminary view in response to PR letter. Accordingly, the Panel considers that the subject-matter of newly proposed claim 1 on file is directed to patentable subject matter and additionally would not have been obvious to the skilled person in view of D1, D4, D5, D6 and the CGK. Therefore, the newly proposed claim 1 constitutes a “necessary” amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSION AND RECOMMENDATION OF THE BOARD

[51] For the reasons set out above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the replacement of the claims on file with the newly proposed claim 1, and the replacement of page 3 with proposed amended page 3 (submitted by the Applicant on September 13, 2018), are necessary for compliance with the *Patent Act* and *Patent Rules*.

Blair Kendall	Stephen MacNeil	Leigh Matheson
Member	Member	Member

DECISION OF THE COMMISSIONER

[52] I concur with the findings of the Board and its recommendation.

[53] Accordingly, under subsection 86(11) of the *Patent Rules*, I notify the Applicant that the deletion of claims 1, 2 and 4 to 15 on file, the renumbering of claim 3 on file as claim 1, and the replacement of page 3 of the description on file with the proposed page 3 of the description of this decision must be made within three months of the date of this decision, failing which I will refuse to grant a patent for this application.

[54] In accordance with subsection 200(b) of the *Patent Rules*, only the following amendments may be made to the application:

- delete claims 1, 2 and 4 to 15 on file;
- renumber claim 3 on file as claim 1; and

- replace page 3 of the description on file with the proposed page 3 of the description (accompanying the RFA on September 13, 2018).

Virginie Ethier

Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 2nd day of November 2021