Citation: Baxter International Inc. (Re), 2020 CACP26
Commissioner's Decision #1546
Décision du Commissaire #1546
Date: 2020-06-15

TOPIC: O00 Obviousness

SUJET: O00 Évidence

Application No. : 2,513,687

Demande n^{o} 2 513 687

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,513,687, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019, has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Board and the decision of the Commissioner are to refuse the application.

Agent for the Applicant:

MARKS & CLERK
100 Simcoe Street, Suite 200
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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,513,687 which is entitled "SYSTEM AND METHOD FOR VERIFYING MEDICAL DEVICE OPERATIONAL PARAMETERS" and is owned by BAXTER INTERNATIONAL INC. ("the Applicant").

[2] 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) ("the *Patent Rules*"). As explained in more detail below, our recommendation to the Commissioner of Patents is to refuse the application.

BACKGROUND

The Application

[3] The application, based on a previously filed *Patent Cooperation Treaty* application, is considered to have a filing date of January 30, 2004, and was laid open to public inspection on August 19, 2004.

[4] The application relates to medical data communication systems and methods. More specifically, it is directed to a system and method for verifying operational parameters of medical devices.

[5] The claims under review are claims 1 to 20 on file at the time of the Final Action ("FA"), dated February 3, 2016 ("the claims on file"), which were rejected in the FA.

Prosecution History

[6] On January 9, 2017, the FA was issued pursuant to subsection 30(4) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 ("the former *Rules*"), in which the application was rejected on the basis of obviousness. The FA stated that the claims on file were obvious and did not comply with section 28.3 of the *Patent Act*.

[7] On May 29, 2017, a response to the FA ("R-FA") was filed by the Applicant. In the R-FA, the Applicant argued that the claims would not have been obvious. In the R-FA, a set of amended claims 1 to 20 were proposed ("the proposed claims") to overcome the obviousness defect raised in the FA. The Applicant also proposed amendments to the description to be consistent with the language of the proposed claims.

[8] Since the Examiner maintained the position that the application did not comply with section 28.3 of the *Patent Act* after considering the R-FA, the application was forwarded to the Board on March 8, 2018, along with a Summary of Reasons (SOR), explaining the Examiner's rationale for identifying the defect.

[9] The SOR was forwarded to the Applicant on March 13, 2018. In a letter dated March 22, 2018, the Applicant expressed continued interest in having the application reviewed by the Board.

[10] The present panel (the Panel) was formed to review the application under paragraph 30(6)(c) of the former *Rules* (now paragraph 199(3)(c) of the *Patent Rules*).

[11] In a preliminary review letter dated January 13, 2020 ("PR letter"), the Panel presented its preliminary analysis and rationale and was of the preliminary view that the claims on file would have been obvious and did not comply with paragraph 28.3(b) of the *Patent Act*.

[12] In the PR letter, the Panel notified the Applicant that an oral hearing was tentatively scheduled on February 28, 2020 and set a deadline for written submission. The Applicant did not indicate a need for a hearing and did not provide any further written submissions.

[13] Given the lack of response from the Applicant to the PR letter and invitation to a hearing, this recommendation is based on the written record to date.

ISSUE

[14] There is only one issue to be addressed in this review:

- Whether the claims on file define subject-matter that would have been unobvious, as required by section 28.3 of the *Patent Act*.

[15] In this review, we will first consider the obviousness issue that pertains to the claims on file. We will then consider whether the proposed claims constitute amendments necessary for compliance with the *Patent Act* and *Patent Rules*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive Construction

[16] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66, essential elements

are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings (see also *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paragraphs 49(f) and (g) and 52). In accordance with the *Manual of Patent Office Practice* (CIPO) at §12.02, revised June 2015 [*MOPOP*], the skilled person and his or her relevant common general knowledge (CGK) are to be identified during purposive construction.

Obviousness

[17] The *Patent Act* requires that the subject-matter of a claim not be obvious. Section 28.3 of the *Patent Act* states:

> 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 more than one year before the filing 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.

[18] 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?

ANALYSIS

Purposive Construction

The Person Skilled in the Art

[19] In the PR letter (page 4), the Panel adopted the identification of the person skilled in the art as stated in the FA (page 2):

> The person skilled in the art, which might comprise a team, is a person familiar with computer programming, computer networking, medical device manufacturing and design, and pharmacology.

[20] The Applicant did not dispute this characterization and we adopt it in this review.

The Common General Knowledge

[21] In the PR letter (page 5), the Panel adopted the identification of the CGK used in the FA (page 2):

> The person skilled in the art is knowledgeable in programming methods and methodologies. He or she would be knowledgeable with networking of medical devices such as infusion pumps with servers and/or computers and be able to program and manufacture medical devices.
>
> It is known in the art to have infusion pumps that can be programmed with a medication order by a physician or a nurse.

[22] The Applicant did not dispute this characterization and we adopt it in this review.

[23] Additionally, in the PR letter (page 5), based on the information from the "Background" section of the application and the identification of the skilled person, the Panel considered the following knowledge as CGK:

- Knowledge of various error handling techniques, in implementing medical device software, wherein the error handling techniques include techniques used to handle missing data, inaccurate data, and malfunction issues of the medical device software (e.g., requesting input of missing data, seeking verifications of possibly incorrect data);

- Knowledge of various techniques used in implementing medical device systems to ensure patient safety (e.g., using secure communications between devices/computers to transmit sensitive information such as patient or prescription data);

- Knowledge of various document formats, such as XML, used to store and transmit text-based information; and

- Knowledge of using micro-electro-mechanical systems (MEMS) technology for medication delivery systems such as infusion pump systems (technology of using MEMS for medication delivery systems were readily-available before the claim date of the application, e.g., DEBIOTECH SA released their MEMS technology on a drug delivery system in 1999: Maillefer, et al., "A High-performance Silicon Micropump for an implantable Drug Delivery System", Twelfth IEEE International Conference on Micro Electro Mechanical Systems (MEMS 99), January 21, 1999).

[24] The Applicant did not dispute this further identification and we adopt it in this review.

The Essential Elements

[25] In this review, we have not undertaken a determination with regard to which claimed elements are essential. By taking into account all the elements of the claims on file, as set out below, it is possible to reach a conclusion regarding obviousness of these claims that would not be affected by the omission of any non-essential elements.

Claim Scope

[26] In the PR letter (page 6), we provided our estimation of the term "missing data associated with the operational parameter", which is used in the claims. The scope of this term is considered to be significant to the analysis of obviousness:

> Based on the specification as a whole, especially page 79 of the description and Fig. 41, which was also cited by the Applicant in the RFA at pages 3 and 4, and CGK of the skilled person, we preliminarily provide our estimation of the skilled person's understanding for this review:
>
> > • "data associated with the operational parameter": any data relating to the operational parameters for programming a medical device, including an infusion pump system. In the case of infusion pump systems, data regarding infusing settings such as infusion rate, infusion doses, and infusion volume, on a label or tag attached to an intravenous (IV) bag is considered to be within the scope of "data associated with the operational parameter".
> >
> > • "missing data": data that is unavailable or corrupted when being retrieved.

[27] The Applicant did not dispute this estimation and we adopt it in this review.

Obviousness

(1)(a) Identify the Notional "Person Skilled in the Art"

[28] The person skilled in the art has been identified above at paragraph [19].

(1)(b) Identify the Relevant Common General Knowledge of That Person

[29] The relevant CGK of the skilled person has been identified above at paragraph [21] and [23].

(2) Identify the Inventive Concept of the Claim in Question or if That Cannot Readily be Done, Construe it

[30] As explained above, we have taken into account all the elements of the claims for our consideration of obviousness.

[31] There are 20 claims on file, including independent claim 1 and dependent claims 2 to 20. In our view, claim 1 is representative of the claims on file:

> 1. A system for comparing medical device settings to orders within a healthcare system, comprising:
>
> a medical device having a communication interface for transmitting data relating to operational parameters of the medical device; and
>
> a first computer having,
>
> a communication interface for receiving the data relating to the medical device's operational parameters and for receiving data relating to a medication order,
>
> a processor for comparing at least one of the operational parameters sent from the medical device to at least a portion of the medication order by:
>
> determining a comparison of the at least one operational parameter to the at least a portion of the medication order is unable to be conducted as a result of missing data associated with the operational parameter,
>
> determining which data associated with the operational parameter is missing,
>
> requesting the determined missing data associated with the operational parameter by prompting a clinician for the determined missing data, and
>
> conducting a comparison of the at least one operational parameter and the additional data to the at least a portion of the medication order; and
>
> a transmitter in communication with the first computer for transmitting a comparison result signal of the comparison results to a remote computer.

(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

[32] In the FA, the following documents were cited for the obviousness defect:

- D1: US 2002/0038392 A1 De La Huerga March 28, 2002
- D3: US 2002/0173875 A1 Wallace et al. November 21, 2002

[33] Additionally, the PR letter (page 7) identified another document as relevant prior art:

- D4: US 5,153,827 Coutré et al. October 6, 1992

[34] D1 discloses a method and apparatus for controlling IV medication delivery and monitoring, the method including providing information tags on IV bags that specify delivery parameters, obtaining delivery parameters for at least one bag, associating a controller with a particular patient, comparing patient information for the particular patient with the delivery parameters, determining the efficacy of delivering the medicament to the patient and affecting pump control as a function of the comparison. The method also includes various timing rules and other verification procedures.

[35] D4 discloses an infusion management and pumping system having an alarm handling system. During operation, the pumping system checks for a variety of alarm conditions.

[36] D1 was the main document cited by the Examiner, representing the "state of the art". In this review, D1 is considered to be the closest prior art. D4 is considered as another relevant document. D3 is not considered during this review.

[37] In the PR letter (page 8), the Panel presented its preliminary view that D1 disclosed the following elements of independent claim 1:

- a medical device having a communication interface for transmitting data relating to operational parameters of the medical device (D1: Fig. 26, 37, and 42);
- a first computer having,
    - a communication interface for receiving the data relating to the medical device's operational parameters and for receiving data relating to a medication order (D1: Fig. 26, 37, and 42; paras 31, 32, and 41),
    - a processor for comparing at least one of the operational parameters sent from the medical device to at least a portion of the medication order (D1: paras 31, 32, and 243);

- a transmitter in communication with the first computer for transmitting a comparison result signal of the comparison results to a remote computer (D1: paras 32 and 257, Fig. 31).

[38] Given the analysis above, in the PR letter (page 8), the Panel identified the differences between D1 and the features of independent claim 1 on file:

1. determining that a comparison of the at least one operational parameter to the at least a portion of the medication order is unable to be conducted as a result of missing data associated with the operational parameter; and

2. determining which data associated with the operational parameter is missing, and requesting the determined missing data associated with the operational parameter by prompting a clinician for the determined missing data.

[39] The Applicant did not dispute 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?

[40] In the PR letter (page 9), the Panel explained why features (1) to (2) would have been obvious to the skilled person in view of the cited prior art:

> With respect to difference (1), for the skilled person with his or her CGK, who is aware of the teaching of D1 that discloses the comparison of at least a portion of a medication order to operational parameters of a medical device, it would have been obvious to perform a check to ensure that the data needed for the comparison is available. D1 does disclose at para [0036] the presentation of an alert when the infusion pump is started but data regarding the patient and/or IV bag is absent. This missing data can be used in checking whether an entered flow rate is within an acceptable dosing range obtained from the IV bag information (D1 at para [0032]). What D1 does not disclose is the identification of specific missing data and the specific prompting for entry of such data, which leads us to the second difference.
>
> With respect to difference (2), the FA argued at page 3 that it would have been obvious for the PSA to request information being re-entered in the event that a user entered it incorrectly the first time. In the RFA at pages 3 to 5, the Applicant argued that none of the cited prior art in the FA disclosed the feature of identifying specific missing data. In this case, "[a] system that does not even know which data is missing would be unable to request only such data from a clinician".
>
> D4 discloses an infusion management and pumping system similar to the instant application, which checks for missing data and the[n] prompts a practitioner to enter the specific missing data (col. 2, lines 30 to 40; col. 10, lines 29 to 36):
>
> > The user, a nurse or other health practitioner, using a bar code reader associated with each pump system, enters the data from the formulation container label into the infusion

> pumping system where it is displayed and accepted. The pumps serial port may be used for this purpose. Data can also be entered manually in addition to or in lieu of entry by bar code reader. The pumping system prompts the user for any necessary data that is missing from the read label but required by the pumping system before the infusion program can begin.
>
> ……
>
> After all the data has been entered, the system checks to see whether all the data has been entered correctly, as shown by step 424. If not, the system prompts for any missing data in step 426. The manual prompt routine, as shown in FIG. 32, runs through all the necessary data in step 450. For any missing data, it displays a prompt in step 452 requesting entry of the data. The user wands or keys in the data in step 454 [Emphases added].

In our preliminary view, the use of known error handling techniques, such as those disclosed in D4 and presented in CGK, in a similar infusion management system as recited in D1 would not produce unexpected results or represent any degree of invention to how the missing data error is handled, given the obvious benefits of such an option. Therefore, it is our preliminary view that difference (2) would have been obvious to the skilled person.

In light of the above, we are of the preliminary view that modifying an infusion pump control system such as that disclosed in D1 by adding an automated data verification option such as that disclosed as part of a similar system in D4, would have been obvious. Therefore, in our preliminary view, the subject-matter of claim 1 on file would have been obvious [Emphases in the original].

[41] In the PR letter (pages 10 to 12), the Panel also provided its rationale as to why the dependent claims would have been obvious:

> Dependent claims 2 to 20 recite further features.
>
> Claim 2 recites that the first computer has a memory for storing the data relating to the medication order. D1 discloses this feature in Fig. 34.
>
> Claim 3 recites a wireless transmitter electrically connected to the medical device to transmit a wireless signal containing the data relating to the medical device's operational parameters to the first computer. D1 discloses this feature in para. 41.
>
> Claims 4 and 7 recite a second computer that transmits the data relating to the medication order, or patient information data, to the first computer. D1 discloses this feature in paras 31, 32, 89, 243, 257, and 259.
>
> Claim 5 recites a secure communication line connecting the first computer and the second computer. It is our preliminary view that a secure line being applied between computers used for medical purposes is part of CGK of the skilled person, to ensure security and privacy.
>
> Claim 6 recites that the remote computer is a wireless handheld device. D1 discloses this feature in para. 197.

Claim 8 recites that the patient information data comprises at least one of a patient identification, a room assignment, a bed assignment, and an admission status. D1 discloses this feature in paras 31, 32, 89, 243, and 257 to 259.

Claim 9 recites that the operational parameters comprise settings manually programmed into the medical device. D1 discloses this feature in para. 44.

Claim 10 recites that the operational parameters are downloaded into the medical device from the first computer or a second computer. D1 discloses this feature in para. 21.

Claim 11 recites that the medical device is a pump controller. D1 discloses this feature in para. 21 and Fig. 26.

Claim 12 recites that the pump controller controls an in-line MEMS device. Since using MEMS technology in medication delivery systems is considered to be a well-known practice, and the specification of the instant application does not disclose the structure of the claimed MEMS device or how it is implemented, we are of the preliminary view that this feature would have been a straightforward implementation option for the PSA.

Claim 13 recites that data relating to operational parameters of the medical device comprises programmed settings in the medical device. D1 discloses this feature in para. 32.

Claim 14 to 16 recite that the data relating to the operational parameters of the medical device comprises at least a programmed infusion rate, dose, or volume, wherein the data relating to the medication order comprises at least a prescribed infusion rate, dose, or volume, and wherein the processor compares the programmed infusion rate, dose, or volume, to the prescribed infusion rate, dose, or volume, respectively. D1 discloses these features at Fig. 18, paras 112 and 259.

Claim 17 recites that the first computer further links a patient identifier and a medication order identifier. D1 discloses this feature at Fig. 6.

Claim 18 recites that the remote computer displays (i) an option to accept the mismatch and (ii) an option to reprogram the medical device and conduct another comparison if the comparison result signal indicates a mismatch between the medical device's operational parameters and the medication order. D1 discloses this feature at paras 260 to 262.

Claim 19 recites that the processor is configured to check whether the data relating to the medical device's operational parameters has been programmed into the medical device within a predetermined time, and if the data relating to the medical device's operational parameters has not been programmed into the medical device within the predetermined time, to request programming of new data relating to the medical device's operational parameters before conducting the comparison. D1 discloses checking whether the data relating to the medical device's operational parameters has been programmed into the medical device within a predetermined time (see para. 39, wherein an electronic badge or PDA "transfers collected information to the IV pump to set its operation. The badge also determine(s) the collection of information and the transfer of it to the pump all occurs within a time limit"). Although D1 does not explicitly disclose requesting programming of new data relating to the medical device's operational parameters before conducting the comparison if the predetermined time expires, it is our preliminary view that this feature is a straightforward follow-up step, which would have been obvious to the skilled person.

> Claim 20 recites that the processor determines the missing data associated with the operational parameter by determining that the missing data includes data that is expected to be within a prescription comparison XML document. Utilizing XML documents for storing and transmitting text-based data is considered to be part of the CGK of the skilled person. Therefore, we preliminarily consider that this feature would have been obvious to the skilled person.

[42] The Applicant did not dispute the analysis above.

Conclusion on Obviousness

[43] We consider that the subject-matter of claims 1 to 20 on file would have been obvious to the skilled person. Therefore, the claims on file do not comply with section 28.3 of the *Patent Act*.

Proposed Claims

[44] In the PR letter (pages 12 to 13), the Panel explained why we did not consider the proposed claims to be "necessary" amendments under subsection 86(11) of the *Patent Rules*:

> The proposed claims were submitted in the RFA to further define the claimed subject-matter, with the following additional features in claim 1:
>
> • identifying which data associated with the operational parameter is missing,
>
> • requesting the identified missing data associated with the operational parameter by causing a display, within a comparison interface screen, of an identification of the missing data associated with the operational parameter including a request for a clinician to provide the determined missing data.
>
> As explained earlier, we are of the preliminary view that the feature of identifying which data associated with the operational parameters is missing does not involve inventive ingenuity.
>
> The additional feature of displaying the comparison and request of manually entering the determined missing data simply adds further display elements to the claims on file. In our preliminary view, adding the display elements would have been obvious. D4 discloses that a health practitioner is prompted, from an inferred display interface, for "any necessary data that is missing from the read label but required by the pumping system" (col. 2, lines 30 to 40). Therefore, it is our preliminary view that the display elements would not add any unexpected benefits or advantages to the claimed subject-matter, and would have been obvious to the skilled person.
>
> In summary, the proposed claims cannot be considered to be "necessary" amendments under subsection 86(11) of the *Patent Rules* because they do not comply with paragraph 28.3(b) of the *Patent Act*.

[45] The Applicant did not dispute this analysis.

CONCLUSIONS

[46] We are of the view that:

- claims 1 to 20 on file would have been obvious and thus do not comply with section 28.3 of the *Patent Act*;
- the proposed claims 1 to 20 are not "necessary" amendments under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[47] In view of the above, the Panel recommends that the application be refused on the ground that all claims on file would have been obvious and therefore do not comply with section 28.3 of the *Patent Act*.

[48] Further, the proposed claims 1 to 20 do not overcome the obviousness defect and therefore the introduction of these claims does not constitute "necessary" amendments pursuant to subsection 86(11) of the *Patent Rules*.

Liang Ji	Stephen MacNeil	Howard Sandler
Member	Member	Member

DECISION OF THE COMMISSIONER

[49] I concur with the findings of the Board and its recommendation that the application should be refused because the claims on file would have been obvious and do not comply with section 28.3 of the *Patent Act*.

[50] Therefore, in accordance with section 40 of the *Patent Act*, 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 15th day of June, 2020