PATENTS ACT 1977

APPLICANT	Samsung Electronics Co., Ltd
ISSUE	Whether patent application GB1820346.3 complies with Section 1(2) of the Patents Act 1977
HEARING OFFICER	J Pullen

DECISION

Introduction

1   Patent application GB1820346.3 entitled 'Determining a cause of a trend in vital sign data of a subject' was filed on 13 December 2018 claiming priority from an earlier application filed on 16 March 2018. It was published on 18 September 2019 as GB2572034A.

2   The combined search and abbreviated examination report, dated 10 June 2019, reported under Section 17(5)(b) that a search would serve no useful purpose and the examiner, Kalim Yasseen, set out his reasoning that the claimed invention was excluded from patentability as a computer program. Subsequent rounds reiterated the points made in the examination opinion together with objections to the claims lacking novelty and inventive step based on documents identified on an EP equivalent application, added matter following amendment, and that the claimed invention was also excluded from patentability as a business method and a method of diagnosis. An offer of a hearing was made in the examiner's letter of 2 March 2022 highlighting that if the agent responded but did not request a hearing then the application may, nonetheless, be passed for a decision on the papers on file. The agent responded on 4 July 2022 with amendments and arguments, but the examiner remained unconvinced, and the case was passed to me for a decision on the papers. The examiner also wrote to the applicant to inform them of this in a letter dated 18 August 2022.

3   After an initial review of the file I asked the examiner to consider some points, including some of those they had deferred, and write to the applicant to give them an opportunity to provide submissions which he did in an exam report dated 4 November 2022. He raised an objection to a lack of inventive step and gave further consideration to the exclusion from patentability as a business method. He also indicated that the objections to added matter and as a method of diagnosis were no longer being pursued.

4   The first matter before me is whether the claimed invention is excluded as a program for a computer and/or a method for doing business as such. The examiner's report dated 4 November 2022 does raise a lack of inventive step objection, but this is not set up on a comprehensive way. Also the agent has not provided any submissions on this matter. Consequently, if I find the claims provide a technical contribution, I will remit the case back to the examiner to expand the inventive step objection and to complete the search and examination.

5   I confirm that in reaching my decision I have considered all documents on file, particularly the amended claims and arguments filed in the agent's letter of 4 July 2022.

The invention

6   The invention relates to computer-implemented methods, apparatus, and programs for determining a cause of a trend in vital sign data of a subject over a time period which encompasses a scheduled medication time, in particular, determining whether a user has performed a certain action such as taking specified medication. It is said that known systems for automatically determining whether a user has removed a pill from a compartment of automated pill dispenser are not a reliable way to verify that the user has consumed the medication.

7   The method obtains vital sign data such as pulse rate, body temperature, respiration rate, blood pressure or bioelectrical impedance of a subject. The vital sign data may be obtained from a wearable electronic device comprising one or more vital sign sensors. The vital sign data is analysed to determine a trend over time such as by applying a moving average filter to track a mean value of the vital sign data to determine if the mean value is increasing or decreasing or remaining stable over time. The analysis may be performed continuously or intermittently but no exemplary time periods or intervals are disclosed.

8   Next the method determines a most likely cause of the trend in the vital sign data over time in dependence on one or more stored weights each associated with one or more possible causes. A machine learning algorithm is used to assign weights to one or more possible causes of a certain trend in the vital sign data, based on the obtained vital sign data and associated metadata. No examples of suitable machine learning methods are given. Examples of possible causes include a medication event, light walk, watching movie, talking on phone, running, missed medication, consumed alcohol, or not enough glasses of water.

9   In response to a determination that the most likely cause of the trend is the missed medication event, an alert can be outputted. This alert may act as a reminder to the user to take their medication or be to a medical professional such as via SMS or email. The likely cause is outputted to a user interface whereby a user can input whether the most likely cause is the actual cause of the trend in the vital sign data and that input used to update the weights. For example, if the user input confirms that the most likely cause is not the actual cause then the weight associated that cause will be decreased; whereas, if the user input confirms that the most likely causes is the actual cause then the weight associated that cause will be increased.

10   The stored vital sign data may subsequently be retrieved and analysed to monitor an effect of the medication on the subject. This allows a user and/or medical professional to confirm that the medication has had the desired effect or modify the dosage regimen or medication if the vital signs data reveals that the medication has not had the intended effect. There are no examples of specific trends associated with causes as they apply to specific medications or medical conditions.

11   The current claim set, as amended 4 July 2022, comprises four independent claims: claims 1 and 15 to computer-implemented methods and claims 19 and 21 to apparatus. These form two pairs of claims which will respectively, stand or fall together; claims 1 and 19, and claims 15 and 21. Claim 1 reads:

> *A computer-implemented method of determining a cause of a trend in vital sign data of a subject, the method comprising:*
> *obtaining vital sign data of a subject;*
> *determining a trend in the vital sign data over time; and*
> *determining a most likely cause of the trend in the vital sign data in dependence on one or more stored weights each associated with one or more possible causes, wherein each stored weight is indicative of a likelihood of the associated cause being responsible for the trend in the vital sign data,*
> *wherein the one or more possible causes includes a medication event in which the subject has taken a specified medication, a time period over which the trend in the vital sign data is determined encompasses a scheduled medication time at which the subject is due to take the specified medication, and the one or more possible causes includes a missed medication event in which the subject has not taken the specified medication, the method further comprising:*
> *outputting an alert in response to a determination that the most likely cause of the trend in the vital sign data is the missed medication event,*
> *wherein the method further comprises:*
> *in response to a determination that the most likely cause of the trend in the vital sign data is the medication event, storing information relating to the vital sign data of the subject after the medication event for monitoring an effect of the medication on the subject,*
> *the method further comprising:*
> *outputting the determined most likely cause through a user interface,*
> *receiving first user input related to whether the outputted most likely cause is the actual cause of the trend in the vital sign data; and*
> *updating the stored weights in dependence on the first user input.*

12   Claim 15 reads:

> *A computer-implemented method comprising:*
> *obtaining vital sign data and associated metadata for each one of a plurality of individuals, wherein the metadata identifies a cause of a trend in the associated vital sign data of said one of the plurality of individuals;*
> *using a machine learning algorithm, assigning weights to one or more causes of a certain trend in the vital sign data based on the obtained vital sign data and associated metadata, wherein the assigned weights are indicative of a likelihood of each of said one or more causes being responsible for said trend in the vital sign data; and*
> *storing the assigned weights in association with information identifying the one or more causes,*

> *wherein the one or more possible causes includes a medication event in which the subject has taken a specified medication, and a missed medication event in which the subject has not taken the specified medication, and*
>
> > *wherein obtaining the vital sign data comprises obtaining information relating to the vital sign data of the subject after the medication event for monitoring an effect of the medication on the subject,*
> >
> > > *the method further comprising:*
> > >
> > > > *receiving first user input related to whether the determined most likely cause is the actual cause of the trend in the vital sign data; and*
> > > >
> > > > > *updating the stored weights in dependence on the first user input.*

The Law

13   The examiner has objected that the invention is excluded from being patented as a program for a computer and a method for doing business. The relevant section of the Act is s.1(2), the most relevant provisions of which are shown below with my emphasis added:

> *1(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of-*
> *(a) ...;*
> *(b) ...;*
> *(c) **a... method for... doing business, or a program for a computer**;*
> *(d) ...;*
> *but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.*

14   The Court of Appeal has said that the issue of whether an invention relates to subject matter excluded by Section 1(2) must be decided by answering the question of whether the invention reveals a technical contribution to the state of the art. The Court of Appeal in *Aerotel/Macrossan*[1] set out the following four-step approach to help decide the issue:

> *(1) Properly construe the claim;*
> *(2) Identify the actual contribution;*
> *(3) Ask whether it falls solely within the excluded subject matter;*
> *(4) Check whether the actual or alleged contribution is actually technical in nature.*

15   The operation of the approach is explained at paragraphs 40-48 of the judgment. Paragraph 43 confirms that identification of the contribution is an exercise in judgment involving the problem said to be solved, how the invention works and what its advantages are; essentially, what it is the inventor has really added to human knowledge, looking at substance, not form. Paragraph 47 adds that a contribution which consists solely of excluded matter will not count as a technical contribution.

16   In *Symbian*[2] the Court of Appeal reaffirmed the *Aerotel* approach while considering a question of "technical contribution" as it related to computer programs emphasising

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[1] Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2007] RPC 7
[2] Symbian Ltd's Application [2009] RPC 1

the need to look at the practical reality of what the program achieved, and to ask whether there was something more than just a "better program".

17 The case law on computer implemented inventions was further elaborated in *AT&T/CVON*[3] which provided five helpful signposts to apply when considering whether a computer program makes a relevant technical contribution. In *HTC v Apple*[4], Lewison LJ reconsidered the fourth of these signposts and felt that it expressed too restrictively. The signposts are:

> *i. whether the claimed technical effect has a technical effect on a process which is carried on outside the computer;*
> *ii. whether the claimed technical effect operates at the level of the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the applications being run;*
> *iii. whether the claimed technical effect results in the computer being made to operate in a new way;*
> *iv. whether the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer;*
> *v. whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented.*

18 The examiner's reports also refer to *Protecting Kids The World Over (PKTWO)*[5] and the Hearing Officer's decision in BL O/057/19[6].

Assessment

(1) Properly construe the claim

19 The examiner says that there are no apparent difficulties in construing the claims and that, whilst there are differences between the two sets of independent claims, they regard them, in substance, as representing the same invention. The agent's letters make no comments on this step.

20 I agree that there are clear similarities between claims 1 and 15 but also significant differences. For example, claim 1 comprises obtaining vital sign data of a subject whereas claim 15 comprises obtaining vital sign data (and associated metadata identifying causes of a trend in the associated vital sign data) of a plurality of individuals. Claim 1 includes determining a trend in the vital sign data over time, determining a most likely cause of the trend in the vital sign data using weights, outputting an alert in response to a determination that the most likely cause of the trend is the missed medication event and outputting the most likely cause through a user interface but these features are not included in claim 15. Claim 15 comprises using a machine learning algorithm to assign weights to one or more causes of a trend in the vital sign data but this feature is not included in claim 1.

21 Both claims involve weights which are indicative of a likelihood of each of said one or more causes being responsible for a trend in the vital sign data and that those

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[3] AT&T Knowledge Ventures/Cvon Innovations v Comptroller General of Patents [2009] EWHC 343 (Pat)
[4] HTC v Apple [2013] EWCA Civ 451
[5] Protecting Kids The World Over (PKTWO, [2011] EWHC 2720 (Pat))
[6] Masimo Corporation's Application BL O/057/19

causes include a medication event and a missed medication event (although claim 15 makes no use of those weights). Both claims create data suitable for monitoring an effect of the medication. Lastly, both claims also comprise receiving first user input related to whether the determined most likely cause is the actual cause and updating the stored weights based on the first user input (although claim 15 lacks antecedent for "the determined most likely cause").

22   I will consider each of claims 1 and 15 separately. I agree that there are no major difficulties in construing the words of the claims.

(2) Identify the actual contribution

23   In their letter of 18 August 2022, the examiner discusses the problem said to be solved and other aspects of the contribution, with reference to the prior art cited in the examination report issued on 11 June 2021 (WO 2015/175207 & WO 2017/032873). They identify the contribution to be:

> *A computer-implemented method of determining a cause of a trend in vital sign data of a subject, the method comprising:*
>   *obtaining vital sign data of a subject;*
>   *determining a trend in the vital sign data over time; and*
>   *determining a most likely cause of the trend in the vital sign data in dependence on one or more stored weights each associated with one or more possible causes,*
>   *outputting an alert (relevant to claims 1 &19) in response to a determination that the most likely cause of the trend in the vital sign data is a missed medication event & further in response to a determination that the most likely cause of the trend in the vital sign data is the medication event, storing information relating to the vital sign data of the subject after the medication event for monitoring an effect of the medication on the subject,*
>   *receiving a user input related to whether the outputted most likely cause is the actual cause of the trend in the vital sign data; and updating the stored weights in dependence on the user input.*

24   The agent's letters make no comment on the contribution.

25   The examination report of 4 November 2022 refers to US 2011/0224912, WO2017/151164 and US 2017/0169191 as further prior art relevant to establishing what the invention adds to human knowledge.

26   I have reviewed the five documents referenced by the examiner. All the documents show obtaining vital sign data from a subject or a plurality of individuals, determining a trend (or pattern) in the vital sign data over time and whether that trend is indicative of a particular cause. Several also refer to consideration of patient compliance with a medication schedule as a possible cause of the trend to monitor the efficacy of the medication and issue alerts if the trend suggests non-compliance (missed medication event). Several also refer to machine learning and/or computational models as part of the analysis being performed. WO 2017/151164 refers to receiving user input about which medications they believe they have taken and using those responses to alter the weight applied to possible causes in analysis.

27   Having considered the contribution put forward by the examiner and as the applicant has not responded to the examination report of 4 November 2022, I see no reason to defer from the contribution of claim 1 provided by the examiner.

28   Determining the contribution of claim 15 is more troublesome. Whilst all the words used make literal sense, the weights (that are assigned using a machine learning algorithm based on vital sign data and then updated based on user input) are not used in the method of claim 15. The prior art shows that obtaining vital sign data and associated causes, including patient (non-) compliance for monitoring an effect of the medication, is well known. The agent's arguments about whether the contribution provides a technical effect are all directed to features found in claim 1 but missing from claim 15. As currently drafted claim 15 does not provide a contribution and I will not consider it further.

(3) Ask whether it falls solely within the excluded subject matter and (4) Check whether the actual or alleged contribution is actually technical in nature

29   I will consider steps (3) and (4) together.

30   The examiner states that the contribution is realised as a computer program. They then go on to determine that the contribution does not solve a technical problem within the computer or have a technical effect on a technical process outside the computer with reference to the signposts discussed in *AT&T/CVON* and *HTC v Apple*. I will also take this approach.

i. whether the claimed technical effect has a technical effect on a process which is carried on outside the computer

31   In their report of 10 June 2019, the examiner asserts that there is no process external to the computer, hence no technical effect outside the computer, and that they do not regard determining the case of a trend in a vital sign as representing an external 'technical effect' outside the computer.

32   The agent's letter of 27 July 2020 proposes that the amended claims involve a technical effect in view of this signpost because of the feature of outputting an alert in response to the most likely cause of the trend in the vital sign data being a missed medication event. They go on to say this provides a reminder to the user to take their medication and provides a technical effect on a process carried on outside of the computer by ensuring the user adheres to the prescribed medication regime which may in turn improve the effectiveness of the medical treatment.

33   The examiner disagrees in their report of 11 June 2021, stating whilst performing the task of determining a probable cause of a trend in a user's vital sign data, and creating alerts may be better, this is not a technical contribution outside, or independent of, the computer. They say the alert and/or cause generated represent useful information but are not concerned with the workings of a technical process.

34   In subsequent letters the agent maintains their position and elaborate that the alert that the user has not taken their medication may be sent to a medical professional. They go on to add that storing information relating to the subject's vital sign data after a medication event has been detected, provides the further advantage that the

system can better distinguish between 'medication' and 'missed medication events' giving more information about how the subject's vital signs are affected by taking the medication.

35 Again, the examiner disagrees saying that the contribution is not characterised by an improved technical characteristic of the data, but by an improvement in the processing of data that considers the nature of the data and the way it is analysed. They go on to propose that distinguishing between 'medication' and 'missed medication events' does not point to a technical effect even if it allows for monitoring the effect of medication on the subject. They refer to the Hearing Officer's decision in BL O/057/19, which concerned a wellness analyser that took account of real-time sensor data and patient medical information but was found to be excluded, as supporting their position.

36 The agent again disagrees with examiner's argument that "*ensuring that the user adheres to their prescribed medication regimen… does not represent a technical effect*", since they say that one can envisage hardware-based mechanisms for ensuring that a user adheres to their prescribed medication regimen, and they propose that these would not be excluded. They go on to discuss an example of a hypothetical improved automated pill dispenser with a more reliable mechanism for detecting when the lid of the dispenser has been opened. Turning to the present invention they acknowledge that the improvement is made in software but propose that the result is analogous to the hypothetical improved automated pill dispenser hardware and therefore provides a technical effect.

37 The examiner does not accept this as a valid analogy. They reiterate that the hardware used to carry out the processing of data is conventional and that the data processing does not produce a relevant 'technical effect' and the task that the program performs does not give rise to a relevant 'technical effect'.

38 In their report of 4 November 2022, the examiner differentiates the alert issued in this case from the one found to have a technical effect in *PKTWO*. They say that the invention in *PKTWO* concerned a system for monitoring the content of electronic communications with the alert prompting a user to terminate communication or shutting down the associated equipment. In contrast the examiner believes that once the alert is sent in this case there are no equivalent technical changes to any process or hardware. They highlight that in paragraph 34 of *PKTWO* Floyd J states that in many cases, generation and transmission of a notification is not technical, and conclude that that is the case here.

39 I agree with the agent that one can envisage hardware-based mechanisms for ensuring that a user adheres to their prescribed medication regimen, and that these would not be excluded. Indeed, some software-based mechanisms for ensuring that a user adheres to their prescribed medication regimen may also not be excluded especially when this improves the effectiveness of a medical treatment. However, the alert in this case falls short of providing a mechanism for ensuring that a user adheres to their prescribed medication regimen and does not necessarily improve the effectiveness of a medical treatment.

40 For example, there are no elements of the contribution that ensure that the alert (whether to the medical professional or user) acts as a *timely* reminder that would

enable the user to adhere to their prescribed medication regimen. The application does not disclose time periods, specific conditions and/or medications when the method would identify missed medication events quickly enough. The contribution covers alerts issued days, weeks or longer after a missed medication event; whilst this may be useful it does not improve the effectiveness of a medical treatment and is not technical. I agree with the examiner's conclusion about *PKTWO*; the alert found to be technical in *PKTWO* is substantially different to the alert in this case.

41   The contribution does not provide a technical effect on a process which is carried on outside the computer.

> **ii. whether the claimed technical effect operates at the level of the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the applications being run**

42   The examiner says that the contribution operates on particular data (patient physiological data, weights associated with causes) for a particular purpose and thus does not provide an effect at the level of the architecture of the computer. None of the agent's letters comment on this signpost and I agree that the claimed technical effect does not operate at the level of the architecture of the computer.

> **iii. whether the claimed technical effect results in the computer being made to operate in a new way**

43   The examiner concludes that there is nothing to suggest that the computer is operating in a new way except in so far as any computer running a new program operates in a new way. Again, none of the agent's letters comment on this signpost and I agree, this signpost does not assist the applicant.

> **iv. whether the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer**

44   The examiner proposes that the computer is not operating more efficiently or effectively as a computer. In their letter of 11 October 2021, the agent proposes that the invention provides a more reliable method, by ensuring that a missed medication event can be more reliably distinguished from a medication event and can therefore be considered to fall under the fourth signpost. I do not agree, the reliability of the computer is not improved, any improvement in reliability lies in the method being performed and the fourth signpost is not met.

> **v. whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented**

45   The examiner asserts that the problem concerns determining a cause of a trend in vital sign data of a subject and that the solution provided is a matter of program design and not technical in their report of 10 June 2019. They subsequently refer to the Hearing Officer's decision in BL O/057/19 as supporting this position. None of the agent's letters comment on this signpost and I agree, this signpost does not assist the applicant.

46   Having fully considered the applicant's arguments I am not persuaded. I find the application is excluded from being patented under Section 1(2) as a program for a computer as such.

Business method

47   The examiner argues that the contribution represents a type of activity carried out by a medical professional or the like and is therefore also excluded as a method for doing business again refer to the Hearing Officer's decision in BL O/057/19 as supporting this position. They believe that there is no relevant technical effect in automating such a process and that the process is an administrative activity.

48   None of the agent's letters specifically address this point (beyond that which can be implied by their assertions that the contribution provides a technical effect).

49   I am not convinced that the contribution can be characterised as a method of doing business method as such. Whilst the contribution generally relates to the business of caring for patients, I believe there is more to it. However, in view of my conclusion above that the application is excluded as a program for a computer and the lack of argument in the agent's letters I do not need to consider this in more detail.

Conclusion

50   I find the application to be excluded from being patented under Section 1(2) as a program for a computer as such. I therefore refuse the application under Section 18(3).

Appeal

51   Any appeal must be lodged within 28 days after the date of this decision.

J Pullen
Deputy Director, acting for the Comptroller