Intellectual Property Office

BL O/057/9

28 January 2019

PATENTS ACT 1977

APPLICANT	Masimo Corporation
ISSUE	Whether patent application GB1212698.3 complies with section 1(2)(c), section 1(1)(b) and section 3.
HEARING OFFICER	Ben Buchanan

DECISION

Introduction

1 This decision considers the issues of whether the invention claimed in patent application GB1212698.3 satisfies the requirement for patentability as defined by section 1(2) of The Patents Act 1977 ("The Act") and whether it satisfies the requirement for inventive step as defined by section 1(1)(b) and section 3 of The Act, specifically whether the claimed invention defines a collocation of separate integers.

2 Patent application GB1212698.3 was filed on 19th January 2011 in the name of Masimo Corporation and entitled "Wellness analysis system". This application claimed priority from US patent application number 61296467, dated 19th January 2010. The application was published as GB2490817 on 14th November 2012. The claims under consideration in this decision are the amended claims filed on 28th March 2018, although I will also consider the three auxiliary claim sets filed on 27th July 2018.

3 The application has been through numerous rounds of substantive examination and amendment where the Applicants (via their attorney D Young and Co) have been unable to persuade the Examiner that the invention relates to patentable subject matter and involves an inventive step over the prior art. A hearing was offered and accepted, a pre-hearing report issued on 17th August 2018 and skeleton arguments were filed on 16th November 2018.

4 The Examiner's pre-hearing report sets out the matters at issue. He reasons that the claimed invention is not patentable because it is a program for a computer and/or a method for doing business as such. He also explains that he considers the claimed invention to lack an inventive step, because the first and second modes of operation are obvious, and they are a collocation of uninventive integers which lack synergy between them. The skeleton arguments confirm the approach to be taken in support of the applicant's case but do not provide much detail. They do, however, refer to amended claims filed as auxiliary requests which I will consider in this decision.

5 In summary the issues to be decided are:

- Whether application GB1212698.3 is excluded from patentability as a program for a computer and/or a method for doing business as defined in section 1(2);
- Whether application GB1212698.3 provides an inventive step as required by section 3;
- If appropriate, whether the auxiliary claims change the assessment above.

6 The issues came before me at a hearing at the Intellectual Property Office on 27th November 2018. The applicant was represented by Dr Nicholas Malden of D Young & Co LLP and the examiner Thomas Davies and hearing assistant Emma Porter also attended.

7 The original compliance date was the 28th July 2018 and was extended as of right to 28th September 2018. Two additional discretionary extensions were discussed favourably at the hearing, and requested the day after, taking the compliance date to 28th January 2019.

8 I confirm in my decision that I have considered all the correspondence on file.

The invention

Definitions

9 As things stand, in my opinion, some of the terminology of the claims is not clearly defined and it is necessary to turn to the description and drawings to understand the scope of the invention. For the purposes of this decision, based upon the specification and discussions during the hearing, I have applied the following meaning to the following terms:

- *Real-time* physiological data: data output from sensors associated with a patient

- *Non-real-time* information: information relevant to the patient from a database; information may be patient-specific e.g. lab test results, a prescription or genealogical information; or non-patient-specific such as relevant medical research

- *Parameter*: the physiological condition(s) determined from sensor data e.g. pulse rate and/or blood oxygen saturation measured by an optical sensor (paragraphs [0008], [0023], [0027] & [0032])

- *Feature*: an indication in a parameter of the state of physiology e.g. a change in pulse rate over time, or passing a threshold (paragraphs [0024] & [0034])

- *Wellness output*: a potential or actual diagnosis e.g. apnoea or heart failure (paragraphs [0025] & [0026])
- *Virtual patient*: a characterisation of a patient based on stored physiological parameters (paragraph [0036])
- *Simulated parameter*: a parameter which is synthesised and incorporated within a virtual patient simulation to generate a predictive wellness output (paragraphs [0037] & [0043])

Inventive concept

10 The present invention relates to “a wellness analysis system” for a patient which system has two modes of operation; a diagnostic mode and a simulation mode. In the diagnostic mode, real-time physiological data from sensors associated with a patient is processed to generate real-time “features”. Non-real time information (e.g. from hospital records such as patient history, labwork/tests and pharma/therapy shown in Fig.1 below) is processed to generate supplemental information. From these real time and non-real time inputs “a wellness output” is generated.

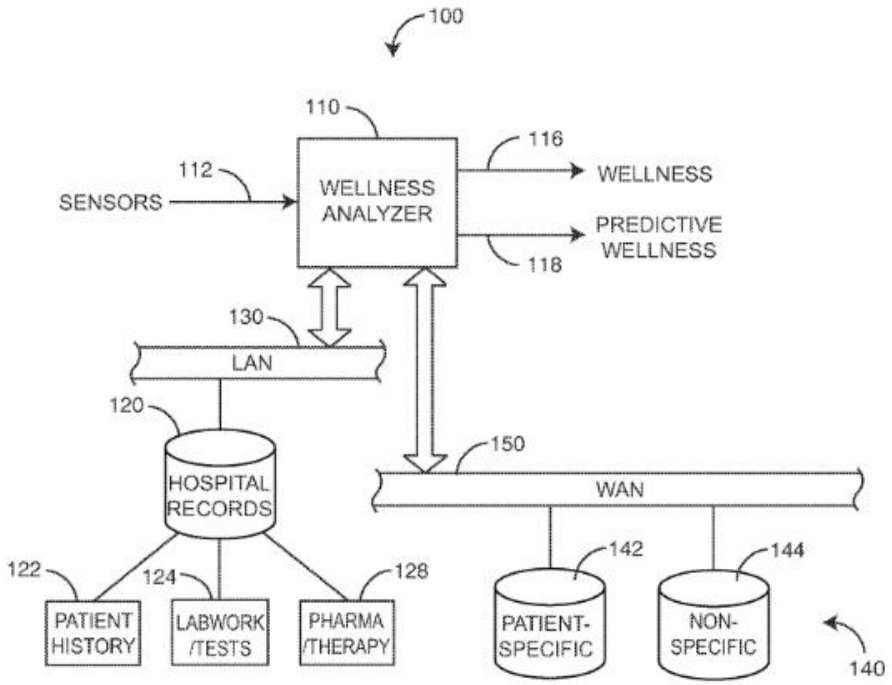

FIG. 1

11 In the simulation mode, a parameter output is synthesised and the parameter output is processed so as to generate “a predictive wellness output” for the scenario that the simulated parameter represents. The data processing uses the simulated parameter output and a historical response of the patient to the simulated parameter output to create the predictive wellness output. The historical response of the patient

may be created from data recorded from the sensors associated with the patient (see e.g. sec [0043]), but this is not an essential feature of current claim 1.

12 The sensors which provide real time patient data are disclosed as being responsive to one or more of a patenting's circulatory, respiratory, neurological, gastrointestinal, urinary, immune, musculoskeletal, endocrine and reproductive systems. The sensors themselves are not described as being new or inventive. The non-real time patient data is disclosed as being medical history, hospital records, medications, therapies, laboratory work, family history, genealogy, environmental or test results. These two sources of data may be complemented by non-patient specified data, such as scientific, medical or environmental research.

The claims

13 The sole independent claim of the current claims on file is claim 1, repeated below:

A wellness analyzer comprising:

a plurality of sensors that generate real-time physiological data from a plurality of sites on a patient;

a plurality of databases that provide non-real-time information relevant to a medical-related assessment of a patient;

a wellness monitor that generates a wellness output in a diagnostic mode and a predictive wellness output in a simulation mode, the wellness monitor including one or more processors,

wherein when the wellness monitor is in the diagnostic mode, the one or more processors are configured to:

receive the sensor data and the non-real time information,

process the non-real time information so as to generate supplemental information,

process the sensor data and the supplemental information so as to generate the wellness output,

wherein the wellness output is based at least in part upon one or more derived features of the sensor data and at least in part upon the supplemental information, the one or more derived features including at least one of a slope, a trend, a variability, a pattern or a waveform morphology of the sensor data; and

wherein when the wellness monitor is in the simulation mode, the one or more processors are configured to:

synthesize at last one simulated parameter output for the patient,

process the at least one simulated parameter so as to generate the predictive wellness output based at least in part upon the at least one simulated parameter output and a historical response of the patient to the at least one simulated parameter output.

The law

Section 1 Patentable inventions

(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—

(a) the invention is new;

(b) it involves an inventive step;

(c) it is capable of industrial application;

(d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;

and references in this Act to a patentable invention shall be construed accordingly.

(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) a discovery, scientific theory or mathematical method;

(b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;

(c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;

(d) the presentation of information;

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.

Section 3 Inventive step

An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

The law on excluded subject matter

14 In order to decide whether an invention relates to subject matter excluded by section 1(2), the Court of Appeal has said that the issue must be decided by answering the question of whether the invention provides 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 (or alleged) 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 essentially a matter of determining what it is the inventor has really added to human knowledge, and involves 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 The case law on computer implemented inventions has been further elaborated in *AT&T/CVON*[2] which provided five helpful signposts to apply when considering whether a computer program makes a relevant technical contribution. In *HTC v Apple*[3], Lewison LJ reconsidered the fourth of these signposts and felt that it had been expressed too restrictively. The reformulated 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; and
v) whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented.

17 Dr Malden agreed that it is correct to use the established *Aerotel* test, and that the *AT&T* signposts should also be considered.

[1] Aerotel Ltd v Telco Holdings Ltd (and others) and Macrossan's Application [2006] EWCA Civ 1371
[2] AT&T Knowledge Ventures LP and CVON Innovations Limited v Comptroller General of Patents [2009] EWHC 343
[3] HTC v Apple [2013] EWCA Civ 451

The law on inventive step

18 The courts have long used the so called *Windsurfing* test to assess issues of inventive step. This test was reformulated by the Court of Appeal in *Pozzoli*[4]. Paragraph 23 of this judgment lays out the test as:

(1) (a) Identify the notional "person skilled in the art"
(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?

19 In *SABAF*[5], Lord Hoffmann held that before you can ask whether the invention involves an inventive step, you first have to decide what the invention is. In particular, the first step is to decide whether you are dealing with one invention or, for the purposes of section 3, two or more inventions. If two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect and one applies section 3 to the idea of combining them. But if each integer performs its own proper function independently of any of the others, and the claim is a mere aggregation or juxtaposition of features, then each is, for the purposes of section 3, a separate invention. The combination of a series of known or obvious features, each playing its usual part in the final entity, will be a matter of design or mere collocation, not of invention, and objection should be raised under section 3.

20 In this decision, Lord Hoffmann quoted with approval passages from the EPO Guidelines for Substantive Examination, providing guidance on how to determine whether two features display synergy. This guidance was re-stated and further explained in the EPO Technical Board of Appeal decision in T 1054/05:

"*Two features interact synergistically if their functions are interrelated and lead to an additional effect that goes beyond the sum of the effects of each feature taken in isolation. It is not enough that the features solve the same technical problem or that their effects are of the same kind and add up to an increased but otherwise unchanged effect.*"

[4] Pozzoli Spa v BDMO SA & Anor [2007] EWCA Civ 588
[5] SABAF SpA v MFI Furniture Centres Ltd [2005] RPC 10, House of Lords

Arguments and Analysis

21 The Examiner's objections had been laid out in the pre-hearing report and were not reiterated at the hearing. In his skeleton arguments Dr Malden had confirmed that he would follow the *Aerotel* approach to determining whether a claimed invention is excluded from patentability, and in respect of the assertion that the claimed invention was a program for a computer, follow the *AT&T* signposts. He would cover the 'business method' exclusion separately. I invited Dr Malden to construe claim 1 and queried that construction. I also invited him to clarify his identified contribution and contrast it with that identified by the Examiner. My reasoning below takes account of the Examiner's objections laid out in the pre-hearing report and the arguments made by Dr Malden at the hearing.

Step 1: Properly construe the claim

22 The plurality of sensors, the real-time physiological data, the plurality of databases, the non-real time information relevant to a medical assessment of a patient, the diagnostic mode, the wellness output and the simulation mode in claim 1 are all clearly defined in the application as filed and so do not present any difficulties of claim construction. This was common ground. I have summarised the definition of some of these features in paragraph 9 above.

23 The term "synthesize at least one *simulated* parameter output for the patient" is not so clear, as the parameter is not explicitly derived from any of the data or information defined previously in the claim or linked to the diagnostic mode. It is also not clear from the claim how the simulated parameter is synthesised. When I questioned Dr Malden about this, he explained that the synthesised parameters are implicitly derived from the diagnostic phase and added that they are processed along with other, stored, parameter values and non-real-time information to obtain the predictive wellness output in the simulation mode, and noted that the synthesised parameter must be something that the patient could have had a historical response to.

24 In construing the claim, I have relied upon the definition of *simulated parameter* in paragraph 9 above. I am satisfied that in light of the description it is clear that in the diagnostic mode a sensor signal is processed to derive a parameter indicative of a physiological condition. In the specification, but not specified in the claim, it is clear that a parameter may be processed so as to identify a feature of the parameter which feeds into the determination of the wellness output, alongside other parameters. In claim 1 these steps are implicit. In light of Dr Malden's comments in the hearing, the simulation mode of the claim is to be construed so as to comprise a simulated parameter which probably, but not essentially, relates to physiological data of a type which may be generated by a sensor and to which the patient has had a historic response.

25 It is probably also worth saying that the description refers to parameter *inputs* as Dr Malden did at the hearing, and yet the claim refers to a simulated parameter *output.* Although at first confusing, this is easily explained. A parameter is an output from the logic block which creates it (see paragraph [0023]) and an input to the logic block which processes it (see paragraph [0024]). As best I can I have used 'input' and 'output' in this sense whilst giving a nod to the usage employed by the specification and Dr Malden.

26 Paragraph [0033] describes “parameter inputs 601 as well as, perhaps, sensor data inputs”; Paragraph [0037] then describes “During simulation, independent parameters 601 and, potentially, some sensor data are simulated and dependent parameters are “played-back”…”. This seems to me to be consistent with Dr Malden’s construction which I am content to accept. I have to say though, it is essential to read the description closely to afford the claim this breadth of scope.

27 The problem of construction is compounded by the fact that there is no mention of the sensor data or non-real-time information in defining the simulation mode. References in defining the diagnostic mode to “supplemental information” and “derived features” omit any reference to parameters, although as I have noted above they are implied. The first reference to a parameter in the claim is in defining the simulation mode to “synthesize at least one simulated parameter output”; but there is no explicit link to the implied parameters which are generated or derived for real during the diagnostic mode. There is no other reference to any real-time or non-real-time data common to the modes. The only explicitly common element is the patient.

28 It is not explicitly clear, for example, that the simulation mode can make use of stored physiological data obtained in the diagnostic mode. Nonetheless, the description in paragraphs [0036], [0037], [0043], [0044] and [0045] makes it clear that this is within the scope of the invention, and this interpretation is apparently agreed by the applicant as the second paragraph on page 4 of their letter dated 27th July 2018 confirms.

29 What links the first and second modes of operation then? Implicitly, the (simulated) parameter which is derived from data relating to a common patient. The parameter is real in the first mode and simulated in the second. Critically the wellness output is derived in part from a *historical response* of the patient to the simulated parameter output. That implies that the first and second modes essentially require both the real (in the first mode) and the simulated (in the second mode) parameter to be taken into account. The conclusion I have come to is that the historical response is created during the first mode of operation when the parameter is real and subsequently used in the second mode in conjunction with the simulated parameter. The first and second modes of operation are therefore implicitly linked by the parameter which is real in the first mode and simulated in the second mode. The simulation mode is reliant upon the diagnostic mode having been previously put into effect; hence *historical* response.

Step 2: Identify the contribution

30 Jacob LJ outlined the considerations to be applied when identifying the contribution made by the claims in paragraph 43 of *Aerotel*:

“The second step – identify the contribution - is said to be more problematical. How do you assess the contribution? Mr Birss submits the test is workable – it is an exercise in judgment probably involving the problem said to be solved, how the invention works, what its advantages are. What has the inventor really added to human knowledge perhaps best sums up the exercise. The formulation involves looking at substance not form – which is surely what the legislator intended.”

31 The Examiner assessed that the problem solved by the invention was the provision of two modes of operation in a single system: a diagnostic mode of operation, where real-time sensor data and supplemental information is processed so as to generate a wellness output; and a simulation mode, in which a simulated parameter output is combined with a historical response of the patient to provide a predictive wellness output.

32 Dr Malden framed the problem solved by the invention differently, starting from the point of the closest prior art. This constitutes a system which provides a wellness output for a patient based on sensor data and a database of *general population* data (as in the citation WO2009/081304 "PHILIPS"). The problem was that such a system could not provide a simulated wellness output based on *that individual patient's historical response* to a specific simulated parameter. Dr Malden argued that the invention allows a practitioner to simulate individual patient wellness in response to a specific "what if" scenario without running more tests or waiting for a patient response to unfold within the actual scenario.

33 He set out that the advantage of the invention was that the predictive wellness output is based on a simulation "tuned to the patient" as a consequence of historical responses of the individual patient to parameters being "re-run" with a specific simulated parameter as an input to the system.

34 In the pre-hearing report dated 17th August 2018, the examiner assessed the contribution as "A computer program to generate a wellness output in a diagnostic mode and to generate a predictive wellness output in a simulation mode" and focussed on the two modes being provided by a single program.

35 Dr Malden explained that the simulation mode uses "simulated parameter data" as an input to the system logic to generate the predictive wellness output based upon the historical response of the particular patient, in conjunction with other parameters and information. He made the argument that this is a different kind of simulation than any that have been done before; an improved simulation, enabling the medical practitioner to more accurately and appropriately treat the patient.

36 I think this is an important and influential argument. What Dr Malden is saying is that the problem, the solution and advantages provided by the invention address the challenge of predicting a patient-specific response to a particular scenario. This was not apparent from the formulation of the contribution by the Examiner. It is clear to me that that the contribution should include taking account of the historical response of the individual patient to a parameter when generating the predicted wellness output in response to the simulated parameter output, because this is a characteristic of the invention defined by the claims and appears to be an addition to the stock of human knowledge. That is not to say that the contribution is not also the provision of a dual mode wellness analyser as proposed by the Examiner, which also appears to be new and indeed is essential according to the claimed invention (as I have construed it) for the contribution to be put into effect.

37 After careful consideration, I consider the contribution to be:

"*a wellness analyser which uses both real-time sensor-derived physiological data from sensors associated with a patient and non-real time medical information*

relevant to a patient, from databases, to provide two modes of operation: (i) a diagnostic mode in which a wellness output is generated by processing real-time data and non-real time information; and (ii) a simulation mode in which a simulated parameter output is synthesised and a predictive wellness output is generated by processing the simulated parameter output and the patient's historic response to that parameter"

Steps 3 and 4: Does the contribution fall solely within excluded matter? Is it technical in nature?

38 The third and fourth steps of the *Aerotel* test involve asking whether the identified contribution falls solely within the excluded categories, and then checking whether it is technical in nature. Given that the consideration as to whether the contribution is technical in nature has a direct bearing on whether it falls solely within excluded subject matter, and the arguments that have been put before me in this case, it seems appropriate to consider these two steps together.

Program for a computer

39 It is common ground that the invention is a computer-implemented one and that the contribution takes the form of a computer program running on conventional hardware. In using the guidance from the *AT&T* signposts for assistance, the first question to be resolved is whether the contribution resides solely in a computer program or whether it has a technical nature which takes it outside of the exclusion of section 1(2)(c) of the Act.

40 Dr Malden stated that the invention is a technical simulation which has never been carried out before, which simulation enables a medical practitioner to make more appropriate, more timely and/or more accurate interventions for a specific patient.

41 Dr Malden referred to signpost one from *AT&T* "*i) whether the claimed technical effect has a technical effect on a process which is carried on outside the computer*" and argued that the effect outside the computer is the removal of a medical practitioner's physical action, or the delay which would otherwise be necessary.

42 I can see that the output of the wellness analyser in diagnostic mode or simulation mode could provide pertinent information to assist a medical practitioner treating the patient. Additionally, the "virtual patient" simulation information tailored to reflect the historical response of the specific patient to a parameter may well have been previously unavailable. Invaluable as this new information may be, it is not providing *a technical effect on a process* which is carried on outside the computer; instead it is providing useful and relevant information for use by a medical professional charged with making decisions and treating the patient.

43 Dr Malden stated that signposts two, three and four were not relevant to this application, but that signpost five was: "*(v) whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented*". The technical problem he had identified was "how to provide a simulated wellness output based upon a patient's historical response to variations of a specific parameter". The prior art, as in PHILIPS, used average population data from a large number of people. This average-based model was biased towards the specific patient by

entering a static variable for the patient, such as age, gender or Body Mass Index (BMI); but it did not use the specific patient's historical response. He argued that the technical problem identified was overcome by virtue of the ability to "tune the simulation to the specific patient" and to quickly model "a new scenario" based upon the inclusion of patient specific non-real time data.

44 In order to satisfy signpost five, the perceived problem must be technical in nature. Using the historical response of a patient to predict a future response to a varying parameter is a data gathering and processing activity. The volume of data and the speed of processing required would be sufficient to make it impossible for a medical practitioner to carry out the data analysis manually but collating and processing large volumes of data is what programmed computer processors are designed to do. The contribution is not characterised by an improved technical characteristic of the data, but by an improvement in the processing of the data by taking account of the nature of the data and the way it is combined. I am of the opinion that the problem solved is not technical and therefore that overcoming the problem does not indicate that the invention is technical.

45 Having considered the alleged contribution in light of the *AT&T* signposts, I am of the opinion that it falls solely within the excluded subject matter of a program for a computer. None of the signposts suggests that the contribution is more than a program for a computer *as such*.

46 Dr Malden stated that if instead of a patient there was a machine running an industrial process, the invention would be to simulate the running parameters based upon previous machine performance, which would save time and enable a controller to optimise the industrial process. The simulation and predicted wellness output of the present invention allows a medical practitioner to carry out patient specific simulation without needing to carry out unethical or impossible experiments. He argued the same technique applied to an industrial process would be technical in nature with benefits for efficiency and safety and by analogy the contribution was the same here.

47 While I can see the advantage of the medical practitioner having the simulation information to hand, the output of the simulation is processed information for the medical practitioner to take into account and potentially manually implement a response to. The last section of claim 1 cannot be seen to be automating the role of the medical practitioner as it is modelling the *expected* response if a parameter were different. The invention allows the medical professional to explore "what if" scenarios using specific patient data. The information output from the simulation is not used to control a technical process and effect a technical improvement, as it may or may not in the analogous industrial process, but instead it is used to inform a medical practitioner.

48 Finally, we briefly discussed the previous IPO decision BL O/283/18 referred to the in the Examiner's pre-hearing report as being similar to the current claims. In this decision it is stated that "the contribution does not encompass the processes of acquiring or inputting data, or of any processing of the data generated by the simulation or any actions taken as a result of the simulation. Therefore, the simulation is an abstract concept prescribing how to operate on numbers, because it has no interaction with anything tangible on which it may have a technical effect". Dr

Malden said that he found the quoted section to be a rather blunt statement "that simulations were not patentable" which required no further arguments or submissions to those already given. I suggested I could take account of written submissions provided after the hearing on this point, but Dr Malden declined.

49 While there are some similarities between the invention and that considered in BL O/283/18, specifically that in both applications the output of the simulation is not used in a technical process, I do not consider comparing them in more detail to be very helpful.

50 In conclusion I find that the current claims relate to a program for a computer as such.

A scheme, rule or method for doing business

51 The business method exclusion was not discussed at length in the hearing. The Examiner had most recently set out arguments concerning it in the pre-hearing report dated 17th August 2018: "The contribution [as the Examiner had identified it] relates entirely to processing data for the purpose of monitoring a patient and for generating a predictive output. In doing so this merely automates a medical professional's role of analysing data to formulate a diagnosis (paragraph 25). This relates solely to the business of medical informatics and thus falls entirely within this excluded area".

52 Dr Malden had provided previous arguments to this objection in his letter dated 28th March 2018, which made clear that the sensors that generate real-time physiological data from a plurality of sites on the patient *and* the sensor data therefrom, are included in the claimed invention. He said that while these sensors and sensor data are not in themselves new or inventive, the supply and complex analysis of the sensor data cannot be said to be a purely administrative or organisational task. Dr Malden went on to argue that even if the medical professional were able to analyse the sensor data and the non-real time information to form a diagnosis, the medical professional would still not be able to generate the sensor data on his or her own or to extract physiological signals from the sensor data. He also argued that the invention did more than just "automate a medical professional's analysis of historic data" – i.e. it went beyond analysing and processing "experience" to present examples of what has happened in the past. The invention enables a practitioner to simulate "what if?" scenarios and predict the wellness output accordingly. This provides additional information beyond expert experience with consequent benefits for medical intervention. He argued this went beyond a "method of doing business as such" even if medical diagnosis and intervention could be regarded as a field of "business".

53 I think here it is necessary to first consider whether the field of endeavour is one which might be regarded as "business" and secondly, if necessary, whether the contribution goes beyond that. I agree with Dr Malden that the invention does not merely automate or facilitate access to "expertise". In that sense, the field of endeavour is not – to my mind – purely administrative. What the invention does do, and where the contribution lies, is to process data and generate a probabilistic outcome. The invention synthesises a parameter and provides a simulation based on a "virtual patient" model which provides an output. I have concluded in respect of

signpost 5 above that in as much as this does not solve a technical problem, it is not a technical field of endeavour. But is the field of endeavour "business"?

54 To answer this question, it is helpful to be reminded of paragraph 43 of *Aerotel* and consider:

"*the problem said to be solved, how the invention works, what its advantages are. What has the inventor really added to human knowledge perhaps best sums up the exercise. The formulation involves looking at substance not form*"

In considering the substance, not the form of the claim, I am reminded that the invention does indeed comprise physical sensors and that they generate signals which are processed by the system as Dr Malden said; but they are not part of the contribution per se. The definition of conventional physical components as an essential integer of the invention does not alter the substance of the claim from being the processing of data to generate a probabilistic outcome. Earlier, Dr Malden formulated the problem as to provide a simulated wellness output based on an individual patient's historical response to a specific simulated parameter. He argued that the invention allows a practitioner to simulate individual patient wellness in response to a specific "what if" scenario without running more tests or waiting for a patient response to unfold within the actual scenario (paragraph 32 above).

55 So what is the field of endeavour? In *Landmark Graphics*[6] (at paragraph 27) the Hearing Officer concluded that one can step back from the actual advance over the state of the art and identify the field of endeavour when considering what the inventor has added to the stock of human knowledge. If that field of endeavour is a technical one, as in *Halliburton*[7], then the invention may be a patentable one under section 1(2). In paragraphs 43-44 above I have explained why I do not consider the problem to be a technical one. The field of endeavour might be characterised as *modelling a specific patient response to predict an outcome on the basis of a previous event*. Is this a field of business? I think it is. The medical profession is the business of caring for patients; if the outcome were to point towards an appropriate treatment or intervention, the business of caring for the patient (and the associated resources and costs) could be more accurately predicted for a "what if?" scenario. The invention is not directed towards the diagnosis or treatment itself and instead constitutes a tool to facilitate a practitioner to make decisions based on probabilistic outcomes from a patient model. I think therefore it does fall solely within the excluded field of a method for doing business. If I am wrong on this point, the invention is nonetheless excluded as a program for as computer as I have found above.

Inventive step

56 The examiner objected to a lack of inventive step of the claimed invention, most recently in the pre-hearing report dated 17th August 2018, stating that the invention as defined in claim 1 was a collocation of known integers which perform their proper function independently of each other and so may be treated as two separate

[6] Landmark Graphics Corporation BL O/112/18
[7] Halliburton Energy Services, Inc. v Smith International (North Sea) & Ors [2005] EWHC 1623 (Pat) (21 July 2005)

inventions: the integers were delineated by the examiner as the diagnostic mode and the simulation mode. The examiner stated that the two modes of operation each lacked an inventive step in relation to selected citations: WO2007/106455 “OPTICAL SENSORS” and US2004/0230105 “GEVA” both cited against the inventive step of the diagnostic mode and WO2009/081304 “PHILIPS” cited against the inventive step of the simulation mode. I note, however, that at no point during his reporting under section 1(1)(b) and section 3, nor in the pre-hearing report, has the Examiner confirmed that he has followed the four-step test *Windsurfing* for inventive step as set out by the Court of Appeal and updated in *Pozzoli*. As a consequence, he has not defined the common general knowledge, nor the “person skilled in the art” to whom he repeatedly refers.

57 Although the matter of inventive step was not covered at length in the hearing, I am obliged to afford it proper consideration and so I shall do so here. However, I shall try to do so simply and on the basis of agreed facts because although I have no reason to suspect Dr Malden would dispute the approach I am taking is the correct one, he has not had the opportunity to consider a reasoned argument by the Examiner following the four-step test, nor has he taken the opportunity to provide one himself.

58 Dr Malden stated that an advantage of the invention is that the individual patient data gathered and processed in the diagnostic mode can be used as the historical response of the patient in the simulation mode, but agrees that it is not an essential feature of the invention as currently claimed. Whilst I accept this point of view at face value, for the reasons I have discussed above with regard to construing the claim, I consider the “simulated parameter” to refer to a parameter previously processed in the diagnostic mode. I agree that the description leaves open the possibility that the synthesised parameter may be based on non-real-time data and that too is within the scope of the diagnostic mode.

59 Dr Malden went on to say that regardless of the presence or absence of explicit synergy between the diagnostic mode and the simulation mode, the simulation mode itself did not lack an inventive step with respect to PHILIPS. PHILIPS includes a patient model used to generate hypothetical clinical scenarios, and this patient model is generated from the average of a large patient population, (as previously discussed in relation to *AT&T* signpost five). Static parameters used in the model are adjusted to suit the specific patent under consideration, such as age, gender or Body Mass Index (BMI) and so the patient model disclosed did not use the specific patient’s historical response at all.

60 In a nutshell, then, the Examiner alleges that the claim comprises two separate integers, each of which lack an inventive step in light of the prior art and which in combination amount to a collocation. Dr Malden made the argument that the second integer, the diagnostic mode of operation, was not obvious in light of the prior art because it enables a scenario to be tested on a patient model taking account of a historical response to a relevant parameter. If I agree that the second mode is inventive, then whether or not I consider the two modes to have any synergistic interaction has no bearing on the inventiveness of the claim as a whole. Dr Malden made no argument as to the inventiveness of the diagnostic mode with respect to the OPTICAL SENSORS or GEVA citations.

61 Following the steps of the *Windsurfing/Pozzoli* test, I consider the person skilled in the art to be a technician familiar with physiological sensors and medical information i.e. both real-time and non-real-time sources in the language of the present invention. He would understand how to obtain data from sensors and information from databases but would not have the knowledge of a medical practitioner to understand what that data meant and how to decide on an appropriate intervention. The skilled person would be able to implement data processing to create parameters and features in the language of the present invention and to combine them to generate a probabilistic indicator of wellness. The person skilled in the art would have a common general knowledge of sensors and databases and would understand that different scenarios would be different for different patients.

62 The inventive concept is closely related to the actual contribution and is construed as:

a wellness analyser comprising sensors and databases which uses both real-time physiological data from the sensors, associated with a patient, and non-real time medical information from the databases, relevant to a patient; and a wellness monitor which provides two modes of operation: (i) a diagnostic mode in which real-time data and non-real time information is received and processed and a wellness output is generated from derived and supplemental components; and (ii) a simulation mode in which a simulated parameter output is synthesised and played back in conjunction with stored components relating to the patient and a predictive wellness output is generated by processing the simulated parameter output and the patient's historic response to that parameter

63 The references to "components", underlined, reflect the parameters and features referred to in the description which are generated in the diagnostic mode but not explicitly defined in the claim. When the independent simulated parameter is processed in the simulation mode, the components are "played back" as dependent parameters and the predictive wellness output is generated as a result.

64 The closest state of the art is PHILIPS, referred to by the Examiner and by Dr Malden at the hearing. Dr Malden argues that the system of PHILIPS relies upon a database of the general population to provide non-real-time information and that it can be "tuned to the patient" by specifying appropriate values for variables such as disease history, lifestyle, age, gender, BMI etc. PHILIPS does refer to outputting data and their behaviour over time, but I can find no reference to the system taking account of a *historical response* to a synthesised parameter *specific to the patient*. The differences between the present invention and the state of the art, then are:

- The provision two modes of operation within a wellness analyser: a diagnostic mode and a simulation mode;
- In the simulation mode, the patient model taking account of the historical response to a synthesised parameter;
- In the simulation mode, the historical response being specific to the patient

65 OPTICAL SENSORS and GEVA disclose only diagnostic modes and do not add to the state of the art except to show that systems using sensors and information from

a database may process data to generate information to inform a diagnosis decision. They do not alter the assessment of the difference between the inventive concept and the state of the art.

66 To the question of whether the differences outlined above would constitute steps which would have been obvious to the person skilled in the art, I conclude that they would not. When faced with the problem of "how to provide a simulated wellness output based upon a patient's historical response to variations of a specific parameter" I cannot see that the skilled person would be pointed towards a solution as claimed by the present invention. None of the three differences are disclosed or suggested by the cited prior art. The second and third – that account is taken of the historical response to a synthesised parameter and that the response is specific to the patient are essential to address the problem and require for their implementation, the first – the provision of two modes of operation to enable the historical response to be generated when the system is in diagnostic mode. In that respect, and for the record as I have intimated all the way through this decision, I consider that the two modes of operation are integers of the invention which do interact with synergy between them. They are separately operable, but based upon my construction of the claim, the simulation mode relies upon the diagnostic mode to take effect.

67 In summary I find that the claims as they stand do not lack inventive step under section 1(1)(b) and section 3.

The auxiliary claim sets

68 Three auxiliary claim sets were filed on the 27th July 2018, each having a single independent claim, and these were briefly discussed at the hearing. Dr Malden requested that they be considered in numerical order but that if any one of them was considered allowable, then the next one(s) need not be considered. For ease of identifying the changes made, I have included the versions with tracked changes in comparison with the previously considered claim 1.

69 Auxiliary claim set 1, claim 1:

1. A wellness analyzer comprising:

a plurality of sensors that generate real-time physiological data from a plurality of sites on a patient;

a plurality of databases that provide non-real-time information relevant to a medical-related assessment of a patient;

a wellness monitor that generates a wellness output in a diagnostic mode and a predictive wellness output in a simulation mode, the wellness monitor including one or more processors,

wherein when the wellness monitor is in the diagnostic mode, the one or more processors are configured to:

receive the sensor data and the non-real-time information,

process the non-real-time information so as to generate supplemental information,

process the sensor data and the supplemental information so as to generate the wellness output, wherein processing the sensor data comprises:

generating a plurality of parameters as outputs based on the received sensor data,

performing a signal extraction function that extracts physiological signals from the sensor data,

performing a signal analysis function that derives the parameters from the physiological signals and generates the plurality of parameters as outputs,

wherein the wellness output is based at least in part upon one or more derived features of the sensor data and at least in part upon the supplemental information, the one or more derived features including at least one of a slope, a trend, a variability, a pattern, or a waveform morphology of the sensor data; and

wherein when the wellness monitor is in the simulation mode, the one or more processors are configured to:

synthesize at least one simulated parameter output for the patient,

process the at least one simulated parameter output so as to generate the predictive wellness output based at least in part upon the at least one simulated parameter output and a historical response of the patient to the at least one simulated parameter output.

70 Dr Malden described this first auxiliary claim set as making explicit that parameters are generated from the sensor outputs. It will be clear from the foregoing that this is consistent with the construction I have applied to the current claims. It is helpful to explicitly define how the parameters are generated from signal data, but it does not change my analysis of whether the contribution is technical or overcomes a technical problem. Consequently, I find that auxiliary claim set 1 is excluded from patentability as a program for a computer as such.

71 Auxiliary claim set two, claim 1:

1. A wellness analyzer comprising:

a plurality of sensors that generate real-time physiological data from a plurality of sites on a patient;

a plurality of databases that provide non-real-time information relevant to a medical-related assessment of a patient;

a wellness monitor that generates a wellness output in a diagnostic mode and a predictive wellness output in a simulation mode, the wellness monitor including one or more processors,

wherein when the wellness monitor is in the diagnostic mode, the one or more processors are configured to:

receive the sensor data and the non-real-time information,

process the non-real-time information so as to generate supplemental information,

process the sensor data and the supplemental information so as to generate the wellness output, wherein processing the sensor data comprises:

generating a plurality of parameters as outputs based on the received sensor data,

performing a signal extraction function that extracts physiological signals from the sensor data,

performing a signal analysis function that derives the parameters from the physiological signals and generates the plurality of parameters as outputs,

performing a feature extraction function on the parameters so as to identify at least one of a parameter level, a parameter trend, a parameter pattern, and a parameter statistics as one or more extracted features,

wherein the wellness output is based at least in part upon one or more derived features of the sensor data and at least in part upon the supplemental information, the one or more derived features including at least one of a slope, a trend, a variability, a pattern, or a waveform morphology of the sensor data,

the wellness monitor further comprising a memory that stores the one or more extracted features when the wellness monitor is in the diagnostic mode; and

wherein when the wellness monitor is in the simulation mode, the one or more processors are configured to:

synthesize at least one simulated parameter output for the patient,

perform a feature playback function that recalls the one or more extracted features from the memory based on the at least one simulated parameter output,

process the at least one simulated parameter output and the extracted features so as to generate the predictive wellness output based at least in part upon the at least one simulated parameter output and a historical response of the patient to the at least one simulated parameter output.

72 Dr Malden described auxiliary claim set 2 as “going further than auxiliary claim set 1”, adding the further steps of extracting features based on the parameters, storing them and linking them explicitly to define how the historic response is utilised in the

simulation mode. This makes explicit the synergistic interaction between the diagnostic mode and the simulation mode integers that was implied in current claim 1 as I construed it. Once the again the claim benefits greatly from improved clarity, but as the claims on file were not considered to be a collocation of known integers and my identification of the actual contribution was based on this construction, the strengthening of the synergy between the integers does not help to overcome the computer program exclusion. I find that auxiliary claim set 2 is excluded from patentability as a program for a computer as such.

73 Auxiliary claim set three, claim 1:

1. A wellness analyzer comprising:

a plurality of sensors that generate real-time physiological data from a plurality of sites on a patient;

a plurality of databases that provide non-real-time information relevant to a medical-related assessment of a patient;

a wellness monitor that generates a wellness output in a diagnostic mode and a predictive wellness output in a simulation mode, the wellness monitor including one or more processors,

wherein when the wellness monitor is in the diagnostic mode, the one or more processors are configured to:

receive the sensor data and the non-real-time information,

process the non-real-time information so as to generate supplemental information,

process the sensor data and the supplemental information so as to generate the wellness output,

wherein the wellness output is based at least in part upon one or more derived features of the sensor data and at least in part upon the supplemental information, the one or more derived features including at least one of a slope, a trend, a variability, a pattern, or a waveform morphology of the sensor data; and

wherein when the wellness monitor is in the simulation mode, the one or more processors are configured to:

synthesize at least one simulated parameter output for the patient, wherein the at least one simulated parameter output is allowed to vary;

generate at least one non-simulated parameter according to a historical response of the patient to like variation in the at least one simulated parameter output; and

process the at least one simulated parameter output and the at least one non-simulated parameter so as to generate the predictive wellness output ~~based at least in part upon the at least one simulated parameter output and a historical response of the patient to the at least one simulated parameter output~~.

74 Dr Malden explained that the third auxiliary claim set made clearer the dynamic nature of the simulated input parameter, to further emphasise that the specific patient's historical response to a varying parameter can be used in the simulation mode. This amendment was intended to further distinguish the invention from that disclosed in PHILIPS.

75 This auxiliary claim set introduces a “non-simulated parameter” generated in response to the “simulated parameter output”. Given that the current claim is not readily clear in respect of its definition of the simulated parameter I do not find the third auxiliary request to be an improvement. Insofar as it may be construed, I have considered the claim.

76 The simulation mode of the invention has already been construed as defined in this third auxiliary claim. As referred to in paragraph 63 above, I have interpreted the current claim 1 in light of the description consistent with the variation of dependent parameters in response to an independent parameter. Therefore my assessment of excluded subject matter is unchanged. I find that auxiliary claim set 3 is excluded from patentability as a program for a computer as such.

Conclusion

77 I find that the claimed invention is excluded under section 1(2)(c) because it relates to a program for a computer as such and a method for doing business. I have considered the three auxiliary claim sets and find that they do not change this assessment.

78 I find that the claimed invention does provide an inventive step as required by section 1(1)(b) and section 3.

79 Having considered the specification as a whole, including the three auxiliary claim sets, I do not think that any saving amendment is possible. I therefore refuse the application under section 18(3).

Appeal

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

Ben Buchanan

Deputy Director, acting for the Comptroller