Intellectual Property Office

BL O/239/15

26 May 2015.

PATENTS ACT 1977

APPLICANT Trakcel Ltd

ISSUE Whether patent application number GB1402346.9 complies with section 1(2)

HEARING OFFICER Peter Slater

DECISION

1 Patent application GB1402346.9 entitled "Tracking of physiological or medicinal samples" is derived from the corresponding PCT application filed on the 7 February 2013 and published as WO2013/117928. The application claims an earliest priority date of 10 February 2012, and was republished on 16 April 2014 with the serial number GB2507019.

2 Following several rounds of examination and amendment, the examiner remained of the view that the claimed invention was excluded from patentability under section 1(2). With the situation unresolved the applicant asked to be heard and the matter came before me at a hearing on the 23 March 2015. The applicant was represented by Dr Cerian Jones of Urquhart-Dykes & Lord LLP. The examiner Stephen Richardson was also present, as was hearing assistant Joseph Mitchell and observer Solomon Williams-Wadley.

3 The examiner also raised objections in relation to excluded matter under Section 4A, inventive step, support and clarity and has noted that a search for independent claim 11 has yet to be performed. However, these matters have been deferred pending the outcome of the hearing.

The invention

4 The invention relates to a method of tracking physiological or medicinal samples through a sequence of processing operations.

5 There are four main steps to the method. The medicinal or physiological sample (for example physiological material harvested or collected from a patient by medical personnel) is provided. The sample then passes through one or more logistic steps, through one or more processing steps and finally, the sample is administered to a patient in an administration step.

6 The sample is tracked throughout the four steps by a tracking system. The tracking system using a number of devices, for example, smartphones or the like, each of which can only be used by registered operators such as doctors, technicians etc. The tracking devices capture or acquire data relating to the sample at each step and this may be done automatically or manually. The tracking devices provide an operator with information relating to the prior step and the current step. The tracking devices synchronise with a central data repository at each step to enable data transfer therebetween.

7 In more detail, initially an operator is required to log in to the system using a tracking device (which provides a register of operators responsible for particular operations), which subsequently synchronises with the repository to initialise the tracking device with appropriate data relating to the harvesting step. The sample is obtained and placed within a receptacle. Time and location data is recorded on the tracking device, a receipt is generated to provide confirmation and the tracking device synchronises with the repository to update this data to the repository. The operator then logs out from the system.

8 The operator responsible for the logistics step logs in to the system using a tracking device, the tracking device synchronises with the repository to update the tracking device about the sample. The operator generates and applies a machine readable label to the sample so that it can be identified. A receipt is generated, subsidiary operations performed and the tracking device synchronises with the repository to update this data to the repository. The operator then logs out from the system.

9 The operator responsible for the processing step typically logs in to the system using a biometric reader to verify the operator. A tracking device is then synchronised with the repository to update the tracking device about the sample. The sample is identified and processed (typically according to instructions provided on a display screen). Once finalised, a receipt is generated and data is synchronised with the repository. The operator then logs out from the system.

10 Finally, the operator responsible for the administrative step logs in to the system using a tracking device, the tracking device synchronises with the repository to update the tracking device about the sample. The operator confirms the identity of the sample, a verification step ensures the correct patient has been identified, and the sample is administered. Once finalised, a receipt is generated and data is synchronised with the repository. The operator then logs out from the system.

11 The most recent set of claims was filed on 14 July 2014. There are 18 claims of which claims 1 and 11 are independent and which read as follows.

> *1. A method of preparing or processing at least one physiological or medicinal sample through a sequence of processing operations using at least one tracking device for tracking the sample, the method comprising the steps of:*
>
> *(a) providing the sample from a source matched to a specific patient, and storing biometric data relating to the patient and data relating to the sample in a data repository;*

(b) capturing in one said tracking device data relating to the sample, including said biometric data;

(c) permitting the sample from step (b) to proceed to subsequent steps only if there is identity between the biometric data captured in step (b) and the biometric data stored in step (a);

(d) in the case where there is such identity, carrying out a first processing operation on the sample;

(e) capturing in one said tracking device, which may be the same as or different to the tracking device used in said step (b), data relating to the sample, including the data captured in step (b) as well as data relating to the first processing operation;

(f) capturing in one said tracking device, which may be the same as or different to the tracking device used in said steps (b) and (e), data relating to the sample, including the data captured in steps (b) and (e);

(g) comparing the biometric data captured in step (f) with biometric data relating to the patient stored in the data repository;

(h) permitting the sample to proceed to a further processing operation (i) only if there is identity between the stored biometric data and the biometric data captured in step (f);

(i) in the case where there is such identity, carrying out a further processing operation on the sample;

(j) capturing in one said tracking device, which may be the same as or different to the tracking device(s) used in said steps (b), (e) and (f), data relating to the sample, including the data captured in steps (b) and (e) as well as data relating to the further processing operation (i), steps (f) to (j) comprising a cycle which is repeated one or more times; and

(k) comparing the captured data obtained in a final step (j) with data relating to the sample stored in the data repository and rejecting the sample if there is not identity between the stored biometric data and the biometric data captured in said final step (j).

11. A system for preparing or processing a biological sample through a sequence of processing operations, the system comprising:

at least one tracking device for tracking sample processing operations; and a data repository for storing data corresponding to the processing of the sample at each processing operation;

wherein the at least one tracking device is arranged to capture and record sample data at each of the processing operations and to synchronise with the data repository, to enable the transfer of sample data corresponding to the respective processing operation, between the repository and the at least one tracking device.

The Law

12 The examiner has raised an objection under section 1(2)(c) of the Patents Act 1977 that the invention is not patentable because it relates to a program for a computer and a business method as such; the relevant provisions of this section of the Act are shown in bold below:

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

13 As explained in the notice published by the UK Intellectual Property Office on 8 December 2008[1], the starting point for determining whether an invention falls within the exclusions of section 1(2) is the judgment of the Court of Appeal in *Aerotel/Macrossan*[2].

14 The interpretation of section 1(2) has been considered by the Court of Appeal in *Symbian Ltd's Application*[3]. *Symbian* arose under the computer program exclusion, but as with its previous decision in *Aerotel*, the Court gave general guidance on section 1(2). Although the Court approached the question of excluded matter primarily on the basis of whether there was a technical contribution, it nevertheless (at paragraph 59) considered its conclusion in the light of the *Aerotel* approach. The Court was quite clear (see paragraphs 8-15) that the structured four-step approach to the question in *Aerotel* was never intended to be a new departure in domestic law; that it remained bound by its previous decisions, particularly *Merrill Lynch*[4] which rested on whether the contribution was technical; and that any differences in the two approaches should affect neither the applicable principles nor the outcome in any particular case. But the *Symbian* judgment does make it clear, that in deciding whether an invention is excluded, one must ask does it make a technical contribution? If it does then it is not excluded.

15 Subject to the clarification provided by *Symbian*, it is therefore still appropriate for me to proceed on the basis of the four-step approach explained at paragraphs 40-48 of *Aerotel/Macrossan* namely:

> 1) Properly construe the claim;

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[1] http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-computer.htm
[2] *Aerotel Ltd v Telco Holdings Ltd* and *Macrossan's Application* [2006] EWCA Civ 1371; [2007] RPC 7
[3] *Symbian Ltd v Comptroller-General of Patents*, [2009] RPC 1
[4] *Merrill Lynch's Application* [1989] RPC 561

2) Identify the actual contribution (although at the application stage this might have to be the alleged contribution);

3) Ask whether it falls solely within the excluded matter, which (see paragraph 45) is merely an expression of the “as such” qualification of section 1(2);

4) If the third step has not covered it, check whether the actual or alleged contribution is actually technical.

16 The operation of this test 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 46 explains that the fourth step of checking whether the contribution is technical may not be necessary because the third step should have covered the point.

17 Dr Jones agreed that this was the correct approach to take.

Arguments and Analysis

18 The examiner maintains that the invention as claimed is excluded under section 1(2)(c) of the Act as it relates to a program for a computer as such and/or a business method as such. Their position is set-out most recently in the examination report dated 13 November 2014. The applicant’s arguments to the contrary are contained in their letter of 14 July 2014. I am also grateful to Dr Jones for having supplied me with a copy of her “skeleton arguments” prior to the hearing which provide a useful summary of the main points which were discussed during the hearing. I do not intend to repeat all the arguments here in full but will summarise them appropriately in the paragraphs which follow.

Claim construction

19 The first step of the test is to construe the claims. I do not think this presents any real problems since both the applicant and the examiner appear to agree as to the meaning of the claims.

Identifying the actual contribution

20 For the second step, it is necessary to identify the contribution made by the invention. Paragraph 43 of *Aerotel/Macrossan* explains that this is to be determined by asking what it is -as a matter of substance not form - that the invention has really added to the stock of human knowledge having regard to the problem to be solved, how the invention works and what its advantages are.

21 It has been acknowledged by both the examiner and Dr Jones that there is a difference in opinion as to what constitutes the contribution in this case.

22 The examiner in their examination report of 13 November 2014 set out what they considered to be the problem said to be solved, how the invention worked and what its advantages were. They were clear that they considered these to relate to an administrative problem (the susceptibility of biological samples to human error), that the invention did not provide true control of a technical process (permitting or

prohibiting steps only by manual intervention alone) and that helping avoid errors being made is entirely administrative in nature. They did not consider an improved sample to form part of the contribution. They identified the actual contribution as an administrative method performed using conventional hardware to track samples through their stages in a processing sequence, and accompanying data logging, wherein samples are only allowed to proceed to subsequent processing steps if the sample is successfully identified by comparing captured sample data with a stored patient biometric.

23 Dr Jones set out her approach to identifying the contribution. She argued that differences arose when taking the form of the claims into account over the substance of the claims. She argued that the correct approach to take, involved the problem said to be solved, how the invention worked and what its advantages are, the so-called 'big picture' approach, and was, she contended, how the courts have approached this issue, by looking at the invention as a whole. Dr jones referred to *Halliburton*[5], *Protecting Kids the World Over (PKTWO) Limited v Comptroller General of Patents*[6], and *HTC v Apple*[7], which, it was contended, were not distracted by lower level details, but instead considered what those inventions had really added. So, for example in *Halliburton*, the contribution was a better design process, rather than a better drill bit and in *HTC v Apple*, in paragraph 154 part iv) in particular, the contribution was a better device.

24 Taking the 'big picture' approach, Dr Jones restated that the contribution here was not a better administrative process, but a better way of providing a technical biological sample. She argued that the contribution is not about making an administrators life easier, nor is it about audit trails, or reports or receipts. It is about providing a better biological sample. Page 1 of the application sets out the background to the invention - that biological samples can be degraded during a process, and the importance of the sample being in an optimum condition, not only because of potential cost implications but also from a safety consideration. The reason the applicant has gone to the effort of ensuring samples are in an optimum condition, and the reasons people pay for this technology, is not because people want an audit trail, it is because they want to ensure a sample is in good condition, they don't want it to be degraded during the process and they want to ensure it gets to the correct patient at the end. In Dr Jones' view, the process is technical, as is the end result. What the applicant has added to human knowledge is how to produce a better biological sample as opposed to a better administrative process.

25 With particular regard to the 'permitting' and 'rejecting' aspects of claim 1, Dr Jones submitted that what this, in substance, is referring to is verification. This is verification of biometric data and is not an administrative step. It is a very technical process. Dr Jones referred to numerous passages in the description where the requirement for verification was required before further processing of a sample would be permitted and again submitted that such verification is not administrative. Although, I note that, the specification is entirely silent regarding the details of how the biometric verification is carried out.

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[5] *Halliburton [2011] EWHC 2508 (Pat)*
[6] *Protecting Kids The World Over (PKTWO) Limited* [2011] EWHC 2720 (Pat)
[7] *HTC v Apple [2013] EWCA Civ 451*

26 Dr Jones acknowledged that there were parts in the description which refer to an audit trail (and which have been specifically referenced by the examiner). It was, they submitted, a somewhat unfortunate drafting of the application which has possibly encouraged a certain influence on the overall understanding of the application, but, as we are required to assess the contribution in relation to the substance and not the form, and if you look beyond the wording and the perhaps unfortunate repetition in certain places of the audit aspect, there is a technical core and purpose to the invention.

27 In considering the contribution I am in agreement with both Dr Jones and the examiner that the problem said to be solved by the invention is the susceptibility of biological samples to human error. Although the application makes it clear that some of the steps and processes involved in processing of samples can be performed automatically, it is clear that the problem areas derive solely from manual steps or operations and it is these issues alone which the invention wishes to address. I am in agreement with the examiner that this problem is not technical. It is an administrative problem.

28 With regards to how the invention works, it is clear that there is a form of verification within claim 1 of permitting and rejecting samples from proceeding further in the method. However, the application can only really be read that such permitting and rejecting actions are taken and applied by a human operator. There is nothing within the application, for example, which suggests any form of automatic operation to allow or prevent further operations to be carried out. As such, the method is entirely reliant upon a human operator for its full and complete performance.

29 With regards to the advantages of the invention, I am in agreement with both the examiner and Dr Jones that it is the proactive nature of the method in avoiding errors being made whilst the sample moves through the various steps.

30 Taking all this into account, in my opinion, the contribution resides in a series of essentially administrative steps which can enable a sample to be processed as desired and prevent any samples which do not meet desired criteria from taking any further part in the method, thus overcoming the possibility of human error having an undesired affect on the sample.

31 Such a method can produce a sample which has been processed and meets all the requirements desired of it. Alternatively, no sample may be produced by the method if samples do not meet the requirement desired of them. It is not about improving the process to produce, for example, a purer sample it’s about improving the consistency with which a conventional sample is produced by eliminating human error. It is for this reason that to my mind, the contribution cannot reside in a better sample alone.

Does the contribution fall solely within excluded subject matter? Is the contribution technical in nature?

Business method

32 The examiner was of the opinion that the contribution fell entirely with the business method exclusion and that the invention fails to provide a relevant technical contribution.

33 Dr Jones, given her differing opinion as to what constituted the actual contribution, came to a different answer. She considered the contribution to be a better sample and that as such it was technical in nature and sufficient to avoid exclusion as a business method or a computer program.

34 After careful consideration, I am of the opinion that the contribution I have identified falls wholly within the business method exclusion. The contribution is an administrative process for ensuring that samples are permitted or rejected from taking further part in a series of processes. The contribution is therefore not technical in nature and relates to a business method 'as such'. The fact that the method is implemented in hardware does not provide a relevant technical contribution to avoid exclusion.

Program for a computer

35 There is no doubt in my mind that the contribution requires a computer program for its implementation. However, the fact that the invention is effected in software does not mean that it is automatically excluded from patentability as a computer program as such. What matters is whether or not the program provides a technical contribution.

36 The task of determining whether the invention provides a technical contribution is a difficult one, as is evident from the plethora of case law in this area. However, I note that both the examiner and Dr Jones have made reference to the 'signposts' set out by Lewison J as he then was in *AT&T/CVON*[8] , which I consider to be a useful guide in determining whether the contribution is technical in nature. The signposts were modified slightly by Lewison L J in *HTC v Apple*[9] and now read as follows:

> 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 application being run.
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> 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.

37 In their examination report of 13 November 2014, the examiner did not consider the contribution to be technical in nature as it did not, in their opinion, satisfy any of the above 'signposts' and concluded that the invention related to a computer program

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[8] *AT&T Knowledge Ventures/Cvon Innovations v Comptroller General of Patents [2009] EWHC 343 (Pat)*

[9] *HTC Europe Co Ltd v Apple Inc [2012] EWHC 1789 (Pat)*

which provides no technical contribution. They argued that the process performed by the invention was not a technical process but an administrative one.

38 With regards to the first signpost in particular, at the hearing Dr Jones reiterated her argument set out in her letter of 14 July 2014 that the invention controls a process performed by human operators, that is it has an effect on a process carried on outside of the computer, and moreover that the monitoring of the process was technical in nature. Specific reference was made to paragraph 34 of *Protecting Kids the World Over (PKTWO) Limited v Comptroller General of Patents*[10] where it was found that monitoring which is technically superior to that produced by the prior art would seem to have the necessary characteristics of a technical contribution outside the computer itself and that this line of reasoning could be equally applied to the present invention. That is, the monitoring of samples as they progress through the four steps is technically superior to the prior art and therefore also has the necessary characteristics of a technical contribution outside the computer.

39 Before looking at these signposts in turn, it will be useful to consider the way the invention is implemented in reality and the effect this may have on the interpretation of the signposts. In particular, whilst it is true to say that the invention here does not use a single computer in its implementation, (instead it uses numerous computing devices communicating over a network) Birss J in paragraph 30 of *Lantana v Comptroller-General of Patents*[11] found that systems operating as a network can be considered, for the purposes of the signposts as 'the computer'. Therefore, this does not mean that any effect taking place outside a single computing device would meet the first signpost for example, the effect would have to be outside of the computer system as a whole.

40 Taking each signpost in turn, it is clear to my mind that the only effect outside of the computer system is an administrative one. When the method of the invention is run, it may, or may not result in a sample with the desired characteristics. However, as I have stated above, I do not consider this to form part of the contribution. The contribution is an administrative process for ensuring that samples are permitted or rejected from taking further part in a series of processes. I do not consider this to be a 'technical effect' on the process carried on outside of the computer.

41 I will group signposts two-four together. There has been no real argument from either the agent or the examiner regarding these signposts. The contribution is clearly not directed towards anything which operates at the level of the architecture of the computer and similarly it has no effect on the way the computer runs or operates.

42 With regards to the fifth signpost. The problem to be solved, to my mind, is purely an administrative one, to overcome human error in the processing of samples. I do not consider this to be a technical problem. Consequently, as the problem to be solved is not a technical problem, the solution (the proactive nature of the method in avoiding errors being made whilst the sample moves through the various steps), cannot take technical character from the problem.

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[10] *Protecting Kids The World Over (PKTWO) Limited* [2011] EWHC 2720 (Pat)
[11] *Lantana v Comptroller-General of Patents* [2013] EWHC 2673 (Pat)[11]

43 Turning to claim 11, the system claim, In the opinion of Dr Jones, claim 11 relates to a novel combination of technical components arranged and configured in a particular way. She submitted that a claim to a novel arrangement of devices should not be *excluded* simply because it is known hardware; arranging and configuring those devices in a certain way is patentable.

44 However, the courts have consistently found that, where claims recite standard hardware, such conventional apparatus does not form part of the contribution. Therefore, an application relating to a computer program cannot be saved simply by claiming conventional computer hardware programmed in a particular way. Jacob LJ specifically rejected the use of standard hardware when determining the contribution in paragraph 73 of *Aerotel/Macrossan*[12]. When assessing whether a particular invention relates to a new system or arrangement of hardware, the question should be asked whether the system is new in itself or whether the system is only new due to the method it performs.

45 In my opinion, the system as claimed in claim 11 is made up entirely of conventional hardware operating in a conventional fashion and the contribution lies in the functions which the system has been programmed to carry out and does not provide the necessary technical contribution to avoid exclusion as a computer program as such.

Auxiliary claims

46 Auxiliary claims were filed along with the agents skeleton arguments and relate to claims 1 and 11 only. They read as follows, with amendments highlighted.

> *1. A **verification** method **for use in** preparing or processing at least one physiological or medicinal sample through a sequence of processing operations using at least one tracking device for tracking the sample, the method comprising the steps of:*
>
> *(a) providing the sample from a source matched to a specific patient, and storing biometric data relating to the patient and data relating to the sample in a data repository;*
>
> *(b) capturing in one said tracking device data relating to the sample, including said biometric data;*
>
> *(c) permitting the sample from step (b) to proceed to subsequent steps only if there is identity between the biometric data captured in step (b) and the biometric data stored in step (a);*
>
> *(d) in the case where there is such identity, carrying out a first processing operation on the sample;*
>
> *(e) capturing in one said tracking device, which may be the same as or different to the tracking device used in said step (b), data relating to the sample, including the data captured in step (b) as well as data relating to the first processing operation;*

[12] *Aerotel Ltd v Telco Holdings Ltd* and *Macrossan's Application* [2006] EWCA Civ 1371; [2007] RPC

(f) capturing in one said tracking device, which may be the same as or different to the tracking device used in said steps (b) and (e), data relating to the sample, including the data captured in steps (b) and (e);

(g) comparing the biometric data captured in step (f) with biometric data relating to the patient stored in the data repository;

(h) permitting the sample to proceed to a further processing operation (i) only if there is identity between the stored biometric data and the biometric data captured in step (f);

(i) in the case where there is such identity, carrying out a further processing operation on the sample;

(j) capturing in one said tracking device, which may be the same as or different to the tracking device(s) used in said steps (b), (e) and (f), data relating to the sample, including the data captured in steps (b) and (e) as well as data relating to the further processing operation (i), steps (f) to (j) comprising a cycle which is repeated one or more times; and

(k) comparing the captured data obtained in a final step (j) with data relating to the sample stored in the data repository and rejecting the sample if there is not identity between the stored biometric data and the biometric data captured in said final step (j).

*11. A system for **verifying** a biological sample through a sequence of processing operations, the system comprising:*

at least one tracking device for tracking sample processing operations; and a data repository for storing data corresponding to the processing of the sample at each processing operation;

wherein the at least one tracking device is arranged to capture and record sample data at each of the processing operations and to synchronise with the data repository, to enable the transfer of sample data corresponding to the respective processing operation, between the repository and the at least one tracking device;

and wherein the system further comprises;

a biometric reader for verification of an operator of the processing operation;

a sensor, wherein the sample is identified using the sensor to verify various parameters of the sample;

and/or

a tracking device for capturing biometric information to verify that a patient and the sample are matched prior to administration of the sample to the patient.

47 The auxiliary claims filed on 16 March 2015 prior to the hearing emphasise the verification aspects of the process and add additional hardware to the system as claimed in claim 11. However, I do not think that these additional features do anything to alter the contribution which I have already decided is excluded as a business method and a computer program as such.

Conclusion

48 In my view, what the applicant has done here is to create a new computer program, albeit a very clever one, which is capable of auditing a series of essentially administrative steps which enable a biological sample to be processed in such a way as to prevent any samples which do not meet certain desired criteria from taking any further part in the process, thus overcoming the possibility of human error having an undesired affect on the sample. The contribution lies in the functions which the system has been programmed to carry out. In essence, the applicant has created a new administrative/business process implemented in software using conventional hardware which does not provide a relevant technical contribution and as such would seem to fall squarely within the business method and computer program exemptions of section 1(2)(c).

49 In the light of my findings above, I conclude that the invention as claimed is excluded under section 1(2) because it relates to both a program for a computer as such and a business method as such. Having read the specification I do not think that any saving amendment is possible. I therefore refuse the application under section 18(3).

Appeal

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

PETER SLATER
Deputy Director, acting for the Comptroller