INTELLECTUAL PROPERTY OFFICE

BL O/117/10

16th April 2010

PATENTS ACT 1977

APPLICANT Forensic Science Service Limited

ISSUE Whether patent application GB0710612.3 complies with section 1(2)

HEARING OFFICER H Jones

Introduction

1 International patent application PCT/GB2005/004641was filed in the name of Forensic Science Service Limited on 5th December 2005 and later entered the UK national phase as application number GB0710612.3. The application was published by WIPO as WO2006/059132 A1 on 8th June 2006.

2 The application relates to a method of modeling a process of analyzing DNA in a biological sample and in then optimising various parameters of the process. The examiner has argued that the invention as presently claimed relates to either a mathematical method or a program for a computer as such, and is therefore excluded under section 1(2) of the Act. Although a search of the prior art remains to be completed, the examiner has also argued that the invention lacks an inventive step in the light of certain prior art documents identified by the European Patent Office in its capacity as International Search Authority. The applicant disagrees and requested a hearing to decide the matter; this hearing was held on 17th March 2010, at which the applicant was represented by Dr Neil Pawlyn and Dr Andrew Alton of UDL.

The application

3 The invention is described as a method for simulating the complete DNA consideration process through all the stages of extraction, aliquot into pre-PCR reaction mix, PCR amplification for a variable number of cycles and visualization of alleles after electrophoresis. Each individual stage of the chemical process is described as being well known, and the prior art documents identified by the EPO all demonstrate that considerable effort has been devoted to modeling the behavior of each stage of the process. The application describes in detail the modeling assumptions and probability functions used to simulate the complete DNA consideration process, and explains the relationships between various input and output parameters which allow the whole process to be simulated and, more importantly, optimised through the use of a computer program. It is not necessary to repeat the complex detail of these modeling assumptions and probability functions in this decision.

4 The application has one independent claim, claim 1, which reads as follows:

> "A process for considering a DNA containing sample, the process for considering a DNA sample including one or more of:
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> extraction from the sample to provide an extracted sample;
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> selection of a sub-sample of the sample;
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> electrophoresis of the sample or sub-sample; and
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> analysis of a sample or sub-sample;
>
> the process for considering a DNA containing sample further including: amplification of the sample or sub-sample to give an amplified product; and
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> wherein one or more of the parameters used in the process for considering a DNA sample is optimized by:
>
> providing a computer implemented method of modeling the process for considering a DNA containing sample, the process being modeled by a graphical model, the graphical model including one or more of: extraction from the sample to provide an extracted sample; selection of a sub-sample of the sample;
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> electrophoresis of the sample or sub-sample; analysis of a sample or sub-sample; the graphical model further including amplification of the sample or sub-sample to give an amplified product;
>
> modeling the process for considering a DNA containing sample using the graphical model and taking into account one or more parameters and determining the effect of one or more of the parameters on one or more of the other parameters;
>
> providing one or more optimized parameters from the method of modeling; and wherein the process for considering a DNA containing sample further comprises using the one or more optimized parameters in the process for considering a DNA containing sample."

The law

5 The relevant provision in relation to excluded inventions is section 1(2). This reads:

> *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.*

6 Current IPO examination practice is to use the structured approach set out by the Court of Appeal in its judgment in *Aerotel/Macrossan*[1] for deciding whether an invention is patentable. The test comprises the following four steps:

1) properly construe the claim
2) identify the actual contribution
3) ask whether the actual contribution falls solely within the excluded subject matter
4) check whether the contribution is technical in nature

7 More recently, the Court of Appeal in the case of *Symbian*[2] confirmed that this structured approach is one means of answering the question of whether the invention reveals a technical contribution to the state of the art. In other words, *Symbian* confirmed that the four-step test is equivalent to the prior case law test of „technical contribution', as per *Merrill Lynch*[3], *Gale*[4] and *Fujitsu*[5].

Arguments and analysis

8 There is no dispute regarding the construction of the claims, so I can proceed immediately to the second step of identifying the actual contribution. I should note at this point that the examiner agrees with the applicant's argument that claim 1 does include both process chemistry steps and data processing steps as part of the process for considering a DNA containing sample.

9 As the Court of Appeal recognised[6] in *Aerotel/Macrossan*, this second step is more problematical as it involves an exercise of judgment "probably involving the problem said to be solved, how the invention works, what its advantages are." The Court goes on to say that this can be best summed up by asking the question of what has been added to the stock of human knowledge. It comes as no surprise that the main area of contention in the present case involves the proper identification of the contribution made, and that, depending on whether one accepts the applicant's view of the contribution or that of the examiner's, two very different conclusions can be reached on whether the claimed invention is excluded under section 1(2).

10 The examiner argues that the actual contribution derived from claim 1 is a graphical computer model which provides parameters to enable optimisation of DNA analysis. The examiner considers that the chemical processes of extraction, electrophoresis, and amplification, are so well known, and that methods of optimisation through experimental trial and error are so well established in this area of activity, that the contribution provided by the invention, or what has been added to the stock of human knowledge, is merely the graphical simulation of the DNA process allowing optimised parameters to be derived by computer rather than through actual experimentation.

11 At the hearing, Dr Alton argued that the examiner had taken too narrow a view of the contribution, and suggested that the contribution had been determined by considering only the novel and inventive parts of the claim whereas what the law requires is an assessment of the claimed invention as a whole. He referred to the analysis of case law at paragraphs 32-38 of *Aerotel/Macrossan*, and likened the examiner's approach to that

[1] Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2007] RPC 7
[2] Symbian Ltd's Application [2008] EWCA Civ 1066, [2009] RPC 1
[3] Merrill Lynch's Appn (1989) [1989] RPC 561
[4] Gale's Appn [1991] RPC 91
[5] Fujitsu Limited's Appn [1997] RPC 608
[6] para. 43 of Aerotel/Macrossan

of the "contribution approach" derived from Justice Falconer's reasoning at first instance in *Merrill Lynch.* This so-called "contribution approach" was later rejected by the Court of Appeal. When adopting the correct approach and viewing the claimed invention as a whole, Dr Alton argued that the contribution made by the invention rests in assessing and measuring the effects of hypothetical parameters within a model of a DNA process, and in using optimised parameters derived from this model in the chemical process of DNA analysis. This translates into improved success rates in the actual DNA consideration process when real samples are used.

12 I accept Dr Alton's argument that the contribution identified by the examiner is cast too narrowly and that it does not take account of the claimed invention as a whole. The description clearly sets out a context in which the ready availability of biological samples for DNA analysis, for example in the field of forensic science, is very often limited, which means that the degree of optimisation of the chemical process in order to yield any meaningful result is limited. What the claimed invention provides is a process for modeling and optimising the DNA consideration process, and uses the information gathered from this model to optimise the real-world chemical DNA consideration process. This optimised chemical process yields improved success rates when real samples are analyzed. Dr Alton summed this up by saying that the contribution is an improved chemical process for considering a DNA containing sample, where optimised parameters generated by modeling steps are fed back into the chemical process so as to improve the chemical processing steps.

13 The link between the computer model and the real-world chemical process was arguably absent in the claims as originally filed, and was later introduced by amendment during the course of examination. The examiner re-assessed the question of what is the contribution made at the time and concluded that "merely adding the final step of using the one or more optimised parameters in the process for considering a DNA containing sample, does not render the claim patentable: such "using" would necessarily be carried out following an optimisation procedure." From this, the examiner appears to have excluded the feature of the claimed invention which tethers the modeling process to the real world and, in view of the guidance from the Court of Appeal, was wrong to do so.

14 Having accepted Dr Alton's assessment of the contribution made by the claimed invention, I now need to decide whether this contribution falls solely within excluded subject matter. Dr Alton's submission is that since the contribution includes carrying out an optimised DNA process chemistry step, it does not fall solely within either a computer program or a mental act. He referred me to the hearing officer's decision in *Waters Investments*[7] as an example of an invention involving known electro-chemical processing steps and novel data processing techniques which was found not to be excluded as either a computer program or a mathematical method. This case is referred to in detail in at paragraph 1.17.2 of the Office's Manual of Patent Practice. In this case*,* the contribution was identified as a method for comparing two samples by an analytical technique which uses chromatography and then spectrometry, followed by a particular sequence of data analysis techniques, to give results which enable the retention time at which the samples differ to be identified. On the question of whether the contribution resides solely in excluded matter, the hearing officer concluded at para. 28 that:

> "..The claims before me do involve some steps that could of themselves be excluded. Mr Mitcheson admitted as much. However, the claimed invention also includes steps that are not excluded - most notably the chromatographic and spectrometric analysis steps through which the data to be analysed is generated. Whilst those chromatographic and spectrometric analysis steps are not of

[7] BL O/146/07 [http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/o14607.pdf]

themselves new, what the inventors have contributed is a better way of analysing samples using those techniques so that significant events in a mass of complex data can be identified more easily. That contribution does not in my view reside solely in excluded matter."

15 In other words, while the claims included steps that could be said to fall within one or more of the categories of excluded matter, the contribution as a whole did not. I agree with Dr Alton that certain parallels can be drawn between the present invention and that considered in *Waters Investments*, and ultimately I am drawn to a similar conclusion that the contribution in the present case does not reside solely within the meaning of a computer program or a mental act. The contribution made is an improved chemical process for considering a DNA containing sample, which happens to include as a key component a computer model to derive certain parameters for optimizing the chemical process. What the inventors have contributed is not solely a new mathematical method or a computer program for implementing that method, but is the practical application of a mathematical model of an electro-chemical process in order to improve the success rates of the electro-chemical process when conducted in practice. It is also technical in nature, which addresses the fourth step of the test.

Other matters

16 In view of the fact that a complete search of the prior art had not been completed at the time of the hearing, I decided that there was little point in considering whether the invention comprises an inventive step over certain documents identified by the EPO if there was a possibility of further documentation appearing from the woodwork on update of the search. I informed Dr Alton and Dr Pawlyn that if I were to find in the applicant's favour on the issue of whether the application complies with section 1(2), I would refer the application back to examiner to complete the search and to raise any further objections through the normal examination process.

Conclusion

17 I have found that the invention defined by claim 1 of the application does not relate to a mathematical method or a program for a computer as such and so is not excluded from patentability under section 1(2) of the Act. Claims 2-13 are dependent on claim 1 and are similarly allowable. As a consequence, the application will be remitted to the examiner to complete the search of the prior art and for further substantive examination.

H Jones
Deputy Director acting for the Comptroller