UK Intellectual Property Office □□□□

For Creativity and Innovation

BL O/146/07

31 May 2007

PATENTS ACT 1977

APPLICANT Waters Investments Limited

ISSUE Whether patent application number GB 0426189.7 complies with section 1

HEARING OFFICER A Bartlett

DECISION

Introduction

1 This decision primarily concerns the issues of whether the invention claimed in UK Patent Application number GB0426189.7 involves an inventive step and relates to non-excluded subject matter as required by section 1 of the Act.

2 The application derives from an application filed under the PCT by Waters Investments Limited on 30 May 2003 and which was published as WO2003/102543. The application is entitled "A method of using data binning in the analysis of chromatography/spectrometry data" and was re-printed in the UK as GB2405972.

3 During the examination process, the examiner reported that the invention defined in the claims is excluded as a mathematical method and/or a computer program and that it does not involve an inventive step. Despite numerous rounds of amendment and re-examination, the Applicants and the examiner were not able to resolve these issues and a hearing was arranged to help me decide the matter. That hearing took place on 16 January 2007. The Applicants were represented by Mr Tom Mitcheson, instructed by Ms Elizabeth Coulson, Mr John Rule and Mr Christopher Hirsch of the Patent Attorneys HLBBshaw. The examiner, Mr Ben Widdows, also attended.

The Application

4 The application concerns a method of analyzing samples which are subject to chromatographic and spectrometric analysis techniques such that a multi-variant statistical analysis technique is employed to make it easier to identify time locations where the characteristics of samples are different. In the example given

in the description, the samples under analysis are urine samples from rats which are analysed to investigate the metabolic effect of various administered compounds.

5 The claims I was asked to consider at the hearing were filed on 15 January 2007 along with a skeleton argument. Following discussion at the hearing regarding an inconsistency in claim 1 a further amendment was filed on 18 January and this decision is based on that version of the claims. There are 15 claims in total of which claim 1 is the only independent claim. It reads:

A method of analyzing the characteristics of two or more samples so as to facilitate comparison of those samples' characteristics, the method comprising the steps of:

a) subjecting each sample to successive chromatographic and spectrometric analytical techniques, in order to generate a first data set for each of said samples, each said first data set having at least three dimensions including a time correlated dimension;

b) performing data binning on each of the first data sets, wherein a bin size is selected based upon the time correlated dimension such that a second data set is obtained for each sample, each said second data set characterised by utilizing two of the remaining dimensions;

c) transforming each of said binned second data sets into aligned binned data sets wherein alignment data points with a null second parameter are added to said binned second data sets, so that all binned second data sets have the same number of data points for each first parameter and in said aligned data sets at least one bin data set has a non-null second parameter;

d) performing a two-dimensional multi-variant statistical analysis on each of the aligned binned second data sets such that a third data set is obtained for each sample;

each third data set comprising only one data value corresponding to each time correlated-bin, which data values are each representative of the sample's characteristics during a time correlated bin, comparison of said third data sets facilitating comparison of each sample's characteristics so that time locations at which the analysed characteristics of said samples differ readily are identifiable.

6 The claims as amended raise a number of issues which I shall address before moving onto the excluded matter and inventive step issues. I am however grateful for the provision of the skeleton argument which facilitated the discussion at the hearing.

Added matter/support

7 Claim 1 as amended specifies (in step a)) that the data set generated from the chromatographic and spectrometric analysis has "**at least three dimensions** including a time correlated dimension". In step b) that data set is then subject to "binning" based on the time dimension to produce a second data set

characterized by utilizing "**two of the remaining** dimensions". This is in contrast to the claim 1 as originally submitted which related specifically to a "Method of analyzing **three** dimensional data".

8 At the hearing I questioned whether this amendment to cover "**at least** three dimensions" added matter contrary to section 76(2). That section of course prohibits any amendment that results in an application disclosing matter extending beyond that disclosed in the application as filed.

9 Mr Mitcheson argued that there was support for this amendment both from the literal meaning of the wording used in the original specification and from a general understanding of the invention. On his "literal" point, he highlighted that claim 1 as originally filed went on to state that the data obtained for the sample was "characterized by **at least three parameters,** at least one of said parameters correlated with time". And as discussed at the hearing, it is stated on page 1 that the invention relates to "a method of analysis of multi-dimensional data by an analysis method applicable to fewer dimensions". This he said made it clear that the invention was not limited to a system allowing three dimensional data to be processed using a two dimensional data processing technique.

10 Mr Mitcheson also thought this to be consistent with the general understanding of the invention that a skilled reader would have after reading the specification. He said that the skilled reader would appreciate that the technique may be applicable to dealing with data that had been analysed via two separate spectrometric techniques (after the chromatographic one) resulting in data having more than three dimensions.

11 I find Mr Mitcheson's first line of argument more persuasive than the latter. I think it is clear that the specification as originally filed is not limited to a technique for processing 3-D data via a 2-D analysis technique – it is more broadly applicable than that. I therefore find the claims as filed on 18 January do not add matter and comply with section 76.

Excluded matter and inventive step

The Law

12 Section 1 of the Patents Act 1977 sets out the requirements that an invention must fulfil for it to be patentable including, in section 1(2), a list of things for which patent protection is not available. The relevant parts of this section read:

> "1(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) below**

1(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -
(a) ....
(b) ....
(c) a 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 purpose of this Act only to the extent that a patent or application for a patent relates to that thing as such."

Interpretation

13 The law relating to the exclusions has been the subject of much scrutiny by the Courts in recent times culminating in the Court of Appeal's consideration of the issue in *Aerotel/Macrossan*[1]. In its judgment in that case the Court approved a new approach for assessing excluded matter which the Patent Office announced it would follow with immediate effect in its practice notice dated 2 November 2006[2]. Mr Mitcheson accepted that to be the approach I should follow in deciding whether the present invention relates to excluded matter but in doing that he also drew attention in his skeleton to a number of other observations made by the Court and upon which the Applicants rely. These were:

> That the relevant provisions are those contained in Articles 52(2) and (3) of the EPC
>
> That the categories should be approached without bias in favour of or against exclusion and
>
> That it is doubtful whether the mental act exclusion extends to electronic means of doing what could otherwise have been done mentally.

14 He also observed that the High Court in *CFPH*[3] said that

> "The fact that the claimed invention might include or use a computer program does not establish that the patent would foreclose the use of a computer program (and thus be excluded)."

15 Whilst I accept those points, I would also draw attention to a number of other points made by the Court of Appeal in the *Aerotel* judgment.

16 First, the Court made it clear that deciding whether an invention was excluded was a question of law and thus there was no benefit of the doubt to be enjoyed by the Applicant in applying these provisions.

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[1] Aerotel Ltd vs Telco Holdings Ltd & Macrossan's Patent Application [2007] RPC 7
[2] Patents Act 1977: Patentable subject matter [2007] RPC 8
[3] CFPH LLC's Application [2006] RPC 5

17 Second the Court made it clear that the excluded categories are not exceptions to what is patentable, rather S1(2) sets out positive categories of things which are not to be regarded as inventions. Accordingly the general UK and European principle of statutory interpretation that exceptions should be construed narrowly does not apply to them.

Applying the test

18 The test for assessing patentability approved by the Court of Appeal in *Aerotel* comprises the following four steps:

> (1) properly construe the claim
>
> (2) identify the actual contribution;
>
> (3) ask whether it falls solely within the excluded subject matter;
>
> (4) check whether the actual or alleged contribution is actually technical in nature.

19 Neither I nor Mr Mitcheson thought that step 1 - construing claim 1 - presented any particular difficulties and I am in broad agreement with the construction offered by Mr Mitcheson in paragraph 4 of his skeleton argument. Thus the invention can be summarized as

> A method of comparing two (or more) samples where the samples are first subjected to successive chromatographic and spectrometric analytical techniques, thus generating data having at least three dimensions including a time correlated dimension (retention time). Data binning is then performed on the results of this analysis based on retention time. The resulting data is aligned and normalized and then two-dimensional multi variant statistical analysis is carried out. This results in a set of data containing one data value corresponding to each time correlated-bin. Comparison of these data values enables the retention time to be identified at which the characteristics of the samples differ.

20 I think it worth noting here that as recognized at the hearing, the claim is not limited to implementation via a computer (although in practice it seems highly likely that at least some of the steps would be computerized) and that the actual identification of the relevant retention times is not included in the claim; rather the claim is directed to the generation of the data via spectrometric and chromatographic techniques and the subsequent processing that allows the identification of relevant retention times to be made. The identification itself is most likely carried out by a human user of the system for example by viewing graphical representations of the processed data.

21 The second step in the *Aerotel* approach is to identify the actual contribution made by the invention. In doing that I think it is helpful to turn first to the specification to see what it says about the prior art methods of analyzing this sort of sample. According to the specification, Nuclear Magnetic Resonance (NMR)

has been the method of choice for conducting this sort of analysis. That though suffers from a number of deficiencies including being slow, insensitive, and subject to various masking difficulties. The specification then goes on to explain how, in an ideal world, the skilled person might use chromatography followed by spectrometry in the analysis process. As Mr Mitcheson explained however, that is subject to its own problems. The techniques commonly used to highlight the times of interest (where the characteristics of various samples differ) are 2-D techniques and thus cannot be used to analyse the 3-D results of chromatographic and spectrometric analysis. Thus prior to the invention the skilled man faced a conundrum – continue to use NMR with all its recognized deficiencies or use chromatography followed by spectrometric analysis but have to discard some of the resulting data to allow the 2-D statistical analysis techniques to be applied.

22 This, according to Mr Mitcheson, was precisely the shortcoming that existed with the solution proposed in what I consider to be the nearest piece of prior art (Greef) identified by the examiner. In the system disclosed in Greef, the output of successive chromatographic and spectrometric analysis steps is subjected to a 2-D multi-variant analysis technique as in the system presently claimed. However, in Greef, the multi-variant analysis is only conducted on the limited number of chromatograms where the entropy (a measure of the signal to noise ratio) of the trace exceeds a threshold or on spectra that fall within a certain time window. This is in contrast to the invention of present claim 1 where no data is discarded but where the multi-variant analysis is conducted on the output of the chromatographic/spectrometric process after it has been subject to "binning".

23 So what is the contribution made by the present invention? In paragraph 43 of the *Aerotel* judgment, Jacob LJ said that the second step of the test – identify the contribution – could best be summed up by asking "what has the inventor really added to human knowledge". In his skeleton, Mr Mitcheson summarized the contribution as being

> "A method for comparing two samples by an analytical technique which uses chromatography and then spectrometry, followed by a number of different data analysis techniques, to give results which enable the retention time at which the samples differ to be identified".

24 When advancing arguments in support of that assessment, Mr Mitcheson accepted that any hardware required to carry out the chromatography, spectrometry and data analysis was conventional. On a point that I will come back to when considering inventive step, he also accepted that the Applicants had not invented the process of "binning". Thus neither of these provides the contribution of itself. The claims are not, however, directed to either of those aspects alone – they are directed to a method of analyzing the characteristics of samples including subjecting each sample to chromatographic and spectrometric analysis and performing data binning and multi-variant statistical analysis on the results of that analysis.

25 Thus I agree with Mr Mitcheson's assessment of the contribution subject to one modification which is that the spectrometry is 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.

26 The third step in the *Aerotel* approach is to decide whether that contribution resides solely in excluded matter. Mr Mitcheson accepted that some of the steps recited in the claim could, in isolation, be considered to be excluded. For example he accepted that the data binning, normalizing and multi-variant analysis techniques of steps b), c) and d) could be viewed as mathematical methods. He also accepted that in all likelihood many of those steps would be implemented via a computer although the claims were not so limited. He did not accept however that the contribution made by the claimed invention resided solely in excluded matter. Nor did he accept that any of the steps fell within the mental act exclusion.

27 Whilst accepting that the Court's comments on mental act were strictly *obiter dicta*, Mr Mitcheson argued that they clearly pointed to a narrow interpretation of that particular exclusion. He said that in his view the Court had made it clear that only a very limited range of activities (like performing mental arithmetic or memory improvement techniques) were caught by the mental act exclusion. Furthermore he said that by suggesting that acts done using a computer were not caught by the exclusion then activities which were too complex to be done by the ordinary skilled person (such as the binning in the present invention) were not excluded. He even went so far as to say that in his view the mental act exclusion was solely aimed at methods which shortcut something that you could otherwise do mentally – for example easier ways to commit things to memory or easier ways to do complex multiplication. I do not agree with him on this latter point. To interpret the mental act exclusion in that way would, it seems to me introduce an element of merit into the test and I can see no basis for that whatsoever. His view that "complex" activities were not caught is also somewhat at odds with the Court's similarly obiter comments on the scope of this exclusion in its judgment in *Fujitsu*[4] where Aldous LJ said at p621 line 11:

> "Methods of performing mental acts, which means methods of the type performed mentally.."

28 Ultimately however I do not think that this is a case where the precise scope of the individual exclusions is really an issue. 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 themselves new, when viewed as a whole, what the inventors have contributed is a better way of analyzing 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.

29 The final step in the *Aerotel* approach (which I must apply in these circumstances to ensure consistency with *Merrill Lynch*[5]*)* is to check that the contribution is

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[4] Fujitsu Ltd's Application [1997] RPC 608
[5] Merrill Lynch's Application [1989] RPC 561

technical in nature. The contribution I have identified as being made by the invention is in the field of sample analysis using chromatography and spectrometric techniques. That it seems to me is a contribution in a technical field and thus the methods defined in the claims are not in my view excluded.

Inventive Step

30 That then leaves the issue of whether the invention is obvious. The approach to be followed in the UK to determine whether an invention is obvious is of course the Windsurfing[6] test. Following that approach, the examiner reported that the difference between the alleged invention and the analysis method disclosed in Greef (which was widely accepted to be the nearest piece of prior art) would have been obvious to the skilled man whose common general knowledge at the priority date of the invention would have included the technique of binning as illustrated in a document referred to as "Binner".

31 "Binner" discusses in abstract terms a process to permit a scattered set of data points to be summarized by dividing up the sample field into a series of "bins". In the words of the document itself "… the data is summarized by grouping or *binning* together all the points that lie within certain coordinate and data ranges". Mr Mitcheson did not dispute that that is the same process as is conducted in the time domain in the present invention. Nor, as I have already indicated, did he claim that the applicants had invented the process of binning. He said, however, that on the basis of the evidence presented, the Applicants were the first people to use the technique of binning in the present field (of chromatographic and spectrometric analysis) and it would not have been obvious to the skilled man in that field to modify the method of Greef using the binning technique which Binner shows to have been known at the priority date.

32 In arguing this Mr Mitcheson raised issues about who is the skilled person, whether he/she would be aware of the technique of binning as disclosed in Binner and whether he/she would appreciate that it could be used to modify the teaching of Greef to solve the problem the invention seeks to address.

33 Taking the first of these points, Mr Mitcheson characterized the skilled person as an analyst of chemical compositions who was used to carrying out the chromatographic and spectrometric techniques disclosed in the application and of applying conventional statistical techniques as part of his work. He accepted that the skilled person would be used to applying Principle Component Analysis (PCA) – a form of multi-variant analysis - to data generated as part of that process. However, in Mr Mitcheson's opinion, the skilled person was not someone seeking to find new techniques for treating the data output by his machines. He said the skilled person here was not reading mathematical journals looking for new techniques which might be useful in his field. Consequently he said that the skilled person would not be aware of the technique of binning as disclosed in Binner and thus it would not have been obvious to him to use it to modify the method of Greef.

34 I think that is too narrow an interpretation of the skilled person. The problem that

[6] Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd [1985] RPC 59

the present invention seeks to address is not in the chromatographic or spectrometric analysis processes, rather it is in the subsequent analysis of the data generated in those processes. I think this is a situation where the analyst would be all too aware of his or her incomplete knowledge of statistical analysis techniques and in seeking to improve the processing of data from that chromatography and spectrometry steps, would turn to someone skilled in the art of statistical analysis. Thus I think this is a situation where it is entirely appropriate to consider the skilled person to be a team having knowledge of both the technical and statistical analysis fields.

35 The next question for me to consider is whether the skilled person (or team) would be aware of the technique of binning as disclosed in "Binner" or put another way was that technique within the common general knowledge of the skilled person in the field. Mr Mitcheson thought it was not (even if the skilled person was in fact a team). He said Binner was a single, highly abstract disclosure that contained nothing to suggest its potential relevance to the person skilled in this particular field, how to use it in this field or what advantages it would provide if applied in this field. In short he said that Binner did little more than disclose that binning exists as a technique. It did not, he said, indicate that the technique was within the common general knowledge of the skilled person in this field.

36 I agree that the "Binner" document is indeed very abstract but whilst it is the only documentary evidence provided to show what was common general knowledge in the data analysis field at the priority date, I do not think that is the whole picture. Whilst the term "binning" might not be widely used, I am at a loss to see how the binning process of claim 1 is anything other than time slicing or sampling the data collected over an extended period of time so that the individual slices can be processed. That is a conventional processing technique, even if referring to it as "binning" is not. Thus in my view the process of binning would have formed part of the common general knowledge of the skilled person (or team) in the present case.

37 The final question to address is whether the skilled person would have found it obvious to use that technique to modify the method of Greef. Mr Mitcheson argued that it would not be obvious to do so even if the skilled person was aware of the technique of binning. He said that the disclosure in Binner was abstract in the extreme with no indication whatsoever as to how it might be employed and in what fields. In the absence of any such indication he said it would not be obvious to use it to modify the method of Greef or, come to that, how you would need to modify the binning process so that it could be used with the standard PCA analysis techniques envisaged in the invention. Furthermore, whilst he acknowledged that the present invention sought to address a similar problem to that solved in Greef, he said it did that in a very different way; Greef being concerned with a method for deciding which traces could be discarded prior to PCA analysis being carried out whereas the present invention used data binning prior to PCA to allow all data to be included in the analysis. All these things he said pointed to there being an inventive step in using the binning technique to analyse the output of chromatographic and spectrometric processes.

38 On the basis of all the evidence available to me I accept that the invention does

provide the required inventive step. Whilst I have found above that the process of binning is within the common general knowledge of the skilled team in this case, I do not consider it obvious to modify the Greef technique in the way specified in present claim 1. The two systems employ different philosophies to address the problems of adapting data from chromatographic and spectrometric analysis for multi-variant analysis: the invention provides a way of dividing that data up to that it can all be subjected to the multi-variant analysis where as the prior art discloses a technique to select the data to be discarded prior to that analysis. Whilst as Mr Mitcheson acknowledged, the technique of binning is not new, I can see nothing in the evidence available to me to suggest that it would be obvious to the skilled man (or team) at the priority date of the application to use the binning and alignment technique to provide such an alternative.

39 I therefore consider claim 1 as amended to involve the inventive step required by section 1(1)(b). It follows that the remaining claims, which are all dependent upon claim 1, are also inventive.

Conclusion

40 I have found that the claims submitted on 18 January 2007 relate to non-excluded subject matter, are inventive and comply with section 76. Those being the only outstanding issues on the application, I find the application to be in order for grant

A BARTLETT
Deputy Director acting for the Comptroller