



PATENTS ACT 1977

APPLICANT	Aueon Inc.
ISSUE	Whether patent application GB1008930.8 complies with sections 1(1)(b), 1(2)(c) and 14(5)(b)
HEARING OFFICER	H Jones

DECISION

Introduction

- 1 The application relates to a method of generating a list of cancer drug treatment options based on the status of molecular markers derived from a sample of a tumour in a patient and also other patient specific information. The list is ranked in order of efficacy on the basis of research data obtained from separate studies and clinical trials into the effectiveness of various drug treatment plans. Given the vast amount of research data available, a computer is required to sift through the possible drug treatment plans and to produce a personalised list of options.
- 2 The application was filed via the PCT route on 4th September 2009 and published on entry into the UK national phase as [GB2467691](#). It claims priority from a number of US patent applications, the earliest of which was filed on 5th September 2008. The compliance period for placing the application in order has been extended as of right under rule 108(2) and also at the discretion of the comptroller under rule 108(3) to 5th July 2013.
- 3 The examiner argues that the invention is a computer program and is therefore not patentable by virtue of section 1(2)(c). The applicant disagrees. The examiner also argues that the invention lacks an inventive step with respect to the prior art and that the claims as currently drafted are misleading and generally unclear. Again, the applicant disagrees, so the matter came before me to decide at a hearing held by videoconference on 21st May 2013, where the applicant was represented by Mr Richard Bizley and Dr Stephen Blance of Avidity IP Ltd. For the convenience of this decision and with no disrespect intended whatsoever, I shall refer to Mr Bizley and Dr Blance as the applicant's representatives.
- 4 Skeleton arguments were submitted shortly before the hearing, together with a signed affidavit from Vernon Norviel, who is one of the named inventors in the application, explaining the differences between the invention and the prior art.
- 5 The application as it currently stands has one independent claim, claim 1, which reads as follows:

A method of diagnosing a cancer comprising:

- a) providing a sample previously obtained from a primary tumour in a patient;
- b) assaying to determine the status of a plurality of molecular markers in the sample so as to diagnose the disease condition of the patient;
- c) interrogating a computer-implemented database storing information relating to potential drug treatment options, the interrogation being based upon patient specific information including the thus-determined molecular marker status, to identify potentially efficacious drug treatment options;
- e) ranking the drug treatment options so as to identify an efficacious option for the patient disease condition for rendering by an output device.

- 6 The examiner has argued that the wording of claim 1 is unclear because it begins by suggesting that the invention is a method of diagnosing cancer whereas the characterising aspects of it are concerned with identifying potential drug treatment options. His argument is that the invention may well include the steps of diagnosing the disease condition of the patient, but the invention as a whole could be more properly described as a method of generating a treatment plan. This was discussed as a preliminary issue at the hearing, and the applicant's representatives agreed that the claim could benefit from an amendment to clarify its precise scope albeit still defined as a method of diagnosis. I shall return to this point later. It was suggested that the wording of the claim could be dealt with after the hearing once the issues of patentability and inventive step had been decided, and I agreed that this was the best way forward. This decision addresses the two issues of patentability and inventive step.

The law

- 7 The relevant provisions in relation to patentability and inventive step are set out in section 1(1)(b), section 1(2) and section 3 of the Act, as set out below:

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) ...*
- (b) it involves an inventive step;*

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) 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.

3. 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).

- 8 Since claim 1 is directed to a method of diagnosis, the applicant contends that section 4A is also relevant to this particular case. The relevant parts of section 4A read as follows:

*4A(1). A patent shall not be granted for the invention of -
(a) a method of treatment of the human or animal body by surgery or therapy, or
(b) a method of diagnosis practised on the human or animal body.*

- 9 Section 1(2) of the Act corresponds to Article 52(2) of the European Patent Convention (EPC), and specifies certain categories of subject-matter which shall not be regarded as inventions. Section 4A(1) of the Act corresponds to Article 53(c) of the current version of the EPC, and states that patents shall not be granted on inventions concerned with methods for treatment or diagnosis on or of a human (or animal) body. The current version of the EPC (EPC 2000) entered into force on 13th December 2007; in the original version of the Convention (EPC 1973), Article 52(4) said that inventions concerned with methods for treatment or diagnosis on or of a human (or animal) body were not patentable because they were not susceptible of industrial application. The effect of the revision of the EPC has been to remove the question of whether such methods are capable of industrial application and to prevent the patenting of such inventions in their own right: page 135 of the "Transitional Provisions" published in Special Edition No. 4, OJ EPO 2001,¹ states that shifting the substance of Article 52(4) to 53(c) is a purely editorial change and does not change the legal position.

- 10 Section 130(7) of the Act states that all of the above provisions are so framed as to have, as nearly as practicable, the same effect. It is well established that whilst I am bound by the decisions of courts in the UK, I must also have regard to the decisions of the European Patent Office Boards of Appeal, at least insofar as they relate to these particular articles of the Convention.

Arguments and analysis

Patentability

- 11 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 reveals a technical contribution to the state of the art (cf. *Symbian*², *Aerotel*³). The Court of Appeal in *Aerotel* set out the following four-step test to help answer the question:

- 1) *construe the claim;*
- 2) *identify the actual (or alleged) contribution;*
- 3) *ask whether it falls solely within the excluded subject matter;*

¹ http://archive.epo.org/epo/pubs/oj001/12_01/12_spe1.pdf

² *Symbian Ltd. v Comptroller-General of Patents* [2008] EWCA Civ 1066

³ *Aerotel Ltd v Telco Holdings Ltd and Macrossan's Application* [2006] EWCA Civ 1371

4) *check whether the actual or alleged contribution is actually technical in nature.*

12 The applicant's representatives argue that methods of diagnosis are in a category of invention that is not subject to the type of analysis set out in *Aerotel* and subsequently applied by the examiner in the present case. They refer to the European Patent Office's Enlarged Board of Appeal Opinion in *G1/04*⁴, which says that diagnostic methods practised on the human or animal body referred to in Article 52(4) EPC1973 (now Article 53(c) EPC) are inventions within the meaning of Article 52(1) EPC, but, by means of a legal fiction, are regarded as not susceptible of industrial application (cf. paragraph 4). Unlike the other categories of subject-matter set out in section 1(2) which are expressly defined as not being inventions, they say that methods of diagnosis are specifically defined in the EPC as being inventions. They say that *Aerotel* is concerned with the scope of various categories of subject-matter which are not regarded as inventions under the Act or the EPC, as well as the meaning of the related term "as such" which appears in both pieces of legislation. They argue that at no point in the judgment are methods of diagnosis considered or any reference made to section 4 of the Act or Article 52(4) of the EPC (or its current equivalent), so there can be no legal basis for applying the *Aerotel* test to the present invention. They also refer to the normal legal rule that where something is conceivably covered by two different provisions of the same statute, the more general provision cannot derogate from a more specific one: they say that this is relevant in the present case because there is a specific provision in the EPC which says that methods of diagnosis are to be regarded as inventions.

13 The argument that methods of diagnosis have a unique character in the EPC is said to be further emphasised with reference to paragraph 5.3 and 6.2.4 of *G1/04*, which read:

5.3 Since diagnostic methods referred to in Article 52(4) EPC are inventions within the meaning of Article 52(1) EPC (cf. point 4 above), it follows that, in a situation where the deductive medical or veterinary decision phase is a purely intellectual exercise, i.e. a step of a non-technical nature, such a method must necessarily further include preceding steps (cf. point 5 above) of a technical nature, in order to satisfy the requirements of Article 52(1) EPC. The subject-matter of a claim including technical and non-technical features may satisfy the requirements of Article 52(1) EPC if the non-technical features interact with the technical features in order to bring about a technical effect (cf. T 603/89 (OJ EPO 1992, 230), point 2.5 of the Reasons).

6.2.4 It has been argued that, in the event of a narrow interpretation as referred to under point 6 above, the exclusion of a diagnostic method under Article 52(4) EPC could perhaps be circumvented by missing out one of the essential features of the method (cf. point 6.2.3 above) in the independent claim concerned. However, this does not seem to pose a real risk having regard to the well-established jurisprudence of the EPO in respect of Article 84 EPC, which requires that, in order to be patentable, an independent claim must recite all the essential features which are necessary for clearly and completely defining a particular invention. These features are for the most part of a technical nature. But, if a non-technical feature is to be regarded as

⁴ <http://www.epo.org/law-practice/case-law-appeals/recent/g040001ex1.html>

constitutive for defining the invention, it must likewise be included as an essential feature in the independent claim. Thus, although diagnosis stricto sensu is a purely intellectual exercise unless it is carried out by a device (cf. point 5.2 above), the feature pertaining to it is such an essential feature to be included in the independent claim. The same applies to a feature relating to a method step of a non-technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes (cf. point 6.4.1 below).

- 14 The argument here is that a method of diagnosis comprising technical features is to be regarded as being patentable regardless of whether the essential feature of the invention is non-technical in nature. The applicant's representatives say that claim 1 of the present application defines a method of diagnosis comprising both technical and non-technical features, so therefore it must be patentable irrespective of whether the essential feature of the invention is non-technical.
- 15 The applicant's representatives have also questioned whether the original approach in *Aerotel* would now survive a review by the Supreme Court in view of the European Patent Office's Enlarged Board of Appeal Opinion in *G3/08*⁵. I am not in a position to answer this; this is for the Supreme Court to answer whenever the question is asked of it. At the present time, the Court of Appeal's decision in *Aerotel* concerning whether an invention is excluded by virtue of section 1(2) is binding on me.
- 16 The arguments advanced on behalf of the applicant require me to begin by deciding whether the invention set out in the present application is a method of diagnosis and then, if necessary, to decide whether such methods are to be treated differently to the exclusions from patentability set out in section 1(2). The question of whether the invention is a method of diagnosis is effectively the one considered by the examiner in relation to the clarity of claim 1.

Method of diagnosis

- 17 In *G1/04*, the Enlarged Board of Appeal said that method steps to be carried out when making a diagnosis within the meaning of Article 52(4), i.e. as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes, include:
- a) the examination and collection of data;
 - b) comparison of the data with normal values;
 - c) recording any deviation from the norm; and finally
 - d) attributing the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.
- 18 If a claimed method includes all these steps and thereby makes it possible to decide on a particular course of treatment, it clearly constitutes a method of diagnosis. The Enlarged Board of Appeal also said that the term "method of diagnosis" should be construed narrowly. In other words, only a method which comprises all of the four steps listed above and allows the identification of a pathological condition falls within this definition (cf. paragraph 6.2.3).

⁵[http://documents.epo.org/projects/babylon/eponet.nsf/0/DC6171F182D8B65AC125772100426656/\\$File/G3_08_opinion_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/DC6171F182D8B65AC125772100426656/$File/G3_08_opinion_en.pdf)

- 19 Claim 1 is set out in terms of a method of diagnosing a cancer, so in a formal sense would appear to fall within the meaning of a method of diagnosis. However, as the examiner has quite rightly pointed out, the invention goes further than this in that it takes an initial diagnosis of the disease condition, identifies possible drug treatment options based on patient specific information and draws up a ranked list of best possible treatment options. In other words, the substance of the invention is not a method of diagnosing cancer; it is something quite different. At the hearing, the applicant's representatives accepted this point, but still considered that the substance of the invention was a method of diagnosis and that it was possible to redraft the claim in such terms.
- 20 The additional steps of identifying drug treatment options based on patient specific information and listing best possible options are essential features of the invention and distinguish it from the acknowledged prior art. These steps inherently acknowledge that that initial diagnosis of the disease condition is incomplete and that further research is required in order to determine a list of potential curative treatments. This research is conducted by interrogating a computer database storing information relating to potential drug treatment options, which leads to the production of a list of most efficacious treatment plans specific to the patient. What this list provides is, in effect, an indication of how to proceed with the further assessment of the disease condition, allowing further observations to be made regarding the efficacy of the drug treatment plans and to determine the particular course of treatment for the patient. The substance of the invention, therefore, is a method of identifying and ranking potential drug treatment plans based on the results of tests performed on samples taken from a patient together with other patient specific information.
- 21 If I compare the substance of the invention with the requirements for methods of diagnosis set out in *G1/04*, the invention quite clearly includes the steps of examination and collection of data and comparing this data with normal values, but it appears to lack the third and fourth steps of recording any deviation from the norm and attributing the deviation to a particular clinical picture. It seems to me that further examination and collection of data is required before a diagnosis for curative purposes can be made. The ranked list of efficacious drug treatment options could, it seems to me, provide direction as to how this further examination and collection of data might proceed, e.g. by working down the list of drug treatment options and observing which option works best, thereby associating in a reverse sense the disease condition with the most effective drug treatment, but the invention falls short of finding a specific symptom and attributing the symptom to a particular clinical picture. The claimed invention does include an initial step of assaying a sample in order to determine the status of a plurality of markers in the sample and to diagnose the disease condition of the patient, but this does not lead directly to a final step of determining the particular clinical picture. This initial step is more akin to the situation set out at paragraph 6.2.3 of *G1/04*, which explains that "intermediate findings of diagnostic relevance must not be confounded with diagnosis for curative purposes *stricto sensu* as referred to in point 5 above, which consists in attributing the detected deviation to a particular clinical picture."
- 22 In view of the above, I find that the claimed invention does not relate to a method of diagnosis. Having reviewed the entire specification of the application, I am also certain that there is no possibility of amending the claim in such a way that it would fall within the meaning of this category of invention. The argument that methods of

diagnosis are to be regarded as patentable inventions regardless of section 1(2) is an interesting one, but is moot as far as the present invention is concerned: the invention is not a method of diagnosis, so the approach set out in *Aerotel* with regard to computer programs and computer-implemented inventions is relevant. I shall proceed by following the four-step test as set out above.

Program for a computer

23 The first step in deciding whether the invention is excluded as being a program for a computer is to construe the claim, which I have already done in some detail above. Although the claim is set out in terms of a method of diagnosing cancer, I agree with the examiner that the scope of the invention set out in claim 1 is more accurately defined in terms of a computer-implemented method of listing possible drug treatments for a cancer in order of efficacy based upon the results of a test to determine the status of a molecular marker associated with the cancer. An example of a list of possible drug treatment options is shown in fig.8 of the application.

24 The next step is to identify the actual (or alleged) contribution made by the invention. Guidance on how to approach this is provided at paragraph 43 of the Court of Appeal's judgment:

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

25 The examiner argues that since diagnosing cancers based on mutations in molecular markers is well known in the art (citing the disclosure in [WO02/029005](#) and [WO2005/030788](#) as examples), the contribution made by the invention rests in the provision of a computer program to identify and rank suitable drugs for the treatment of a cancer from a bank of research data based upon the status of molecular markers associated with the cancer. At the hearing, the applicant's representatives suggested an alternative description of the contribution, namely an improved method of diagnosis which involves database interrogation and treatment option ranking for rendering by an output device based on molecular marker status and other factors such as age, family history, etc. I have already dismissed the suggestion that invention can be described as a method of diagnosis, and by implication this also extends to the contribution made by it. Save for this, I am happy to accept the contribution proffered by the applicant's representatives, accepting as well that the database interrogation yields the advantages of faster, more informed clinical treatments observed outside of the computer as opposed to simply a more efficient computer program.

26 The next step is to decide whether the contribution falls within the meaning of a program for a computer. The applicant's representatives referred me to a number of authorities which say that the meaning of the exclusion should be construed narrowly. The Court of Appeal has also said in *Symbian*⁶ that this third step can be combined with the fourth step of deciding whether the contribution is technical in

⁶ *Symbian Ltd v Comptroller-General of Patents* [2008] EWCA Civ 1066

nature, with the outcome that what is being looked for is essentially whether the contribution identified in the second step is a “technical contribution”. This is the approach I shall follow in deciding whether the invention is excluded by section 1(2). While I have dismissed the need to consider whether methods of diagnosis are patentable regardless of the exclusions set out in section 1(2) (and Article 52(2)), I note that paragraph 5.3 of *G1/04* says that in claims for methods of diagnosis, the method claim must “necessarily further include preceding steps of a technical nature” and that the “subject-matter of a claim including technical and non-technical features may satisfy the requirements of Article 52(1) EPC if the non-technical features interact with the technical features in order to bring about a technical effect”. This reinforces the point that what I need to decide is whether the invention makes a technical contribution or provides a technical effect.

- 27 The contribution is a computer-implemented method for interrogating a database and outputting results in a particular way based on certain input criteria. This, in my view, is quite clearly a program for a computer. The nature of the data being interrogated by the computer and the criteria being input into it does not alter the matter. In other words, the benefits gained by using a computer to trawl through vast amounts of research data relating to the efficacy of drug treatments and providing a list of the most efficacious treatments to a patient or clinician are just those one would expect in the use of a computer program in any other field of application, namely faster retrieval of relevant results. The consequence of this faster retrieval is that the patient or clinician has earlier access to a list of relevant drug treatments listed in order of efficacy, which, as was argued at the hearing, can lead to faster and more effective treatment of the patient. The direct benefit derived from the invention is the faster retrieval of relevant results, which I do not consider to be technical in the sense required by section 1(2). The indirect advantages of better and faster treatment are also not technical in the sense required by section 1(2). As a consequence, I find that the claimed invention is a program for a computer as such and is excluded by section 1(2). I also find that there is nothing in the application that would save it from being regarded any differently. On the basis of these findings, I see little purpose in considering whether the invention also fails to meet the requirement for inventive step.

Conclusion

- 28 I find that the invention is excluded under section 1(2)(c) as a program for a computer. I can find no possible amendment in the specification that will render the claims patentable. I therefore refuse the application under section 18(3).

Appeal

- 29 Any appeal must be lodged within 28 days.

H JONES

Deputy Director, acting for the Comptroller