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For Creativity and Innovation

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PATENTS ACT 1977

APPLICANT Genego Inc

ISSUE Whether patent application number GB 0427256.3 complies with section 1

HEARING OFFICER J J Elbro

DECISION

1 This decision concerns whether patent application GB 0427256.3 titled "Methods for identifying compounds for treating disease states" relates to excluded subject matter.

2 The case is derived from PCT application number PCT/US2003/019325, claiming priority from US 60389474. The earliest date for the case is 18 June 2002. During the prosecution various objections have been raised, and to some degree overcome. The outstanding objection now is that the invention does not relate to patentable subject matter, being both a mental act and a computer program.

3 Despite numerous rounds of correspondence, the examiner and Applicants have been unable to reach agreement as to the patentability of the invention. The Applicants declined the opportunity to attend a hearing on the issue and asked instead for a decision to be issued on the basis of the papers on file, all of which have been submitted through their Patent Attorneys Boult Wade Tennant.

The invention

4 The invention relates to a method of identifying drug targets. This identification is made possible by the use of a methodology for organising existing information about multiple metabolic pathways (from expressed sequence tag data or similar) into a formalised hierarchical representation (the metabolic map), such that interconnections or gaps between the pathways may be identified. Information derived from organisms in both disease and non disease states may also be used, with differences in the resulting metabolic maps highlighting areas which may play a crucial role in the action of the disease. In both cases, the areas of the metabolic map identified are areas that are alleged to have the potential for fruitful further research.

5 The claims I must consider were filed on 16 May 2006 and amended by the addition of further claims on 27 October 2006. There are 11 in total with claim 1 being the only independent claim. It reads:

> A method of identifying drug targets, the method comprising the steps of:
> creating a map of the metabolism of an organism based upon a plurality of metabolic pathways; and
> identifying drug targets by comparing differences between non-disease and disease states of the organism using the map;
> wherein the step of creating the map comprises the steps of;
> representing each of the plurality of metabolic pathways as a hierarchy of biochemical units;
> collecting and storing data associated with each biochemical unit; and
> automatically forming a metabolic network by linking the metabolic pathways, wherein two metabolic pathways are linked if the data associated with a biochemical unit of one of the two metabolic pathways is linked to the data associated with a biochemical unit of the other one of the two metabolic pathways.

The Law

6 The examiner has reported that the invention is excluded from patentability under section 1(2)(c) of the Act as relating to a method for performing a mental act and/or a program for a computer. The relevant parts of this section read:

> "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) ....
>
> 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."

7 My approach to interpreting section 1(2) will be governed by the judgment of the Court of Appeal in *Aerotel Ltd v Telco Holdings Ltd (and others) and Macrossan's Application* [2006] EWCA Civ 1371 and the Practice Notice that was issued thereafter (2 November 2006). In that judgment, a four step test was advocated which can be summarised as:

> (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.

8 As stated at paragraphs 45 – 47 of the judgment, reconciling the new test with

the earlier judgments of the Court of Appeal in *Merrill Lynch* [1989] RPC 561 and *Fujitsu* [1997] RPC 608, the fourth step of checking whether the contribution is technical may not be necessary because the third step – asking whether the contribution is solely of excluded matter – should have covered the point.

9 Regarding the mental act exclusion, in paragraph 62 the Court of Appeal states "we are doubtful as to whether the exclusion extends to electronic means of doing what could otherwise have been done mentally". In doing so they explicitly doubted the reasoning given in *Fujitsu* (quoted in para 94 of *Aerotel/Macrossan*) that "Methods of performing mental acts, which means methods of the type performed mentally, are unpatentable, unless some concept of technical contribution is present." In both cases, however, the Court of Appeal declined to decide the issue and thus both comments are *obiter*.

Arguments and Analysis

Construction of Claim 1

10 The claim is explicitly to a method of identifying drug targets, and is characterised by a series of steps. It is plain that these steps can be performed by a suitably programmed computer, and indeed this is how they are done in the described embodiments.

11 However, it could be argued that the method can be performed mentally, for suitably simple examples. This is clear for most steps of the method, the only one which would appear to give a difficulty being the final one of "automatically" forming a metabolic network.

12 Among other meanings, the Concise Oxford Dictionary for "automatic" gives "(of a machine, device,etc. or its function) working by itself, without direct human intervention" and "necessary and inevitable". If I take the former meaning, then "automatically" serves to limit the claim to automated processing by a device (which would in practice be a computer). If I take the latter, the word serves only to indicate that the formation of a metabolic network is the inevitable consequence of linking the data as required by the claim.

13 In the context of the specification as a whole, I consider it clear that the intention is to limit the claim to automated processing. Performing the equivalent method mentally would therefore fall outside the scope of the claim. Performing the method on a computer, however, clearly falls within it.

Contribution made by the invention

14 In his final examination report of 18 December 2006, the examiner indicated that he considered the difference between the claimed invention and the prior art to be, as previously acknowledged by the applicant, to lie in the organization of the data into hierarchical metabolic units and subsequently linking pathways that share at least some common data between their biochemical units. He therefore considered that as the claims do not limit the method to any particular targets or pathways, and no actions beyond the creation of the map are specified, the contribution must lie in the modeling technique itself.

15 The applicant's agent disputed this in a letter of 20 December 2006. In particular, they argued that the step of comparing disease and non-disease states of the map was not known or suggested by the prior art. They argue that the contribution must include both this and the actual identification of the drug targets.

16 I accept these points. I therefore find that the contribution is an automated method of identifying drug targets, characterized by representing metabolic pathways as a hierarchy of biochemical units and subsequently linking pathways that share at least some common data between their biochemical units, and by using this representation to identify drug targets by comparing differences between non-disease and disease states of the organism.

Whether the contribution falls wholly within excluded matter

17 The automated method found above is one which may be, and in reality is, performed by a computer. There is nothing in the contribution which is not data processing by the computer and thus the contribution falls wholly within the computer program exclusion. As such, the claimed invention is excluded from patentability by Section 1(2)(c).

18 The applicant's agent argues in their letter of 20 December 2006 that there is a "real world" effect – in the form of an identified drug target – that takes the invention outside the computer program exclusion. I do not agree. There is no new drug target claimed here; rather, there is a method which may or may not find one, depending on, among other things, whether such a new drug target actually exists.

19 If I were to follow the obiter reasoning in *Fujitsu* on mental acts quoted above, I would find that this method is of the type performed mentally, and therefore excluded as a method for performing a mental act. On the other hand, if I were to follow the obiter reasoning in *Aerotel/Macrossan* quoted above, I would find that this method is not actually performed mentally, as it is automated, and thus is not so excluded. Given my finding on the computer program point, I do not need to decide this.

Check that the contribution is actually technical

20 Given my finding on step 3, I do not need to apply step 4 of the *Aerotel/Macrossan* test.

Other Claims

21 The dependent claims all claim further features of the method or the nature of the data used. The applicant has not argued that any of them will avoid the exclusions if claim 1 does not and I see nothing in any of them which would take the invention outside the scope of the exclusions.

Conclusion and next steps

22 I find that the invention as claimed in this application is excluded from patentability under section 1(2) as a computer program. I therefore refuse the

application in accordance with section 18(3).

Appeal

23 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

J J ELBRO
Deputy Director acting for the Comptroller