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21st December 2009

PATENTS ACT 1977

APPLICANT	Clive Neil Galley
ISSUE	Whether patent application GB0522962.0 complies with sections 14(3) and 14(5)
HEARING OFFICER	H Jones

Introduction

1 Patent application GB0522962.0 was filed on 11th November 2005 claiming priority from an earlier UK patent application filed on 24th August of the same year. The title of the invention is given as "A clinical trial design template", and the specification, which comprises five pages of description and a total of seven claims, was published as GB2429547 on 28th February 2007.

2 A search report under section 17(5)(b) was issued on the basis that the invention was considered to relate to a method for evaluating the effectiveness of clinical trials and, therefore, was not patentable. This objection to the invention relating to non-patentable subject matter was maintained during the course of substantive examination of the application, but only as a secondary consideration to the more fundamental objections to lack of clarity in both the specification and claims, and to the specification not being complete enough for the invention to be performed by a person skilled in the art. The applicant responded to these objections by way of argument on a number of occasions but failed to convince the examiner that the application should be allowed.

3 The applicant was twice invited to attend a hearing to decide the matter and informed that in the absence of a response that a decision would be issued on the basis of the papers on file. Although the applicant did continue to write to the to the examiner concerned, there is nothing in these letters to suggest that he wished to attend a hearing or to submit any additional arguments before a decision was issued. This decision is therefore based on the papers on file at the date of issue.

The law

4 Section 14(3) specifies that the specification of an application "shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art". The specification is

required to contain a description of the invention, a claim or claims and any drawing referred to in the description or any claim. As far as the claims are concerned, section 14(5) requires that they should be clear and concise and be supported by the description.

The application

5 The title of the invention given on the application form and repeated on page 1 of the description suggests that the invention is concerned with a clinical trial design template. The claims would appear to be similarly concerned with a clinical trial design template of some fashion, and are set out below:

1) Our system provides clinical trial dimensions for an equivalence class of non-deterministic and simultaneously deterministic events above a maximum non-chance determined function.

2) A template system as claimed in claim 1 also gives instances for the same equivalence class allowing interpretation of adjunct trails as both adjuncts and replacements.

3) A template system as claimed in claim 1 separates the placebo effect of brain diseases forming poly-double logarithmic reductions within our equivalence class.

4) A template system as claimed in claim 1 also gives the chances of success of an opposing class legal action adversarial on the dimensioned clinical trial's disease, with a loglog n exponential difference obliged for that opposition, where the grouping becomes the legal team sizes, for that best chance of success fixed under 100%.

5) A template system as claimed in claim 1 applies to many events with the same dimensions for all four steps including the repeated step 2.

6) A template system as claimed in claim 1 finds an arbitrary legal class action (as in claim 4) bias obligation above a maximum non-chance determined probability, and this bias is uncheckable, with this interpretation being a verification heuristic reduction.

7) A template system as claimed in claim 1 has an underwriting value which can be costed based on claim 4 repeatedly, and claim 6 to end.

6 The specification provides a brief reference to the prior art on page 1 and appears to distinguish the invention over this prior art in the following two paragraphs:

> *Considering equivalence classes of non-determinism applied beyond the above approximable systems functionality, to within double logarithmic reductions, the ratio gives a separated placebo effect particular solution, to a single equivalence class of events hidden by chance, when the ratio is considered as a probability.*
>
> *Moreover by fixing the percentage benefit and then considering a double*

logarithmic kernel iteratively we find an adjunct and replacement clinical trial approximate interpretation, where the approximation gives a further approximate variance percentage benefit.

7 The examiner reports that he is unable to determine what is being described in the application and that he is unable to determine which systems/acts might infringe upon the claims of the invention. The examiner considers that the applicant's various responses are equally unclear, and provide little assistance in clarifying the nature of the invention.

Discussion

8 I have read the specification and the correspondence on file a number of times, and I am still at a loss to understand what the invention is concerned with or even in which field of technology it lies. The objection to the invention relating to non-patentable subject matter seems to me to be slightly speculative given that the description of the invention is so unclear, but appears a reasonable ground for objection given the pointer in the title to the invention being a clinical trial. However, the fundamental objection remains that the specification is not clear enough or complete enough for the invention to be performed by a person skilled in the art, and I find that I am in total agreement with the examiner in this regard. I also agree with the examiner that the lack of clarity in the description extends into the claims, to the point where I find it difficult to identify any connection whatsoever between what is claimed and what is described.

9 As the examiner has pointed out on a number of occasions, it is clear that the applicant has gone to some lengths to file his patent application, to describe the invention in a manner which he believes is clear and to respond to the examiner's objections as sincerely as possible. Unfortunately for the applicant, the test for whether the description or claims are clear is not whether the applicant understands what his own words mean but what a skilled person would understand. I do not consider that a skilled person would a) understand the invention described, b) be able to perform it without considerable effort or c) understand whether he would infringe any of the claims if granted.

Conclusion

10 The specification of the application is not clear enough or complete enough to enable a person skilled in the art to perform the invention. The claims of the application are also unclear, and I can see no way of amending the application without adding additional subject matter, which is not allowed. I therefore refuse the application under section 18(3) on the basis that it fails to meet the requirements of sections 14(3) and 14(5).

Appeal

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

H Jones
Deputy Director acting for the Comptroller