Intellectual Property Office

BL O/814/21

03 November 2021

PATENTS ACT 1977

APPLICANT	Innoplexus AG
ISSUE	Whether application GB 1804882.7 complies with Section 1(2) of the Patent Act 1977
HEARING OFFICER	Dr Stephen Brown

DECISION

Introduction

1 Patent Application GB 1804882.7 has a filing date of 27 March 2018. It was published as GB 2572353 on 2nd October 2019.

2 The Examiner issued an Abbreviated Examination Report under Section 18(3), in which he argued that the application was excluded from patentability under Section 1(2) of the Act. The Examiner declined to search the application due to the Section 1(2) issues. The applicant filed a response to the examination report on 26 March 2020 but was unable to persuade the examiner that the application is allowable under Section 1(2). The applicant waived the offer of a hearing and requested a decision based on the papers on file on 21 July 2021. The applicant did not make any amendments or further arguments. The file was thus sent to me for a decision on 29 September 2021.

The Application

3 The application concerns a method of amalgamating clinical trial data from a plurality of different trials. Chart 1.1 of the application (reproduced below) provides an example of a source of clinical trial data for a particular trial in the US. Clinical trial entries (as listed in the bottom row of Chart 1.1) are classified in predefined classes: “Trail ID”, “Condition”, “Drugs”, “Phase” and “Date”. According to the invention, clinical trial entries (e.g. “US2009”, “Atopic Dermatitis” etc.) are extracted for a plurality of different trials from a plurality of data sources.

US				
Trial ID	Condition	Drugs	Phase	Date
US2009 (also published as GM4080, CH7409)	Atopic Dermatitis	Baricinib, Placebo, Triamcinolone	1	Feb 2016 – Dec 2016

Chart 1.1

4 For each predefined class, a class-specific clinical trial entry is generated. The class-specific clinical trial entry combines each of the clinical trial entries for the predefined class in a manner which ensures any set of clinical trial entries within the predefined class which are deemed to be "similar" to each other (e.g. duplicates of each other) are replaced by a single clinical trial entry. So, for example, if the clinical trial entry "Baricinib" was present in trial data for two different trials, it would appear only once in the class-specific clinical trial entry for the class "Drugs". Generation of class-specific clinical trial entries is claimed in comparing and compiling steps of the independent claims.

5 The class-specific clinical trial entries for each predefined class are collated to provide aggregated clinical trial data from the plurality of clinical trials, with no data redundancy. Chart 4.1 (reproduced below) provides an example of such aggregated clinical trial data from three different trials. In Chart 4.1 the class-specific clinical trial entry for the class "Drugs" is "Baricinib, Placebo, Triamcinolone".

Trial ID	Condition	Drugs	Phase	Date
US2009, GM4080, CH7409	Atopic Dermatitis	Baricinib, Placebo, Triamcinolone	1 2	Feb 2016 – Dec 2016 Jan 2016 – Feb 2016 Mar 2015 – Nov 2016

Chart 4.1

The Claims

6 The claims have not been amended. Method claim 10 reads:

> *A method of managing clinical trials data, wherein the method includes using a computer system, characterized in that the method comprises:*

- identifying a set of clinical trials, wherein the set of clinical trials comprises clinical trials having a relation therebetween;

- extracting clinical trials data from existing data sources, wherein clinical trials data comprises clinical trial entries of each of the clinical trials in the set of clinical trials;

- classifying the clinical trial entries into one or more predefined classes;

- comparing the clinical trial entries in each of the one or more predefined classes, to identify similarity or dissimilarity between the clinical trial entries in a predefined class,

wherein upon identification of similarity between clinical trial entries in the predefined class, one of the similar clinical trial entries is stored in a first aggregated clinical trial entry corresponding to the predefined class; and

wherein upon identification of dissimilarity between clinical trial entries in the predefined class, the dissimilar clinical trial entries are stored in a second aggregated clinical trial entry corresponding to the predefined class;

- compiling the first and second aggregated clinical trial entries to obtain class-specific clinical trial entries corresponding to each of the one or more predefined classes; and

- collating class-specific clinical trial entries corresponding to each of the one or more predefined classes to obtain an aggregated clinical trial.

7 While there is a system claim, claim 1, and a computer readable medium claim, claim 16, I believe that they are the same in substance as claim 10. It is thus sufficient to consider only claim 10 in detail. Claims 1 and 16 will stand or fall with my decision on claim 10.

Issues considered

8 This decision will only consider the issues raised under Section 1(2) of the Act. As the search has not been completed, and consideration of compliance with other Sections of the Act has been deferred, I will need to remit the application back to the Examiner should I find in the applicant's favour.

The Law – Section 1(2)

9 The section of the Act concerning inventions excluded from patentability 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 –

...

(c) a scheme, rule or method for performing a mental act, playing a game or doing business or a program for a computer;

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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."

10 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. The Court of Appeal in *Aerotel/Macrossan*[1] set out the following four-step approach to help decide the issue:

1) Properly construe the claim;

2) Identify the actual (or alleged) 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.

11 The operation of the approach is explained at paragraphs 40-48 of the judgment. Paragraph 43 confirms that identification of the contribution is essentially a matter of determining what it is the inventor has really added to human knowledge, and involves looking at substance, not form. Paragraph 47 adds that a contribution which consists solely of excluded matter will not count as a technical contribution.

12 The case law on computer implemented inventions has been further elaborated in *AT&T/CVON*[2] which provided five helpful signposts to apply when considering whether a computer program makes a relevant technical contribution. In *HTC v Apple*[3], Lewison LJ reconsidered the fourth of these signposts and felt that it had been expressed too restrictively. The revised signposts are:

i) whether the claimed technical effect has a technical effect on a process which is carried on outside the computer;

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[1] Aerotel Ltd v Telco Holdings Ltd (and others) and Macrossan's Application [2006] EWCA Civ 1371

[2] AT&T Knowledge Ventures LP and CVON Innovations Limited v Comptroller General of Patents [2009] EWHC 343

[3] HTC v Apple [2013] EWCA Civ 451

ii) whether the claimed technical effect operates at the level of the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the applications being run;

iii) whether the claimed technical effect results in the computer being made to operate in a new way;

iv) whether the program make the computer a better computer in the sense of running more efficiently and effectively as a computer; and

v) whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented.

Application of the Aerotel Test

Step 1 - Properly construe the claim

13 Construing the claim does not present a major problem in this case. However, I note that where claim 10 states "*one of the similar clinical trial entries is stored in a first aggregated clinical trial entry…*", "one" should be construed as "only one". Lines 7 and 8 of page 18 suggest "*only one clinical trial entry is retained*". Furthermore, the storing of only one clinical trial entry in the first aggregated clinical trial entry would seem essential to the stated aim of substantially eliminating data redundancy (see lines 11 and 12 of page 10 of the description).

14 It is clear from the description (e.g. from line 2 of page 17 to line 2 of page 18) that two entries which are identical are classed as "similar" within the meaning of claim 1. It is less clear whether two entries with a similarity score of less than unity, but greater than a threshold, should also be regarded as falling within the scope of "similar". However, I don't believe that the precise scope of "similar" and "dissimilar" is essential to the identification of the contribution.

Step 2 - Identify the contribution

15 The next step of the Aerotel test is to identify the contribution. I identify the contribution, to be:

Extracting clinical trial data for a plurality of clinical trials from a plurality of existing data sources, aggregating the extracted data and reducing data redundancy where the clinical trial data is sufficiently similar.

Step 3 – Does the contribution fall solely within excluded subject matter

16 The third step of the *Aerotel* test involves asking whether the identified contribution falls solely within the excluded categories. The Examiner has objected that the invention should be excluded from patentability as a program for a computer as such and as a business method. I will consider each of these in turn.

i. Program for a computer

17 Clearly the invention is enacted by software running on a computer. In their letters the applicant argues that the invention meets the first AT&T signpost. They maintain that the contribution provides the technical effect of expediting drug development which, the applicant says, is obviously external to the computer system.

18 I'm afraid I do not agree. Although the aggregated data produced by the invention might well be useful for drug development, the *contribution* made by the invention is not a new drug, or even a formulation for a new drug, but merely a new way of amalgamating and presenting data from drugs trials. I can see no direct effect external to the computer from this.

19 The question of whether a drugs trial is "technical", as the applicant asserts, is not relevant because the contribution of the invention does not include the drugs trial itself. Furthermore, as the invention is not tethered to managing drugs trials, the applicant's suggestion that the aggregated data produced by the invention could be used to reduce the number of future trials is also not relevant. I conclude that the invention does not have a technical effect on a process carried on outside the computer and so it does not meet the first AT&T signpost.

20 I will now very briefly consider the other AT&T signposts. The contribution made by the invention is entirely reliant on the data being processed and it is not at the level of the computer's architecture. Thus, the second AT&T signpost is not satisfied. The invention uses a standard computer operating in a standard way. Thus, the computer itself is not being made to operate in a new way and neither is it being made to run more efficiently or effectively. Thus, neither the third nor fourth signposts are met. For the fifth signpost to be met, a technical problem must be solved. In this case, the problem solved is one of data aggregation, which is not technical for the purposes of section 1(2). The contribution therefore also fails the fifth signpost. I thus conclude that the contribution consists of no more than a program for a computer as such.

ii. Method of doing business

21 The examiner argued that the contribution of the invention is purely administrative and should therefore be excluded as a method of doing business. The applicant, on the other hand, argues that the invention should not be excluded because it would be impractical for a user to manually perform the invention. Irrespective of whether the invention could be performed by a user (or perhaps more realistically a large team of staff) it nevertheless relates to the mere aggregation of data. As such, it seems to me to be a purely administrative act. I therefore conclude that the contribution is excluded as being no more than a method of doing business where the business is compiling the results of medical trials.

Step 4 – Is the contribution technical in nature

22 The final step of the *Aerotel* test is to check whether the contribution is technical in nature. Since I have decided that the invention does not make a technical contribution beyond that of a program running on a computer, it also fails this step.

Decision

23 I have decided that the invention defined in independent claim 10 falls solely within matter excluded under Section 1(2) as a program for a computer and as a method of doing business, as such. Furthermore, independent claims 1 and 16 are also excluded from patentability, for the same reasons. Having reviewed the application, I do not consider that any saving amendment is possible. I therefore refuse this application under section 18(3).

Appeal

24 Any appeal must be lodged within 28 days after the date of this decision.

Dr Stephen Brown

Deputy Director, acting for the Comptroller