



PATENTS ACT 1977

APPLICANT Flatiron Health, Inc

ISSUE Whether application GB 1916451.6 complies with
Section 1(2) of the Patent Act 1977.

HEARING OFFICER Dr Stephen Brown

DECISION

Introduction

- 1 Patent Application GB 1916451.6 is the national phase of a PCT application published as WO 2018/191471 and has a filing date of 12th April 2018. It was subsequently republished as GB2575611 on 15th January 2020. The Examiner issued examination reports indicating that he considered the invention to be excluded under Section 1(2) of the Act. The applicant was unable to convince the Examiner that the application meets the requirements of Section 1(2) and requested a hearing to resolve this matter.
- 2 This took place on 24th June 2022 by video. The applicant was represented by Mr Nicholas Fox of Finnegan Europe LLP, to whom I would add my thanks for his skeleton arguments. My assistant, Dr John Cullen, was also present at the hearing.

The Application

- 3 The application concerns a model to automatically select a cohort of individuals, for participation in a medical trial, from a population of individuals.
- 4 Each individual has one or more medical records associated with them. The medical records include unstructured data which is not in a standardised format – patient notes for example. The unstructured data is searched for keywords or key phrases. Each time a keyword / key phrase is identified in the unstructured data a snippet of text surrounding the keyword / key phrase is extracted. The snippets are analysed, using natural language processing, to assign a score to each of one or more predetermined features. For example, a keyword searched for could be “metastatic”, and analysis of the snippets could lead to a score of “0” for the feature “metastatic” and “1” for the feature “not metastatic”. The scores need not be binary but could indicate frequency of occurrence. The features, and their respective scores are represented by a feature vector, which could be multi-dimensional. Fig. 3B,

reproduced below, provides an example of analysing unstructured text 360 to extract features and respective scores 370 (in Fig. 3B, the term “value” is used as a synonym for “score”).

- 5 For each individual, one or more feature vectors are derived and provided to a machine learning model which has been trained using medical information. The machine learning model provides an output for each individual. The output indicates whether an individual should be included in the cohort, or the likelihood the individual should be included. The model forms the first part of a two-step cohort selection process. Paragraph 23 of the description explains that the second step confirms cohort selection using another model, or a manual sorting procedure performed by a medical expert.

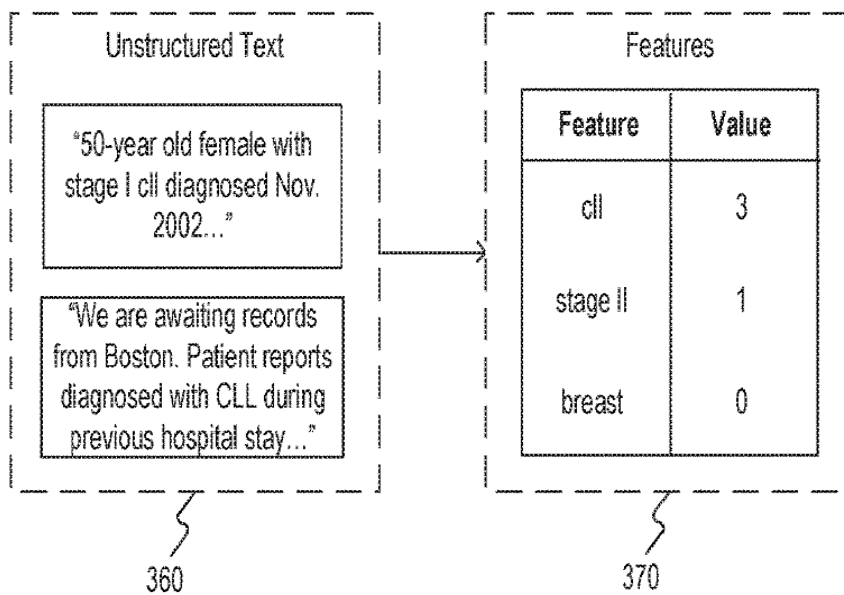


FIG. 3B

The Claims

- 6 The most recently amended claims were filed on 25 April 2022. Claim 1 of those is reproduced below:

A model-assisted selection system for identifying candidates for placement into a cohort, the system comprising:

a data interface; and

at least one processing device programmed to:

access, via the data interface, a database from which feature vectors associated with an individual from among a population of individuals can be

derived, wherein the database comprises electronic data representations of documents from an electronic medical record associated with the individual including both structured and unstructured data;

derive, for the individual, one or more feature vectors from the database by: uploading the plurality of electronic data representations via the data interface; and

searching the unstructured data of the plurality of electronic data representations for the presence of at least one term or phrase predetermined as associated with the cohort;

after identifying the at least one term or phrase as present in the plurality of electronic data representations, extracting a text grouping from the unstructured data of the plurality of electronic data representations, wherein the text grouping includes one or more words located in a vicinity of the identified term or phrase; and

generating the one or more feature vectors based on analysis of the identified term or phrase together with analysis of the extracted text grouping;

provide the one or more feature vectors to a machine learning model, wherein the machine learning model comprises a trained machine learning model which has been trained based on sets of structured and/or unstructured medical information;

receive an output from the model; and

determine whether the individual from among the population of individuals is a candidate for the cohort based on the output received from the model.

- 7 There is only one other independent claim, method claim 11. Claim 11 is sufficiently similar to claim 1 that I consider that it is enough to consider only claim 1. Claim 11 will stand or fall with my decision on claim 1.

The Law – Section 1(2)

- 8 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;

...

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.”

9 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.

10 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;
- 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.

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

Application of the Aerotel Test

Step 1 - Properly construe the claim

- 11 The first step of the Aerotel test is to construe the claims. Construing claim 1 does not present a major problem in this case as it is largely self-explanatory. However, it is worth clarifying that I understand “feature vector” to refer at least one pairing of a feature (such as “not metastatic” or “c11”, for example) and its respective score as determined from an analysis of text groupings, i.e. snippets. If multiple features are considered the feature vector will include multiple pairings.
- 12 I note that the final step of claim 1 is to determine whether an individual is merely a candidate for cohort selection. Claim 1 does not require that a final decision is made as to whether the candidate is selected. Furthermore, the final determining step of claim 1 is made by the programmed processing device. This would exclude the determining step from being performed in a manual sorting procedure by a medical expert. It therefore seems clear to me that the invention of claim 1 relates only to the first step 120 of the two-step cohort selection filter of figure 1.

Step 2 - Identify the contribution

- 13 The examiner considered the contribution to be:

“a computer program to select a cohort from a population by processing electronic data representations of medical records associated with individuals from the population, the processing involving generating feature vectors based on identification and analysis of a term or phrase and a text grouping in the vicinity of the term or phrase in the data representations of medical records for an individual, and processing the feature vectors using a trained machine learning model.”
- 14 Mr Fox discussed the prior art documents US2013/124224 and US2012/065987 cited in the examination reports. He argued that neither of these documents disclosed a machine learning model and that they were “a long way away from” the invention claimed here. This led him to the conclusion that the contribution was “all of the processing”. He defined the contribution as the data extraction, the feature identification, the vector creation and the processing by a machine learning model in the context of a two-step process in which the model is playing a role but is not the final element. Mr Fox was in-effect arguing that the contribution of the invention should be regarded as including at least the automated sifting stage of selecting candidates for a cohort, as defined in claim 1. It is not entirely clear whether he also considered the contribution to extend to the manual cohort confirmation stage as well. However, inclusion of this latter stage would seem at odds with Mr Fox’s opening remarks, in which he described the invention as providing a “rough-cut” to enable the whole group of potential members of a cohort to be brought down to a more manageable number.

15 I agree with Mr Fox that neither of the citations are relevant enough to influence the actual contribution. However, I cannot extend the contribution to include manual processing steps, which clearly fall outside the scope of claim 1.

16 Having taken account of the view of Mr Fox, I will consider the contribution to be:

A computer program to select candidates for a cohort from a population by processing medical records associated with the individuals to extract text groupings of words which are in the vicinity of predefined terms or phrases which occur in the medical records, analysing the text groupings to create at least one feature vector for each individual, the feature vector comprising one or more features associated with the terms or phrases and a score for each feature, and processing the feature vectors using a trained machine learning model.

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

i. Program for a computer

17 The third step of the *Aerotel* test involves asking whether the identified contribution falls solely within the excluded categories. Clearly the invention is enacted by software running on a computer but the relevant question is whether the identified contribution is solely a program for a computer, as such. The AT&T signposts can often help to answer this question.

18 Mr Fox argued that the invention meets the first AT&T signpost and referred to *Halliburton* to support his contention. In *Halliburton*⁴, Birss J held that “*the contribution is not solely a mathematical method (on top of being a computer program) because the data on which the mathematics is performed has been specified in the claim in such a way as to represent something concrete (a drill bit design etc.)*”. So, does the invention of the present application produce something as concrete and technical as the drill bit design of *Halliburton*? In my opinion, the answer to this is no. The computer program of the present application does not output anything as concrete as a formulation of a new drug, it merely outputs candidates for possible inclusion in a clinical trial which could be used in testing a drug.

19 In office decision O/814/21⁵ I considered whether an invention involving aggregating data from a plurality of clinical trials fell solely in excluded matter. I decided that the invention was excluded because the contribution was not a new drug but merely a new way of amalgamating data. The question of whether a drugs trial was “technical” was not considered relevant because the invention was not tethered to managing drugs trials. Similarly, although Mr Fox emphasised the drugs trial context of the invention, I do not consider the present invention to relate to a drug trial itself, but merely the selection of candidates who may be suitable for inclusion in a cohort for a drugs trial. Again, there is no need for me to decide whether a drugs trial is technical.

⁴ *Halliburton Energy Services Inc's Applications* [2012] RPC 129 at [72]

⁵ BL O/814/21, [Innoplexus AG]

However, I am sceptical a drugs trial could be considered “technical” or “concrete” in the same way as a drill bit design or a new drug.

- 20 Mr Fox also observed that the cohort selection method of the invention did not relate to mere automation of previous manual processes but was rather a completely new way of identifying candidates for cohorts. I agree with this point. Mr Fox went on to explain that the combination of the model of the invention with a later manual processing confirmation stage provided several advantages over the previous, purely manual methods. These included operating faster and more efficiently and producing a cohort of higher quality. Mr Fox argued that these advantages provide a technical effect outside of the computer. However, I do not agree that the generation of candidates for a cohort can be regarded as producing a technical effect outside of the computer. To me, the generation of such candidates relates to mere data processing which takes place entirely within the computer.
- 21 Mr Fox then sought to draw comparisons between the present invention and the Aerotel invention from *Aerotel/Macrossan*⁶. Aerotel concerned a telephone system for routing calls in a way which reduced call charges. Jacob LJ held that the Aerotel invention was more than just a method of doing business as such; it was a “new combination of hardware” which included a “special exchange”. I note, however, that the High Court⁷ later found the Aerotel patent to be excluded when it was shown that the only non-conventional part of the “special exchange” was the payment scheme, a business method. Mr Fox argued that the present invention involved a new combination of hardware, namely a data interface and a processing device. Although the processing device of the present invention may be programmed in a new way, I can see no evidence at the hardware level of anything non-conventional. Similarly I can see no non-conventional data interface. Furthermore, the way these hardware components are combined is also entirely conventional. I therefore do not see how *Aerotel/Macrossan* helps the applicants.
- 22 Mr Fox also referred to *Lenovo*⁸, which addressed the problem of “card clash”, encountered when multiple contactless payment devices (e.g. credit cards) are simultaneously presented to a reader. The invention of *Lenovo* automatically split payments between cards/accounts based on pre-set user preferences, thus avoiding the user having to press a selection button at the point of sale. Birss J observed that the key question to consider was whether the invention involved “*a different physical interaction with the world outside the computer, as compared to what had gone before*”. He held that obviating a button press provided a different physical interaction and therefore imbued the invention with technical character, meeting the requirements of Section 1(2). Mr Fox argued that as *Lenovo* related to making payments, it had more of a business method context than the present application. He described the avoidance of button pressing as a “downline benefit” and observed that this step was sufficient to escape the business method exclusion. He argued that the present invention provides analogous “downline benefits” in the form of an improved cohort and less manual processing. However, to me, the present invention provides no new **physical** interaction with the outside world. The pre-sifting provided

⁶ *Aerotel Ltd v Telco Holdings Ltd (and others) and Macrossan’s Application* [2006] EWCA Civ 1371 at [50]-[57]

⁷ *Aerotel Ltd v Wavecrest Group Enterprises Ltd & Ors* [2008] EWHC 1180 (Pat).

⁸ *Lenovo (Singapore) v. Comptroller General of Patents* [2020] EWHC 1706 (Pat)

by the invention may potentially reduce manual processing “downline” but, in my view, this does not amount to a new **physical** interaction with the outside world. The present invention does not provide a physical output, nor any data which leads directly to a physical output. I cannot identify any step in the invention which is equivalent to obviating a button press. The invention relates to a new machine-based pre-sift of a cohort, which sits firmly in the category of processing data. Thus, I conclude that the invention does not meet the first signpost.

23 Turning now to the fifth signpost, the problem being overcome is how to provide an initial sift of a cohort for use in medical trials. Mr Fox argued that this problem is not merely being circumvented. That may be well be the case, but, as I have explained above, I do not consider the problem to be a technical problem. Furthermore, the problem is solved in a non-technical way - running a computer program on a standard system. The fifth signpost does not apply.

24 Mr Fox did not address me on any of signposts two through four, and none of these signposts appear relevant to me. I am confident that the computer itself is not operating in any new way. Moreover, as I can see no technical effect outside of the signposts, I conclude that the invention is excluded under Section 1(2) as a computer program as such.

ii. Method of doing business

25 Having already found that claim 1 is excluded as a computer program, there is no real need for me to consider whether it is also excluded as a business method, but for the sake of completeness I shall briefly do so.

26 The examiner argued that the contribution of the invention relates solely to automation of an administrative task and therefore the invention should be excluded as a method of doing business. Mr Fox, on the other hand, maintains that the invention operates on technical data (medical records) and involves medical evaluation of whether potential members fulfil the requirements for cohort membership. However, irrespective of whether the data which is being processed could be said to be “technical”, the invention merely performs the administrative task of sifting data. It may be a task normally performed by trained medical staff, but it is an administrative task nonetheless. I therefore conclude that the contribution is also excluded as no more than a method of doing business, where the business is preparing data for use in medical trials.

Step 4: Is the contribution technical in nature

27 The final step of the *Aerotel*¹ test is to check whether the contribution is technical in nature. Since I have decided that it does not have a technical effect beyond that of a program running on a computer it also fails this step of the test. I thus decide that claims 1 is excluded under section 1(2).

- 28 The other independent claim, claim 11, is directed to similar subject matter as claim 1 and makes the same contribution. I therefore consider claim 11 to be excluded as a program for a computer and a business method as such for the same reasons. Moreover, none of the dependent claims provide the required technical contribution.

Decision

- 29 I have decided that the invention defined in the claims falls solely within matter excluded under Section 1(2) as a program for a computer and a business method as such. Having reviewed the application, I do not consider that any saving amendment is possible. I therefore refuse this application under Section 18(3).

Appeal

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

Dr Stephen Brown

Deputy Director, acting for the Comptroller