



## PATENTS ACT 1977

APPLICANT	Personalis Inc
ISSUE	Whether application GB 1607223.3 complies with Section 1(2) of the Patent Act 1977
HEARING OFFICER	Dr Stephen Brown

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### DECISION

#### Introduction

- 1 This decision concerns application GB 1607223.3 which was published as GB 2535066 on 10<sup>th</sup> August 2016. It is the national phase of WO 2015/051275 which takes its priority date of 3<sup>rd</sup> October 2013 from an earlier US priority application 61/886555.
- 2 There have been several rounds of correspondence but the applicant has been unable to persuade the Examiner that the application meets the requirements of Section 1(2) of the Act. As a consequence, the applicant has requested a decision on the papers to settle the issue.

#### The Current Status

- 3 It is helpful to briefly set out the stage the application has reached. In the normal course of an examination, an examiner would undertake a “top up” search in order to satisfy themselves concerning the novelty and inventive step of an application. In case however, as the examiner has raised an objection under Section 1(2) this has been deferred. The search is therefore considered incomplete.
- 4 While there have been several rounds of correspondence, for the purpose of this decision I will only consider the last few. On 22<sup>nd</sup> June 2021, the examiner issued an exam report with objections under Section 1(2) to excluded matter and Section 76 to added matter. At this point, the examiner also offered the applicant a Hearing.
- 5 The Applicants responded on 9<sup>th</sup> August 2021 with revised claims and observations.
- 6 The examiner then provided a further examination in the form of a “pre Hearing Report” on 20<sup>th</sup> August. This again set out objections under section 1(2) and section 76 of the Act.

- 7 The applicants responded on 3<sup>rd</sup> September 2021 with further revised claims and more observations. I will return to these observations later in this decision and I will take the these claims as the current set and base my decision on them.

## Section 20

- 8 The current Section 20 date is 10<sup>th</sup> October 2021. This is a result of the first examination of the application taking place on 10<sup>th</sup> June 2020 in which the compliance date was extended in accordance with Rule 30(2)(b). If I find in the applicant's favour, I will of course exercise my discretion in allowing for an extension of time to allow for the examination to be completed.

## Format of this Decision

- 9 Although there is an unresolved issue regarding added matter, I have, as will become apparent below, deferred consideration of this issue. Specifically, I do not believe that the question of added matter alters my assessment of excluded matter under Section 1(2), in this case.

## The Law

- 10 The section of the Act concerning inventions excluded from patentability is Section 1(2), which reads:

*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 purposes of this Act **only to the extent that a patent or application for a patent relates to that thing as such.***

- 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. The Court of Appeal in *Aerotel/Macrossan*<sup>1</sup> 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.*

12 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.

13 The case law on computer implemented inventions has been further elaborated in *AT&T/CVON*<sup>2</sup> which provided five helpful signposts to apply when considering whether a computer program makes a relevant technical contribution. In *HTC v Apple*<sup>3</sup>, 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.*

## **The Application**

14 The application is directed to a computer implemented method and related program that takes data relating to phenotypes of a subject, correlates these with one or more

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

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

<sup>3</sup> *HTC v Apple* [2013] EWCA Civ 451

genes stored in memory and ranks them according to the degree of association with the phenotype. Having identified the causative genes, it then looks for these in a genetic sequence of the subject and generates a numerical or graphical output.

## The Claims

- 15 The current claims on file are dated 3<sup>rd</sup> September 2021 and comprise two independent claims. The first claim, Claim 1, is directed to a computer implemented method and the second, Claim 36, to a computer programmable medium implementing the diagnostic method of claim 1. A copy of these claims are given in Annex 1 of this decision.

## The Applicant's Observations

- 16 As this is a decision on the papers, before I begin my analysis under Aerotel, I think will be helpful if I formally record the applicant's observations in connection with the examiner's excluded matter objection. They have argued:

*"The Examiner has not at any stage made an assessment of the contribution which the invention makes. No prior art document has been referred to that would allow assessment of the contribution, the problem resolved, and what has been added to human knowledge. The applicant has referred to the identification of genes in the context of diagnosis as well as the biological interactions between genes and phenotypes as evidence of the technical character of the invention.."*

- 17 The applicant then states:

*"The Aerotel/Macrossan test has therefore been carried out with no account being taken of:*

*How knowledge of the identity of the genes that relate to phenotype is helpful to diagnosis, and*

*The technical contribution made by recognition of the biological links between genes and phenotypes"*

- 18 The applicant then submits that

*"for a complex invention such as this, the prior art must be considered as part of the assessment of the contribution."*

They further argue that failure to do this would lead to the

*"danger of an arbitrary concept or feature being chosen as the contribution".*

- 19 They follow on to argue that the application has "technical character" and that I should defer any decision until the "inventive step" has been assessed".

- 20 Whilst, I understand their point of view, I think it is beholden on me to point out that the correct approach under UK law is to use the test set out in *Aerotel/Macrossan*<sup>1</sup>. This makes clear that the question is not one of “inventive step”, but rather one of whether the technical contribution made by an application lies in an excluded area or not. I will now begin my analysis on this basis.

## **Analysis**

### ***Construing the Claim***

- 21 The first step in *Aerotel* requires me to construe the claim. In this case, it is essential I do this as on the face of it, and as the applicants rightly point out, this could be viewed as a complex invention.
- 22 The applicants have very helpfully, in paragraphs 0030-0034 of the description, clearly defined what they mean by the terms ‘subject’, ‘phenotype’, ‘affected status’ and ‘ranking’ in the claims. I am happy to accept their definitions of these terms and so will not consider them any further here.
- 23 However, what I do need to do, is identify what is actually happening in the claim and give due consideration to that when construing it. More precisely, I need to consider the substance of the claim rather than its form. Specifically, the biological terms describe the relationship between the inputs and outputs of the system but not the mechanism by which the end result of generating a numeric or graphical output is achieved.
- 24 So what then is actually happening? Step a) is not difficult. The system receives data about a subject relating to a phenotype. In effect, it is a “trait” associated with the subject. It is my understanding that this can be viewed as an “ontology profile” for each subject. In effect, it may be a list of traits.
- 25 Step b) requires a little more understanding. It is a well established fact, as the applicants state that certain genes are associated or closely related to a given trait. What this step does is use that fact to identify those genes linked to the trait. Where that information may be found is not so clear but the specification at paragraph [0064] refers to “public and/or proprietary databases” and at paragraph [0065] provides a list of “public databases”. On this basis, I take this clause of the claim to mean that for each trait in the subjects “ontology profile” the program searches a database for relevant information about genes associated with that trait. In effect, the database is searched for matches to a specific criterion.
- 26 Once identified, the data is then stored in a memory and further processing takes place. This is the associating of the gene to the trait as causative (b)(i), neutral (b)(ii) or unlikely (b)(iii). The ways of associating a phenotype or trait and a gene are discussed in paragraphs 0066-0071. Put simply, the method decides how relevant to the trait the identified gene is.
- 27 The next step of the claim (c) is to use the program to rank the gene associations with the phenotype. This is covered in paragraph [0072] of the description. It is, as I understand it, a simple ranking by association score. The specification makes clear

that a high association score can rank a gene as highly likely to be causative for a given disease.

- 28 Step d) of the claim is, I believe, relatively simple to understand. The claim refers to it as “intersecting the one or more genes with the variants of the subject”. I understand this to mean that you look for the identified gene pattern in the subject’s genes or sequenced data.
- 29 The final step e) is simply a report from step d). It may simply be an annotated list as described in paragraph [0077].
- 30 On this basis, I believe that the claim can be construed as

*A method of looking up data (relating to a phenotype) in databases (of genes), identifying matches and ranking the matches by a score (indicating a suspected causative relationship or otherwise), and for each match searching the subjects genetic data for a match and reporting this to the user.*

### ***Assessing the actual or alleged Contribution***

- 31 The next step of the Aerotel test is to assess the actual or alleged contribution. In this case the search has not been completed and I am therefore restricted to identifying an alleged contribution.
- 32 The Examiner has identified the contribution as:
- “A computer program to rank a plurality of genes based on their association score with one or more phenotypes of a subject, and generate an output based on their ranking.”*
- 33 The applicants for their part argue that the examiner has “*not at any stage made an assessment of the contribution*” as they have not identified any prior art. As such, the applicants argue they have not taken into account the technical character of the invention. This can be summed up, I believe, by the comments I have reproduced at paragraphs 16-19 above.
- 34 For their part the applicants assert that the technical contribution is “*the recognition of the biological links between genes and phenotypes.*”
- 35 I have no doubt that the application relates to technical information about phenotypes and genes. However, there are two key points to take into account. Firstly, I firmly believe that the skilled person would be well aware that certain genes are associated with certain diseases. By way of example, it is well known that the BRCA1 and BRCA2 genes are associated with breast cancer. Thus the mere act of making such associations cannot form part of the contribution.
- 36 Secondly, the applicants’ argument about technical character is about the nature of the information being processed rather than the mechanism by which the invention works. In effect, although the applicants may try to explain their application in terms of the nature of the information it is processing, that is exactly what it is - information

and the crux of the application lies in how you process that information and not, I believe, in its nature.

- 37 In this regard, I will at this point refer to two IPO decisions brought up by the examiner in their examination reports, Forensic Science Services (BL 0/386/11) and Population Diagnostics (BL/022/12). Both instances involved searching and identifying relevant data where the data was related to DNA. In Forensic Science the claims were directed to a computer implemented method of searching databases of stored DNA profiles whilst in Population Diagnostics the claim was to a method of identifying a copy number of a variant in a genome for a given phenotype.
- 38 In Forensic Science, the hearing officer found that even though the data being searched was DNA data that was not part of the contribution. The contribution lay in the method of searching a database.
- 39 A similar view is expressed by the Hearing Officer in Population Diagnostics. In this instance the contribution was about the comparison step involving reference data to identify a phenotype. The Hearing Officer found that this wasn't the technical contribution as in effect that was a computer processing data. For these reasons the fact that the data is DNA data does not mean it is part of the contribution. While these two decisions are not binding on me, they are very similar on the facts and I see no good reason to deviate from their approaches.
- 40 What then is the contribution? The examiner is, I believe, close to the contribution, but has omitted one activity. Specifically, that is looking for the highest ranked genotype in the subjects sequenced data. I therefore believe the contribution to be:

*“a computer program to search relevant data and rank a plurality of genes based on their association score with one or more phenotypes of a subject, searching the subjects sequenced data for the ranked genes and generating an output based on this search.”*

### ***Does the Contribution lie in an excluded area?***

- 41 At its simplest expression, the contribution is a computer program that searches various data sets, compares and ranks relevant data and produces an output based on this activity. As explained above, I do not consider the nature of the data to form part of the contribution. On this basis, the contribution would appear to be excluded as a programme for a computer as such.
- 42 Normally, at this stage of a decision I would assess the contribution against the AT&T Signposts. These are recognised as guidance and not determinative although ultimately can be helpful in determining whether a contribution is a technical or not. However, as the applicants in their submissions have not offered any views on their applicability or otherwise, I don't believe it is necessary for me to do so.
- 43 I will though make one observation in respect of signpost 2. At no point in the specification has it ever been suggested that the computer used is anything other than a standard general purpose computer. Similarly, the application has focussed

on the data being processed so it clearly does not work at the level of the architecture of a computer. This leads to only one conclusion: the claimed invention works on a highly specific set of data and that is not, in my view, enough to establish a technical contribution. In the wording of the second signpost, it does not operate irrespective of the data being processed. If anything, it is the exact opposite and only works on a very narrow and specific type of data.

### ***Is the contribution technical in nature?***

- 44 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.

### **Conclusion**

- 45 I have decided that the invention defined in the independent claims falls solely within matter excluded under Section 1(2) as a program for a computer as such. Having reviewed the application, I do not consider that any saving amendments are possible. I therefore refuse the application under section 18(3).

### **Other Matters**

- 46 Having decided the application is excluded as a computer program, there is to my mind no merit in considering any other matters. The issue of added subject matter is one that often requires in depth analysis. In this case, I am of the view that it would have no effect on any contribution the claims might make and whether the application was excluded or not. As a result, I see no need to consider it further.
- 47 I note that claim 36 is directed to a “a diagnostic method”. Whenever, a diagnostic method is mentioned in an application Section 4 of the Act needs to be considered. However, it is my view that as I have decided that the application is excluded under Section 1(1), the issue of whether it is a diagnostic method or not is rendered moot.

### **Appeal**

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

### **Stephen Brown**

Deputy Director, acting for the Comptroller



## ANNEX 1 - CLAIMS

### **Claim 1**

1. A computer-implemented method, comprising:

(a) receiving data relating to one or more phenotypes of a subject or family members of the subject;

(b) generating an association score by:

generating, with the aid of a computer processor, a correlation between

(i) one or more genes

and

(ii) a given phenotype or associated clinical feature

among the one or more phenotypes or associated clinical features, to provide one or more sets of genes stored in a memory location and

designating each of the one or more sets of genes as

(i) likely to be a causative of a given phenotype or associated clinical feature among the one or more phenotypes if the given set of genes is associated with a plurality of search criteria correlated with the given phenotype or the associated clinical feature,

(ii) neutral if the given set of genes is not associated with any phenotype or clinical feature, or

(iii) unlikely to be causative of the given phenotype or clinical feature if the set of genes is associated with a plurality of phenotypes or associated clinical features that do not include the given phenotype or associated clinical feature;

(c) using a program led computer processor, ranking a plurality of genes based at least in part on their association score with the one or more phenotypes;

(d) intersecting the one or more sets of genes with the one or more variants of the subject or family members of the subject having a phenotype or associated clinical feature that is caused by, or IS suspected to be caused by, one or more genetic variants, wherein the one or more variants are identified using a genetic sequencing system;

and

(e) generating a numeric or graphical output with at least a subset of the plurality of genes ranked based on their association scores with the one or more phenotypes.

### **Claim 36**

36. A computer readable medium comprising executable code that, upon execution by one of more computer processors, implements a diagnostic method, the method comprising:-

(a) receiving data relating to one or more phenotypes of a subject or family members of the subject;

(b) generating an association score by:

generating a correlation between

- (i) one or more genes and
- (ii) a given phenotype or associated clinical feature among the one or more phenotypes or associated clinical features,

to provide one or more sets of genes stored in a memory location and

designating each of the one or more sets of genes as

- (i) likely to be a causative of a given phenotype or associated clinical feature among the one or more phenotypes if the given set of genes is associated with a plurality of search criteria correlated with the given phenotype or the associated clinical feature,
- (iii) neutral if the given set of genes is not associated with any phenotype or clinical feature, or
- (iv) unlikely to be causative of the given phenotype or clinical feature if the set of genes is associated with a plurality of phenotypes or associated clinical features that do not include the given phenotype or associated clinical feature;

(c) ranking a plurality of genes based at least in part on their association score with the one or more phenotypes;

(d) intersecting the one or more sets of genes with the one or more variants of the subject or family members of the subject having a phenotype or associated clinical feature that is caused by, or IS suspected to be caused by, one or more genetic variants, wherein the one or more variants are

identified using a genetic sequencing system;

and

(e) generating a numeric or graphical output with at least a subset of the plurality of genes ranked based on their association scores with the one or more phenotypes.