Intellectual Property Office

BL O/446/22

24 May 2022

PATENTS ACT 1977

APPLICANT	Perspectum Diagnostics Ltd
ISSUE	Section 4A: Methods of treatment or diagnosis
HEARING OFFICER	Peter Mason

DECISION

Introduction

1 This decision concerns patent application GB 2107140.2 entitled "Method for providing a quantitative volumetric assessment of organ health" in the name of Perspectum Diagnostics Ltd. and whether the invention as defined in the claims is excluded from patentability under Section 4A(1) of the Patents act 1977.

2 The application was filed 20th January 2017 and was divided from patent application number GB 1701005.9 which was granted 11th August 2021. The first examination report, issued 9th June 2021, set out an objection under Section 4A(1) of the Act. The applicant has made a number of submissions rebutting the Section 4A(1) objection but has been unable to persuade the examiner of the patentability of the claims. In their examination report dated 5th October 2021 the examiner offered the applicant a hearing. A further submission was received 15th October 2021, again the applicant was unable to persuade the examiner on the patentability of the claims. A prehearing report was issued 29th October 2021. On 11th February 2022 the applicant requested that a decision be made with respect to the papers on file and the applicant filed skeleton arguments 1st March 2022. I will therefore make a decision based on the papers available on file.

Preliminary matters

3 The only matter before me is whether the invention relates to a method of treatment or diagnosis and is consequently exempt from patentability. I note that the search is complete, and no other objections remain outstanding. Therefore, if I find the claimed invention allowable I will return the application to the examiner to conclude the examination process.

4 The Section 20 date was extended with a Patents Form 52, the appropriate fee and filed 9th July 2021. The extended Section 20 date expired on 20th November 2021. Therefore, there appears to be no recourse available if I find the main claim to be excluded. In light of this I have only considered the independent claim(s).

The Invention

5 The invention relates to analysing medical images, such as MRI images, in order to determine a volumetric map of organ health, aligning the derived map to an organ model by image registration, and calculating a viability measure, where the viability measure is provided as a visual indication on a display. The invention finds particular application in liver resection for treatment of primary liver cancers where the extent of liver surgery, generally, determines the risk of complications. Typically, a surgeon will leave at least one third of a healthy liver volume post resection however where the liver is in poor health a similar functional liver remnant (FLR) may prove fatal. The invention can be used to inform a medical practitioner on the available extent of any surgical intervention based on the condition of the organ.

6 The claims have been amended since filing and are now presented, as filed 15th October 2021. There is a single independent claim that, [including my additional subdivision1.1 – 1.7], reads;

1.1 A method of displaying a visual indication of a liver viability measure providing a quantitative volumetric assessment of liver health; the method comprising:

1.2 obtaining a volumetric map of organ health generated from one or more MRI scan data sets, comprising information defining a state of tissue health across at least part of the liver and aligning the volumetric map of organ health to a functional model by an image registration,

1.3 displaying a graphical representation of the functional organ model to the user,

1.4 receiving an input from the user defining at least one organ section in relation to the displayed graphical representation, said section relating to a part of a functional section defined by a functional organ model,

1.5 determining an assessment organ volume based at least partly on the at least one defined functional organ model section, where the assessment organ volume comprises one of the at least one defined organ section, and the remaining organ volume excluding the at least one defined organ section,

1.6 calculating a liver-viability measure for the assessment organ volume based at least partly on information within the volumetric map defining the state of tissue health across the organ volume, and

1.7 outputting a visual indication of the liver-viability measure to a display.

The Law

7 The examiner raised an objection under Section 4A of the Act that the invention is not patentable because it relates to a method of treatment or diagnosis. The relevant provisions of this section of the Act are shown below:

> *A patent shall not be granted for the invention of-*
>
> > *(a) a method of treatment of the human or animal body by surgery or therapy, or*
> >
> > *(b) a method of diagnosis practised on the human or animal body.*

8 The scope of the term “diagnostic methods practised on the human or animal body” within the meaning of Article 53(c) EPC (equivalent to section 4A(1)) is discussed by the EPO Enlarged Board of Appeal decision in G 01/04 Diagnostic Methods [2006] 5 OJEPO 334, [2006] EPOR 15[1]. The Enlarged Board refers to the following point of law;

> *1. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:*
>
> *(i) the diagnosis for curative purposes stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise,*
>
> *(ii) the preceding steps which are constitutive for making that diagnosis, and*
>
> ***(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.****[my emphasis added]*

The Enlarged Board additionally states;

> *From the very wording of Article 52(4) EPC in respect of diagnostic methods it already follows that the various method steps of a technical nature (cf. point 6.4.1 above) relating to such a method are basically meant to be performed on the human or animal body,* ***implying an interaction with the latter, rather than in vitro****. Since a narrow interpretation of the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods is equitable (cf. point 6.1 above), it is thus justified to require that all method steps of a technical nature of such a method should satisfy the criterion "practised on the human or animal body", i.e.* ***the performance of each and every one of these steps should imply an interaction with the human or animal body, necessitating the presence of the latter*** *(cf. point 6.4.2 above). This is true all the more as a broad interpretation of that criterion, to the effect that only one single method step of the diagnostic method needs to be performed on the human or animal body, which may or may not be the step that constitutes an essential diagnostic activity (cf. paragraphs II.(xi) and II.(xii) above), would contravene the overriding principle of legal certainty for the reasons already indicated under points 6.1, 6.2.3 and 6.3 above. [my emphasis added]*

9 Typically, the process of diagnosis involves a number of steps leading towards identification of a condition. The Enlarged Board characterised these steps as being;

(i) the examination phase involving the collection of data

(ii) the comparison of these data with standard values,

[1] G01/04 Diagnostic Methods [2006] 5 OJEPO 334, [2006] EPOR 15

(iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and

(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase

10 The Enlarged Board held that for a claim to fall under this prohibition, it must include both the deductive step of making the diagnosis (step iv) and the preceding steps constructive for making that diagnosis involving specific interactions of a technical nature with the human or animal body. The exclusion is therefore a narrow one, and also requires all the method steps of a technical nature to be practised on the body.

Arguments and analysis

Step (i): the examination and collection of data

11 The examiner asserts that step (i) is provided by element 1.2 of claim 1 which reads*; "obtaining a volumetric map of organ health generated from one or more MRI scan data sets"*. Here, the examiner argues that in order to process any MRI dataset then an MRI scan will have been necessarily performed (at some point in time) on the person being assessed. However, it would be amiss for me to ignore the examiners comments in the pre-hearing report concerning step (i), which reads;

> *However, I would encourage you to consider this issue when formulating any further response, as there may be a question of whether the obtaining step of your method does indeed involve specific interactions of a technical nature with the human or animal body, given that the method could be construed as being applied to "pre-existing" data.*

12 Here it seems that there is some uncertainty from the examiner whether there is indeed some interaction with the human in the method.

13 The applicant, with respect to step (i); states

> *Concerning step (i), of the test outlined above, claim 1 requires obtaining a volumetric map from one or more MRI data scan sets.* ***Whilst this is a step related to the collection of data****, we do not agree that this step requires any examination of the data. Therefore, amended claim 1 does not even satisfy step (i) of the steps required for a method of diagnosis. [my emphasis added]*

It is not clear whether the applicant, when stating 'Whilst this step…" is referring to step (i) of the steps set out by the EPO Enlarged Board of Appeal decision in G 01/04 or the first step of the claim as set out in feature 1.2. It seems likely the applicant meant the latter. Therefore, it appears that the applicant acknowledges that feature 1.2 of claim 1 relates to the collection of data and further argues that the data is not examined as such, and therefore does not satisfy step (i). However, step (i) relates to the examination of a human or animal body which includes collection of data from the subject, rather than relating to the examination of any data collected during the examination. Therefore, the applicant's comments in regard to the *'examination'* do not appear to be pertinent to step (i); I have therefore set aside this particular argument.

14 That said, the applicant's affirmation that feature 1.2 of claim 1 includes the collection of data requires some attention. The claim relates to obtaining a volumetric map from an MRI scan data set, the claim does not explicitly include a step of obtaining an MRI data set from a patient. Therefore, particularly in light of the applicants' assertions, I am led to the description to identify whether collection of MRI scan data from the subject is implied or is otherwise an essential method step of the invention.

15 The application discusses the method of generating a volumetric map of organ health in detail with respect to figure 4. The application discusses the use of voxels within one or more MRI scan datasets but is apparently silent with respect to how that MRI dataset is obtained. Furthermore, I am unable to identify any disclosure that teaches the reader that the collection of MRI scan data is intended to be included in the process of obtaining a volumetric map. Therefore, collection of the MRI dataset cannot be implied as an essential method step of the invention. It is my understanding that the invention is not intended to include any collection of the MRI data and is restricted only to the manipulation of that data to produce an output. Consequently, none of the steps of the invention are performed via interaction with the human or animal body.

16 I sympathise with the examiners position that in order to perform any analysis on a dataset relating to MRI scan data then some MRI scan must first be performed via some interaction with the human body. However, in EPO Enlarged Board of Appeal decision in G 01/04 there is a clear distinction between methods which are performed on the human or animal body, implying an interaction with the latter, and other methods that are performed *in vitro* in a laboratory for example.

17 Therefore, I am required to take a narrow interpretation of the scope of this exclusion in this respect and whilst some previous interaction with a human or animal body is inevitable, the method steps do not include, in their scope, this interaction. The method steps are therefore not practiced on the body; they are practiced on a data set.

Conclusion

18 I have found that the contribution made by the invention defined by the claims is not excluded under Section 4(A). I therefore remit the case to the examiner so that the examination can be concluded.

Peter Mason

Deputy Director, acting for the Comptroller