Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 28 October 2021

Case Number: T 2103/18 - 3.2.08

Application Number: 12718390.3

Publication Number: 2699142

IPC: A61B1/00, A61B5/00

Language of the proceedings: EN

Title of invention:
CLASSIFICATION OF TUMOR TISSUE WITH A PERSONALIZED THRESHOLD

Applicant:
Koninklijke Philips N.V.

Headword:

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2103/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 28 October 2021

Appellant: (Applicant)	Koninklijke Philips N.V. High Tech Campus 52 5656 AG Eindhoven (NL)
Representative:	Philips Intellectual Property & Standards High Tech Campus 5 5656 AE Eindhoven (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 9 April 2018 refusing European patent application No. 12718390.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	P. Acton
Members:	A. Björklund
	Y. Podbielski

Summary of Facts and Submissions

I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the patent application in suit (hereinafter "the application").

The examining division decided *inter alia*that the subject-matter of claim 1 of the then valid main, and first to eight auxiliary requests did not comply with Article 84 EPC.

II. Oral proceedings were held before the Board on 28 October 2021.

III. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with the grounds of appeal, or on the basis of the 1st auxiliary request filed with the grounds of appeal, or on the basis of one of auxiliary requests II-VII filed with letter dated 15 October 2021, or on the basis of one of the 2nd to 7th auxiliary requests filed with the grounds of appeal.

IV. Claim 1 of the **main request**, with feature designations added by the Board, reads as follows:

A "A system for obtaining at least one threshold for the discrimination among different tissue types, the system comprising:

B - an optical probe (130) arranged for guiding light from a console (110) to one or more

positions in a tissue of a first type in an individual patient and vice versa, wherein the console (110) comprises a spectrometer device (116) for obtaining spectroscopic measurements at the one or more positions in the tissue of the first type; and

C - the console (110), wherein the console (110) is arranged for defining data points, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a first threshold for the cloud of data points belonging to this first tissue type class,

D - wherein the optical probe (130) is further arranged for guiding light from the console (110) to further positions in the tissue of the individual patient and vice versa, in order to obtain further spectroscopic measurements at further positions in the tissue; and

E - wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements."

Claim 1 of the **first auxiliary** request differs from claim 1 of the main request in features C and D. Additions are underlined and deletions struck through.

Amended feature C reads:

"- the console (110), wherein the console (110) is arranged for defining datapoints, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a personalized first threshold for the cloud of data points belonging to this first tissue type class,"

Amended feature D reads:

"- wherein the optical probe (130) is further arranged for ~~guiding light from the console (110) to further positions in the tissue of the individual patient and vice versa, in order to~~ obtaining further spectroscopic measurements at further positions in the tissue; and"

Claim 1 of **auxiliary request II** differs from claim 1 of the first auxiliary request in features B, C and D.

Amended feature B reads:

"- an optical probe (130) arranged for guiding light from a console (110) to one or more positions in a tissue of a first type in an individual patient and vice versa, wherein the console (110) comprises a spectrometer device (116) for obtaining spectroscopic measurements, which are diffuse reflectance spectroscopic measurements, at the one or more positions in the tissue of the first type; and"

Amended feature C reads:

"- the console (110), wherein the console (110) is arranged for defining data points in a score plot of a multivariate statistical analysis, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a personalized first threshold for the cloud of data points belonging to this first tissue type class,"

Amended feature D reads:

"- wherein the optical probe (130) is further arranged for obtaining further spectroscopic measurements, which are diffuse reflectance spectroscopic measurements, at further positions in the tissue;"

Claim 1 of **auxiliary request III** differs from claim 1 of auxiliary request II in feature C which reads:

"- the console (110), wherein the console (110) is arranged for defining datapoints in a score plot of a multivariate statistical analysis, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a personalized first threshold for the cloud of data points belonging to this first tissue type class, wherein the first threshold is defined relative to the first tissue type class formed by the cloud of data points,"

Claim 1 of **auxiliary request IV** differs from claim 1 of auxiliary request III in feature C which reads:

"- the console (110), wherein the console (110) is arranged for defining datapoints in a score plot of a multivariate statistical analysis, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a personalized first threshold for the cloud of data points belonging to this first tissue type class, wherein the first threshold is defined relative to the first tissue type class formed by the cloud of data points and wherein a priori knowledge on the predetermined spectral characteristics of the tissue of the first type is used to define the first threshold for the cloud of data points belonging to the first tissue type class,"

Claim 1 of **auxiliary request V** differs from claim 1 of auxiliary request IV in feature B which reads:

"- an optical probe (130) arranged for guiding light from a console (110) to one or more positions in a tissue of a first type, which is normal breast tissue, in an individual patient and vice versa, wherein the console (110) comprises a spectrometer device (116) for obtaining spectroscopic measurements, which are diffuse reflectance spectroscopic measurements, at the one or more positions in the tissue of the first type; and"

Claim 1 of **auxiliary request VI** differs from claim 1 of auxiliary request IV in feature E which reads:

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the first tissue type class relates to fat or gland breast tissue and the second tissue type class relates to adenocarcinoma or ductal carcinoma in situ breast tissue."

Claim 1 of **auxiliary request VII** differs from claim 1 of auxiliary request VI in feature C which reads:

"- the console (110), wherein the console (110) is arranged for defining datapoints in a partial least squares discriminant analysis (PLS-DA) score plot ~~of a multivariate statistical analysis~~, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a personalized first threshold for the cloud of data points belonging to this first tissue type class, wherein the first threshold is defined relative to the first tissue type class formed by the cloud of data points and wherein a priori knowledge on the predetermined spectral characteristics of the tissue of the first type is used to define the first threshold for the cloud of data points belonging to the first tissue type class,"

Claim 1 of the **second auxiliary request** differs from claim 1 of the first auxiliary request in feature E which reads:

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the console (110) is arranged for recognizing data points of the second tissue type class from the shape of a plot of data points."

Claim 1 of the **third auxiliary request** differs from claim 1 of the second auxiliary request in feature E which reads:

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the console (110) is arranged for recognizing data points of the second tissue type class from the shape of a score plot of a multivariate statistical analysis ~~plot of data points~~."

Claim 1 of the **fourth auxiliary request** differs from claim 1 of the third auxiliary request in feature E which reads:

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the console (110) is arranged for recognizing data points of the second tissue type class from the shape of a

score plot of ~~a multivariate statistical analysis~~ partial least squares discriminant analysis (PLS-DA) predictions."

Claim 1 of the **fifth auxiliary request** differs from claim 1 of the fourth auxiliary request in feature E which reads:.

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the console (110) is arranged for recognizing data points of the second tissue type class from the shape of a score plot of partial least squares discriminant analysis (PLS-DA) predictions, wherein the first tissue type class relates to fat or gland tissue and the second tissue type class relates to adenocarcinoma or ductal carcinoma in situ tissue."

Claim 1 of the **sixth auxiliary request** differs from claim 1 of the second auxiliary request in feature E which reads:

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the console (110) is arranged for recognizing data points of the second tissue type class from the shape of a plot of data points, wherein the console (110) is arranged for defining a third tissue type class and

using the orientation of a triangle defined by data points of the three tissue type classes to assign a tissue type to the second and third tissue type classes."

Claim 1 of the **seventh auxiliary request** differs from claim 1 of the fifth auxiliary request in feature E which reads:

"- wherein the console (110) is further arranged for testing whether the further spectroscopic measurements fall outside the first threshold and if this is the case defining a second tissue type class on the basis of the further spectroscopic measurements, wherein the console (110) is arranged for recognizing data points of the second tissue type class from the shape of a score plot of partial least squares discriminant analysis (PLS-DA) predictions, wherein the first tissue type class relates to fat or gland tissue and the second tissue type class relates to adenocarcinoma or ductal carcinoma in situ tissue, wherein the console (110) is arranged for defining a third tissue type class and using the orientation of a triangle defined by data points of the three tissue type classes to assign a tissue type to the second and third tissue type classes."

V. The appellant's arguments can be summarised as follows:

The invention concerned the classification of tissue, in particular normal and cancerous breast tissue.

It belonged to the skilled person's knowledge how predetermined spectral characteristics of tissue from

fits in spectroscopic measurements could be used to form clouds of data points using PLS-DA or other multivariate statistical analysis. Over a larger population, there was a considerable amount of overlap between clouds of data points from various tissues, and it was thus difficult to set a threshold which could be used to reliably classify different tissues. This was represented in Figure 2 of the application.

However, looking at individual patients, the clouds of data points for different tissues were grouped much closer. The clouds for two different patients had e.g. different centers of gravity and spread or standard deviation as shown in Figures 3(a) and 3(b) of the application. These figures taught the skilled person that it was possible to set a reliable personalized threshold based on the measurements from the individual patient.

It belonged to the the skilled person's common general knowledge that the normal fatty breast tissue had a considerably higher amount of fat than cancerous tissue. Since the aim was to detect potentially cancerous cells, the skilled person knew that the threshold should be selected to be close to the cloud of data points belonging to normal fat tissue in order to minimise the risk of falsely negative classifications. It also belonged to their common general knowledge that the position of a cloud of data points relative to other clouds and the spread of the data points, or the standard deviation, within a cloud could be used as criteria for defining the threshold and further that the more data points were available, the closer to the cloud of data points a reliable threshold could be defined.

Finally, the skilled person was able to program a console in order to set a threshold according to these criteria.

The information in the application in combination with the skilled persons common general knowledge would thus enable the skilled person to carry out the claimed invention.

Reasons for the Decision

1. Article 83 EPC

1.1 Claim 1 of all requests on file define "A system for obtaining at least one threshold for the discrimination among different tissue types,..."

According to feature C of claim 1 of the main request, "the console [of the system] is arranged for defining data points, which form a cloud of data points, to form a first tissue type class on the basis of predetermined spectral characteristics from fits in the spectroscopic measurements, thereby defining a first threshold for the cloud of data points belonging to this first tissue type class,".

The core of the invention lies in the definition of the first threshold according to feature C.

1.2 It is not doubted that the skilled person can provide a console which is arranged for defining data points which form a cloud of data points as defined in feature C, based on their knowledge of spectroscopy and using multivariate statistical analysis, e.g. PLS-DA. Nor is

there any doubt that the skilled person is able to program the console accordingly.

1.3 The application is however completely silent as to which criteria the console should use when defining the first threshold for the cloud of data points belonging to the first tissue type class.

In particular, it is neither described that the threshold should be set close to the cloud of data points representing the first tissue when this is fat tissue, nor that the threshold could be based on the position of a cloud of data points relative to other clouds or the spread of the data points, or the standard deviation, within a cloud. A relation between the number of data points within a cloud and how close the threshold can be set to the cloud of data points is also not described.

The appellant asserts that these criteria would belong to the skilled person common general knowledge, but this assertion has not been substantiated.

1.4 The appellant submitted that Figures 3(a) and 3(b) would show the skilled person the possibility of setting suitable thresholds.

These figures show score plots of PLS-DA predictions of breast tissue classification of (ex vivo) breast tissue of two individual patients. According to the description page 7, lines 18 to 19, "*As an example, a simple threshold PLS-DA score 3 > 0.5 separates normal tissue (...) from adenocarcinoma*". Why this threshold was defined and according to which criteria it was defined is not described.

Furthermore, this threshold is not close to the cloud of data points representing the normal tissue but appears to be at the middle between the data points representing normal and malign tissues. This contradicts the appellant's assertion that the skilled person would select a threshold close to the cloud of data points representative of the first tissue based on their common general knowledge.

It is also noted that although the spread of the data points and the number of data points of the cloud of data points for fat tissue differs between the individual patients in Fig. 3(a) and 3(b), the same PLS-DA score 3 threshold has been defined for both patients. This does not corroborate the appellant's assertion that it would belong to the skilled person's common general knowledge to define the threshold on the basis of the spread of, or the number of data points within a cloud.

1.5 The application as a whole does thus not provide the skilled person with any teaching regarding the criteria which can be used for defining the first threshold for the cloud of data points belonging to the first tissue class, nor has it been substantiated that such criteria belong to the skilled person's common general knowledge.

Consequently, the application does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art as required by Article 83 EPC.

1.6 The lack of information to the skilled person regarding criteria which are usable to define a first threshold for the cloud of data points belonging to the first

tissue type class is a deficit of the application as a whole.

The amendments made to the claims of the auxiliary requests can therefore not overcome this fundamental deficiency.

1.7 It follows that none of the requests on file comply with the requirements of Article 83 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated