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Datasheet for the decision
of 18 May 2021

Case Number: T 1028/18 - 3.2.02

Application Number: 08745084.7

Publication Number: 2131733

IPC: A61B5/04

Language of the proceedings: EN

Title of invention:
SYSTEM AND METHOD FOR PAIN DETECTION AND COMPUTATION OF A PAIN
QUANTIFICATION INDEX

Applicant:
New York University

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84
RPBA 2020 Art. 11, 12(2)

Keyword:
Added subject-matter (no)
Clarity (yes)

Decisions cited:
T 0731/17

Catchword:

Case Number: T 1028/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 May 2021

Appellant: (Applicant)	New York University 650 First Avenue, 6th Floor New York, NY 10016 (US)
Representative:	Pfenning, Meinig & Partner mbB Patent- und Rechtsanwälte Joachimsthaler Straße 10-12 10719 Berlin (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 29 November 2017 refusing European patent application No. 08745084.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	M. Stern
	C. Schmidt

Summary of Facts and Submissions

I.   The applicant lodged an appeal against the decision of
the Examining Division refusing European patent
application No. 08 745 084.7 on the grounds that the
main request and auxiliary requests 1 to 9 then on file
did not meet the requirements of Article 123(2) EPC
and/or the clarity requirement of Article 84 EPC and
that auxiliary requests 10 and 11 then on file were not
admitted into the procedure under Rule 137(3) EPC. In
particular, the independent claims of auxiliary
request 9 then on file were held to satisfy the
requirements of Article 123(2) EPC, but not those of
clarity of Article 84 EPC.

II.   In a communication under Rule 100(2) EPC dated
24 February 2021, the Board informed the appellant that
independent claims 1 and 4 of the main request filed
with the statement of grounds of appeal contained a
feature which seemed to have no basis in the
application as filed, contrary to the requirements of
Article 123(2) EPC. The Board indicated, moreover, that
apart from this objection, claims 1 and 4 of the main
request were allowable under Articles 123(2) and 84
EPC.

III.   By letter dated 27 April 2021, the appellant filed an
amended main request indicating that, in order to
resolve the pending objection, the offending feature in
claims 1 and 4 of the former main request had been
cancelled.

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 letter dated

27 April 2021 or, in the alternative, on one of
auxiliary requests 1 to 6, all filed with letter dated
27 April 2021. If a grant of a patent before the Board
was not possible, remittal of the case to the Examining
Division was requested without holding oral proceedings
(page 2, penultimate paragraph; page 3, last
paragraph).

IV.   Independent claims 1 and 4 of the main request read as
       follows:

"1. A computer-implemented method for detecting pain in
a subject, comprising the steps of:
    comparing, using a processor, brain wave data
generated based on brain wave activity of the subject
to reference data to generate result data, the
reference data corresponding to at least one of
(i) population normative data indicative of brain wave
activity of a first plurality of individuals in an
absence of pain, (ii) population reference data
indicative of brain wave activity of a second plurality
of individuals generated in response to pain events
inflicted on the second plurality of individuals,
(iii) subjective population reference data indicative
of brain wave activity of a third plurality of
individuals reporting a sensation of pain, and
(iv) population of reference data indicative of brain
wave activity of a fourth population of individuals
following an intervention which has changed a
subjective report of pain; and
    wherein the reference data is a pain quantification
index including values corresponding to one of a
plurality of levels of pain and a plurality of types of
pain;

inputting, using the processor, the brain wave data into a first classifier function A indicating a probability that pain is being sensed;

determining, using the processor, a presence of pain experienced by the subject as a function of the result data; and

comparing the probability to the values in the pain quantification index."

"4. A device for detecting a pain sensation, comprising:

a receiving arrangement receiving electrical signals from a plurality of electroencephalogram (EEG) electrodes;

a processor generating brain wave data based on brain wave activity of a subject detected by the EEG electrodes;

a memory storing reference data corresponding to at least one of (i) population normative data indicative of brain wave activity of a first plurality of individuals in an absence of pain, (ii) population reference data indicative of brain wave activity of a second plurality of individuals generated in response to pain events inflicted on the individuals, (iii) self normative data indicative of brain wave activity of the subject in an absence of pain and (iv) subjective population reference data indicative of brain wave activity of a third plurality of individuals reporting a sensation of pain, wherein the processor compares the brain wave data to the reference data to generate result data,

wherein the reference data is a pain quantification index including values corresponding to one of a plurality of levels of pain and a plurality of types of pain, and

wherein the processor inputs the brain wave data
into a first classifier function A indicating a
probability that pain is being sensed,
    the processor determining a presence of pain in the
subject as a function of the result data,
    and the processor comparing the probability to the
values in the pain quantification index."

Reasons for the Decision

1.   The application relates to a method and a system for
       detecting, quantifying and imaging pain. The method
       comprises, in essence, the steps of extracting brain
       wave data (such as quantitative electroencephalographic
       features, or qEEG) from brain electrical activity
       recorded from electrodes located at standardized
       positions on the scalp and forehead of a subject,
       comparing the brain wave data to reference data to
       generate result data, and determining the presence and/
       or chronicity and/or intensity of pain experienced by
       the subject (see paragraph [16]).

2.   *Article 123(2) EPC*

2.1   Claim 1 is based on original claims 1, 2 and 4, further
       limited to a computer-implemented method in which the
       comparison of brain wave data to reference data and the
       determination of the presence of pain is performed
       using a processor. These limitations find a basis for
       instance in paragraph [41] of the application as
       originally filed.

       It is noted that the step in original claim 1 of
       generating brain wave data based on brain wave activity
       of the subject has been replaced in claim 1 by an

equivalent definition formulated in the passive form, as "brain wave data generated based on brain wave activity of the subject". Therefore, the originally defined step of generating brain wave data based on brain wave activity of the subject is encompassed by claim 1.

2.2   Independent device claim 4 is based mainly on original independent device claim 33 to which the same limitations stemming from original claims 2 and 4 and paragraph [41] were added.

2.3   As a consequence, independent claims 1 and 4 of the main request satisfy the requirements of Article 123(2) EPC.

3.   *Article 84 EPC*

3.1   In the appealed decision, it was held that independent claims 1 and 4 of auxiliary request 9 then on file did not satisfy the requirements Article 84 EPC, since the claims were considered to be unclear for the reasons given under point 39 referring to point 18.2 of the decision. The current main request corresponds to auxiliary request 9 underlying the decision wherein, however, following an objection raised by the Board, the comparison of brain wave data to "at least one source of reference data" in claims 1 and 4 was replaced by the comparison of brain wave data to "reference data", in accordance with original independent claims 1 and 33.

3.2   The Examining Division considered that independent claims 1 and 4 lacked clarity in the sense that the data flow was not clear (point 18.2). It was said (point 39) that in a first branch of the data flow,

result data was generated on the basis of brain wave data, and the result data was used to determine the presence of pain. According to another branch of data flow, brain wave data was input to a classifier function to obtain a probability that pain was sensed, and that probability was compared to values in a pain quantification index. That second branch did not contribute to the result of detecting pain in the subject.

The Board considers that, on the one hand, the Examining Division correctly summarised that the claims defined two ways, i.e., the two aforementioned "branches", how the generated brain waves were processed. On the other hand, however, the Examining Division did not explain why the flow of data was supposed to lack clarity, and the Board in fact sees no reason for this assertion. Moreover, the other aspect mentioned in the decision, that the second branch did not contribute to the result of detecting pain in the subject, is no reason either to conclude a lack of clarity. First, even if the second branch for processing the generated brain wave data would only produce intermediate results for detecting pain in a subject, this, by itself, would be no reason to consider that the claims were unclear. Far from that, the second processing branch is defined to obtain a probability that pain is sensed and to compare this probability to pain quantification indexes (PQI) corresponding to pain levels and types of pain (as explained in paragraph [43]). Hence, the second branch indeed constitutes an additional way for detecting pain in a subject.

3.3   The Board therefore comes to the conclusion that independent claims 1 and 4 of the main request satisfy the clarity requirement of Article 84 EPC.

4.   Since the impugned decision was only based on the grounds of Articles 123(2) and 84 EPC, the examination of all further legal requirements concerning the main request is still outstanding. The appellant requested remittal of the case to the Examining Division without holding oral proceedings if the grant of a patent before the Board was not possible (point III above).

        As held in T 731/17 (point 7.3 of the Reasons), not remitting the case to the Examining Division would require the Board to examine all further legal requirements in both first and last-instance proceedings and to effectively replace the Examining Division rather than review the contested decision in a judicial manner (Article 12(2) RPBA 2020). It follows that special reasons within the meaning of Article 11 RPBA 2020 present themselves.

        Hence, the Board remits the case to the Examining Division for further prosecution.

Order

For these reasons it is decided that:

1.   The decision under appeal is set aside.

2.   The case is remitted to the Examining Division for
       further prosecution.

The Registrar: The Chairman:

D. Hampe   M. Alvazzi Delfrate

Decision electronically authenticated