BESCHWERDEKAMMERN   BOARDS OF APPEAL OF   CHAMBRES DE RECOURS
DES EUROPÄISCHEN   THE EUROPEAN PATENT   DE L'OFFICE EUROPÉEN
PATENTAMTS   OFFICE   DES BREVETS

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

Datasheet for the decision
of 12 January 2021

Case Number: T 0434/18 - 3.5.05

Application Number: 10803688.0

Publication Number: 2517133

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
MANAGEMENT METHOD AND SYSTEM FOR IMPLEMENTATION, EXECUTION,
DATA COLLECTION, AND DATA ANALYSIS OF A STRUCTURED COLLECTION
PROCEDURE WHICH RUNS ON A COLLECTION DEVICE

Applicant:
Roche Diabetes Care GmbH
F. Hoffmann-La Roche AG

Headword:
Primary and secondary samples/ROCHE

Relevant legal provisions:
EPC Art. 84
RPBA 2020 Art. 13(2)

Keyword:
Claims - clarity (no)
Amendment after summons - cogent reasons (no)

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 0434/18 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 12 January 2021

Appellant:	Roche Diabetes Care GmbH
(Applicant 1)	Sandhofer Strasse 116
	68305 Mannheim (DE)

Appellant:	F. Hoffmann-La Roche AG
(Applicant 2)	Grenzacherstrasse 124
	4070 Basel (CH)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 27 October 2017 refusing European patent application No. 10803688.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	F. Blumer

Summary of Facts and Submissions

I.   The appeal is against the examining division's decision
        to refuse the application on the grounds that the main
        request and auxiliary requests I to VI did not meet the
        requirements of *inter alia* Article 84 EPC.

II.   With their statement setting out the grounds of appeal,
        the appellants withdrew auxiliary request VI and filed
        auxiliary request VII. They requested that the decision
        be set aside and that a patent be granted on the basis
        of the main request or auxiliary requests I to V or
        VII. They requested oral proceedings, argued a
        substantial procedural violation in the examination
        proceedings, due to the violation of their right to be
        heard, and requested that the case be remitted to the
        examining division.

III.   In its preliminary opinion issued in preparation for
        the oral proceedings, the board disagreed with the
        clarity objections in the contested decision, but
        raised, *inter alia*, other clarity objections of its own
        motion. The board saw no violation of the appellants'
        right to be heard or a substantial procedural violation
        in the examination proceedings which would have
        required the case to be remitted to the examining
        division.

IV.   In response to the summons to oral proceedings, the
        appellants filed arguments and maintained all their
        requests.

V.   Oral proceedings were held before the board. At the
        beginning of the oral proceedings, the appellants

withdrew their request for the case to be remitted to the examining division. They also filed auxiliary request VIII.

VI.   Claim 1 of the main request reads as follows:

"A method of performing a structured collection protocol by utilizing a collection device comprising a processor, wherein the method comprises:

-       collecting one or more sampling sets of biomarker data using the collection device, wherein each sampling set comprises a sufficient plurality of sampling instances recorded over a collection period, wherein each sampling instance comprises a biomarker reading;

-       determining compliance with adherence criteria for the sampling instances of the sampling set via the processor, wherein noncompliance with adherence criteria is recorded as an adherence event;

-       classifying sampling instances as primary samples or secondary samples via the processor, wherein

        o primary samples, which do not have corresponding recorded adherence events, are sampling instances utilized in calculations performed by the processor that yield therapy results for a diabetic person, and

        o secondary samples are sampling instances not utilized in calculations performed by the processor that yield therapy results for a diabetic person, unless one or more secondary samples, which do not have corresponding recorded adherence events, are promoted to primary samples; and

- performing via the processor at least one additional task if one or more sampling instances is a primary sample with a corresponding recorded adherence event wherein the one at least additional tasks preferably comprises collecting at least one additional primary sample."

VII. Claim 1 of auxiliary request I differs from claim 1 of the main request in that its last paragraph reads as follows:

"- performing via the processor at least one additional task if one or more sampling instances is a primary sample with a corresponding recorded adherence event wherein the at least one additional task comprises replacing via the processor one or more primary samples with corresponding recorded adherence events with one or more secondary samples if the secondary samples have no corresponding recorded adherence events in particular wherein the replacement of the primary samples is performed automatically via the processor."

VIII. Claim 1 of auxiliary request II differs from claim 1 of auxiliary request I in that its last paragraph reads as follows:

"- performing via the processor at least one additional task if one or more sampling instances is a primary sample with a corresponding recorded adherence event wherein the processor includes algorithms that calculate which additional task should be performed based on the contextual information for the sampling instances, the number of sampling instances, the

classification of the sampling instances, or the adherence of the sampling instances."

IX.   Claim 1 of auxiliary request III differs from claim 1 of the main request in that the following text was added to the end:

"wherein biomarker data are selected from blood glucose values, interstitial glucose values, or HbA1c values."

X.   Claim 1 of auxiliary requests IV and V differs from claim 1 of the main request and auxiliary request III, respectively, in that the following text was added to the end:

"wherein when replacing a primary sample with a secondary sample, the processor requires that the secondary sample comprises the same, substantially identical, partially identical or similar contextual information or metric as the primary sample to be replaced."

XI.   Claim 1 of auxiliary request VII differs from claim 1 of the main request in that the last paragraph was replaced with the following text:

"performing via the processor at least one additional task if one or more sampling instances is a primary sample with a corresponding recorded adherence event wherein the at least one additional task comprises replacing via the processor one or more primary samples with corresponding recorded adherence events with one or more secondary samples if the secondary samples have no corresponding recorded adherence events,

wherein biomarker data are selected from glucose values."

XII.   Claim 1 of auxiliary request VIII differs from claim 1 of auxiliary request VII in that the classifying step reads as follows:

"classifying sampling instances as primary samples or secondary samples via the processor,
        wherein primary samples are sampling instances intended to be utilized in calculations performed by the processor that yield therapy results for a diabetic person and are construed as critical events, which should not be missed when conducting the structured testing protocol; however, they can be replaced with secondary samples,
        wherein primary samples, which do not have corresponding recorded adherence events, are sampling instances utilized in the calculations performed by the processor that yield therapy results for the diabetic person, and
        wherein secondary samples are non-critical sampling instances not intended to be utilized in calculations performed by the processor that yield therapy results for the diabetic person and are not utilized in calculations performed by the processor that yield therapy results for the diabetic person, unless one or more secondary samples, which do not have corresponding recorded adherence events, are promoted to primary samples; and"

Reasons for the Decision

1.   Main request and auxiliary requests I to V and VII

1.1   The method in claim 1 of the main request and auxiliary
          requests I to V and VII classifies sampling instances
          of biomarker readings collected from a diabetic person
          as "primary samples" or "secondary samples"; however,
          it is entirely unclear what distinguishes a so-called
          "primary sample" from a so-called "secondary sample"
          and consequently on the basis of which rule the
          classification step of the claimed method is to be
          carried out.

1.2   The claim mentions two aspects of "primary samples" and
          "secondary samples", but fails to define them clearly
          and hence to distinguish them from each other.

          The first aspect is given by the relative clause "which
          do not have corresponding recorded adherence
          events" (wherein "adherence event" means noncompliance
          with adherence criteria), repeated identically for both
          primary and secondary samples. The appellants confirmed
          at the oral proceedings that this is not the definition
          of primary or secondary samples. Indeed, it follows
          from the next step ("performing ... an additional
          task") that there might also be one or more primary
          samples "with a corresponding recorded adherence
          event".

          The other aspect mentioned is the primary samples being
          "utilized in calculations performed by the processor
          that yield therapy results", but the secondary samples
          being "not utilized in calculations performed by the
          processor that yield therapy results"; however, since
          the claim also states that a secondary sample can be

"promoted" to a primary sample, it follows that a
secondary sample can also end up being "utilized in
calculations performed by the processor that yield
therapy results". Therefore, a so-called primary sample
and a so-called secondary sample are indistinguishable
by their nature.

1.3   The appellants cited several passages of the
       description, in particular paragraph [00250], and
       referred to different figures of the application, both
       in their written submissions and at the oral
       proceedings; however, what is in the description and
       the drawings but not in the claims cannot remedy the
       lack of clarity of unclear claims. Such submissions are
       therefore irrelevant to an objection under Article 84
       EPC.

1.4   At the oral proceedings, the appellants presented a use
       case to illustrate how the terms "primary sample",
       "secondary sample" and "tertiary sample", which is
       introduced later, in dependent claim 4, should be
       understood. An example set of rules for classifying
       sample instances in an example structured collection
       protocol was given as follows: primary sample "if there
       are several bG values on one day in the morning, the
       first one is used", secondary sample "if a first bG
       value in the morning turns out not to be a fasting
       value (> 8h fasting), the next measure bG value in the
       morning may be used that is a fasting value" and
       tertiary sample if "taken after 10 am"; however, the
       board cannot see how such a rule set may be derived
       from the claim wording. Claim 1 itself does not specify
       any classification rule. The appellants submitted that
       since there was a classifying step, it was implicit
       that there should be classification rules in claim 1.
       The claim was therefore broad, but not unclear. It was

unfair to expect the appellants to specify classification rules in the claim at the level of detail given in the example. It is not the appropriate level of generalisation of a clear classification rule that the board objects to, however, but the utter lack of any such rule. When a rule that is implicitly expected to exist is rendered as unclear as the classification rule in the present case, it is indeed no longer a rule.

1.5   Therefore, claim 1 of the main request and auxiliary requests I to V and VII is unclear (Article 84 EPC).

2.   Auxiliary request VIII

2.1   The appellants filed auxiliary request VIII during the oral proceedings before the board.

2.2   According to Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned. The underlying principle is that amendments filed at an advanced stage of the appeal proceedings are not to be taken into consideration. This principle is even more valid at the latest stage of the appeal proceedings, namely at oral proceedings.

2.3   The appellants submitted that the board had raised new clarity objections in its preliminary opinion other than those on which the contested decision was based. It was during the course of the discussion at the oral proceedings that the appellants became aware that further defining the terms "primary sample" and

"secondary sample" in accordance with paragraph [00250] of the description might address the board's objections.

2.4   The board did not raise its objection of lack of clarity to the terms "primary sample" and "secondary sample" at the oral proceedings, however, but rather in its preliminary opinion (see point 4.2.1 of the preliminary opinion). The relevance of paragraph [00250] to the interpretation of these terms did not only become apparent to the appellants at the oral proceedings, either (see the statement setting out the grounds of appeal, page 9, third paragraph; points 4.2.2 and 4.2.3 of the board's preliminary opinion; the appellants' letter of reply of 28 February 2020, page 5, third paragraph). Therefore, filing auxiliary request VIII at the oral proceedings is not justified with any cogent reasons.

2.5   For these reasons, auxiliary request VIII is not admitted into the proceedings.

3.   As none of the requests is allowable, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

A. Chavinier-Tomsic   A. Ritzka

Decision electronically authenticated