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**Datasheet for the decision
of 15 December 2020**

Case Number: T 1818/16 - 3.2.02

Application Number: 10179887.4

Publication Number: 2319403

IPC: A61B5/00, A61M5/172, A61B5/15,
B01L3/00, B01J19/00

Language of the proceedings: EN

Title of invention:
Analyte monitoring and drug delivery

Applicant:
Labrador Diagnostics LLC

Headword:

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 25(2)
EPC R. 137(3)
EPC Art. 113(2)

Keyword:

Admissibility of all requests (no) -
primary object of appeal proceedings to review decision -
appeal case directed to requests on which decision was based
(no)

Decisions cited:

G 0010/93

Catchword:



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Case Number: T 1818/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 December 2020

Appellant: Labrador Diagnostics LLC
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Representative: EIP
EIP Europe LLP
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 7 March 2016
refusing European patent application No.
10179887.4 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. 10 179 887.4.

In the decision it was held that the only request submitted by the applicant was inadmissible under Rule 137(3) EPC so that the application lacked an agreed text for the examination according to Article 113(2) EPC (points 8 and 12 of the reasons of the appealed decision).

II. The appellant requested in its statement of grounds of appeal dated 15 July 2016 that the decision under appeal be set aside and that the Board finds the main request, or any of auxiliary requests 1 to 8, to satisfy the requirements of Article 54 EPC and remits the application to the Examining Division for consideration of inventive step.

III. The Board issued summons to oral proceedings, dated 26 May 2020, indicating in an attached communication that, according to its provisional opinion, none of the requests appeared to be admissible (Article 12(4) RPBA 2007).

IV. The appellant did not reply to the Board's preliminary opinion. The appellant only announced, by letter dated 10 December 2020, that it would not be attending the oral proceedings. By communication dated 14 December 2020, oral proceedings were cancelled.

V. Claim 1 of the **main request** reads as follows:

"1. An ingestible medical device comprising:

- a) a microarray 4 comprising a plurality of test sites arranged on a surface that permits many tests to be performed in parallel, each site comprising affixed thereto a polypeptide bioactive agent capable of interacting with a disease marker biological analyte, wherein the microarray is able to simultaneously process a plurality of different tests and provide for the interaction of one or more said bioactive agents with one or more said biological analytes;
- b) a reservoir 10 comprising a therapeutic agent;
- c) a microchip comprising:
 - (i) an optical microarray scanning device 7 that is configured to optically detect signals from a plurality of test sites, wherein the signals are indicative of a physical parameter representing an interaction at said plurality of test sites between the disease marker biological analyte with said polypeptide bioactive agent;
 - (ii) a biometric recognition device 9 that is configured to compare said physical parameter data with an analyte interaction profile;
 - (iii) a therapeutic agent releasing device 10 that is configured to control release of said therapeutic agent from said reservoir; and
 - (iv) an interface device 8 that is configured to facilitate communications between said microarray scanning device and said biometric recognition device; and
- d) a biocompatible polymer coating 1, coated on said ingestible medical device."

In claim 1 of **auxiliary request 1**, feature (ii) of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"(ii) a biometric recognition device 9 that is configured to compare said physical parameter data with an analyte interaction profile stored either in the biometric recognition device or externally from the medical device;"

In claim 1 of **auxiliary request 2**, feature (ii) of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"(ii) a biometric recognition device 9 that is configured to analyse the physical parameter data collected by the microarray scanning device to determine the absence of biological analytes and presence of other biological analytes, and to compare said physical parameter data with an analyte interaction profile stored either in the biometric recognition device or externally from the medical device;"

In claim 1 of **auxiliary request 3**, feature (ii) of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"(ii) a biometric recognition device 9 that is configured to analyse the physical parameter data collected by the microarray scanning device to determine the presence, absence and quantity of the biological analytes and compare said physical parameter data with an analyte interaction profile stored either in the biometric recognition device or externally from the medical device;"

In claim 1 of **auxiliary request 4**, feature (d) of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"d) a biocompatible polymer coating 1, coated on said ingestible medical device, and wherein the medical device contains a compartment for the mixing of therapeutic agents prior to release."

In claim 1 of **auxiliary request 5**, the opening clause of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"1. An ingestible medical device configured to provide continuous diagnosis, the device comprising:"

In claim 1 of **auxiliary request 6**, feature (i) of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"(i) an optical microarray scanning device 7 that is configured to optically detect signals from a plurality of test sites, wherein the signals are indicative of a physical parameter representing an interaction at said plurality of test sites between the disease marker biological analyte with said polypeptide bioactive agent, and wherein the microarray scanning device comprises a total internal reflection fluorescence (TIRF) spectrometer;"

In claim 1 of **auxiliary request 7**, feature (d) of claim 1 of the main request has been replaced by the

following expression (amendments highlighted by the Board):

"d) a biocompatible polymer coating 1, coated on said ingestible medical device, and wherein the medical device further comprises a pump(s); pressurized microfluidic channels/lanes; and/or Personal Area Network transmitters 5, 6, directing the flow of bodily fluid into the device."

In claim 1 of **auxiliary request 8**, feature (d) of claim 1 of the main request has been replaced by the following expression (amendments highlighted by the Board):

"d) a biocompatible polymer coating 1, coated on said ingestible medical device, and wherein the microarray comprises microbeads."

Reasons for the Decision

1. During the oral proceedings before the Examining Division, the applicant filed a first main request (marked "9,05"), subsequently replaced it by a second main request (marked "10,15"), which in turn was subsequently replaced by a final, third main request (marked "10,45"; see points 4 and 7 of the reasons of the appealed decision).

The Examining Division refused the application holding that the latter main request, the single request eventually maintained by the applicant, was inadmissible under Rule 137(3) EPC so that the application lacked an agreed text for the examination

according to Article 113(2) EPC (points 8 and 12 of the reasons of the appealed decision).

2. *Admissibility of the appellant's requests*

2.1 With the statement of grounds of appeal, the appellant filed a main request and auxiliary requests 1 to 8 and provided reasons why these requests complied with the requirements of Articles 123(2), 76(1), 54 and 56 EPC. However, the Examining Division had been prevented from giving a reasoned decision on these matters since the applicant deliberately withdrew each of the requests considered in substance during the oral proceedings by replacing it with a new one.

2.2 By virtue of the transitional provisions of Article 25(2) RPBA 2020, for the present case Article 12(4) RPBA 2007 applies. It allows the Board to disregard requests which could have been presented or were not admitted in the first instance proceedings.

2.3 The present **main request and auxiliary request 1** correspond, respectively, to the first main request (marked "9,05") and the second main request (marked "10,15") filed during oral proceedings before the Examining Division. Each of these requests was replaced by a subsequent request, and thus withdrawn, so that the Examining Division was prevented from giving a reasoned substantial decision on them (points 1 to 6 of the reasons of the appealed decision reflect the discussion of the replaced requests during the oral proceedings).

Under these circumstances, in exercise of its discretion under Article 12(4) RPBA 2007, the Board does not allow to reintroduce in appeal those requests

that were withdrawn during the examination proceedings. Thus, the main request and auxiliary request 1 are not admitted into the appeal proceedings.

- 2.4 **Auxiliary request 2** corresponds to the final, third main request (marked "10,45") filed during oral proceedings which the Examining Division held inadmissible under Rule 137(3) EPC.

The appellant did not indicate in its statement of grounds of appeal, however, why it considered the decision not to admit this request under Rule 137(3) EPC to be wrong.

Thus, in the absence of any arguments from the appellant against the discretionary decision of the Examining Division holding auxiliary request 2 inadmissible, the Board does not admit this request into the proceedings, following Article 12(4) RPBA 2007.

- 2.5 **Auxiliary requests 3 to 8** were not filed in the first instance proceedings.

The appellant had numerous opportunities to present amended application documents during the examining proceedings, both during the written procedure (as summarised under points 4 and 5 of the Summary of Facts and Submissions of the appealed decision) and during the oral proceedings (see minutes). Thus, if the appellant intended the Board to consider these requests in appeal it only appears reasonable that they should have been filed in due time - and maintained - allowing the Examining Division to give a reasoned decision on them, in particular on the requirements of Articles 123(2), 76(1), 54 and 56 EPC addressed by the appellant

in its statement of grounds of appeal. Absent such a decision, to expect the Board to give a first ruling on these matters would be contrary to the primary purpose of appeal proceedings to review the decision under appeal in a judicial manner. It is established case law that proceedings before the boards of appeal are primarily concerned with examining the contested decision (G 10/93, OJ 1995, 172, point 4 of the Reasons). Appeal proceedings are intended to review the correctness of the decision of the first instance rather than to continue examination by other means.

Therefore, the Board does not admit auxiliary requests 3 to 8 into the appeal proceedings, following Article 12(4) RPBA 2007.

3. Since none of the requests is admissible, the appeal fails.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated