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# Datasheet for the decision of 22 July 2022

Case Number: T 0336/21 - 3.4.02

16707298.2 Application Number:

Publication Number: 3254082

G01N21/27, G01N21/64 IPC:

Language of the proceedings: ΕN

#### Title of invention:

METHODS AND SYSTEMS FOR PURE DYE INSTRUMENT NORMALIZATION

#### Applicant:

Life Technologies Corporation

Headword:

## Relevant legal provisions:

EPC Art. 84

#### Keyword:

Claims - clarity (no)

#### Decisions cited:

T 0728/98

## Catchword:



# 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 0336/21 - 3.4.02

DECISION
of Technical Board of Appeal 3.4.02
of 22 July 2022

Appellant: Life Technologies Corporation

(Applicant) 5823 Newton Drive

Carlsbad, CA 92008 (US)

Representative: Hoffmann Eitle

Patent- und Rechtsanwälte PartmbB

Arabellastraße 30 81925 München (DE)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 19 November 2020 refusing European patent application No. 16707298.2 pursuant to Article 97(2) EPC.

#### Composition of the Board:

Chairman R. Bekkering Members: C. Kallinger

B. Müller

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# Summary of Facts and Submissions

- I. The applicant lodged an appeal against the decision of the examining division refusing European patent application No. 16 707 298.2.
- II. The examining division held that the independent claims of the main and auxiliary request 1 were not clear (Article 84 EPC).
- III. With its statement of grounds of appeal the appellant requested that the examining division's decision be set aside and that a patent be granted on the basis of the main or the auxiliary request on which the appealed decision was based.
- IV. This decision refers to the following documents:
  - D5 WO 2008/003053 A2 D6 US 2007/0100569 A1
- V. In a communication pursuant to Article 15 (1) RPBA the appellant was informed about the board's unfavourable preliminary opinion with respect to Article 84 EPC.
- VI. In reply to this communication the appellant submitted further arguments supporting clarity of the claims.
- VII. Oral proceedings before the board were held on 22 July 2022.
- VIII. The appellant's final request were that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main

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request filed with a letter dated 21 May 2019 or the auxiliary request filed with a letter dated 2 October 2020.

- IX. Claim 1 of the main request (with the feature numbering as used by the appellant) reads as follows:
  - [1.1] A method (800) for normalizing laboratory instruments with pure dyes, comprising:
  - [1.2] providing at least one reference instrument
    (200) and a test instrument (200), each
    instrument comprising at least one excitation
    filter (214A) and at least one emission filter
    (216A) arranged in pairs;
  - [1.3] providing a plurality of pure dyes, each dye comprising a fluorescent component and contained in a pure dye plate comprising a plurality of wells;
  - [1.4] generating (805) fluorescent spectra from the reference instrument and the test instrument for multiple pure dyes across multiple filter combinations;
  - [1.5] creating (820) a pure dye matrix, Mref, for the reference instrument and a pure dye matrix, M, for the test instrument, the pure dye matrix for the reference instrument and the pure dye matrix for the test instrument respectively containing pure dye and filter combinations for the fluorescent spectra, wherein the fluorescent spectra obtained from the test instrument contribute to the pure dye matrix, M, for the test instrument and the fluorescent spectra obtained from the reference instrument contribute to the pure dye matrix, Mref, for the reference instrument;

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- [1.6] calculating (835) correction factors for each filter pair and multiplying the correction factors by the pure dye spectra resulting in corrected pure dye spectra, wherein the correction factor for each filter pair is the product of an emission filter factor and an excitation filter factor, and wherein adjustment factors for the correction factors are iteratively modified until the difference between the pure dye matrix M and the pure dye matrix Mref is minimized;
- [1.7] normalizing (845) the corrected pure dye spectra;
- [1.8] generating (850) multicomponent data, wherein the multicomponent data is the product of fluorescence data and an pseudo-inverse of the pure dye matrix M.
- X. Claim 1 of the auxiliary request (with the feature numbering as used by the appellant and the amendments with respect to the main request marked by underlining and strike-through) reads as follows:
  - [1.1] A method (800) for normalizing laboratory instruments with pure dyes, comprising:
  - [1.2] providing at least one reference instrument (200) and a test instrument (200), each instrument comprising at least one excitation filter (214A) and at least one emission filter (216A) arranged in pairs;
  - [1.3] providing a plurality of pure dyes, each <u>pure</u> dye <del>comprising a having only one fluorescent</del> component and contained in a pure dye plate comprising a plurality of wells;
  - [1.4] generating (805) fluorescent spectra from the reference instrument and the test instrument for

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- multiple pure dyes across multiple filter
  combinations;
- [1.5] creating (820) a pure dye matrix, Mref, for the reference instrument and a pure dye matrix, M, for the test instrument, the pure dye matrix for the reference instrument and the pure dye matrix for the test instrument respectively containing pure dye spectra for the pure dye and filter combinations for the generated fluorescent spectra, wherein the generated fluorescent spectra obtained from the test instrument are matrix contributionse to the pure dye matrix, M, for the test instrument and the fluorescent spectra obtained from the reference instrument are matrix contributionse to the pure dye matrix, Mref, for the reference instrument;
- [1.6] iteratively modifying and multiplying (830) adjustment factors with the pure dye matrix M for the instrument until the difference between the pure dye matrix M and the pure dye matrix Mref is minimized, whereby the pure dye matrix M is multiplied by a set of adjustment factors and compared to the pure dye matrix Mref; calculating (835) correction factors for each filter pair of the multiple filter combinations and multiplying the correction factors by the pure dye spectra resulting in corrected pure dye spectra in the pure dye matrix M, wherein the correction factor for each filter pair is the product of an emission filter factor and an excitation filter factor, and wherein adjustment factors for the correction factors are iteratively modified until the difference between the pure dye matrix M and the pure dye matrix Mref is minimized;

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- [1.7] normalizing (845) the corrected pure dye spectra in the pure dye matrix M to a maximum value of 1;
- [1.8] generating (850) multicomponent data, wherein the multicomponent data is the product of fluorescence data for dye mixtures having overlapping excitation and emission spectra and an pseudo-inverse of the pure dye matrix M.

#### Reasons for the Decision

- 1. Main request Clarity Article 84 EPC
- 1.1 The examining division held that independent claim 1 was not clear. In particular, in feature [1.8] the term "fluorescence data" was undefined, and, consequently, the step of "generating multicomponent data" was not clear.
- 1.2 The appellant explained how the features of claim 1 had to be interpreted and that in particular feature [1.8] was clear to the skilled person.

The appellant argued with reference to the Guidelines for Examination (Guidelines for Examination, March 2021, Part F IV.4.2.) that (i) each claim had to be read giving the words the meaning and scope which they normally had in the relevant art and (ii) that the claim had to be read with an attempt to make technical sense out of it.

The appellant argued that the skilled person fully and clearly understood feature [1.8] as it referred to the - as such - commonly known "multicomponenting". This was evidenced by documents D5 (see paragraphs [0026],

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[0028] and [0029]) and D6 (see paragraph [0031]), which were both cited in the international search report as "A-documents", i.e. documents defining the general state of the art. In this respect the appellant referred to decision T 728/98 in which the board considered documentary evidence in order to establish whether an unequivocal generally accepted meaning existed in the relevant art for a term in the claims.

Furthermore, even without the common general knowledge of the term "multicomponent data", feature [1.8] clearly defined how the "multicomponent data" was generated, i.e. as the product of fluorescence data and an pseudo-inverse of the pure dye matrix M. "Fluorescence data" itself was also clear, as the skilled person was aware that this data was obtained by a test instrument having excitation and emission filters, which itself was a standard biological instrument for the purpose of PCR applications. This was again evidenced e.g. by document D5 (see paragraph [0029]), which explained that "multicomponenting" involved the calculation of the contribution of each dye in a complex experimental spectrum, and might comprise a matrix multiplication of each measurement vector by the inverse of the calibration matrix.

1.3 The board is not convinced by the appellant's arguments for the following reasons.

With respect to the interpretation of the claims, the board notes that it is established case law that the claims must be clear in themselves when read by a person skilled in the art (see Case Law of the Boards of Appeal, 2019, II.A.3.1, Clarity of claims).

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In decision T 728/98, which was referred to by the appellant, the board held that a claim could not be considered clear if it comprised an unclear technical feature for which no unequivocal generally accepted meaning existed in the relevant art (see headnote, point 1). In order to establish whether the term "substantially pure" was clear, the board in that case consulted the document "US Pharmacopeia", a compendium of drug information establishing written standards used by regulatory agencies and manufacturers.

In the case in hand, the appellant argued that patent documents D5 and D6 showed that the terms "multicomponent data" and "fluorescence data" had a generally accepted meaning in the relevant art. This was in particular the case, as documents D5 and D6 were categorized as "A-documents" and therefore described the general state of the art.

The board disagrees.

According to established case law, common general knowledge is to be found in basic handbooks, monographs, encyclopaedias, textbooks and reference books (Case Law of the Boards of Appeal of the EPO, 9th edition 2019, section I.C.2.8.1). As the common general knowledge does not normally include patent literature (Case Law of the Boards of Appeal of the EPO, 9th edition 2019, section I.C.2.8.2), patent documents are generally not suitable to establish the generally accepted meaning in the relevant art of a specific term.

The board is of the opinion that the current case is not an exception to the above rule. The passages referred to by the appellant describe a "process called"

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multicomponenting" (see D5, paragraphs [0026] to [0029]) and a process "often referred to as multicomponenting" (see D6, paragraph [0031]). The board is of the opinion that such specific disclosures do not document the common general knowledge of the skilled person. This is in particular the case, as both documents D5 and D6 are from the same applicant.

The categorisation of documents D5 and D6 in the search report as "A-documents" indicates that these documents represent the state of the art. However, the state of the art is not common general knowledge per se.

The content of patent documents D5 and D6 is therefore not suitable to define the generally accepted meaning of the term "multicomponent data". As the board is also not aware of a commonly known definition of the term "multicomponent data", it comes to the conclusion that the term has no unequivocal generally accepted meaning in the relevant art.

Feature [1.8] itself defines "multicomponent data" as the product of fluorescence data and a pseudo-inverse of the pure dye matrix M. However, the term "fluorescent data" is vague and appears in feature [1.8] for the first time in the claim. For the reader it is therefore unclear, to what kind of fluorescent data the feature refers and how this fluorescent data has been generated.

The appellant's reference to patent document D5 is not suitable to define the term "fluorescent data" applying the above principles.

As it is not clear to what kind of data the feature refers and how this data has been generated, it follows

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that the definition of "multicomponent data" based on this term is unclear.

In conclusion, the term "multicomponent data" has no unequivocal generally accepted meaning in the relevant art and the definition given for this term in feature [1.8] is not clear either.

Consequently, independent claim 1 of the main request does not fulfil the requirements of Article 84 EPC.

2. Auxiliary request 1

Feature [1.8] of claim 1 of the auxiliary request has been amended as indicated below:

- [1.8] generating (850) multicomponent data, wherein the multicomponent data is the product of fluorescence data for dye mixtures having overlapping excitation and emission spectra and an pseudo-inverse of the pure dye matrix M.
- 2.1 The examining division held that independent claim 1 was not clear. In particular, in feature [1.8] the term "fluorescence data" was still undefined as the newly introduced feature did also not define what the "fluorescent data" actually was.
- 2.2 The appellant argued that feature [1.8] now clearly indicated what the fluorescent data was: in contrast to the pure dye spectra which were used for the calibration defined in the other features of claim 1, it concerned fluorescent data which was obtained for dye mixtures after the calibration.
- 2.3 The board is not convinced by the appellant's argument.

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The claim now further specifies that the "fluorescence data" stems from dye mixtures having overlapping excitation and emission spectra. However, the term "fluorescent data" itself is still vague and it is in particular not clear to what kind of data the term refers and how this data is obtained.

With respect to feature [1.8] of the auxiliary request the board therefore comes to the conclusion that the term "multicomponent data" as such is not clear, as, for the same reasons as those given above, the term itself has no unequivocal generally accepted meaning in the relevant art.

In addition, as it is not clear to what kind of data the feature "fluorescent data" refers and how this data has been generated, this term is also not clear, and, consequently, the definition for "multicomponent data" given in feature [1.8] is also not clear.

In conclusion, independent claim 1 of the auxiliary request does not fulfil the requirements of Article 84 EPC.

#### Order

## For these reasons it is decided that:

The appeal is dismissed.

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The Registrar:

The Chairman:



L. Gabor R. Bekkering

Decision electronically authenticated