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## Datasheet for the decision of 24 February 2012

T 1428/08 - 3.4.02 Case Number:

96928167.4 Application Number:

Publication Number: 850412

IPC: G01N27/447

Language of the proceedings: ΕN

#### Title of invention:

ELECTROPHORETIC SYSTEM INCLUDING MEANS FOR REPLACING SEPARATION MEDIUM

#### Applicant:

Beckman Coulter, Inc.

Headword:

#### Relevant legal provisions:

EPC Art. 123(2)

#### Keyword:

Claim 1 (Main Request) - Added Subject Matter(no)

Decisions cited:

#### Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T1428/08 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 24 February 2012

Appellant: Beckman Coulter, Inc. (Applicant) 250 S. Kraemer Boulevard

Brea, CA 92821 (ETATS-UNIS D'AMERIQUE)

Representative: Baldock, Sharon Claire

Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 12 February 2008

refusing European patent application No. 96928167.4 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: A. Klein Members: M. Rayner

B. Müller

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# Summary of Facts and Submissions

- I. The applicant has appealed against the decision of the examining division refusing European patent application number 96 928 167.4 (=WO-A-97/08545) concerning electrophoretic separation apparatus. Documents including the following have been referred to in the proceedings before the first instance:
  - Dl EP-A-0 607 495,
  - D2 EP-A-0 497 480.
- II. Claim 8 as originally filed was worded as follows:
  - " A method for delivering a viscous separation medium to one or more capillaries employing conduit means for supplying viscous separation medium to the one or more capillaries; comprising the steps of:
  - (a) delivering new viscous separation medium to displace old viscous separation medium in the conduit means; and
  - (b) delivering new viscous separation medium to said one or more capillaries through said conduit means."
- III. Amendments made during prosecution before the first instance included filing of claims 1 to 11 as main request with the applicant's letter dated 27 December 2007. Fresh description pages 2 to 4 were filed with the applicant's letter dated 28 May 2003 and page 5 with the letter dated 07 June 2006.
- IV. In point 3.3 of its communication dated 29 July 2002, the examining division objected that the term "viscous" is unclear in scope since it is not clear when a composition or solution is to be considered viscous or

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not viscous, that is, exactly where the border between the two conditions is.

V. In its letter dated 18 December 2007, the applicant made submissions including the following.

References to gel and separation medium are interchangeable as it is specifically stated at page 5, lines 1 to 3 of the specification as filed and published that "the invention is described below by reference to gel as a separation medium". Thus any reference to separation medium in the specification or claims can also be read as gel or vice versa (see page 5 of letter).

After a number of electrophoretic runs gel in capillaries (old gel) needs to be replaced and thus a filling procedure repeated. The present invention provides for an apparatus as defined in claim 1 in which the features in combination provide for an online system in which it is not necessary to break and reseal a capillary in order to fill.

The combination of features recited in claim 1 provides a first state in which replacement gel is delivered to capillaries which are then ready for use in electrophoretic separation of samples, a second state by which delivery of new gel purges the system of old gel and a third state in which the system can conduct electrophoresis and thereby provides separation of the sample, all without any need for removal of any capillary or breakage of the seal connecting any of the one or more capillaries. It is only the fact that the apparatus has the combination of all these features and is configured as recited in claim 1 that allows it to function in such a way. Document Dl is different in

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that its teaching is intended to prepare a gel in situ within a capillary. The apparatus provides for the delivery of a solution at high pressure into a capillary, and a switch over valve permits injection of a solution directly into the capillary in one setting, but injection of acrylamide plus polymerised agent via a side loop is brought into play by the switchable valve in a second setting. More importantly it is to be noted that the capillaries taught by document Dl are not refilled online as in the case of the present invention. Gelling of acrylamide does not occur in the flow channels during the feeding operation and a fresh capillary is prepared for every sample analysis. There is no disclosure of displacement/purging of used viscous gel from any capillary by injection of fresh viscous gel. Further, there is no provision of an electrophoretic separation apparatus having three states comprising replacement of gel or separation medium, purging of old gel or separation medium and electrophoresis. Document Dl clearly requires user intervention or manipulation of the capillaries after loading in order to set up electrophoresis, thus the capillary cannot be reloaded in an operational position but has to be dismantled from the filling apparatus and then subsequently installed in an electrophoretic apparatus. Hindsight analysis of the prior art is impermissible.

Document D2, whilst avoiding manipulation of the capillary by replacing the gel in a displacement manner from within the system, does not describe or teach any valving system but instead describes an inline system in which the capillary has been coated with an internal coating to avoid bonding of the gel to the capillary. This permits the gel's subsequent expulsion from the capillary and controls the gel composition to allow

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direct injection of the preformed gel into the capillary without shearing.

Therefore, the claims are directed to subject matter which is both novel and inventive in light of the prior art.

VI. The amended set of claims filed with the applicant's letter dated 18 December 2007 was not admitted by the examining division because the division considered that claim 1 thereof contained subject matter extending beyond the content of the application as filed. Consequently, there was no agreed text and the application had to be refused. The reasons given in relation to subject matter extending beyond the content of the application as filed can be summarised as follows.

Assessment of the application as filed leads to the conclusion of added subject to matter having regard to introduction of the term "gelintroduction means". In particular, the original application disclosed only a syringe and a pump system, respectively, as possible means for introducing the gel into the conduits of the apparatus whereas the term "gel introduction means" also covers further means like electrophoretic introduction means and gas pressure introduction means, respectively, for which no basis was apparent in the original application. In applying the modified novelty test in order to assess added subject to matter one would need to find unambiguous support in the original application for the subject to matter falling under the expression "introduction means" or "delivery means" other than syringe and pump system. The original application describes at various parts possible means to deliver/inject the gel medium, see for example page

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9, lines 1 to 3, page 10, lines 20, 21, page 11, lines 31 to 33, page 19 to 21 and page 17, lines 34 to 36, which all relate to a syringe or to a pump system. Consequently Article 123(2) EPC is not complied with. The same considerations as outlined above for the term "gel introduction means" also apply for the term "delivery means".

- VII. The appellant requested that the decision under appeal be set aside and a patent granted on the basis of the claims as filed on 18 December 2007 as main request or of claims as filed with the statement of grounds for appeal dated 12 June 2008 as auxiliary request.
- VIII. In support of its case, the appellant advanced arguments including the following.

The application as filed contains a broad basis for delivery of the separation medium without specifying how this is done. On this point, reference is made to claim 8 as filed which refers to "delivering new viscous separation medium" both in clause (a) and (b) of the claim. There is no suggestion that this delivering must be done by means of a pump or a syringe. Thus, claim 8 provides clear basis in the application as filed for broad reference to "delivery means".

Moreover, it is quite clear throughout the specification as filed that all that is important is to deliver the separation medium. The precise manner of delivery is clearly inconsequential to the invention. There is nothing to suggest that one particular delivery means is essential given that two different alternative delivery means (syringe and pump) are disclosed. The person skilled in the art would have no

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difficulty in understanding that anything which delivers the separation medium whether it be pump, syringe or some other device would be understood to be suitable.

- IX. Independent claim 1 according to the main request of the appellant is worded as follows.
  - "1. Electrophoretic separation apparatus comprising at least one separation capillary (16,16',18) capable of receiving a sample to be tested, said capillary (16,16',18) having a sample inlet and an outlet end, said apparatus further comprising delivery means (30,102) operable to deliver separation medium to said capillary (16,16',18) via a sample outlet end thereof and to a connector (T1,T2,U1), wherein the capillary (16,16,18) is in sealable communication at a sample outlet end thereof with the connector (T1,T2,U1); and a valving system operable between a first state in which separation medium is directed via the connector (T1,T2, U1) to said capillary (16,16',18) to provide separation medium replacement therein; a second state in which separation medium is directed to the connector (T1) such that same is purged of old separation medium, the apparatus further comprises means for applying an electrical current between said input and output ends of the capillary (16,16',18), and wherein the valving system is operable to provide a third state in which the system is capable of electrophoresis whereby the sample is electrophoretically separated in said capillary (16,16',18) by application of the electrical current. "

It is not necessary for the present decision to give the wording of claim 1 according to the auxiliary

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request in the light of section 4 of the Reasons for the Decision set out below.

#### Reasons for the Decision

- 1. The appeal is admissible.
- 2. Amendment
- 2.1 The appellant is correct in arguing that claim 8 as originally filed was not limited to how delivery is done. It is a method claim, but it needs a means to be carried out. Therefore, the board is satisfied that "delivery means" without limitation to a pump or syringe was disclosed in the documents as filed.

  Moreover, consistent with the appellant's position, the description does not render a pump or syringe essential.
- 2.2 Claim 1, in contrast with claims as originally filed, no longer includes the word "viscous", which the examining division did not consider clear. However, not only does the skilled person know what a separation medium is, but the appellant has also declared during the examination proceedings that any reference to separation medium in the specification or claims can also be read as gel or vice versa. Accordingly, since, amongst other things, a gel is viscous, whatever the merits of the objection of the examining division in respect of the word viscous, the understanding of the skilled person has not been changed consequent to the division's objection so as to make the claim extend beyond the application as originally filed.

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2.3 The board is therefore satisfied that the amendments made do not contain subject matter extending beyond that of the application as originally filed.

#### 3. Patentability

- 3.1 The board has examined the contents of the file in relation to patentability and neither disagrees with the submissions of the appellant made during the examination proceedings and set out in section V of the Facts and Submissions nor considers the available prior art otherwise to call patentability into question. In particular, there is no specific objection to three state valving in the examining procedure other than might be inferred from reference to claims involving a number of features dealt with in a very general way as not being inventive because of falling within the customary practice of a person skilled in the art. Such arguments do not effectively challenge the specific reasoned arguments of the appellant.
- 3.2 The board is therefore satisfied as to patentability.
- 4. Auxiliary Request

Since the board reached a positive view in relation to the main request, consideration of the auxiliary request is not necessary in the present decision.

#### 5. Procedure

In view of the foregoing and since the board sees no other bar to grant of a patent, the board considers it appropriate to exercise powers within the competence of the first instance and order grant of a patent. - 9 - T 1428/08

# Order

## For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the first instance with the order to grant a patent based on the following documents:

Description

Pages 2 to 4 received with the letter dated 28 May 2003

Page 5 received with the letter dated 07 June 2006,

Pages 1 and 6 to 18 as published,

Claims

1 to 11 received with the letter dated 18 December 2007, and

Drawing Sheets

1/7 to 7/7 as published.

The Registrar:

The Chairman:



M. Kiehl A. Klein

Decision electronically authenticated