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Datasheet for the decision of 24 July 2017

Case Number: T 2274/10 - 3.3.02

Application Number: 04748978.6

Publication Number: 1631824

IPC: G01N33/543, C12Q1/68, G01N33/557

Language of the proceedings: EN

Title of invention:
METHOD AND SYSTEM FOR DETERMINATION OF MOLECULAR INTERACTION PARAMETERS

Applicant:
GE Healthcare Bio-Sciences AB

Headword:
Determination of molecular interaction/GE HEALTHCARE

Relevant legal provisions:
EPC Art. 123(2), 111(1)

Keyword:
Amendments - added subject-matter (no)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
G 0010/93

Catchword:

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Case Number: T 2274/10 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 24 July 2017

Appellant: (Applicant)	GE Healthcare Bio-Sciences AB Björkgatan 30 75184 Uppsala (SE)
Representative:	Brann AB P.O. Box 3690 Drottninggatan 27 103 59 Stockholm (SE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 June 2010 refusing European patent application No. 04748978.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	P. de Heij

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application 04748978.6, based on an international application published as WO 2004/109284, under Article 97(2) EPC. The examining division decided that claim 1 of the sole request on file contravened the requirements of Article 123(2) EPC.

II. The applicant (hereinafter the appellant) lodged an appeal against that decision, requesting that it be set aside and that a patent be granted according to the sole request on file.

III. The board issued a communication pursuant to Rule 100(2) EPC and Article 17(1) RPBA, expressing its preliminary opinion that the amendments made to claim 1 had no basis in the application as originally filed. In a reply to this communication, dated 13 March 2017, the appellant sent a new set of claims and requested that a patent be granted on the basis of the new claims.

IV. In a further communication, the board noted that the amended claims overcame the previous objections and that further examination would be necessary. In reply thereto, in the letter dated 6 April 2017, the appellant requested remittal for further prosecution.

V. The **sole request** on file comprises 16 claims. Claim 1 reads as follows:

"1. A method of determining kinetic parameters for a reversible molecular interaction between a ligand immobilised to a solid support surface and a binding

partner to the ligand in solution, comprising the steps of:
a) sequentially, without intermediate regeneration or renewal of the immobilised ligand,
- flowing a plurality of fluid volumes containing different known concentrations (C_1 to C_n) of the binding partner over the solid support surface to permit association of binding partner to the immobilised ligand,
- flowing over the solid support surface a fluid volume free from binding partner to permit dissociation of binding partner from the ligand,
b) monitoring using surface plasmon resonance biosensor during step a)
- the momentary amount of binding partner bound to the solid support surface related to time and solution concentration of binding partner and collecting the binding data, and
- for each fluid volume, the time point when injected (tOn) and when stopped (tOff), and
c) determining the kinetic parameters by fitting globally a predetermined kinetic model for the interaction between the binding partner and the immobilised ligand to the collected binding data, which model allows for mass transport limitation at the solid support surface, wherein the global fitting is based on the time dependent concentration of the binding partner with respect to the time points when each fluid volume was injected (tOn) and stopped (tOff), and the density of ligand at the solid support surface."

VI. The appellant's arguments, in so far as relevant to the present decision, may be summarised as follows:

Present claim 1 was restricted to surface plasmon resonance biosensor (SPR), as requested by both the

board and the examining division. In addition, the following amendments had been made to overcome the board's objections: deletion of the sentence "from each fluid volumen the concentration of the binding partner (C_1 to C_n) is held constant" in claim 1; replacement of "at least one" by "a" in claims 1 and 5; introduction of a reference to a specific part of step a) of claim 1 in claims 4, 10 and 13.

VII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution.

Reasons for the Decision

1. The appeal is admissible.

2. Article 123(2) EPC

2.1 Present claim 1 reads as follows, the features added to claim 1 as originally filed being shown in bold:

"1. A method of determining kinetic parameters for a reversible molecular interaction between a ligand immobilised to a solid support surface and a binding partner to the ligand in solution, comprising the steps of:
a) sequentially, without intermediate regeneration or renewal of the immobilised ligand,
- flowing a plurality of fluid volumes containing different known concentrations **(C_1 to C_n)** of the binding partner over the solid support surface to permit association of binding partner to the immobilised ligand,

~~b)~~ - flowing over the solid support surface a fluid volume free from binding partner to permit dissociation of binding partner from the ligand,
~~c)~~ **b)** monitoring **using surface plasmon resonance biosensor** during step~~s~~ a) ~~and b)~~
- the momentary amount of binding partner bound to the solid support surface related to time and solution concentration of binding partner and collecting the binding data, and
- for each fluid volume, the time point when injected (tOn) and when stopped (tOff), and
~~d)~~ **c)** determining the kinetic parameters by fitting~~,~~ ~~preferably~~ globally~~,~~ a predetermined kinetic model for the interaction between the binding partner and the immobilised ligand to the collected binding data, which model allows for mass transport limitation at the solid support surface, **wherein the global fitting is based on the time dependent concentration of the binding partner with respect to the time points when each fluid volume was injected (tOn) and stopped (tOff), and the density of ligand at the solid support surface.**"

2.2 The present claim is based on originally filed claim 1, in combination with originally filed claim 24, which further restricted the subject-matter of all preceding claims to detection by surface plasmon resonance. The other added features are taken from the disclosure starting on page 18, line 16, and ending on page 20, line 7, which specifically refers to detection by surface plasmon resonance, as exemplified by the use of the commercially available biosensor BIACORE®. More specifically, the further features are disclosed in the last paragraph of page 18 and the first paragraph of page 19 of the application as filed. The feature "for each fluid volume, the time point when injected (tOn) and when stopped (tOff)" is disclosed e.g. on page 18,

lines 24 to 25, which state that "Before analysing the binding curve, start and end times for each injection of analyte are identified"; the feature defining the global fitting is disclosed in the next passage, namely lines 25 to 28. The feature "density of the ligand at the solid support surface" is disclosed on page 19, line 7, which equates "concentration of immobilised ligand" to "ligand density" and teaches that ligand density is taken into account in the differential equation used for the fitting (this is disclosed further on too, on page 19, lines 25 to 29).

2.3 The board is hence satisfied that present claim 1 fulfils the requirements of Article 123(2) EPC. Furthermore, the passages of the description listed above for claim 1 also provide a basis for the new combinations of features, arising from the dependency on new claim 1, in dependent claims 2 to 16.

3. Remittal for further prosecution

3.1 As stated by the Enlarged Board of Appeal in its decision G 10/93, OJ EPO 1995, 172 (see point 4 of the Reasons), the power of a board of appeal to include new grounds in *ex parte* proceedings does not mean that it carries out a full examination of the application as to patentability requirements. This is the task of the examining division. Proceedings before the boards of appeal are intended to review the correctness of the decision of the department of first instance rather than to continue examination by other means.

3.2 The sole ground for refusal of the patent application in the decision under appeal was based on Article 123(2) EPC. The present claims overcome the reasons for

refusal given in the decision and hence the appealed decision must be set aside.

3.3 According to the minutes of a telephone conversation, dated 16 April 2010, the examining division stated that "The Auxiliary Request filed with the letter of 25.03.2010 is considered acceptable under the provisions of the EPC". This statement, which was made in relation to a claim request similar to the present request (i.e. also restricted to "surface plasmon resonance"), is however not binding on the board of appeal. Moreover, the brief indication given by the examining division with respect to the then pending auxiliary request does not allow the conclusion to be drawn that the current application documents are ready for the grant of a patent. In fact, the board would have to satisfy itself that all EPC requirements are indeed fulfilled, which would require further examination, contrary to the role of appeal proceedings.

3.4 The board does not consider it appropriate to go beyond its primary task of reviewing the contested decision. Under these circumstances, the board exercises the power conferred upon it by Article 111(1) EPC to remit the case to the department of first instance for further prosecution, as requested by the appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

N. Maslin A. Lindner

Decision electronically authenticated