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Datasheet for the decision of 28 April 2022

Case Number: T 1444/20 - 3.3.01

Application Number: 15784662.7

Publication Number: 3215853

IPC: G01N33/68

Language of the proceedings: EN

Title of invention:
METHOD FOR THE DETERMINATION OF ANTI-DRUG ANTIBODIES AGAINST AN EFFECTOR FUNCTION SUPPRESSED HUMAN OR HUMANIZED DRUG ANTIBODY

Applicant:
F. Hoffmann-La Roche AG

Relevant legal provisions:
RPBA 2020 Art. 12
EPC R. 139
EPC Art. 123(2), 84

Keyword:
Amendment of the description

Decisions cited:
T 0412/03, T 1989/18, T 0490/90

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Case Number: T 1444/20 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 28 April 2022

Appellant: (Applicant)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Burger, Alexander Roche Diagnostics GmbH Patentabteilung Nonnenwald 2 82377 Penzberg (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 3 December 2019 refusing European patent application No. 15784662.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. European patent application No. 15 784 662.7 was published as international application No. WO 2016/071119 A1. The European publication number is EP 3 215 853.

II. On 15 February 2019, the examining division issued a communication under Rule 71(3) EPC advising the applicant that the division intended to grant a patent based on the following text:

- claims, numbers 1-12 filed in electronic form on 21 September 2018;
- description, pages 1-28, 42-54 as published;
- drawings, sheets 1/15-15/15 as published;
- sequence listings, SEQ ID NO 1-5 as published;

with the following modifications proposed by the examining division:

- deletion of pages 29 to 41 of the description;
- amendments on pages 28 and 42 of the description.

Claim 1, which is the only independent claim, reads as follows:

"1. An anti-drug antibody immunoassay for the determination of the presence of an anti-drug antibody (ADA) against an effector function suppressed human or humanized drug antibody (EFS-DA) in a sample comprising the following steps in the following order:

a) incubating a solid phase on which the effector function suppressed human or humanized drug antibody or a FAB thereof has been immobilized with a sample comprising mammalian blood serum,

b) incubating the solid phase with full length human Fcgamma receptor I or an Fc-region binding fragment thereof, whereby the full length human Fcgamma receptor I or the Fc-region binding fragment thereof is conjugated to a detectable label, and

c) determining the formation of a solid-phase-bound complex in step b) by determining the presence of the detectable label and thereby determining the presence of an anti-drug antibody against an effector function suppressed human or humanized drug antibody in the sample."

III. The applicant did not give its consent to the text intended for grant because it objected to the amendments in the description made by the examining division.

IV. The decision under appeal is the examining division's decision refusing the application, posted on 3 December 2019.

The decision is based on the appellant's sole request of 11 November 2019, which differs from the text proposed by the examining division by including a different amended version of the description (pages 1 to 40 filed in electronic form on 11 November 2019).

According to the decision under appeal, the set of claims 1 to 12 met the requirements of the EPC. The description pages did not contain added subject-matter (Article 123(2) EPC). However, pages 20 to 28 of the description contained numbered claim-like clauses, and this gave rise to a lack of clarity within the meaning of Article 84 EPC.

V. The applicant (appellant) appealed this decision. With its statement setting out the grounds of appeal dated 13 April 2020, the appellant filed amended

versions of the description according to its new main request and three auxiliary requests. A "clean" and a "marked-up" version were provided in each case, which amounts to a total of eight versions.

VI. In a communication pursuant to Rule 100(2) EPC, dated 21 May 2021, the board requested clarification on various points and advised the appellant of its preliminary opinion, indicating *inter alia* that the main request would foreseeably not be admitted.

The board observed that the amended versions of the description provided with the appellant's letter of 13 April 2020 were not labelled, in other words, it was not indicated which version belonged to which request.

VII. With its reply dated 16 July 2021, the appellant withdrew the main request. Auxiliary request 1 became the appellant's new main request; auxiliary requests 2 and 3 became auxiliary requests 1 and 2, respectively.

The appellant confirmed the board's assumptions regarding the matching of the different description texts to the individual requests. The appellant *inter alia* identified the description according to the new main request (clean version) as having 40 pages with two lines of the table in example 12 being on page 40, and the section "Specific embodiments of the invention" running from page 20, line 17, to page 27, line 23 (see points 2.3 and 3.1 of the appellant's letter).

VIII. The appellant's arguments with regard to the main request may be summarised as follows:

The main request (filed as auxiliary request 1 with the grounds of appeal) was identical to the request on which the decision under appeal was based, except for

the correction of further occurrences of an obvious error. It was thus admissible under Article 12 RPBA.

The request also met the requirements of Article 123(2) EPC, as acknowledged in item 3.1 of the board's communication.

The embodiments listed on pages 20 to 27 of the description could not be mistaken for claims. They also related to the same subject-matter as the current claims. Hence, there was no reason for objection under Article 84 EPC against this section of the description.

The passage on page 9, lines 19 to 30, of the description provided a general technical teaching in the context of the invention and was not objectionable under Article 84 EPC.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 12 filed on 21 September 2018, drawing sheets 1/15 to 15/15 as published, the sequence listings SEQ ID NO 1-5 as published, and a description as follows:

- the version of the description according to the main request (filed as auxiliary request 1 with the statement setting out the grounds of appeal of 13 April 2020);

or in the alternative,

- the version of the description according to the main request with deletion of lines 19 to 30 on page 9; or
- the version of the description according to auxiliary request 1 or 2 (filed as auxiliary requests 2 and 3 with the statement setting out the grounds of appeal).

Reasons for the Decision

1. Main request - admittance and amendments

1.1 The description according to the main request (clean version, see point VII. above) is identical to the description of 11 November 2019, except that the words "or humanized drug antibody in the sample" have been inserted in three additional text passages (see main request: page 3, line 28; page 5, lines 25-26; page 19, line 17 in comparison with the request of November 2019: page 3, line 30; page 5, line 31; page 19, line 26).

1.2 The insertions, in several occurrences, of the words "or humanized drug antibody in the sample" are obvious corrections under Rule 139 EPC that do not contravene Article 123(2) EPC, as it is evident from the context in each instance that the wording employed at the beginning of the description of the embodiment concerned was to be repeated at the end, and was omitted by mistake.

(See the application as filed: page 4, line 26 / page 8, line 31 / page 25, line 13 / page 29, line 32 / page 34, line 1 / page 38, line 34 and current main request: page 3, line 28 / page 5, lines 25-26 / page 19, line 17 / page 21, line 17 / page 23, line 32 / page 26, line 11.)

1.3 Thus, the main request corresponds essentially (except for obvious corrections) to the request on which the decision under appeal is based. The board sees no reason to hold this request inadmissible under Article 12 RPBA.

2. Requirements of Article 84 EPC (main request)

2.1 The claims of a patent application define the matter for which protection is sought. Article 84 EPC requires this definition to be clear. This means that the claims must be clear in themselves for a person skilled in the art with common general knowledge of the technical field in question, without the need to refer to the description (T 412/03, Reasons 2.4.1). Article 84 EPC also requires the claims to be concise and be supported by the description.

2.2 The application documents according to the main request (see point IX. above) comprise a section entitled "Amended Claims", listing 12 claims in the version of 21 September 2018, and a description.

2.3 Nothing suggests that the current claims are not clear in themselves to a person skilled in the art.

Passage on page 20, line 17, to page 27, line 23, of the description

2.4 The numbered embodiments listed on pages 20 to 27 of the description under the heading "Specific embodiments of the invention" cannot be mistaken for claims, since it is evident that they are a part of the description text, and they are not denoted as "claims", either. Rather, the description refers to them as embodiment, item, immunoassay, method or use.

2.5 Thus, there is no reason why the presence of the section "Specific embodiments of the invention" in the description should affect the clarity of the claims.

2.6 As an additional remark, the Guidelines for Examination in the EPO (version of 11 November 2019), in point

F-IV, 4.4, are inconsistent in that they acknowledge, on the one hand, that claim-like clauses may (or may not) give rise to a lack of clarity, but require, on the other hand, that such claim-like clauses must always be removed. If claim-like clauses in the description do not result in a lack of clarity of the actual claims, Article 84 EPC cannot provide the justification for removing them.

2.7 Moreover, the entire section "Specific embodiments of the invention" relates to the same subject-matter (defined by the same method steps) as the current claims and may be taken to provide additional support for the claims in the description, as also required in Article 84 EPC.

2.8 According to the decision under appeal (see page 7), the "specific embodiments" recited on pages 20 to 27 of the description belong to different claim categories (immunoassay, method or use) and this must result in either lack of clarity or lack of conciseness.
This objection fails simply because Article 84 EPC relates to the claims and not to embodiments mentioned in the description.

Passage on page 9, lines 19 to 32, of the description

2.9 Since the passage on page 9, lines 19 to 32 is not in the section "Specific embodiments", the board accepts the appellant's explanation that this passage relates to more general aspects in the context of the invention.

2.10 Under the circumstances set out in points 2.1 to 2.9 above, the board does not see any reason for objection to the main request under Article 84 EPC.

3. Removal of "redundant" subject-matter (main request)

3.1 The decision under appeal also asserts that, independently of Article 84 EPC, there is a requirement for removing redundant subject-matter from the description, and that the section "Specific embodiments of the invention" comprises such redundant subject-matter. This objection is based on two approaches relying on the Implementing Regulations to the EPC (Article 78(1) EPC).

(a) The first approach relies on the reasoning in decision T 490/90 (Reasons 5), which in turn was based on Rule 27 EPC 1973.

(b) The second approach relies on Rule 48(1)(c) EPC.

3.2 Rule 42(1)(c) EPC

3.2.1 Decision T 490/90 merely stated that it did not seem questionable that the presence of claim-like clauses in the description did not satisfy the requirements of Rule 27 EPC. Rule 27 EPC 1973 corresponds to current Rule 42 EPC. The pertinent sub-paragraph would appear to be Rule 42(1)(c) EPC.

3.2.2 As per Rule 42(1)(c) EPC (Rule 27(1)(d) EPC 1973 and Rule 27(1)(c) EPC 1973, before and as of 1 June 1991, respectively) the description must disclose the invention, as claimed, in such terms that the technical problem and its solution can be understood, and state any advantageous effects of the invention with reference to the background art. In line with the concept of a technical invention on which the EPC is founded, the first half-sentence requires the description to disclose how the invention can be understood as the solution to a technical problem.

3.2.3 However, in the absence of an objection of lack of unity under Article 82 EPC, this does not translate into a requirement to bring the description in line with claims intended for grant, and to remove passages of the description that disclose embodiments which are not claimed.

3.2.4 In the present case, the passages on pages 20 to 27 of the description objected to by the examining division do not impair the understanding of the technical problem and its solution as set forth in the "Summary of the Invention" provided in the description on pages 2 to 8.

3.2.5 Thus, the main request meets the requirements of Rule 42(1)(c) EPC.

3.3 Rule 48(1)(c) EPC

3.3.1 Under Rule 48(1)(c) EPC, a European patent application must not contain any statement or other matter obviously irrelevant or unnecessary under the circumstances.

3.3.2 A number of decisions have relied on Rule 48(1)(c) EPC as a potential legal basis for requiring the description to be adapted to the subject-matter as claimed.

3.3.3 Nevertheless, on closer analysis, the wording and history of this provision suggest that this was not its intended purpose. The board agrees in this regard with the analysis provided in decision T 1989/18, Reasons 9 and 10.

3.3.4 As a consequence, Rule 48(1)(c) EPC cannot serve as a legal basis for the refusal of the present main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of

- claims 1 to 12 filed on 21 September 2018,
- the description (pages 1 to 40) according to the main request (filed as auxiliary request 1 with the statement setting out the grounds of appeal)
- drawing sheets 1/15 to 15/15 as published,
- the sequence listings SEQ ID NO 1-5 as published.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated