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**Datasheet for the decision
of 3 March 2020**

Case Number: T 0800/16 - 3.3.01

Application Number: 07114174.1

Publication Number: 1890154

IPC: G01N33/68

Language of the proceedings: EN

Title of invention:

Cardiac troponin as an indicator of advanced coronary artery disease

Patent Proprietor:

F. Hoffmann-La Roche AG
Roche Diagnostics GmbH

Opponents:

BioMérieux
Adams, Harvey Vaughan John

Headword:

Cardiac troponin as biomarker for heart disease/ROCHE

Relevant legal provisions:

EPC R. 115(2)
RPBA 2020 Art. 15(3)
EPC Art. 123(2)

Keyword:

Summons to oral proceedings - non-attendance of party
Amendments - allowable (no)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0800/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 3 March 2020

Appellants:

(Patent Proprietors)

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(Opponent 1)

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Respondent II:

(Opponent 2)

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 25 January 2016
revoking European patent No. 1890154 pursuant to
Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chairman A. Lindner
Members: T. Sommerfeld
 M. Blasi

Summary of Facts and Submissions

- I. European patent No. 1 890 154, based on application No. 07 114 174.1, is entitled "Cardiac troponin as an indicator of advanced coronary artery disease" and was granted with 11 claims.
- II. Two oppositions were filed against the granted patent, both opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).
- III. By its decision announced at the oral proceedings in opposition, the opposition division revoked the patent, on the grounds that none of the claim sets on file met the requirements of sufficiency of disclosure.
- IV. The patent proprietors (appellants) lodged an appeal against that decision. With the statement of grounds of appeal, they requested that the patent be maintained as granted, i.e. that the opposition be rejected (main request), or alternatively, that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1, 1a, 2, 2a, 3, 3a, 4 and 4a, all filed with the grounds of appeal and identical to the claim sets which had been decided on by the opposition division.
- V. With their replies to the statement of grounds of appeal, both respondents requested that the appeal be dismissed. Respondent I (opponent 1), moreover, requested that the case be remitted to the opposition

division for further prosecution should the board come to the conclusion that the requirements relating to sufficiency of disclosure and added subject-matter were met.

- VI. A summons for oral proceedings before the board was issued, followed by a communication pursuant to Article 15(1) RPBA providing the board's preliminary opinion regarding the admission of new facts, evidence and requests.
- VII. By letter dated 20 December 2019, the appellants withdrew the main request. Auxiliary request 1 became the main request and the remaining requests were renumbered accordingly. Sets of claims of all requests were resubmitted with the same letter.

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

"1. A method for diagnosing an advanced ischemic coronary heart disease caused by a coronary vessel disease in an asymptomatic risk group patient selected from the group consisting of smokers, diabetes patients, obese patients, subjects suffering from hyperlipidemia, subjects suffering from arterial hypertension, subjects with a family history of coronary heart disease, myocardial infarction or stroke, and persons suffering from rheumatoid arthritis comprising the steps of:

- a) determining the amount of a cardiac Troponin in a sample of a subject;
- b) diagnosing the disease by comparing the amount determined in step a) with reference amounts, wherein an increased amount of the cardiac troponin over the reference amount of 0.003 ng/ml is indicative

for an advanced coronary artery disease, and wherein said cardiac Troponin is Troponin T."

VIII. Oral proceedings before the board took place on 3 March 2020 as scheduled. As announced by letters dated 7 February 2020 and 10 February 2020, the respondents did not attend. In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the oral proceedings were held in their absence. At the end of the oral proceedings, the chairman announced the board's decision.

IX. The appellants' submissions, in so far as relevant for the present decision, may be summarised as follows.

The feature "over the reference amount of 0.003 ng/ml" had a basis in the application as filed on page 18, lines 3 to 6, which also taught higher reference values, and again at line 16. The reference value of 0.003 ng/ml could also be derived from the examples, being the mean value of the measurements obtained. The passages on page 18 as well as on page 19, lines 21 and 22, always referred to this value as a "reference amount", and it would be immediately clear for the skilled person that a positive diagnosis implied values above the reference value.

X. The respondents' arguments may be summarised as follows.

All the relevant passages in the application as filed (e.g. page 18) taught "at least 0.003 ng/ml" and did not state that a positive diagnosis required that the measured value had to be above or increased in relation to this reference value. The two terms "at least" and

"over" had different technical meanings and could not be used interchangeably.

XI. The appellants requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the claims of the main request ("MR") or, alternatively, on the basis of one of the sets of claims of auxiliary requests "MRa", "AR1", "AR1a", "AR2", "AR2a", "AR3" and "AR3a", all filed with the letter of 20 December 2019.

Both respondents requested in writing that the appeal be dismissed.

The further requests of the appellants and respondents, in particular concerning the (non-)admittance of documents into the proceedings and remittal of the case to the opposition division for further prosecution, had not to be decided upon by the board in these proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. Main request - Article 123(2) EPC
 - 2.1 In the appealed decision, the opposition division came to the conclusion that the then main request (patent as granted) met the requirements of Article 123(2) EPC, and that the ground for opposition pursuant to Article 100(c) EPC did not prejudice the maintenance of the patent as granted. The respondents disagreed with these conclusions and maintained their objections

relating to added subject-matter, in particular regarding the features "caused by a coronary vessel disease", "asymptomatic risk group patient", and "increased amount of the cardiac troponin over the reference amount of 0.003 ng/ml is indicative for an advanced coronary artery disease", as well as the combination of the features recited in claim 1. All these features are still part of claim 1 of the main request before the board.

- 2.2 Claim 1 of the main request is based on claim 1 of the application as filed, which was amended. The added features are underlined.

"1. A method for diagnosing an advanced ischemic coronary heart disease caused by a coronary vessel disease in an asymptomatic risk group patient selected from the group consisting of smokers, diabetes patients, obese patients, subjects suffering from hyperlipidemia, subjects suffering from arterial hypertension, subjects with a family history of coronary heart disease, myocardial infarction or stroke, and persons suffering from rheumatoid arthritis comprising the steps of:

- a) determining the amount of a cardiac Troponin in a sample of a subject;
- b) diagnosing the disease by comparing the amount determined in step a) with reference amounts, wherein an increased amount of the cardiac troponin over the reference amount of 0.003 ng/ml is indicative for an advanced coronary artery disease, and wherein said cardiac Troponin is Troponin T."

- 2.3 Contrary to the conclusions of the opposition division, the board considers that the feature "wherein an increased amount of the cardiac troponin over the

reference amount of 0.003 ng/ml is indicative for an advanced coronary artery disease" does not have any basis in the application as filed.

- 2.4 The appellants indicated claim 4 in combination with page 18, lines 3 to 6 and 15 to 18 of the application as filed, as providing a basis for the disputed feature.
- 2.5 In fact, this feature is derived from claim 4 as filed, but differs from it. Additions and deletions are shown by underlining or strikethrough, respectively: "... wherein an increased ~~reference~~ amount for the cardiac ~~T~~troponin over the reference amount of ~~{at} least~~ 0.003 ng/ml, ~~preferably 0.1 ng/ml~~, is indicative for an serious advanced coronary artery disease". Hence, claim 4 as filed does not teach that a value over 0.003 ng/ml is indicative of *advanced coronary artery disease*, but rather that a value of *at least* 0.003 ng/ml is indicative of a *serious advanced coronary artery disease*. It therefore cannot provide any basis on its own for the disputed feature.
- 2.6 As to the passages on page 18, lines 3 to 6 and 15 to 18 of the application as filed, they are indeed in the context of *advanced ischemic coronary heart disease*; nevertheless, they refer to at least 0.003 ng/ml (as in claim 4 as filed) as being indicative of the disease, and they do not disclose that the measured amount has to be increased in relation to that reference amount. There is thus no passage in the application as filed teaching that the value should be over 0.003 ng/ml, as now in present claim 1.
- 2.7 The appellants essentially argued that it was clear from the disclosure of the application as a whole that

the value of at least 0.003 ng/ml was a reference value and that, as such, the skilled person would immediately understand that a positive diagnosis would require a measurement above that reference value. The board agrees that this would be a common understanding of the concept of "reference value", but notes that this interpretation is contrary to the whole teaching of the application as filed, which is that a value of "at least 0.003 ng/ml" is indicative of advanced coronary heart disease, meaning that a value of 0.003 ng/ml is already interpreted as positive, i.e. as indicative of the presence of disease.

2.8 Claim 1 of the main request is thus considered to contravene Article 123(2) EPC. The main request is therefore not allowable.

3. Auxiliary requests - Article 123(2) EPC

3.1 The feature "wherein an increased amount of the cardiac troponin over the reference amount of 0.003 ng/ml is indicative for an advanced coronary artery disease" is present in claim 1 of all auxiliary requests. Hence, for the same reasons as given above for the main request, claim 1 of all requests on file is considered to add subject-matter contrary to Article 123(2) EPC.

3.2 Auxiliary requests MRa, AR1, AR1a, AR2, AR2a, AR3 and AR3a are thus not allowable for lack of compliance with Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated