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Datasheet for the decision of 30 June 2023

Case Number: T 0066/20 - 3.3.04

Application Number: 09800069.8

Publication Number: 2321651

IPC: G01N33/68

Language of the proceedings: EN

Title of invention:
IDENTIFICATION OF SUBJECTS BEING SUSCEPTIBLE TO ANTI-ANGIOGENESIS THERAPY

Patent Proprietor:
F. Hoffmann-La Roche AG
Roche Diagnostics GmbH

Opponent:
Mathys & Squire LLP

Relevant legal provisions:
EPC Art. 113(1)
EPC R. 103(1)(a), 111(2)
RPBA 2020 Art. 11

Keyword:

Substantial procedural violation - appealed decision not sufficiently reasoned
Remittal to the opposition division - fundamental deficiency in the opposition proceedings
Reimbursement of appeal fee - equitable by reason of a substantial procedural violation

Decisions cited:

T 1713/20

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Case Number: T 0066/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 30 June 2023

Appellants: (Patent Proprietors)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH) and Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Theodor-Heuss-Anlage 2 68165 Mannheim (DE)
Respondent: (Opponent)	Mathys & Squire LLP The Shard 32 London Bridge Street London SE1 9SG (GB)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 October 2019 concerning maintenance of the European Patent No. 2321651 in amended form**

Composition of the Board:

Chair	M. Pregetter
Members:	S. Albrecht
	M. Blasi

Summary of Facts and Submissions

I. European patent 2 321 651 ("the patent") was granted on the basis of a set of 11 claims.

Claim 1 as granted reads as follows:

"1. A method for predicting the risk of an acute cardiovascular event and/or heart failure as a consequence of a future anti-angiogenesis-therapy 5 with a VEGF-antagonist, comprising the steps of

a) determining the amount of a cardiac Troponin in a sample of a subject; and
b) comparing the amount of a cardiac Troponin as determined in step a) with reference amount for a cardiac Troponin,

wherein the risk of an acute cardiovascular event and/or heart failure of a future anti-angiogenesis therapy with a VEGF-antagonist is predicted for said subject."

II. Opposition proceedings were based on the grounds for opposition under Article 100(a) EPC for lack of novelty and lack of inventive step, and under Article 100(b) and (c) EPC.

III. The documents filed during the opposition proceedings included:

D8: C. D. Britten *et al.*, "A phase I and pharmacokinetic study of sunitinib administered daily for 2 weeks, followed by a 1-week off period", Cancer Chemother Pharmacol 61, 2008, 515-524

IV. The opposition division decided that the patent as amended in the form of auxiliary request 12 and the invention to which it related met the requirements of the EPC.

The decision was based on a main request and 12 auxiliary requests. The main request was the patent as granted. The set of claims of auxiliary request 1 was filed as auxiliary request 2A with letter of 11 July 2019. The sets of claims of auxiliary requests 2 to 11 were filed as auxiliary requests 1, lA, lB, 2, 3, 3A, 3B, 4, 4A, and 4B, respectively, with the same letter. The set of claims of auxiliary request 12 was filed during the oral proceedings before the opposition division.

In its decision, the opposition division found that the subject-matter of claim 1 of each of the main request and auxiliary requests 1 to 11 lacked an inventive step based on document D8 as the closest prior art (Article 100(a) EPC in conjunction with Article 56 EPC). Auxiliary request 12 was found to fulfil the requirements of the EPC.

V. The joint patent proprietors ("appellants") lodged an appeal against the opposition division's decision.

VI. In their statement of grounds of appeal, the appellants challenged the opposition division's finding, arguing that the technical problem of providing a method for predicting an acute cardiovascular event and/or heart failure as consequence of a future anti-angiogenesis therapy had been plausibly solved and would not have been obvious in light of the cited prior art. It was also submitted that the opposition division's reasons

provided by the opposition division in writing were contradictory. With the same statement, the appellants requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), implying that the opposition be rejected. As an auxiliary measure, the appellants requested that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1, 1A, 1B, 2, 2A, 3, 3A, 3B, 4, 4A, and 4B, all filed with letter of 11 July 2019.

VII. Oral proceedings were set to be held before the board on 29 June 2023.

VIII. In a communication under Article 15(1) RPBA dated 2 May 2023, the board observed that the decision under appeal did not appear to contain a reasoning within the meaning of Rule 111(2) EPC on the basis of which the board could understand why the ground for opposition of lack of inventive step prejudiced the maintenance of the patent as granted. The board noted that this deficiency amounted to a substantial procedural violation under Article 113(1) EPC and informed the parties of its intention to remit the case to the opposition division and to reimburse the appeal fee in full. Moreover, the board indicated that a decision in written proceedings would be issued without holding oral proceedings, should the appellants agree to the proposed remittal and withdraw their request for oral proceedings.

IX. In a letter dated 24 May 2023, the appellants expressed their agreement to the proposed remittal, withdrew their request for oral proceedings and requested the reimbursement of the appeal fee in full due to a

substantial procedural violation committed by the opposition division.

X. Subsequently, the board cancelled the oral proceedings and informed the parties that it would issue a decision in due course.

XI. The opponent did not make any submissions or file any requests in the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. Article 113(1) EPC and Rule 111(2) EPC - substantial procedural violation

2.1 Rule 111(2) EPC stipulates, *inter alia*, that decisions of the European Patent Office which are open to appeal shall be reasoned. The purpose of this requirement is to enable the party or parties adversely affected by the decision to understand whether or not the decision was justified and to decide whether or not to lodge an appeal. It likewise ensures that the board of appeal, whose primary task it is to review the decision under appeal in a judicial manner, is enabled to understand the conclusions on which the decision is based and why they have been drawn. On the basis of the reasoning given in the decision under appeal, the board assesses whether the conclusions drawn by the department which took the decision were correct (see T 1713/20, point 1.3 of the reasons).

2.2 For a decision to be reasoned, all facts, evidence and arguments essential to the decision must be dealt with. Moreover, the decision must contain a logical chain of

reasoning which led to the relevant conclusion (see also Case Law of the Boards of Appeal, 10th edition 2022, III.K.3.4.3).

2.3 Insufficient reasoning of a decision may amount to a violation of the right to be heard under Article 113(1) EPC. The latter provision establishes a party's right not only to present comments but also to have the comments duly considered by the deciding body. By providing adequate reasoning the deciding body can demonstrate that it adhered to this (see T 1713/20, *supra*).

2.4 In the case at issue, the decision under appeal contains reasons, but the board must conclude that the reasoning is insufficient under Rule 111(2) EPC and that this amounts to a violation of Article 113(1) EPC. The reasons are as follows.

2.4.1 In the appealed decision, the opposition division concluded that the subject-matter of claim 1 of the main request did not involve an inventive step. The opposition division arrived at this conclusion by considering that document D8 represented the closest prior art and by defining the objective technical problem as the provision of a method for predicting an acute cardiovascular event and/or heart failure as a consequence of a future anti-angiogenesis therapy. In the opposition division's view, the solution proposed in claim 1, i.e. the comparison of cardiac troponin values measured in a sample with a reference amount, did not credibly solve this problem, because the skilled person faced with predicting the claimed risk would not have been able to do so in absence of a defined reference amount. Notably, from the experiments reported on pages 26 and 27 of the application as filed

for patients 4201 and 4210, the skilled person would not have been in a position to predict any risk. The skilled person would have only known that "high initial values of troponin T lead to cardiovascular events and that low values do not lead to these (the same conclusions as in D8)" (see decision under appeal, page 9, third paragraph).

2.4.2 After reaching this finding, the opposition division did not reformulate the objective technical problem and did not assess obviousness of the claimed solution to that reformulated problem in the light of the cited prior art (see Guidelines for Examination in the EPO, November 2018, i.e. the edition applicable to the decision under appeal, G-VII, 5.2, in particular fourth paragraph, and 5.3). Nor did the opposition division indicate that and for which reasons it would deviate from the problem-solution approach as foreseen in the Guidelines for Examination for assessing inventive step (see also Guidelines for Examination, *supra*, General Part, point 3; G-VII, 5). The opposition division merely observed that document D8 contained the implicit knowledge that high values of troponin T ("cTnT") or troponin I ("cTnI") resulted in cardiac toxicity, whereas low values of cTnT and cTnI were known to be correlated with low chances of an individual being afflicted with a cardiovascular event (see decision under appeal, page 9, last paragraph). The relevance of this observation to the issue of inventive step cannot be derived from the decision under appeal. This applies irrespective of whether or not the problem-solution approach has been followed in assessing inventive step.

2.4.3 However, Article 56 EPC requires that "an invention shall be considered as involving an inventive step if,

having regard to the state of the art, it is not obvious to a person skilled in the art". In the case at issue, the board is unable to understand from the decision under appeal why the opposition division concluded that the claimed invention would have been obvious starting from document D8 (see point 2.4.2 above).

2.5 The impugned decision is thus not properly reasoned within the meaning of Rule 111(2) EPC, amounting to a violation of the appellant's right to be heard under Article 113(1) EPC. Since the ground for opposition of lack of inventive step was the sole ground invoked by the opposition division against the maintenance of the patent as granted, a substantial procedural violation has occurred and the impugned decision has to be set aside.

3. Remittal

3.1 According to Article 11 RPBA, the board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. As a rule, fundamental deficiencies which are apparent in the proceedings before that department constitute such special reasons.

3.2 The deficiency set out above in points 2.1 to 2.5 amounting to a violation of the appellant's right to be heard (Article 113(1) EPC) constitutes a fundamental deficiency within the meaning of Article 11 RPBA, justifying remittal to the opposition division.

4. Reimbursement of the appeal fee

4.1 According to Rule 103(1)(a) EPC the appeal fee is to be reimbursed in full where the board deems an appeal allowable, if such reimbursement is equitable by reason of a substantial procedural violation.

4.2 The remittal of the case to the opposition division implies that the appellants' appeal is allowable. Since furthermore the board has come to the conclusion that a substantial procedural violation has occurred, due to which the decision under appeal is to be set aside, reimbursement of the appeal fee in full is equitable in accordance with Rule 103(1)(a) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division.

3. The appeal fee is reimbursed.

The Registrar: The Chair:

I. Aperribay M. Pregetter

Decision electronically authenticated