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Datasheet for the decision of 22 May 2026

Case Number: T 1046/24 - 3.3.08

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

Headword:
VEGF-antagonist/ROCHE

Relevant legal provisions:
EPC Art. 56, 111(1)

Keyword:
Inventive step - (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
G 0001/03, T 0066/20

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Case Number: T 1046/24 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 22 May 2026

Appellant: (Patent Proprietor 1)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Appellant: (Patent Proprietor 2)	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 32 London Bridge Street The Shard London SE1 9SG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 6 June 2024 concerning maintenance of the European Patent No. 2321651 in amended form**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	A. Schmitt
	D. Rogers

Summary of Facts and Submissions

I. The present appeal concerns European patent No. 2 321 651, entitled "*Identification of subjects being susceptible to anti-angiogenesis therapy*" (the patent), which was granted on the basis of European patent application No. 09 800 069.8, itself filed as an international application published as WO 2010/010153 (the application).

II. An opposition was filed against the patent, the opposition proceedings being based on the grounds for opposition under Article 100(a) EPC in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), as well as those under Article 100(b) and (c) EPC.

III. In a first interlocutory decision of 11 September 2019, (hereafter "OD Decision 1"), the opposition division had considered that the claims of the patent as granted did not contain subject-matter going beyond the content of the application as filed and were novel, but that the subject-matter of claim 1 did not involve an inventive step. Claim 1 of each of auxiliary requests 1 to 11 were found to lack an inventive step for the same reasons as claim 1 of the main request. The claims of auxiliary request 12 were found to comply with the requirements of Article 56 EPC and those of Article 83 EPC.

IV. The patent proprietor's appeal against OD Decision 1 was dealt with in decision T 66/20 of 30 June 2023 (hereafter "First Board Decision"). The board held that OD Decision 1, as far it concerned inventive step, was not sufficiently reasoned and that this amounted to a

violation of Article 113(1) EPC. The case was thus remitted to the opposition division.

V. In a second interlocutory decision, dated 15 May 2024 (OD Decision 2), the opposition division considered inventive step of a main request (patent as granted) and 14 auxiliary requests and found that the main request and auxiliary requests 1 to 13 lacked an inventive step in view of the disclosure in document D8. Auxiliary request 14, identical to auxiliary request 12 considered in OD Decision 1, was found to be allowable.

VI. The present appeal has been filed by the patent proprietor (appellant) against OD Decision 2 (hereafter the decision under appeal). With the statement of grounds of appeal, the appellant maintained all requests considered by the opposition division. It also requested reimbursement of the appeal fee in view of a substantial procedural violation.

VII. Claim 1 of the patent as granted (main request) 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 [*sic*]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."

VIII. The opponent (respondent) did not reply to the appeal.

IX. The board summoned the parties to oral proceedings and, in a communication under Article 15(1) RPBA, expressed its preliminary opinion, *inter alia*, that if the main request or any of the auxiliary requests other than auxiliary request 14 underlying the decision under appeal was found to meet the requirements of Article 56 EPC, sufficiency of disclosure would have to be assessed for these requests.

X. In a submission dated 16 February 2026, the appellant requested, *inter alia*, that the case be remitted to the opposition division for the assessment of sufficiency of disclosure.

XI. The respondent did not make any submissions in substance in the appeal proceedings and stated in writing that they would not attend the oral proceedings scheduled for 16 April 2026. The opposition was not withdrawn.

XII. In a further communication, the board informed the parties that the main request appeared to meet the requirements of Article 56 EPC and that it intended to remit the case to the opposition division for the assessment of, in particular, sufficiency of disclosure. The only topic to be discussed in the oral proceedings hence appeared to be the appellant's request for reimbursement of the appeal fee. The appellant was asked to state their current requests.

XIII. In a submission dated 14 April 2026, the appellant withdrew the request for reimbursement of the appeal fee and stated their remaining requests.

XIV. The board then cancelled the oral proceedings.

XV. The following document is referred to in this decision:

D8 C. D. Britten et al., Cancer Chemother Pharmacol 61, 2008, 515-524

XVI. The arguments of the appellant relevant to this decision are referred to, where necessary, in the Reasons for the Decision. The respondent did not submit any arguments on appeal.

XVII. The parties' requests relevant for the decision are as follows.

The appellant requests that the decision under appeal be set aside with respect to inventive step of the main request (patent as granted) and auxiliary requests 1 to 13 and that the case be remitted to the opposition division for further prosecution with respect to sufficiency of disclosure.

The respondent did not formulate any requests.

Reasons for the Decision

Main request (patent as granted)
Inventive step (Article 100(a) EPC and Article 56 EPC)

1. The opposition division considered that the method of claim 1 lacked an inventive step over the disclosure in document D8 alone (points 21.9 to 21.18 of the decision under appeal). Document D8 is a report on a phase 1 and pharmacokinetic study "*performed to investigate the*

safety, tolerability, and pharmacokinetics of sunitinib" (page 515, first paragraph of the Abstract) with respect to a specific treatment schedule (last sentence of the paragraph bridging right-hand and left-hand column on page 516). It discloses that prior to the treatment, *inter alia*, serum cardiac troponin T (cTnT) and/or serum cardiac troponin I (cTnI) levels were assessed and that only patients in which these levels were below or equal to the upper limit of normal (ULN) were eligible for this study (last paragraph of right-hand column on page 516 of D8).

2. As indicated by both the opposition division and the appellant, the claimed method differs from this disclosure in that D8 does not disclose that the cTnT and/or cTnI levels measured before the treatment with sunitinib predicted the risk of an acute cardiovascular event and/or heart failure as a consequence of the future treatment with sunitinib (point 21.14 on page 6 of the decision under appeal; second paragraph on page 11 of the statement of grounds of appeal).

3. The objective technical problem to be solved by the claimed method was hence seen as the provision of a method for predicting this risk (point 21.14.3 on page 6 of the decision under appeal; third paragraph on page 11 of the statement of grounds of appeal). The board agrees with this assessment.

4. The opposition division was then of the opinion that this problem was not credibly solved because "*a skilled person faced with predicting the claimed risk would not be able to do so in the absence of a defined reference amount*" (point 21.15.1 of the decision under appeal).

5. However, the claim comprises the feature "*wherein the risk of an acute cardiovascular event and/or heart failure as a consequence of a future anti-angiogenesis-therapy with a VEGF-antagonist is predicted for said subject*" and this is also the purpose of the claimed method, i.e. this effect is expressed in the claim. For this reason alone, the question whether the claimed method achieves this effect cannot be a question of inventive step but must be addressed under sufficiency of disclosure (G 1/03; third paragraph of point 2.5.2 of the Reasons). The board sees no reason to deviate from the Enlarged Board on this issue.

6. Following on from G 1/03, it is thus evident that the opposition division erroneously reasoned to the extent that in its discussion of inventive step, it took into account considerations that rightly belong to a discussion of sufficiency of disclosure. This has the consequence that the considerations set out by the opposition division in points 21.15.1 to 21.15.7 of the decision under appeal are irrelevant under the provision of Article 56 EPC and cannot demonstrate a lack of inventive step.

7. The technical problem as formulated by the opposition division and by the appellant (see point 2. above) is thus, per definition, considered to be solved. This leaves the question to be reviewed by the board whether the solution claimed, namely a method as defined in the claim, was obvious over the disclosure in D8 alone, for the reasons asserted in points 21.16 to 21.18 of the decision under appeal.

8. The opposition division based its considerations on the facts that in the study described in document D8,

1) cTnT and cTnI levels were determined in patients prior to the treatment and only patients that had cTnT and cTnI levels ≤ ULN were selected for the treatment, a fact that implied that the significance of elevated values of cTnT and cTnI for cardiovascular toxicity was known (points 21.11 and 21.17 of the decision under appeal; chapter "Patient selection" on page 516 of D8), and that
2) patients who developed serum cTnT or cTnI levels above the ULN were required to discontinue sunitinib (point 21.16 of the decision under appeal; first paragraph of right-hand column on page 517 of D8).

9. However, as pointed out by the appellant, in the study described in D8, patients were selected for the study based on several eligibility criteria including an "*adequate cardiac function*", and it was in this context that, among other criteria, such as the absence of cardiovascular events and heart failure in the previous 12 months, cTnT and cTnI levels were assessed (see section "Patient selection" on page 516 of D8).

10. Hence, in the study described in D8, cTnT and/or cTnI levels were determined prior to the treatment with sunitinib in order to include only patients with normal cTnT and cTnI levels in the study. This allows the evaluation of the safety and side effects, including cardiotoxicity, of the new drug administration protocol (see also point 1. above) by assessing possible changes of, *inter alia*, these parameters by the treatment. No conclusion can be drawn from this on whether particular levels of these markers allowed to predict the risk of an acute cardiovascular event and/or heart failure as a consequence of the future treatment with sunitinib.

11. The disclosure on page 517 of D8 that patients who developed serum cTnT or cTnI levels above the ULN or had evidence of cardiac dysfunction were required to discontinue sunitinib means that elevated serum levels of cTnT and cTnI were indicators of heart muscle damage, and that VEGF antagonists may have cardiotoxic effects. This was not contested by the appellant. However, as pointed out by the appellant, D8 also discloses that patients who developed any of these signs of cardiac dysfunction were not mandatorily required to stop the treatment, but that "*they could resume study treatment after discussion with a cardiologist*" under certain conditions (first paragraph of right-hand column on page 517 of D8).

12. D8 therefore teaches that elevated cTnT and/or cTnI levels are indicators of a current cardiac dysfunction and that they are possible side effects of a treatment with sunitinib. However, since D8 only assessed the side effects of sunitinib on patients with normal cardiac function, including normal cTnT and/or cTnI levels, the skilled person could not know or reasonably expect from this teaching whether initially elevated levels of cTnT and/or cTnI levels would predict a patient's risk of an acute cardiovascular event or heart failure as a consequence of a future treatment with sunitinib.

13. In view of these considerations, the opposition division's reasons as to why the claimed method was obvious in view of the disclosure in D8 cannot be followed. Inventive step of the method of claim 1 - and that of dependent claims 2 to 11 - is therefore acknowledged (Article 56 EPC).

Remittal (Article 111(1) EPC)

14. Despite the indication in point 20.1 on page 3 of the decision under appeal, no decision on sufficiency of disclosure was taken by the opposition division with respect to the main request.

15. Indeed, sufficiency of disclosure was only considered for former auxiliary request 12 in OD Decision 1 (points 9.1 and 9.2; see also section III. above). It is clear from this decision that objections on sufficiency of disclosure had been raised in the notice of opposition that are relevant for the current main request. In particular, it seems that objections were raised in respect to the reference in the claim to cardiac Troponin in general and in respect to the question whether or not the claimed method enabled the skilled person to predict the risk recited in the claim. No decision open for review by the board was taken on these objections under the provisions of Article 83 EPC.

16. In view of these circumstances and in line with the appellant's request, the board considers it appropriate to remit the case to the opposition division for the assessment of sufficiency of disclosure.

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 for further prosecution.

The Registrar: The Chairwoman:

L. Stridde T. Sommerfeld

Decision electronically authenticated