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**Datasheet for the decision  
of 22 July 2010**

**Case Number:** T 1477/08 - 3.3.04

**Application Number:** 00965898.0

**Publication Number:** 1212081

**IPC:** A61K 38/55

**Language of the proceedings:** EN

**Title of invention:**

Use of ACE inhibitors in the prevention of congestive heart failure

**Patentee:**

Sanofi-Aventis Deutschland GmbH

**Opponent:**

BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG

**Headword:**

ACE inhibitors/SANOFI-AVENTIS

**Relevant legal provisions:**

EPC Art. 123(2), 111(1)

**Keyword:**

"Main request - amendments, remittal (yes)"

**Decisions cited:**

T 1091/00

**Catchword:**

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Case Number: T 1477/08 - 3.3.04

**DECISION**  
of the Technical Board of Appeal 3.3.04  
of 22 July 2010

**Appellant:** Sanofi-Aventis Deutschland GmbH  
(Patent Proprietor) Brünigstrasse 50  
D-65929 Frankfurt am Main (DE)

**Representative:** Bösl, Raphael Konrad  
Isenbruck Bösl Hörschler Wichmann LLP  
Prinzregentenstrasse 68  
D-81675 München (DE)

**Respondent:** BOEHRINGER INGELHEIM PHARMA GmbH & CO KG  
(Opponent) D-55216 Ingelheim/Rhein (DE)

**Representative:** Klusmann, Peter  
HOFFMANN EITLE  
Patent- und Rechtsanwälte  
Arabellastraße 4  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 2 June 2008  
revoking European patent No. 1212081 pursuant  
to Article 101(3)(b) EPC.

**Composition of the Board:**

**Chairman:** C. Rennie-Smith  
**Members:** M. Wieser  
R. Gramaglia

## Summary of Facts and Submissions

- I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European patent No. 1 212 081 was revoked pursuant to Article 101(3)(b) EPC.
- II. The patent had been opposed by two parties (Opponents 01 and 02) under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Articles 100(b) and 100(c) EPC. Opponent 01 withdrew its opposition with letter dated 15 March 2007 and is no longer a party to the proceedings.
- III. The Opposition Division decided that the patent according to claim 1 of each of the main request and auxiliary requests 1 and 2 before it did not meet the requirements of Article 123(2) EPC.
- IV. The Board expressed its preliminary opinion in a communication dated 18 May 2010.

The Respondent (Opponent 02) informed the Board by a letter dated 21 June 2010 that it would not be present at the oral proceedings.

Oral proceedings were held on 22 July 2010 in the absence of the Respondent.

- V. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or the auxiliary request both filed on 22 June 2010. Should the Board decide that one

of these requests met the requirements of Article 123(2) EPC, the case should be remitted to the department of first instance for further prosecution of the outstanding issues.

The Respondent requested in writing that the appeal be dismissed.

- VI. The sole claim of Appellant's main request is identical to the sole claim of auxiliary request 2 before the Opposition Division and reads:

"The use of rampril in the manufacture of a medicament for the prevention of congestive heart failure (CHF) in a patient with no preexisting CHF, where the patient is at high risk for a cardiovascular event due to a history of previous ischaemic heart disease, stroke or peripheral arterial disease, and wherein the patient exhibits normal or low blood pressure."

- VII. The Appellant's arguments in writing and at the oral proceedings, in so far as they relate to this decision, can be summarised as follows:

The claim of the main request had a basis in the original application, published as WO 01/15 673, and met the requirements of Article 123(2) EPC. In particular the feature requiring that "the patient exhibits normal or low blood pressure", which was objected to by the Opposition Division, was based on the disclosure in the example on page 10 and 11 and on page 3, lines 22 to 23 of the application as published.

Should the Board agree with the Appellant on this point, the case should be remitted to the department of first instance for further prosecution as fundamental substantive issues, like novelty and inventive step, have not yet been assessed by the Opposition Division.

VIII. The Respondent's arguments in writing, in so far as they relate to this decision, can be summarised as follows.

Claim 1 of Appellant's new main request had no basis in the application as published. The only example did not refer to the specific patient group indicated in the claim.

IX. The decision refers to the following document:

(20) NIH Publication No. 98-4080, November 1997,  
The sixth report of the joint national committee  
on prevention, detection, evaluation and treatment  
of high blood pressure; page 11.

## **Reasons for the Decision**

### *Amendments - Article 123(2) EPC*

1. The example contained in the application as published relates to a large-scale clinical trial to examine the effect of ramipril versus placebo in reducing cardiovascular events (page 10, lines 18 to 19).

The 9541 participants of the study were said to be at high risk for cardiovascular events due to a history of

previous ischaemic heart disease, stroke, peripheral disease or diabetes (page 10, lines 21 to 24).

The patients were defined as being "normotensive" at study start (page 10, line 27).

The results showed a clear reduction of cardiovascular deaths, heart attacks and strokes in patients taking ramipril. In addition there was also a reduction in the need for vascularisation procedures and diabetic complications. The number of patients who developed CHF was reduced by 21% in the ramipril group, which was unexpected since the patients had no signs or symptoms of CHF when the study started (page 11, lines 2 to 14).

2. The Respondent argues that the disclosure of patients not having signs or symptoms of CHF did not mean that these were patients with no preexisting CHF, as required by claim 1. Patients with CHF could be free of symptoms with the consequence that the patient group of the example was different from the one specified in claim 1.

Example 1 is a clinical study. The participants of this study have been selected on the basis of several clinical parameters (see page 10, lines 21 to 29) which require a detailed medical check-up. The disclosure on page 11, lines 12 to 14, saying that the patients had no signs or symptoms of CHF when the study started, is not therefore considered to be a perfunctory statement, by which it cannot be excluded that symptom free CHF patients are included in the study, but is considered to be the result of a medical examination which shows that the participants indeed had no preexisting CHF.

3. The Opposition Division, in point (4.2) of the decision under appeal, decided that the feature requiring that "the patient exhibits normal or low blood pressure" had no basis in the application as published, and in particular not in the example.

It argued, that "based on the average value of blood pressure of 138 mmHg of the example, it was impossible to determine or conclude that the blood pressure of the individual participants in the study was indeed normal or low." The value of 138 mmHg was defined in prior art documents, such as document (20), as "high-normal" blood pressure. The Opposition Division concluded that neither the interpretation of the value 138 mmHg as average value of several measurements in the same patient, nor as collective average of all patients, allowed the conclusion "that the term 'normal or low blood pressure' has a clear and ambiguous basis in the originally filed documents."

4. The application as published reads on page 10, lines 26 to 27 (paragraph [0008] of the patent), directly after the disclosure that the systolic blood pressure of the patients was on average 138 mmHg: "... thus the patients were normotensive at study start."

This technical term is defined on page 3, lines 22 to 23 of the application as published, which read:

"Patients exhibiting a normal or low blood pressure are known as normotensive patients."

For this reason alone, independent of the definition of "normal or low blood pressure" in the prior art, the

Board is convinced that the introduction of this feature into the claim of the main request does not constitute an amendment which contravenes the requirements of Article 123(2) EPC.

5. Moreover, document (20), which is referred to on page 3, lines 23 to 26 of the application as published (paragraph [0008] of the patent), defines hypertension as systolic blood pressure (SBP) of 140 mmHg or greater, diastolic blood pressure (DBP) of 90 mmHg or greater or taking antihypertensive medication (page 11, left column, lines 1 to 4). Table 2 on page 11 discloses a classification of blood pressure for adults aged 18 and older. The indicated categories are defined as "Optimal", "Normal", "High-Normal" and "Hypertension" with the sub-categories "Stage 1", "Stage 2" and Stage 3". The typical SBP of the category "High-normal" is 130 to 139 mmHg.

A SBP of 138 mmHg, which is the average SBP of patients participating at the clinical study of example 1, qualifies the patients as members of the category "High-normal". According to the definition of hypertension in document (20) this is not a pathologic state requiring special treatment or medication. Rather, the Board is of the opinion that the category "High-normal" as defined in document (20) is a sub-category of "Normal" at the alarming end thereof.

6. In summary, the Board decides that the sole claim of the main request has not been amended in such a way as to contain subject-matter extending beyond the content of the application as published, and thus meets the requirements of Article 123(2) EPC.



*Remittal - Article 111(1) EPC*

7. According to Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to the department for further prosecution.

Remittal to the department of first instance is at the discretion of the board (cf decision T 1091/00, 2 July 2002).

Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should preferably be given the opportunity to have two readings of the important elements of the case. The essential function of appeal proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally remitted, if essential questions regarding the patentability of the claimed subject matter have not yet been examined and decided by the department of first instance.

8. In particular, remittal is taken into consideration by the Boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other essential issues outstanding. If, following appeal proceedings, the particular issue is decided in favour of the Appellant, the case is normally remitted to the first instance department for consideration of the undecided issues.

9. The Opposition Division in the appealed decision has dealt with the requirements of Articles 123(2) EPC, without comprehensively touching any other substantial requirements of the EPC. Thus, fundamental requirements for the maintenance of a patent have not yet been examined by the department of first instance. Consequently, the examination was not carried out in a way to put the Board in a position to decide now, on the basis of a comprehensive examination of the department of first instance, whether or not the substantial requirements of the EPC are met by the invention as presently claimed.

Therefore, at its discretion under Article 111(1) EPC, the Board decides to remit the case to the department of first instance for further prosecution.

**Order**

**For these reasons it is decided:**

1. The decision under appeal is set aside.
  
2. The case is remitted to the department of first instance for further prosecution on the basis of the claim of the main request filed on 22 June 2010.

Registrar:

Chairman:

P. Cremona

C. Rennie-Smith