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**D E C I S I O N**  
**of 13 September 2002**

**Case Number:** T 0346/01 - 3.3.4

**Application Number:** 93810161.5

**Publication Number:** 0560723

**IPC:** A61K 37/36

**Language of the proceedings:** EN

**Title of invention:**

Method and composition for the treatment of osteoporosis

**Applicants:**

Novartis AG, et al

**Opponent:**

-

**Headword:**

Osteoporosis/NOVARTIS

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

"Main and auxiliary requests - added subject-matter (yes)"

**Decisions cited:**

T 0597/92, T 0917/94, T 0596/96, T 0863/96

**Catchword:**

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**Case Number:** T 0346/01 - 3.3.4

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.4**  
**of 13 September 2002**

**Appellants:**

Novartis AG  
Lichtstrasse 35  
CH-4056 Basel (CH)

and

Novartis-Erfindungen  
Verwaltungsgesellschaft m.b.H.  
Brunner Strasse 59  
A-1235 Wien (AT)

**Representative:**

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**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted 22 December 2000  
refusing European patent application  
No. 93 810 161.5 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey

**Members:** L. Galligani  
S. C. Perryman

## Summary of Facts and Submissions

- I. The applicants lodged an appeal against the decision of the examining division dated 22 December 2000 whereby the European patent application No. 93 810 161.5 (published as EP-A-0 560 723) was refused on the grounds of lack of novelty and lack of inventive step. Basis of the rejection were claims 1 to 15 filed on 20 July 1998 of which claim 1 read as follows:

"Use of a compound selected from IGF-I, an active fragment thereof, an active analog thereof, or an active fragment of either IGF-I or its analog for the production of a pharmaceutical composition for the treatment of osteoporosis in a mammal having reduced cortical bone mineral density or preventing the same in a mammal prone thereto".

Dependent claims 2 to 15 concerned particular embodiments of the use according to claim 1.

- II. With the statement of grounds of appeal the appellants filed a new main request and an auxiliary request. The two requests contained the limitation of the treatment of osteoporosis either to "*a mammal having reduced cortical bone mineral density but not a significantly reduced trabecular bone mineral density*" (**main request**) or to "*a mammal having reduced cortical bone mineral density but not reduced trabecular bone mineral density*" (**auxiliary request**). In support of such an amendment reference was made to page 2, last paragraph of the application as filed.

In their view, the amended claims fulfilled the novelty and inventive step requirements as the prior art cited by the examining division did not disclose an effect of the compounds quoted in claim 1 on osteoporotic diseases involving only cortical bone loss.

- III. On 27 May 2002, the appellants were summoned to oral proceedings scheduled to take place on 13 September 2002. In the communication annexed to the summons the board drew the appellants' attention to the fact that there was no basis in the application as filed for the proposed amendments of both the main and auxiliary requests, and that also the introduction of the proposed new features as a disclaimer was not admissible as it was not in line with the established case law on disclaimers (cf eg T 863/96 of 4 February 1999; T 596/96 of 14 December 1999; T 917/94 of 28 October 1999; T 597/92 OJ 1996, 135).
- IV. On 2 September 2002 the appellants informed the board that they did not intend to appear at oral proceedings. They provided no reply to the board's objections. Nor were further requests filed. The appellants stated: "We are however maintaining all our objections set forth in previous correspondences against maintenance of the aforementioned EP application". The board interpreted this peculiar request, in the light of the request stated in the grounds of appeal "...we respectfully request that the decision be reversed...", as meaning maintenance of the previous requests, namely that the decision under appeal be set aside, the case be prosecuted on the basis of either one of the claim requests filed on appeal and the appeal fee be reimbursed.

- V. Oral proceedings took place on 13 September 2002. The appellants did not appear.

### Reasons for the Decision

1. Claim 1 of the main and auxiliary requests contains - with reference to mammal to be treated - the feature "having reduced cortical bone mineral density **but not a significantly reduced trabecular bone mineral density**" and "having reduced cortical bone mineral density **but not reduced trabecular bone mineral density**", respectively (emphasis added).
2. As a support for such an amendment, the appellants refers to page 2, last paragraph of the application as filed which reads: "Surprisingly, IGF-I has now been found to be useful in the treatment of osteoporosis in mammals exhibiting decreased cortical bone mineral density and those exposed to drugs or environmental conditions which tend to result in bone density reduction and potentially to an osteoporosis condition".
3. The said passage relied upon by the appellants, while referring to mammals exhibiting decreased cortical bone mineral density, fails to refer to a condition of non-(significantly) reduced trabecular bone mineral density. As stated also in the description of the background of the invention (cf page 1 of the application as filed), neither type I nor type II osteoporosis are characterised by such a sharp distinction in zonal bone density. Nowhere else in the application as filed can a reference be found to mammals affected by an osteoporotic disease involving

only cortical bone loss, without (significant) reduction of trabecular bone mineral density.

Thus, the two features represent added matter which constitutes an offence against Article 123(2) EPC.

4. Also the introduction of the said features in the respective claim requests as a disclaimer vis-à-vis the prior art cited by the examining division in relation to novelty and inventive step is not admissible because it is not in line with the established case law on disclaimers. The case law indicates that the instrument of the disclaimer is to be used **only** for excluding from the ambit of a claim an "accidental disclosure" by a document which is then no longer taken into account in the substantive examination (cf eg T 863/96, T 596/96, T 917/94, supra), and that it should not be used for purposes of inventive step (eg T 597/92, supra).
5. For the above reasons, none of the claim requests on file is allowable under Article 123(2) EPC, and the appeal must be dismissed.
6. As the appeal must be dismissed, one of the prerequisites of Rule 67 EPC for the reimbursement of the appeal fee is not fulfilled, and the request for reimbursement accordingly must be refused.

**Order**

**For these reasons it is decided that:**

1. The appeal is dismissed.
2. The request for reimbursement of the appeal fee is refused.

The Registrar:

The Chairperson:

P. Cremona

U. Kinkeldey