

**Internal distribution code:**

- (A)  Publication in OJ  
(B)  To Chairmen and Members  
(C)  To Chairmen  
(D)  No distribution

**D E C I S I O N**  
**of 22 May 2006**

**Case Number:** T 0232/06 - 3.3.04

**Application Number:** 99902261.9

**Publication Number:** 1105145

**IPC:** A61K 35/78

**Language of the proceedings:** EN

**Title of invention:**

Method and pharmaceutical composition for reducing serum  
homocysteine concentration

**Applicant:**

Wakunaga of America Co. Ltd., et al

**Opponent:**

-

**Headword:**

Homocysteine/WAKUNAGA

**Relevant legal provisions:**

EPC Art. 109, 113(1)

EPC R. 67

**Keyword:**

"Interlocutory revision"

"Substantial procedural violation (no)"

"Reimbursement of appeal fee (no)"

**Decisions cited:**

G 0003/03, T 0201/98

**Catchword:**

-



Case Number: T 0232/06 - 3.3.04

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.04  
of 22 May 2006

**Appellant:** Wakunaga of America Co. Ltd., et al  
23501 Madero  
Mission Viejo, CA 92691-2744 (US)

**Representative:** Audier, Philippe André  
Brevalex  
3, rue du Docteur Lancereaux  
F-75008 Paris (FR)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 14 September 2005  
refusing European application No. 99902261.9  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chair:** U. Kinkeldey  
**Members:** D. Rogers  
R. Gramaglia

## Summary of Facts and Submissions

- I. This appeal lies against the decision of the Examining Division dated 14 September 2005, refusing European patent application No. 99 902 261.9 relating to a "Method and pharmaceutical composition for reducing serum homocysteine concentration". The appeal fee was paid, and the notice of appeal and the statement of grounds were filed together on 23 November 2005.
- II. The application as filed included claims 1 to 20, with the independent claims being claims 1 and 10. In a communication dated 21 June 2004 the Examining Division cited the following documents D1 to D6:

D1: US-A-5 231 114A

D2: Kailash C. Agarwal: "Therapeutic Actions of Garlic Constitutents" Medicinal Research Reviews, vol. 16, no. 1, 1996, pages 111-124, XP002917171

D3: US-A-4 737 364A

D4: WO 95 15750 A1

D5: Kendler BS: "Recent Nutritional Approaches to the Prevention and Therapy of Cardiovascular Disease" Progress in Cardiovascular Nursing, Lippincot, Philadelphia, US, vol. 12, no. 3, 21 June 1997 (1997-06-21), pages 3-23, XP000978849 ISSN: 0889-7204

D6: DATABASE WPI Section Ch, Week 199747 Derwent Publications Ltd., London, GB; Class D13, AN 1997-503713 XP002269773 & CN 1 123 113 A (GUO X) 29 May 1996 (1996-05-29)

The Examining Division stated that, in respect of claims 1 to 9, they were not allowable in the form they were drafted as they related to treatment of the human

or animal body, and that a claim in the form of "use of a substance or composition X for the manufacture of a medicament for therapeutic application Z" would be allowable for a second or further medical application provided that such an application was new and inventive.

In addition the communication stated that claims 1, 4, 5, 7, and 9 were not novel in the light of documents D1 or D2; that claims 10 to 16 and 19 were not novel in the light of document D3; that claims 1, 2, 5, 7 and 9 were not novel in the light of document D5; and that claims 1 to 20 did not involve an inventive step in the light of document D4. Under point 5.1 of the communication reference was made to clarity objections that had already been stated in the IPER ("International Preliminary Examination Report"). Under point 6 of the communication it was stated that it was not apparent which part of the application could serve as a basis for new allowable claims. Furthermore, in the letter accompanying the communication it was stated that:

"The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC".

III. With a letter of 29 December 2004 the applicant filed a new set of claims 1 to 9 with amendments addressing the second medical use format objections, as well as

arguments with respect to novelty, and inventive step. Claims 10 to 20 were deleted.

IV. The Examining Division then refused the application on the grounds that the subject-matter of claims 1, 4, 5, 7, and 9 was not novel in the light of the disclosure of documents D1 or D2; and that the subject-matter of claims 1, 2, 5, 7, and 9 was not novel in the light of the disclosure of document D5.

V. With the statement of the grounds of appeal the applicant submitted a new set of claims and requested that the decision under appeal be set aside and that the appeal fee be reimbursed. The applicant argued at point 7 of its Notice of Appeal that:

"Reimbursement of the Appeal fee is requested according to Rule 67 EPC. Indeed, the principle of the right to be heard enshrined in Article 113(1) EPC has been violated. The Applicants had no opportunity to present comments on the grounds for the contested decision. The decision is based on a new set of claims filed in response to a first EPO Communication pursuant to Article 96(2) EPC".

In the Notice of Appeal, the Applicant also requested oral proceedings in the "...event that the Board of Appeal intended to reject the patent Application".

VI. Following the appeal by the applicant, the Examining Division ordered rectification and set aside its decision of 14 September 2005 pursuant to Article 109(1) EPC. However the Examining Division did not allow the applicant's request for reimbursement of the appeal fee,

this request being forwarded to the Board of Appeal for a decision.

### **Reasons for the Decision**

1. The decision of the Enlarged Board of Appeal in the case G 3/03 of 28 January 2005 deals with the questions of whether in the event of interlocutory revision under Article 109(1) EPC, the department of the first instance whose decision has been appealed has the power to refuse a request of the appellant for reimbursement of the appeal fee and, if the department of the first instance does not have that power, how the competent Board of Appeal should be constituted. The Enlarged Board decided that the department of the first instance is not competent to deal with the matter and instead the Board of Appeal which would have been competent under Article 21 EPC to deal with substantive issues of the appeal if no interlocutory revision had been granted is competent to decide on the request. Accordingly the present Board is competent to decide on the request for reimbursement of the appeal fee.
  
2. According to Rule 67 EPC, in the event of interlocutory revision the appellant's request for reimbursement of the appeal fee can only be granted if equitable by reason of a substantial procedural violation. In the present case the applicant's argument is that the Examining Division issued its decision upon the basis of a new set of claims filed in response to a single earlier EPO communication, and without giving the applicant any further opportunity to respond, and that the decision is thus based on grounds or evidence on

which the applicant did not have the opportunity to present his comments, so that the decision does not comply with Article 113(1) EPC.

The applicant was informed in the communication dated 21 June 2004 of the Examining Division's view that claims 1 to 9 were not allowable in the form drafted because they related to treatment of the human or animal body, and that they did not have the correct format for a second or further medical application, that claims 1, 2, 4, 5, 7, 9 to 16 and 19 were not novel, and that claims 1 to 20 did not involve an inventive step. Reasons for these views were given in the communication. The new set of claims filed on 29 December 2004 in response to the communication consisted of amended claims 1 to 9 with claims 10 to 20 being deleted. Claims 1 to 9 were amended to take into account the treatment of the human or animal body and second medical use format objections of the Examining Division. Thus the amended claims did not contain subject matter on which the Examining Division had not given its view.

The decision of the Examining Division was based on the reasons given in its communication of 21 June 2004 - inter alia the lack of novelty of the claims. The applicant had had the opportunity to present comments and/or amended claims, not only in respect to the second medical use format and treatment of the human or animal body objections, but also with respect to the novelty issue.

The applicant's argument in favour of the request for reimbursement of the appeal fee is that the decision of

refusal was made without giving the applicant the opportunity to present comments on the grounds of the contested decision. In essence, the applicant objects that the Examining Division refused the application after only a single communication.

It is the established jurisprudence of the Boards of Appeal (see e.g. decision T 201/98 of 27 July 1999) that an Examining Division is not obliged to issue a further communication if the applicant has presented his comments on a first communication and a decision can be made based on the reasons of the first communication. Although a previous version of the Guidelines for Examination in the European Patent Office, Part C, Chapter VI, Section 4.3, suggested that refusal might be appropriate if the applicant had not made any real attempt to deal with the Examining Division's objections, the present version, dated June 2005, merely states that if the applicant has not dealt with all the main objections, and no positive reaction is to be expected from drawing deficiencies to his attention then immediate refusal should be considered. This is also reflected by the wording of the letter accompanying the Examining Division's communication of 21 June 2004 - see section II, last two paragraphs, above.

The Examining Division indicated in its communication of 21 June 2004 that it was not clear to it which part of the application could serve as a basis for new, allowable claims. The letter accompanying the communication also states that if the various deficiencies referred to in the communication are not remedied then the application could be refused - see



last paragraph of section II above. Thus the applicant should have been aware that, if its arguments were not deemed to be persuasive, there was a possibility that the application would be refused. Although it was open to the applicant to file a request for oral proceedings to deal with this eventuality, no such request was made.

The Examining Division clearly stated in the communication dated 21 June 2004 that, amongst other things, original claims 1, 2, 4, 5, 7 and 9 were not considered to be novel in the light of the disclosures of documents D1, D2, D5 (see section IV above), and that claims 1 to 20 were considered to lack inventive step in the light of the disclosure of document D4. However, the redrafted claims 1 to 9 in the applicant's response of 29 December 2004 are directed towards meeting the objections to the original claims that concerned treatment of the human or animal body and the incorrect second medical use format of claims 1 to 9 as originally filed.

Even though it might be appropriate in many cases to draw the applicant's attention to such deficiencies e.g. by a telephone call, as suggested in the Guidelines for Examination in the European Patent Office, edition of June 2005, Part C, Chapter VI, Section 4.3, in the Board's view the Examining Division did not exceed its discretionary power in the present case by not doing so. No substantial procedural violation can be found, which would justify the reimbursement of the appeal fee.

**Order**

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

The request for reimbursement of the appeal fee is refused.

Registrar:

Chair:

P. Cremona

U. M. Kinkeldey