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**D E C I S I O N**  
**of 31 May 2005**

**Case Number:** T 0188/04 - 3.3.4

**Application Number:** 94908462.8

**Publication Number:** 0765171

**IPC:** A61K 39/395

**Language of the proceedings:** EN

**Title of invention:**

Treatment of autoimmune and inflammatory disorders

**Applicant:**

THE KENNEDY INSTITUTE OF RHEUMATOLOGY

**Opponent:**

-

**Headword:**

Treatment of autoimmune disorders/THE KENNEDY INSTITUTE OF  
RHEUMATOLOGY

**Relevant legal provisions:**

EPC Art. 82, 68(2), 67

**Keyword:**

"Lack of unity of invention: inadequate reasoning"  
"Substantial procedural violation (yes)"  
"Reimbursement of appeal fee (yes)"

**Decisions cited:**

W 0013/87, W 0011/89, W 0006/90, W 0006/91, W 0050/91,  
W 0022/92, W 0052/92, W 0008/94, T 0001/96, W 0006/97,  
W 0017/03, T 0048/00, T 0278/00, T 0375/00, T 0897/03

**Catchword:**

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Case Number: T 0188/04 - 3.3.4

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 31 May 2005

**Appellant:**  
(applicant)

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**Decision under appeal:**

Decision of the Examining Division of the  
European Patent Office posted 27 August 2003  
refusing European application No. 94908462.8  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairwoman:** U. M. Kinkeldey  
**Members:** R. E. Gramaglia  
S. C. Perryman

## Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division to refuse European patent application 94908462.8, published as WO 95/09652. The decision is on the application as filed with amended claims 1-19 as received on 5 February 2002 and amended pages 9,10 and 36 as received on 30 June 2000.

II. The Examining Division refused the application for the reason that the claims lacked unity within the meaning of Article 82 EPC. For coming to its decision of lack of unity of invention the Examining Division gave the following reasons:

*"1. The present application concerns the treatment of autoimmune or inflammatory disease such as rheumatoid arthritis. The single general inventive concept identified by the Examining Division is that stated on p.3 lines 19-24, namely "the current invention pertains to the discovery that combination therapy, involving the use of a CD4+ T cell inhibiting agent in conjunction with a TNF antagonist, produces markedly superior results than the use of each agent alone ....*

*1.2. Analysis of the amended claims, in the light of the above, produces the following groups of claims:*

(a) Claims 1-8, 9(part), 10, 11, 12(part), 16(part), 18 and 19: *Product comprising CD4+ T cell inhibiting agent in conjunction with TNF antagonist, use thereof.*

- (b) Claims 9(part), 12 (part) and 16(part): Product comprising cyclosporin A and an inflammatory mediator comprising an agent which interferes with the activity or synthesis of IL-1 or IL-6 or a cytokine with anti-inflammatory properties, use thereof.
- (c) Claims 13-15, 16(part) and 17: product comprising methotrexate and an anti TNF $\alpha$  antibody or soluble TNF $\alpha$  receptor, use thereof.

1.3. It is clear that the single general inventive concept as defined in paragraph 1 does not encompass all groups of claims as methotrexate is an anti-inflammatory agent (page 7 line 32) not a CD4+ T cell inhibiting agent as defined at page 6 lines 3-22. Therefore the claims lack unity, contrary to Article 82 EPC." (italics added, bold and certain underlining omitted by the Board).

III. In addition and before referring to further objections explicitly stated as not forming the ground for refusal (reasons 2 to 7), the decision under appeal contains the following statements:

"1.4. The original search strategy was primarily designed around identifying documents which disclosed CD4+ T cell inhibiting agent as defined at page 6 lines 3-22 and TNF antagonists as defined at page 6 lines 23-31. Furthermore it also tried to include the use of inflammatory mediators as defined on page 7 lines 1-31 as these formed embodiments specifically claimed. The use of methotrexate was not originally claimed. Therefore, having regard to claim group (c)

*defined above, the subject matter of this group relates to subject matter that has not been searched and thus infringes Rule 86(4) EPC and need not be considered further.*" (bold omitted by the Board), and

*"1.5. Even if it were to be established that claim group (c) is unitary, serious objections under Article 83 EPC and 123(2) EPC would arise as the only passage in the description which actually refers to methotrexate (page 7 line 33 - page 8 line 2) is ambiguous in meaning ("..in conjunction with.."; "..and/or..") with regard to the precise combinations in which methotrexate might be used and so cannot form the basis for the claims group (c)." (bold omitted by the Board).*

- IV. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request (claims as subject to the decision under appeal) or on the basis of auxiliary requests 1 or 2 filed with the statement of the grounds of appeal.
- V. With letter dated 31 March 2005 and in response to a communication annexed to a summons to oral proceedings, Appellant clarified that his request for oral proceedings did not apply if the Board, on the basis of the written submissions on file, were to come to the decision that the decision under appeal was to be set aside and the case was remitted to the Examining Division for further prosecution of the main request. Subsequently, the Board cancelled the scheduled oral proceedings.

## Reasons for the Decision

1. The appeal is admissible.
2. As basis for the decision under Appeal the Board sees only the reasoning relating to lack of unity of invention contrary to Article 82 EPC. The further comments relating to Rule 86(4) EPC and the "serious objections" to claims 13 to 17 under Articles 83 and 123(2) EPC (see above section VI) do not appear to have been relied on as a basis for the decision, and in any case contain no separate reasoning.

### *Unity of invention*

3. Pursuant to Article 82 EPC the European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Rule 30(1) EPC gives an interpretation of the concept of unity of invention where a group of inventions is claimed. In such case the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features, i.e. those features which define a contribution which each of the claimed inventions as a whole makes over the prior art.
4. According to the established case law of the Boards of Appeal (see Case Law of the Boards of Appeal of the EPO, 4<sup>th</sup> Edition, 2001, page 184 ff.), determining unity of invention requires as a precondition an analysis of the technical problem or problems underlying the respective

groups of inventions (see decision W 11/89, OJ EPO 1993, 225, followed by numerous decisions including e.g. W 6/91 of 3 April 1992; W 8/94 of 21 November 1994, W 6/97 of 18 September 1997 and W 17/03 of 20 September 2004).

- 4.1 In particular, in the context of Article 17(3)(a) PCT, the Board held in decision W 11/89 (*supra*, Headnote) that "to demonstrate that a group of inventions does not form a single inventive concept, an invitation to pay additional search fees ... must address the problem underlying the invention unless it is immediately clear that the technical details listed in the invitation cannot reasonably be seen as parts of an overall problem. If the invitation does not, when so required, address the problem set out in the application, it is not legally effective and any additional search fees must be refunded."
- 4.2 In decision W 6/91 (*supra*, reasons, point 4) the Board held that "the determination of the technical problem underlying the invention is ... a mandatory precondition for the assessment of unity of invention, i.e. whether or not the subject-matter claimed as solution of such a problem represents a single general inventive concept. The disregard of this principle would be in itself sufficient justification for the reimbursement of the additional search fees."
- 4.3 In decision nW 8/94 (*supra*, reasons, point 5.1) the Board held that a discussion of the problem underlying the claimed subject-matter was required, because only then was it possible to decide whether or not a common

special technical feature existed for different embodiments.

5. Lack of unity may be directly evident *a priori*, i.e. before the examination of the merits of the claims in comparison with the state of the art revealed by the search; alternatively a lack of prior art may follow from an objection *a posteriori*, i.e. after having taken the prior art revealed by the search into closer consideration (cf. decision W 1/96 of 22 May 1996, reasons, point 3; W 13/87 of 9 August 1988, reasons, point 3; W 6/90, OJ EPO 1991, 438). If the objection of lack of unity is raised *a priori*, the technical problem must be defined on the basis of the description and possibly the prior art acknowledged therein (cf. decisions W 50/91 of 20 July 1992, reasons, point 4; W 22/92 of 16 November 1992, point 3.1; W 52/92 of 2 April 1993, reasons, point 2). Similarly, in an *a posteriori* non-unity situation, establishing the technical problem underlying a claimed invention or group of inventions in relation to the state of the art should start, as a rule, from what is considered in the description as having been achieved by the claimed invention. As soon as the search reveals relevant prior art it is then necessary to determine the particular technical problem in view of both the disclosure of the international application as a whole and the prior art. Unity of invention may be assessed only after the technical problem had been determined in such a manner (see e.g. decision W 6/97, *supra*, reasons, points 6.3 and 6.4).
6. For the purpose of the present decision, the Board considers it irrelevant whether the Examining Division



argued in the reasons for the decision lack of unity of invention pursuant to Article 82 EPC on an *a priori* or *a posteriori* basis. In fact, as can be taken from the above and in accordance with established case law of the Boards of Appeal, both assessment approaches for the examination of the requirement of unity of invention require as a precondition an analysis of the technical problem or problems underlying the respective groups of inventions it needs to be established whether the decision under appeal complies with this requirement.

7. Pursuant to Rule 68(2), first sentence, EPC, decisions of the European Patent Office which are open to appeal shall be **reasoned**. In accordance with established jurisprudence of the Boards of Appeal (see e.g. decisions T 48/00 of 12 June 2002; T 897/03 of 16 March 2004 and T 375/00 of 7 May 2002) this means that a decision of a department of the first instance must contain the grounds upon which a decision is based as well as, in detail and in logical sequence, all decisive considerations in respect of the factual and legal aspects of the case which justify the tenor of the decision. The reasons make a party adversely affected aware of why a decision was taken in a particular direction and enable that party to consider whether, in view of the reasons, the decision is correct.
  
8. In the present context the Board considers that, if a decision denying compliance of a patent application with the requirement of Article 82 EPC is devoid of an analysis of the technical problem or problems underlying the respective groups of inventions, such a

decision is seriously deficient so as to not be in compliance with the requirements of Rule 68(2), first sentence, EPC

8.1 In the reasons for its decision that the application lacks unity of invention pursuant to Article 82 EPC, the Examining Division has adopted the following approach (see points 1, 1.2 and 1.3 in section V above):

- it identifies a "*single general inventive concept*" in the description of the application
- subsequently divides the claims in three groups "*in the light of the above*", and
- argues that the identified concept does not encompass all groups of claims.

8.2 Hence, the Examining Division did not define a technical problem underlying the claimed inventions be it in the light of the description or of the description read in the light of the revealed prior art. The Board therefore considers, in line with the established case law, that the decision under appeal as to the reasons for finding lack of unity of invention is inadequately reasoned and, hence, seriously deficient so as to not be in compliance with the requirements of Rule 68(2), first sentence, EPC.

*Reimbursement of the appeal fee*

9. Pursuant to Rule 67, first sentence, EPC the reimbursement of the appeal fee shall be ordered in the event that the appeal is deemed allowable and if such

reimbursement is equitable by reason of a substantial procedural violation. In the present case, the Board deems the appeal allowable.

10. Deficiencies of the requirements of Rule 68(2), first sentence, EPC in decisions under appeal have been recognised in the jurisprudence as being procedural defects which may constitute substantial procedural violations rendering the reimbursement of the appeal fee equitable within the meaning of Rule 67 (Case Law of the Boards of Appeal of the European Patent Office, 4<sup>th</sup> edition 2001, VII.D.15.4.4, page 558; see also e.g. decision T 278/00 of 11 February 2003). In the Board's judgment, the absence of adequate reasoning in relation to lack of unity of invention (Article 82 EPC), the only ground for refusal in the decision under appeal, amounts to a substantial procedural violation. Furthermore, although the appellant has not requested reimbursement of the appeal fee, the board considers this substantial procedural violation equitably to justify the reimbursement of the appeal fee.

*Remittal of the case to the department of first instance*

11. As numerous issues remain to be examined properly, the case is remitted to the Examining Division for further prosecution on the basis of the application documents that formed the basis for the decision under appeal.

*Other issues*

12. In view of the decision of the Board, oral proceedings were not necessary in the present case.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.
3. The appeal fee is reimbursed.

The Registrar:

The Chairwoman:

P. Cremona

U. Kinkeldey