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**D E C I S I O N**  
of 28 April 1995

**Case Number:** T 0891/92 - 3.3.4

**Application Number:** 86402171.2

**Publication Number:** 0218531

**IPC:** C07K 7/00

**Language of the proceedings:** EN

**Title of invention:**

Immunogenic peptides of human interleukin-1 and the corresponding anti-peptide antibodies

**Applicant:**

MERCK & CO. INC.

**Opponent:**

-

**Headword:**

Immunogenic peptides/MERCK

**Relevant legal provisions:**

EPC Art. 113(1), 96(2), 111(1)  
EPC R. 51(3), 67

**Keyword:**

"Basis of decision - opportunity to comment (no)"  
"Substantial procedural violation (yes)"  
"Reimbursement of appeal fee (yes)"  
"Remittal (yes)"

**Decisions cited:**

T 0640/91, T 0162/82

**Catchword:**

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Case Number: T 0891/92 - 3.3.4

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 28 April 1995

**Appellant:**

MERCK & CO. INC.  
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**Representative:**

Warcoin, Jacques  
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**Decision under appeal:**

Decision of the Examining Division of the European Patent Office dated 16 April 1992 refusing European patent application No. 86 402 171.2 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 Appellants (Applicants) lodged an appeal against the decision of the Examining Division dispatched on 16 April 1992 on the refusal of the application No. 86 402 171.2, published as EP-A-0 218 531.

In a communication pursuant to Article 96(2) and Rule 51(2) EPC, the Examining Division had informed the Appellants that the application did not meet the requirements of the EPC, because the subject-matter of Claims 1 to 3 lacked an inventive step having regard to the following documents:

- (1) J.Exp.Med., Vol. 160, 1984, pages 772 to 787;
- (2) Nature, Vol. 315, 1985, pages 641 to 647,

and the subject-matter of Claims 4 to 7 provided no inventive contribution, having further regard to the following document:

- (3) EP-A-0 044 710.

In reply to the letter of the Appellants dated 14 February 1992, the Examining Division issued the decision to refuse the application according to Article 97(1) EPC on the grounds that the subject-matter of Claim 1 lacked an inventive step in the light of the combined disclosures of documents (3) and (2). The Examining Division considered that document (3), which taught the use of synthetic peptides in the generation of antibodies, represented the closest prior art and that, in view of the disclosure in document (2) of the complete primary structure of interleukin-1 $\beta$  (IL-1 $\beta$ ), the selection of the peptides of Claim 1 for the generation of antibodies was to be considered obvious.

It is worth noting that document (3) which had been referred to as D3 in the first and only official communication of the Examining Division, was referred to as D1 in the subsequent decision of refusal.

- II. The Appellants requested that the decision under appeal be set aside and a patent granted on the basis of the application documents as originally filed or, as a subsidiary request, on the basis of Claims 1 to 35 as filed with the statement of grounds on 17 August 1992. Moreover, the Appellants requested the reimbursement of the appeal fee in view of the fact that, firstly, there had been a violation of Article 113 EPC and, secondly, the appealed decision was not properly reasoned.

#### Reasons for the Decision

1. The appeal is admissible.

#### *Procedural violation and reimbursement of appeal fee (Rule 67 EPC)*

2. According to Article 113(1) EPC, "the decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments".
3. According to Article 96(2) EPC, "if the examination of a European patent application reveals that the application or the invention to which it relates does not meet the requirements of this Convention [the EPC], the Examining Division shall invite the applicant, in accordance with the Implementing Regulations and as often as necessary, to file his observations within a period to be fixed by the Examining Division". As stated in decision T 640/91

(OJ EPO 1994, 918, see point 6.1 of the Reasons), the words "as often as necessary" implicitly recognise that in certain circumstances there will be a legal obligation upon an Examining Division to invite further observations from the Applicant before issuing a decision. For example, it would be legally mandatory to invite further observations from an Applicant before issuing a decision based on grounds or evidence on which the Applicant had not previously had an opportunity to present his comments (Article 113(1) EPC). In such circumstances a failure to invite further observations would be a substantial procedural violation within the meaning of Rule 67 EPC (cf. T 640/91, loc.cit.). However, as stated in that decision and also in decision T 162/82 (OJ EPO 1987, 533, see point 12 of the Reasons), in the absence of circumstances which create such a legal obligation, the Examining Division has a discretion in each individual case as to whether or not to communicate with the Applicant before issuing a decision. Article 96(2) EPC "relieves the Examining Division of any obligation to send communications which on a reasonable, objective basis could be considered superfluous" (cf. T 162/82, loc.cit.).

4. According to Rule 51(3) EPC, "any communication pursuant to Article 96, paragraph 2, shall contain a reasoned statement covering, where appropriate, all the grounds against the grant of the European patent."
5. In the present case, the application was refused after only one communication from the Examining Division and observations in reply from the Appellants, with no invitation to them to file further observations, and with no warning letter to them of the likelihood that the application would be refused. It should therefore be decided whether in its decision the Examining Division has exercised its discretion according to the wrong

principles, or without taking into account the right principles, or in an unreasonable way (see decision T 640/91 supra, point 6.3 of the Reasons).

5.1 In the first and only official communication before the refusal of the application, the Examining Division denied an inventive step for the subject-matter of claims 1 to 3 on the basis of the combined teachings of documents (1) and (2) which disclosed, respectively, purified human IL-1 $\beta$  from natural source and the complete amino acid sequence of the mature and precursor form of human IL-1 $\beta$  as deduced from the corresponding gene. In the opinion of the Examining Division, the selected peptides of Claim 1 were completely based on the data available from the prior art, no special effects being presented. Furthermore, in view of the fact that the use of synthetic peptides in the generation of antibodies was known from document (3), the Examining Division concluded that no inventive contribution was contained in Claims 4 to 7, especially in consideration of the sequence alignments of human IL-1 $\alpha$  and IL-1 $\beta$  disclosed in document (2). Similar objections were said to apply to Claims 8 to 28, no reasoning therefor being given. The quoted communication also denied an inventive step for the subject-matter of Claims 29 to 36 having regard to two newly cited, additional prior art documents; however, this aspect can be left out of consideration for the purpose of the present decision.

5.2 In their letter of reply, the Appellants maintained that the present invention concerned unique and highly specific polypeptides which could not have been selected among the hundreds of polypeptides contained within the sequence of human IL-1 $\beta$  without the directions given by the present application. Moreover, with reference to the objections raised by the Examining Division in respect

of Claims 4 to 7, they maintained that the claimed antibodies were not just antibodies against IL-1 $\beta$ , but rather monospecific antibodies directed against regions of human IL-1 $\beta$  corresponding to the immunogenic peptides of Claim 1.

- 5.3 In the appealed decision, the Examining Division identified document (3) as the closest prior art, defined the underlying technical problem as the selection of new peptides to be used in the generation of antibodies binding specifically to precursor and mature human IL-1, pH 6.8 or fragments thereof, and arrived at the conclusion that the selected peptide sequences of Claim 1 were obvious having regard to document (2), said peptides being merely predictable examples of the general method disclosed in document (3). For the same reasons, the Examining Division rejected Claims 5 and 7 and stated that the remaining claims shared the same fate.
- 5.4 The Board observes that the reasoned statement on which the rejection of the application is based differs from the objections put forward in the first and only official communication. While in the latter the inventive step objection to Claim 1 was based on the combined teachings of documents (1) and (2), in the appealed decision Claim 1 was rejected on the basis of the combined teachings of documents (3) and (2). The submissions by the Appellants in reply to the first official communication prompted the Examining Division to use a reasoning based on a different combination of documents in its inventive step attack on Claim 1. Under these circumstances, there was a legal obligation under Article 113(1) EPC on the Examining Division to issue a further communication to the Appellants in order to give them an opportunity to present their comments on the new argument for refusal put forward. The fact that

document (3) had already been referred to in the first official communication is immaterial because in the latter this document was used in the context of a different reasoned statement, namely in support of the rejection of Claims 4 to 7. This is quite different from developing a "problem-solution" type of reasoning using the said document as starting point in order to assess the inventive step of Claim 1. Thus, without entering into the merit of the reasoning given by the Examining Division, it is a fact that the Examining Division by issuing a decision refusing the application without giving to the Appellants the opportunity to present their comments on the newly taken position took the Appellants by surprise and, thus, committed a substantial procedural violation of the provisions of Articles 113(1) and 96(2) EPC.

- 5.5. In order to ensure that the Appellants have the opportunity of having the question of inventive step decided by the Examining Division on the basis of arguments submitted countering the new objection raised, and with the possibility of a further appeal remaining open, the Board considers it appropriate to make use of the power granted to it under Article 111(1) EPC to remit the case to the Examining Division for further prosecution.
6. The procedural violation referred to in point 5.4 above also makes it equitable to reimburse the appeal fee under Rule 67 EPC.

*Further matters*

7. In the Board's judgement, the question of the inventive step of the claimed subject-matter has been discussed only in general terms during the Examination proceedings so far and deserves a more detailed analysis which,



while avoiding any hindsight, takes due account of all that is known in the prior art and gives fair weight to the arguments submitted by the Appellants.

8. In view of the further prosecution of this case, the attention of Examining Division is drawn to the fact that Claims 4, 11, 18 and 25 could encompass subject-matter which is not patentable under the provision of Article 52(4) EPC.

### Order

For these reasons it is decided that:

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

The Registrar:

The Chairwoman:

L. McGarry

U. Kinkeldey

