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File Number: T 184/91 - 3.3.2

Application No.: 85 304 848.6

Publication No.: 0 169 016

Title of invention: Polypeptide cartilage-inducing factors found in bone

Classification: C07K 13/00

D E C I S I O N
of 11 June 1993

Applicant: Celtrix Pharmaceuticals, Inc.

Headword: Glu-Gln/CELTRIX

EPC Article 123(2);
Article 111(1); Rule 86(3)

Keyword: "Substantially amended claims - following decision G 11/91 -
remittal to Examining Division"

Case Number : T 184/91 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 11 June 1993

Appellant : Celtrix Pharmaceuticals, Inc.
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Palo Alto
CA 94303 (US)

Representative : Harrison, David Christopher
Mewburn Ellis
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London EC4A 1BQ (GB)

Decision under appeal : **Decision of the Examining Division of the European Patent Office dated 24 September 1990 refusing European patent application No. 85 304 848.6 pursuant to Article 97(1) EPC.**

Composition of the Board :

Chairman : P.A.M. Lançon
Members : A.J. Nuss
C.M.C. Holtz

Summary of Facts and Submissions

- I. European patent application No. 85 304 848.6 was filed on 8 July 1985 and published under No. 0 169 016. The application contained eight claims.
- II. In a decision dated 24 September 1990 the Examining Division i.a. refused a request by the Appellants to correct in the patent application, i.e. description and some of the claims, the amino acid residue in position 12 of the N-terminal sequence of CIF-B, originally given as **(Glu**, to read **(Gln**. The main reason for refusing this correction was that it did not satisfy Rule 88 EPC, in that it was not immediately evident either that an error had occurred or that the correct amino acid should be **(Gln**. In arriving at the second conclusion, the Examining Division noted that **(Gln** could neither be derived from the documents as originally filed taken by themselves, nor from the priority document, but only from a laboratory report provided by a third party.
- III. The Appellants lodged an appeal against this decision.

The Appellants, in their written submissions, pointed out that only dependent claims were affected by the refusal to allow the offered correction and that no other issue was at stake with regard to the granting of a patent.

The Appellants argued that the offered correction at the date of application was (a) known and (b) before the applicant. This knowledge was objective, having been derived from a third party (an analytical

laboratory) and reduced to writing before the date of preparation of the specification. The Appellants had submitted evidence not contested by the Examining Division from third parties to this effect. The error was purely clerical, the " n" in (**Gln** having been mistyped as " u".

- IV. (i) In an interlocutory decision dated 25 October 1991, the present Board referred the questions of law formulated in case G 3/89 (pending at that time) to the Enlarged Board of Appeal again considering that these points were of decisive importance when considering the present case. The Enlarged Board answered these questions in its decision G 11/91 dated 19 September 1992.
- (ii) The Board informed the Appellants in a communication dated 14 January 1993 that in view of the Enlarged Board decision G 11/91 it had come to the provisional conclusion that the suggested correction to replace (**Glu** with (**Gln** would not be admissible, unless evidence was filed to show that the skilled person would immediately realise that Glu not only was the wrong amino acid residue in position 12 of the N-terminal sequence of CIF-B, but also that the only possible correction would be the offered Gln. In addition, the Appellants were given the opportunity to file their comments to the Enlarged Board decision, as well as to the above conclusion, and also to file any evidence they would find useful in order to settle the issue of correction.

(iii) In their response the Appellants argued that evidence of the origin of the mistake and the fact that the true formula of the termination of CIF-B sequence was objectively available, was already before the Board. In this connection, reference was made to the earlier submitted letters from the analytical laboratory. Whether this material met the tests laid down by the Enlarged Board was considered by the Appellants to be a matter to be decided by the present Board. In their opinion, the arguments in support of the allowability of their initial requests had already been fully laid out.

(iv) In a subsequent letter, the Appellants informed the Board that the previous first auxiliary request should be considered as main request.

V. The Appellants requested that the decision under appeal be set aside and that the claims as now submitted in accordance with either the main request or any of the auxiliary requests, be considered to be allowable.

VI. Claims of the main request

- Claim 4 for the Contracting States BE, CH, DE, FR, GB, IT, LI, LU, NL and SE read as follows:

"4. A polypeptide cartilage-inducing factor, which factor:

- (a) is found in mammalian bone;
- (b) is a co-factor for inducing cartilage formation;
- (c) has activity in the TGF- β assay;

- (d) is a dimer having an approximate molecular weight of 26,000 daltons as determined by SDS-PAGE;
- (e) is isolatable by a process according to Claim 1 or Claim 2;
- (f) does not have the N-terminal sequence
Ala-Leu-Asp-Thr-Asn-Tyr-Cys-Phe-Ser(Ser)Thr-Glu-
Lys-Asn-Cys-Cys-Val-Arg-Gln-Leu-Tyr-Ile-Asp-Phe-
Arg-Lys-Asp-Leu-Gly-Trp-."

Reasons for the Decision

1. The appeal is admissible.
2. The Board considers that in view of the decision G 11/91 of 19 November 1992 of the Enlarged Board of Appeal (to be published in OJ EPO), the decision of the Examining Division regarding the refused claims appears to have been correct.
3. The claims of the present main request however no longer include the contested amendment. In particular, the complete N-terminal sequence of CIF-B containing it has been deleted from the claims. Instead, the claimed cartilage-inducing factor is now defined in a first set of claims by two additional features, namely 1) its isolatability by the methods of Claims 1 and 2, and 2) the fact that it does not have the N-terminal sequence of CIF-A, i.e. the second of the two CIFs isolated in accordance with the present invention (cf. Claim 4 for the Contracting States other than AT under VI above). An amendment similar to the one mentioned under 2) has also been made in the set of claims for AT.

None of these amendments contravenes the requirements of Article 123(2) EPC because it is clear from the originally filed application that two CIFs can be isolated by the claimed process whereby one of them, designated CIF-A, has a partial (30 amino acid) N-terminal sequence that is identical to that reported in the literature for human placenta-derived TGF- β ; the other CIF, designated CIF-B, has a partial N-terminal sequence that is different from the human placenta-derived TGF- β sequence (cf. page 2, lines 11 to 18 and page 2, line 26 to page 3, line 17 of the original description).

Consequently, with the amendments discussed above the objections raised in the decision under appeal are completely overcome.

- 3.1 However, in addition to the thus resulting unavoidable renumbering of the claims and/or rearrangement of their dependencies the Appellants have also introduced a number of amendments unrelated to the only point at issue of replacing Glu by Gln in the N-terminal sequence of CIF-B (see section " III. Amendment requested in any case"). The first of these requested amendments concerns the deletion of the earlier introduced limitation to the presence of osteogenic/chondrogenic cofactors found in (previous) Claim 7, and also in (previous) Claim 5 of the Austrian set. However, the previous wording of these claims resulted from objections raised during examination (cf. point 3 c) of the communication dated 18 May 1989), which objections the primary examiner had considered to be overcome by the amendments and arguments submitted in Appellant's letter dated 25 August 1989 (cf. point 3

of the result of the personal consultation of 21 November 1989). The second of these amendments concerns an error that had occurred in (previous) Claim 9 (Claim 7 of the previous Austrian set) in that it referred to chondrogenesis/-osteogenesis instead of referring to normal cell proliferation and whereby component (b) should be TGF- β activating agent. These amendments go beyond the actual object of the present appeal. This leads the Board to observe the following.

The essential function of an appeal under the EPC is to consider whether a decision issued by a first instance department is correct on its merits - see in particular Article 106(1) EPC. It is therefore not normally the function of a Board of Appeal to examine and decide upon issues in the case which have been raised for the first time during appeal proceedings. The principle of having two instances of decision has been referred to in many previous decisions by the Boards of Appeal.

Moreover, as stated in decision T 63/86 (see OJ EPO 1988, 224), in a case where substantial amendments to the claims are proposed on appeal, which require substantial further examination, the case should be remitted to the Examining Division so that such examination should be carried out, if at all, by the Examining Division after the latter has exercised its discretion under Rule 86(3) EPC, final sentence, according to which no further amendment is possible without the consent of the Examining Division after the opportunity to amend in reply to the first communication of the Examination Division has passed. However, in cases of minor amendments filed during the appeal, it may still be appropriate for a Board of

Appeal to exercise the discretion of the Examining Division under Rule 86(3) EPC by making use of its powers under Article 111(1) EPC (see in particular point 2 of the Reasons for the Decision). In the present case, the Board finds it appropriate to deal only with the amendment directly related to the point at issue, but not to the further substantial amendments introduced in the claims at the stage of appeal as the latter would require examination in relation to both the formal **and** substantial requirements of the EPC for the first time at the appeal stage, which would be contrary to the principle of having two instances of decision.

- 3.2 In the circumstances of this case, the Board has accordingly decided to exercise its power under Article 111(1) EPC to remit the case to the Examining Division for further prosecution.

4. Given the above outcome, there is no need for the Board to consider at this stage of the proceedings the claims of Appellants' first and second auxiliary request.

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 on the basis of the claims of the main request.

The Registrar:

The Chairman:

P. Martorana

P.A.M. Lançon