

**Internal distribution code:**

- (A) [ ] Publication in OJ  
(B) [ ] To Chairmen and Members  
(C) [X] To Chairmen

**D E C I S I O N**  
**of 13 September 1999**

**Case Number:** T 0484/98 - 3.3.4

**Application Number:** 90904399.4

**Publication Number:** 0463024

**IPC:** C12N 15/56

**Language of the proceedings:** EN

**Title of invention:**

DNA construct and modified yeast

**Applicant:**

Elsworth Biotechnology Limited

**Opponent:**

-

**Headword:**

Modified yeast/ELSWORTH

**Relevant legal provisions:**

EPC Art. 84, 96(3), 97(1), 108, 111(1), 121  
EPC R. 67

**Keyword:**

"Admissibility of the appeal (yes)"

"Clarity (yes)"

"Reimbursement of appeal fee (yes) - substantial procedural violation"

"Remittal (yes)"

**Decisions cited:**

-

**Catchword:**

-



Europäisches  
Patentamt

European  
Patent Office

Office européen  
des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

**Case Number:** T 0484/98 - 3.3.4

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.4**  
**of 13 September 1999**

**Appellant:** Elsworth Biotechnology Limited  
Grove Cottage, 21 Smith Street  
Elsworth, Cambridge CB2 8HY (GB)

**Representative:** Perry, Robert Edward  
Gill Jennings & Every  
Broadgate House  
7 Eldon Street  
London EC2M 7LH (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 15 December 1997  
refusing European patent application  
No. 90 904 399.4 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** U. Kinkeldey  
**Members:** L. Galligani  
W. Moser

## Summary of Facts and Submissions

I. The European patent application No. 90 904 399.4 published as International application WO-A-90/10703 entered the regional phase before the European Patent Office as EP-A-0 463 024.

II. The examining division issued a first communication raising novelty objections, in response to which on 21 July 1994 new claims 1 to 22 were filed.

**On 5 August 1994**, a further communication pursuant to Article 96(2) EPC and Rule 51(2) EPC was sent to the appellants (applicants). Therein objection was raised under Article 84 EPC to claims 1 and 9, which were considered to define merely the result to be achieved by paraphrasing the underlying technical problem. The communication invited the appellants to file observations and insofar as the deficiencies were such as to be rectifiable to correct the indicated deficiencies within a period of four months from the notification of the communication, this period being computed in accordance with Rules 78(3) and 83(2)and(4) EPC.

III. On 1 December 1994, the appellants requested a two-month extension of the term for response. In reply thereto, the time limit was extended by two months to a total of six months, from the date of notification of the above-mentioned communication.

IV. On 6 February 1995, the appellants filed observations and new claim page 16 with **an amended claim 1** and

unamended claims 2 to 12 and 13 (partially).

- V. On 20 February 1995, a further communication pursuant to Article 96(2) EPC and Rule 51(2) EPC was sent to the appellants by the examining division, stating that, when filing the new set of claims, the objections raised by the examining division in its previous communication had totally been ignored, and inviting them to file observations and insofar as the deficiencies were such as to be rectifiable to correct the indicated deficiencies within a period of four months from the notification of the communication, this period being computed in accordance with Rules 78(3) and 83(2) and (4) EPC.
- VI. On 22 June 1995, the appellants filed observations and proposed to further amend claim 1 and to **delete claim 9** on file.
- VII. On 8 August 1995, another communication pursuant to Article 96(2) EPC and Rule 51(2) EPC was sent to the appellants by the examining division, accepting that the deletion of claim 9 had overcome the respective objection raised, but further stating that claim 1 was still not acceptable. The appellants were invited to file observations and insofar as the deficiencies were such as to be rectifiable to correct the indicated deficiencies within a period of four months from the notification of the communication, this period being computed in accordance with Rules 78(3) and 83(2) and (4) EPC.
- VIII. On 11 December 1995, the appellants requested a two-month extension of the term for response. In reply

- thereto, the time limit was extended by the examining division by two months to a total of six months, from the date of notification of the above-mentioned communication.
- IX. The appellants filed observations on 12 February 1996, reiterating previous submissions and including a declaration by Prof. B.S. Hartley.
- X. On 19 March 1996, a further communication pursuant to Article 96(2) EPC and Rule 51(2) EPC was sent to the appellants by the examining division, expressing the view that the objections raised were not yet overcome and that the declaration by Prof. B.S. Hartley supported this view. The appellants were invited to file observations and insofar as the deficiencies were such as to be rectifiable to correct the indicated deficiencies within a period of four months from the notification of the communication, this period being computed in accordance with Rules 78(3) and 83(2) and (4) EPC.
- XI. On 9 July 1996, the appellants requested a two-month extension of the term for response. In reply thereto, the time limit was extended by the examining division by two months to a total of six months, from the date of notification of the above-mentioned communication.
- XII. On 29 October 1996, the examining division informed the appellants that the European patent application was deemed to be withdrawn under Article 96(3) EPC, because the invitation to file observations on its communication dated 19 March 1996 had not been complied with.

- XIII. On 7 January 1997, the appellants requested further processing of the application in accordance with Article 121 EPC. The fee for further processing was paid at the same time.
- XIV. On 30 January 1997, the appellants were informed that it had been decided under Article 121(3) EPC that the processing of the application would be resumed.
- XV. On 9 October 1997, summons to attend oral proceedings on 9 December 1997 were sent to the appellants. In reply thereto, they informed the examining division that they would not attend oral proceedings. On 10 November 1997, they withdrew their request for oral proceedings and requested that the examining division take a decision according to the state of the file.
- XVI. The examining division issued on 15 December 1997 a decision whereby the European patent application was refused on the basis of Article 97(1) EPC. The reasons for the decision were as follows: (i) "the applicant filed no comments or amendments" in reply to the communication dated **5 August 1994**, but (ii) "requested a decision according to the state of the file by a letter received in due time on 6 November 1997" (NB the latter date was in fact 10 November 1997; cf. Section XV supra).
- XVII. On 22 January 1998, the appellants lodged an appeal and paid the appeal fee on 6 February 1998. A written statement setting out the grounds of appeal was filed on 16 April 1998.
- XVIII. The appellants submitted that claim 1 of the set

refused by the examining division defined, in clear functional language, the distinguishing features of the invention.

Said claim 1 read as follows:

"A yeast capable of secreting a protein expressed thereby, the yeast having been transformed with a DNA construct comprising DNA coding for a  $\beta$ -galactosidase, said DNA being obtainable from a source in which the  $\beta$ -galactosidase is naturally secreted extracellularly, said DNA being flanked at its 5' end by a yeast leader sequence, whereby the yeast is capable of growth on lactose as the sole C source."

In their view, it would not have been possible to define the invention more precisely without restricting the scope of the invention. They submitted that the following document referred to by the examining division:

(1) EP-A-0 261 534

did not disclose any  $\beta$ -galactosidase which was secreted (cf. *ibidem*, column 7, line 43). In order to assay the enzyme activity the cells had to be permealised. They filed a further prior art document in order to show that a naturally cytosolic protein like the one of document (1) contained sequences which were incompatible with the secretion process. A cytosolic protein would not have functioned outside of the cell as it was incapable of forming the 3-dimensional structure in that environment.



XIX. On 27 May 1999, the board issued a communication pursuant to Article 110(2) EPC essentially with the following preliminary opinion on the case:

- The factual situation as stated in the decision under appeal, according to which the appellants had filed no comments or amendments in reply to the communication by the examining division dated 5 August 1994, was not correct.
  
- The appeal would probably be considered admissible in spite of the fact that in their statement of grounds of appeal the appellants had failed to deal with the main reasons given in the contested decision.
  
- Contrary to the finding of the examining division, the wording of claim 1 allowed a clear enough distinction between the claimed subject-matter and the subject matter described either in document (1) or in the following document which had also been cited during the prosecution of the case:

(2) GB-A-2 178 431

- Due to the deletion of claim 9, some of the claims needed renumbering. Furthermore, in the text of claim 21 the term "gene encoding a secreted  $\beta$ -galactosidase" had preferably to be replaced by the term "a gene encoding a  $\beta$ -galactosidase which is naturally secreted".

The appellants were invited to file a complete set of

claims amended accordingly.

XX. On 26 July 1999, the appellants filed a revised set of claims (claims 1 to 21) in compliance with the observations made by the board.

XXI. The appellants requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution in accordance with Article 111(1) EPC.

## **Reasons for the Decision**

### *Admissibility of the appeal*

1. Although the appellants' written statement setting out the grounds of appeal fails to deal with the main reasons given for the decision under appeal, it is nevertheless considered to meet the requirements of Article 108, third sentence EPC for the following reasons:

(i) The order of the decision under appeal was erroneous and misleading as it had no relationship with the reasons given, the application being refused under Article 97(1) EPC with reasons pertaining to Article 96(3) EPC (cf. points 9 to 14 *infra*).

(ii) Pursuant to Article 97(1) EPC, a European patent application is refused if the examining division is of the opinion that the application or the

invention to which it relates does not meet the requirements of the EPC. Having regard to the order of the decision under appeal, the appellants were thus justified in assuming that the examining division was of the opinion that the application or the invention to which it related did not meet the requirements of the EPC; all the more so because, with a communication of the examining division dated 30 January 1997 (cf. Section XIV supra), the appellants had been informed that the processing of the application, which they had requested (cf. Section XIII supra), would be resumed and that, consequently, the application would not be deemed to be withdrawn. Thus, they would never have expected reasons pertaining to Article 96(3) EPC to be still at issue.

*Amendments (Article 123(2) EPC) and clarity of the claims  
(Article 84 EPC)*

2. The claims now on file essentially correspond to the claims on the basis of which the examining division issued the decision of refusal, these being claims 1 to 8, 10 to 12 and 13 (partially) filed on 6 February 1995 (cf. Section IV supra), and claims 13 (partially) to 22 filed on 21 July 1994 (cf. Section II supra). In view of the deletion of claim 9 (cf. Section VI supra), the claims needed renumbering. This was done by the appellants on 26 July 1999 in response to the board's invitation (cf. Section XIX supra). The amendments introduced into the claims are in compliance with Article 123(2) EPC, being supported by the application as filed. This is true also for the slight change in the wording of claim 21 (from "gene encoding a secreted

- $\beta$ -galactosidase" to "a gene encoding a  $\beta$ -galactosidase which is naturally secreted extracellularly") (cf. application as filed, page 8 line 31 to page 9, line 26).
3. Throughout the proceedings before the first instance, the clarity of claim 1 was the main point of disagreement between the appellants and the examining division which eventually lead to the refusal of the application. The examining division repeatedly objected that the said claim did not contain features which could allow a distinction over the prior art, the latter being essentially represented by documents (1) and (2), and insisted that it was necessary to introduce into the claim the feature of claim 5, namely "the DNA coding for the  $\beta$ -galactosidase is the *Aspergillus niger lacA+* gene". In the examining division's view, the claim defined merely the result to be achieved by paraphrasing the underlying technical problem.
  4. Claim 1 is directed to a yeast which is essentially characterised by the following features: (i) it is capable of secreting a  $\beta$ -galactosidase, and (ii) is capable of growth on lactose as the sole C source. Both these features are of technical nature and are testable by means of routine methods. They define the claimed yeast by reference to two testable properties which it should display, so that it is clear to the skilled person what is meant by the claim: if any yeast has both properties it falls under the scope of the claim.
  5. Document (1) describes DNA constructs which are capable of improving the expression levels of a polypeptide of

interest, said polypeptide being **possibly** secreted out of the cell (cf. passage bridging columns 3 and 4 as well as passage on page 5, column 7, lines 41 to 43). An example of a DNA fusion with an E. coli  $\beta$ -galactosidase gene is disclosed. However, the results reveal that the enzyme **was not** secreted. Moreover, it is not shown that the transformed yeast is capable of growth on lactose as the sole C source. Thus, the yeast described in this document does not display features (i) and (ii) indicated under point 4 above. Therefore, a distinction between the subject-matter of claim 1 and this prior art is possible on the basis of technically testable features.

6. Document (2) describes genetically engineered yeast strains capable of utilising lactose as a carbon source (cf. eg claim 1). However, the  $\beta$ -galactosidase that they produce must be **intracellular** because it is necessary for the utilisation of lactose that a lactose permease gene also be present (cf. eg page 3, lines 6 to 7). Thus, these strains do not display feature (i) indicated under point 4 above. Therefore, a distinction between the subject-matter of claim 1 and this prior art is equally possible on the basis of a technically testable feature.
7. For these reasons, in the board's judgement, a rejection of the application under Article 84 EPC on the grounds that claim 1 did not contain technical features which allowed a distinction over the prior art was not justified.
8. It still remains to be examined whether the extent of generalisation in the claims is justified or not in

view of the disclosure of the application as filed (issues of support by the description, Article 84 EPC, and of sufficiency of disclosure, Article 83 EPC) and in the light of the prior art (issue of extent of disclosure vs. inventive step, Article 56 EPC). Thus, now that the board has decided that the claims on file meet the requirement of clarity of Article 84 EPC, the case is remitted to the examining division for further prosecution in accordance with Article 111(1) EPC, in order to give the appellants the opportunity of having these substantive issues considered by two instances.

*Reimbursement of the appeal fee (Rule 67 EPC)*

9. The grounds for the decision to refuse the application as given by the examining division are as follows: "In the communication dated 05.08.1994 the applicant was informed that the application does not meet the requirements of the European Patent Convention. The applicant was also informed of the reasons in that communication. **The applicant filed no comments or amendments in reply thereto** but requested a decision according to the state of the file by a letter received in due time on 06.11.1997." (emphasis added)
10. In the said communication of 5 August 1994, the examining division had raised inter alia objections under Article 84 EPC to claims 1 and 9 of the set which had been filed by the appellants in response to a previous communication. An objection of this kind, if not met, can indeed lead to the refusal of a European Patent application under Article 97(1) EPC.
11. The period of four months from the notification of the

communication of 5 August 1994, computed in accordance with Rules 78(3) and 83(2) and (4) EPC, expired on 15 December 1994. On 1 December 1994, ie before the expiry of that period, the appellants requested a two-month extension of the term for response (cf. Section III supra). In reply to this request, the time limit was extended under Rule 84, second sentence EPC by two months to a total of six months from the date of notification of the communication (ie 5 August 1994). Thus, the extended period expired on 15 February 1995. On 6 February 1995, ie before the expiry of that extended period, **the appellants filed observations and an amended claim 1** (cf. Section IV supra).

12. Consequently, the assessment by the examining division of the factual situation underlying the decision under appeal, according to which the appellants had "filed no comments or amendments" in reply to the communication dated 5 August 1994, is **wrong**. Had the appellants indeed failed to comply with the invitation to file in due time observations and/or correct deficiencies in reply to the official communication of 5 August 1994, the application would have been deemed to be withdrawn pursuant to Article 96(3) EPC, as warned in the EPO Form 2001 accompanying the communication. In such a situation, the examining division would have issued a further communication under Rule 69(1) EPC ("Noting of loss of rights"), which would have opened for the appellants the possibility of applying for a decision under Rule 69(2) EPC or of requesting further processing of the application under Article 121 EPC. However, such a situation did not occur in relation to the communication of 5 August 1994 because the appellants had duly replied within the fixed time

limit.

13. The only time limit the appellants did not comply with during the prosecution before the first instance was the time limit to file observations on the communication of the examining division dated 19 March 1996 (cf. Sections X to XII supra). However, the appellants successfully requested further processing under Article 121 EPC; consequently, the processing of the application was resumed (cf. Sections XIII and XIV supra).
  
14. But even if the appellants had omitted to file comments or amendments in reply to the communication dated 5 August 1994, the decision under appeal would still violate the principle of legitimate expectations because, after the communication dated 5 August 1994, three more communications of the examining division under Article 96(2) EPC were sent to the appellants clearly showing that the processing of the application was continued. Furthermore, on 30 January 1997, the appellants were informed by the examining division that the finding that the European patent application was deemed to be withdrawn was revoked, and that the processing of the application would be resumed.
  
15. Against the background of the legal and factual situation in the case at issue, it is obvious that not only the decision under appeal was erroneous and misleading, but also that it was taken on the basis of grounds (that the appellants had allegedly filed no comments or amendments in reply to the communication dated 5 August 1994) on which the appellants had no opportunity to present their comments. This was in



breach of Article 113(1) EPC and thus constitutes a substantial procedural violation which justifies the reimbursement of the appeal fee under Rule 67 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 on the basis of claims 1 to 21 filed on 26 July 1999.
3. Reimbursement of the appeal fee is ordered.

The Registrar:

The Chairperson:

U. Bultmann

U. Kinkeldey