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D E C I S I O N
of 26 May 1998

Case Number: T 0379/95 - 3.3.4

Application Number: 85900268.5

Publication Number: 0160699

IPC: C12N 15/85

Language of the proceedings: EN

Title of invention:
Production of heterodimeric human fertility hormones

Patentee:
Applied Research Systems Ars Holding N.V.

Opponent:
Akzo Pharma B.V.

Headword:
Hormones/ARS

Relevant legal provisions:
EPC Art. 123(2), 111(1)

Keyword:
"Added subject-matter (no)"
"Remittal"

Decisions cited:
G 0009/92, T 1046/96

Catchword:
-



Case Number: T 0379/95 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 26 May 1998

Respondent: Akzo Pharma B.V.
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Appellant: Applied Research Systems Ars Holding N.V.
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Representative: Sheard, Andrew Gregory
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 15 March 1995
rejecting the opposition filed against European
patent No. 0 160 699 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
C. Holtz

Summary of Facts and Submissions

I. The appeal lies from the interlocutory decision within the meaning of Article 106(3) EPC of the opposition division issued on 15 March 1995 whereby the European patent Nr. 0 160 699, against which opposition had been filed by one party on the grounds of Article 100(a) to (c) EPC, was maintained in amended form on the basis of claims 1 to 36 for all designated contracting states except Austria (non-AT states) and claims 1 to 36 for Austria filed on 7 June 1994 (auxiliary request). While claims 1 to 36 as granted in both versions for non-AT states and for AT were found to offend against Article 123(2) EPC, the claims of the auxiliary request were found to meet all the requirements of the EPC.

Independent claims 1, 15, 26 and 31 (non AT-states) of the granted patent were as follows:

"1. A process for the preparation of a biologically active, post-translationally modified, proteinaceous hormone composed of a plurality of subunits, the process comprising commonly synthesising each of the subunits in a eukaryotic cell transfected with one or more expression vectors comprising heterologous DNA encoding each of the subunits.

15. A eukaryotic cell transfected with one or more expression vectors, the cell being capable of producing a biologically active post-translationally modified proteinaceous hormone having a plurality of subunits, the subunits of the hormone being encoded by heterologous DNA in the expression vector(s).

26. An expression vector capable of transfecting a eukaryotic cell, the vector comprising heterologous DNA encoding the subunits of a biologically active, post-translationally modified, proteinaceous hormone having a plurality of subunits.

31. A set of expression vectors, each vector being capable of transfecting a eukaryotic cell, each vector comprising heterologous DNA encoding a respective subunit of a biologically active, post-translationally modified, proteinaceous hormone having a plurality of subunits, wherein all the subunits of the hormone are encoded by heterologous DNA in the vectors."

Claims 2 to 14, 16 to 25, 27 to 30 and 32 to 34 were dependent from to claims 1, 15, 26 and 31, respectively. Claim 35 was dependent from claim 1, while claim 36 concerned a process for preparing a pharmaceutical composition comprising a process according to claims 1 to 14 and 35.

Claims 1 to 36 (non-AT states) of the auxiliary request differed from the granted claims only in that the qualifier "autonomously replicating" was added in claims 1, 15, 26 and 31 before "expression vectors".

The corresponding claims for Austria were all formulated in the terms of a process.

The opposition division decided that the claims as granted had no basis in the application as filed because they did not contain the qualifier "autonomously replicating". As the teaching of the application as filed was limited only to the use of "autonomously replicating" expression vectors, the removal from the claims of the said qualifier during the pre-grant procedure had brought about a violation of Article 123(2) EPC. This could only be cured by

reinstating it as done in the auxiliary request. As regards this request, the opposition division found that it fulfilled the requirements of the EPC, having examined the substantive objections raised by the opponents-respondents.

- II. The appellants (patentees), seeking the maintenance of the patent as granted, contended that the decision of the opposition division was wrong in its conclusion on the Article 123(2) EPC issue and submitted in support of their contention two further expert declarations. They made a conditional request for oral proceedings.
- III. The respondents (opponents) did not comment upon the statement of grounds of appeal. In a fax letter dated 1 April 1998, in reply to an inquiry by the board into the possibility of arranging oral proceedings as requested by the appellants, they stated that they would not attend the oral proceedings.
- IV. The appellants requested that the decision under appeal be set aside and that the patent be maintained unamended. As a result of a telephone consultation on 20 May 1995, the appellants agreed that the case be remitted to the opposition division for further prosecution, should the decision under appeal be set aside by the board. Auxiliarily, they requested that three questions related to the case law of the boards of appeal on Article 123(2) EPC be referred to the Enlarged Board of Appeal.

Reasons for the Decision

- 1. As the patentees are the sole appellants against the interlocutory decision maintaining the patent in amended form, the maintenance of the patent as amended in accordance with the interlocutory decision may not

be challenged (cf. G 9/92 OJ EPO 1994, 875). This means that the appeal review is limited to the examination of the question whether the claims as granted offended against Article 123(2) EPC.

2. It has thus to be decided whether for a person skilled in the art the teaching of the application as filed was strictly limited to autonomously replicating expression vectors, or whether it included also other expression vectors.

3. According to the established case law of the boards of appeal, in order to determine whether an amendment (here: an amendment carried out in the pre-grant phase) does or does not extend beyond the content of the application as filed, it is necessary to examine whether the amendment (here: the absence from the granted claims of the limitation to "autonomously replicating expression vectors") results in the introduction in the specification of information which the skilled person cannot derive directly and unambiguously, either explicitly or implicitly, from that originally presented (cf T 1046/96 of 19 January 1998, in particular points 2 to 4 of the reasons).

4. In the present* case, the application as filed, although focusing on the use of autonomously replicating expression vectors because - as stated on page 3, lines 23 to 26 - it "prevents undesirable influence of the desired coding regions by control sequences in the host chromosome", **quite explicitly** refers on page 22 under the heading "Other Embodiments" to the use of "other...vectors..." (cf line 20) and, for example, to "...non-replicating viral DNA..." as a vector (cf lines 23 to 24) and refers in particular to SV-40-containing vectors (cf line 27). The latter are vectors which "allow expression of proteins in mammalian cells,

either in a transient manner or as a consequence of stable integration into the host genome" (cf eg as an expert opinion letter of Dr J. Larry Jameson to Mr Ebbink dated 22 December 1992).

5. The statements on page 22 in the application as filed show unambiguously that, while the use of autonomously replicating expression vectors was preferred, the use of other vectors was also **explicitly** envisaged. Thus, from a strictly formal point of view (cf decision T 1046/96 supra), there is no added subject-matter in this case.

While it is true that the claims as filed were indeed limited to the preferred embodiments, it is also a fact that up to the grant of a patent applicants are entitled to amend and, if necessary, to broaden the claims as filed, provided that the resulting claimed subject-matter does not extend beyond the content of the application as filed.

6. The opposition division noted the passage on page 22, line 24, but dismissed it as being in contradiction with the original claims (cf point 3.3 of the decision under appeal). As shown above, this cannot be a proper basis for a rejection as the original claims can always be amended as long as the amendments do not result in an extension of the application as filed. Furthermore, the reasoning provided by the opposition division is in contradiction with its own later statement (cf point 3.7 ibidem) that it would have been satisfied with a single sentence stating "other vectors than autonomously replicating expression vectors are known to the man skilled in the art". In fact, by the same token, such a sentence would also have been in

contradiction with the original claims. As a matter of fact, the indications given on page 22 in the application as filed correspond to the single sentence that the opposition division was looking for.

7. In the board's judgement, the statements on page 22 of the application as filed constitute a proper formal basis under Article 123(2) EPC for the subject-matter of the claims as granted. For these reasons, the appellants' request that the decision under appeal be set aside can be allowed. In view of this finding in favour of the appellants, there is no need to consider the auxiliary request (cf. Section IV supra).

8. It is noted that the opposition division only examined the substantive objections under Articles 54, 56 and 83 EPC raised by the opponents-respondents in respect of the claims of the auxiliary request. Since the scope of the claims as granted is broader than that of the claims of the auxiliary request allowed by the opposition division, these substantive objections have to be examined before a final decision can be taken. In order to ensure the parties' right to two instances, the board considers it appropriate to make use of its power under Article 111(1) EPC to remit the case to the opposition division for further prosecution. The appellants agreed with this way to proceed (see Section IV supra).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution on the basis of the claims as granted.

The Registrar:

D. Spigarelli

The Chairperson:

U. M. Kinkeldey

