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

Case Number: T 0636/97 - 3.3.4

Application Number: 84308654.7

Publication Number: 0148605

IPC: C12N 15/00

Language of the proceedings: EN

Title of invention:
Production of erythropoietin

Patentee:
Kirin-Amgen, Inc.

Opponent:
Genzyme Corporation
Elanex Pharmaceuticals Inc.
Merckle GmbH Chem.-pharm. Fabrik
Boehringer Mannheim GmbH Patentabteilung
Hoechst AG
Akzo Pharma B.V.

Headword:
Erythropoietin II/KIRIN-AMGEN

Relevant legal provisions:
EPC Art. 84
EPC R. 27

Keyword:
"Adaptation of description missing"
"Res judicata - no"
"Referral to Enlarged Board - no"

Decisions cited:
T 0412/93, T 0996/92, T 0694/92, T 0409/91, T 0113/92,
T 0757/91

Catchword:
-



Case Number: T 0636/97 - 3.3.4

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

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Decision under appeal:

Interlocutory decision of the Opposition Division
of the European Patent Office posted 26 May 1997
concerning maintenance of European patent
No. 0 148 605 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

I. European Patent No. 0 148 605 (application No. 84 308 654.7) relating to the production of erythropoietin was granted on the basis of 37 claims. Notices of opposition were filed by six opponents all requesting the revocation of the European patent on the grounds of Article 100(a) and (b) EPC. By a decision notified on 20 January 1993 the opposition division held that the patent as granted fulfilled the requirements of the EPC. Four of the opponents (opponents 02 to 05) filed appeals against the decision of the opposition division. The appeal was allocated number T 412/93. Oral proceedings took place on September 20 to 23rd 1994 at the end of which judgement was reserved. On 21 November 1994, the board, in the same composition as in the present appeal proceedings, orally announced the following order:

"1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of claims 1 to 31 of the eleventh auxiliary request submitted on 22 September during the oral proceedings."

II. The question of any adaptation of the description was not discussed during the oral proceedings on September 20 to 23, 1994, nor in the written reasons for the decision T 412/93.

III. With a communication dated 25 September 1995 the opposition division invited the patentee to bring the description into line with claims 1 to 31 of this eleventh auxiliary request.

- IV. At oral proceedings held on 18 March 1997 the opposition division rejected the main request of the patentee that the patent be maintained on the basis of claims 1 to 31 of the eleventh auxiliary request according to the order in case T 412/93 with the description as granted. However, the auxiliary request, namely the maintenance of the patent on the basis of claims 1 to 31 of the eleventh auxiliary request with the description as amended during the oral proceedings was considered to be allowable under Article 84 and Rule 27(1) EPC. Thus, all requests for further amendments made by the opponents were rejected.
- V. The appellants (the patentee and opponents O2 to O5) filed a notice of appeal against this decision together with statements of ground of appeal and paid the fees.
- VI. On 29 December 1997, together with the summons to oral proceedings the board issued a communication according to Article 11(2) of the Rules of Procedure of the Boards of Appeal pointing out the issues to be discussed during oral proceeding and informing the parties of its provisional opinion that any amendment of the description to conform with the claims maintained in decision T 412/93 should be kept to a minimum and should be a relatively simple matter. If any suggested change in the description was not necessary and appropriate it should not be made: to do otherwise would be to re-open the proceedings that led to decision T 412/93. Further, amendment of the description was considered not to involve any important point of law.
- VII. Oral proceedings took place on 26 March 1998.

VIII. Appellant I (patentee) argued in writing and during oral proceedings essentially as follows:

Main request

- Decision T 412/93 was res judicata and thus binding on the lower instance. The opposition division was barred from reconsidering the issue of adaptation of the description to the claims and contravened Article 111(2) EPC stipulating that the department whose decision was appealed shall be bound by the ratio decidendi of the board of appeal, in so far as the facts are the same. Since the board of appeal in decision T 412/93 has not given the order to adapt the description, the facts before the opposition division were the same as before the board of appeal in case T 412/93. From several decisions by board of appeal 3.3.4, where the adaptation of the description in order to cope with amended claims held patentable by the board was ordered one could conclude that this board ordered the adaptation of the description if it felt it necessary to do so. If not, nothing was said in the order, like in the present case.

Auxiliary requests 1 and 2

- In case that notwithstanding the arguments put forward in relation to the main request the board required that the description be amended in order to be in line with the claims maintained by the board in decision T 412/93 according to the eleventh auxiliary request one should prosecute according to decision T 757/91 of 10 March 1992 according to which the requirements of Article 84

and Rule 27(1) EPC could best be met by literal repetition of the claims in the specification. Thus, in the first auxiliary request respective amendments were carried out. Further amendments proposed by the Board were included.

- In the second auxiliary request same amendments were carried out as in the first auxiliary request and further it was left to the Board to amend the description as it felt it necessary.

IX. The appellants II to V (opponents 02 to 05) argued in writing and during oral proceedings essentially as follows:

- Since the order and the reasons of decision T 412/93 were silent as regards adaptation of the description to the claims maintained by decision T 412/93, it was up to the opposition division to decide whether an adaptation of the description to the claims was necessary. The res judicata situation related to the claims only.
- Adaptation of the description to the claims as carried out by the appellant I before and accepted by the opposition division was insufficient (Article 84 EPC) because there was no statement therein that human cDNA - which was according to decision 412/93 not sufficiently described in the specification and thus a claim directed to this subject matter not allowable under Article 83 EPC - was excluded from the scope of claim 1.
- The description had not been adapted to the wording of claims 19 to 26 directed to polypeptides.

- There were still passages of the description covering no longer claimed subject-matter (page 9, line 44 to page 10, line 15).

- That the description be adequately adapted to claims maintained in amended form is a central requirement of the EPC reflected in Article 84 EPC. This view was confirmed e.g. by decision T 996/92 of 23 March 1992 stating that if an description has not been brought into complete agreement with amended maintained claims this could lead to legal uncertainty as to its actual scope.

- There were numerous infringement law suits pending all over Europe relating to the patent in suit which showed that there is uncertainty about the scope of maintained claim 1 of the eleventh auxiliary request. Since, however, in decision T 412/93 it was found that the human cDNA coding for erythropoietin was not repeatably described in the patent in suit, this embodiment of the unamended claim 1 has to be considered as not to be comprised by claim 1 and for the necessary legal certainty this mandatorily has to be laid down in the amended description, which, according to Article 69 EPC, serves to interpret, when necessary, the scope of a claim.

- Appellants IV submitted a "Rechtsgutachten" by Professor Straus who analysed decision T 412/93, mentioned all the infringement cases relating to the patent in suit and in particular quoted from the decision of the Hoge Raad to stand the infringement suit in the Netherlands that "it is essential to the assessment of the validity and of the scope of protection of the patent that the text of the description is established". Under the

headline "Zur Funktion der Beschreibung in der Patentschrift" Professor Straus draws attention to the importance of the description in the patent and that patent claims must not extend a scope justified by the description and drawings. Reference was made e.g. to decision T 694/92 (OJ EPO 1997, 408) which supported the view that the scope of a sufficient disclosure of an invention is of decisive importance for the question of the support by the description within the meaning of Article 84 EPC, because both requirements reflected the same general principle according to which the scope of a granted patent has to be equal to the technical contribution provided by the patent. It was one of the most important tasks of the EPO to achieve a reasonable degree of legal certainty. This situation fully justified to consider the task to be taken here as an important question of law which may in case have to be answered by the Enlarged Board of Appeal. Finally, the board in T 412/93 has made legally binding statements of facts and the requirement for legal certainty by Article 84 EPC and Rule 27(1) EPC required that this board cannot accept a description which contradicts its own statements in decision T 412/93 being res judicata also for this board.

- X. The appellant I (patentee) requested that the decision of 26 May 1997 be set aside and the patent be maintained on the basis of claims 1 to 31 of the eleventh auxiliary request allowed by the board in decision T 412/93-334 and,

as main request, the description and drawings as granted, or

as first auxiliary request, the description and drawings as granted, but as amended by pages 8, Annex A, 9, 10, 29, 44, 45 attached, or

as second auxiliary request, the description and drawings adapted as in the first auxiliary request, but with additional amendment(s) considered necessary by the board.

XI. Appellant II requested as main request:

1. that the decision under appeal be set aside; and
2. that each of the patentee's requests be refused; and
3. that therefore as a legal consequence the patent be revoked

or, as first auxiliary request,

that the patent be re-published as amended with the following notice on the front page:

"The claims were upheld by the Technical Board of Appeal on the basis of certain assumptions set out in Decision T 412/93."

or, as second auxiliary request,

that the following question be referred to the Enlarged Board of Appeal:

"If a patent has been upheld in amended form on the basis of certain assumptions made by the first or second instance, should the re-published patent be amended to indicate what assumptions have been made or, at the least, to indicate the fact that assumptions

have been made? If yes, should the amendment be by way of adaptation of the description or insertion of a notice on the front sheet of the re-published patent?"

- XII. Appellant III requested that the decision of the opposition division of 26 May 1997 be set aside and that the patentee be required to amend the description as suggested by the board (with exception of the amendment to page 29) and to insert in the description the clarifications set out in the annexes:

Annex 1:

to claim 1: (from section 114 of T 412/93)

"In its decision T 412/93, the technical board was unable to assume from the mere existence of dependent claim 3 as granted that cDNA necessarily falls within claim 1."

to claim 26: (from section 146 of T 412/93)

"It appears that expression in a eucaryotic host cell will ensure glycosylation of the product, thus distinguishing it from aglyco Epo of the prior art. Furthermore, the limitation to the polypeptide being a product makable using the DNA of claim 1, is a technical feature that ensures that it has a glycosylation pattern different from the human u-Epo."

Annex 2:

Suggested insert on page 8 of the description after the repetition of the wording of claim 1:

"Not claimed are DNA sequences originating by reverse transcription from human mRNA."

XIII. Appellant IV requested as main request

that the decision under appeal be set aside and that the patentee be required to amend the description as suggested by the board, and in addition to introduce the requested inserts relating to human cDNA as in annex A (namely insert on page 8 after the repetition of the wording of claim 1: "Not claimed are DNA sequences originating by reverse transcription from human mRNA"), and relating to the interpretation of claims 26 and 27 as per the request of Opponent V (see below under Appellant V), and not to delete the penultimate paragraph of example 10, and that the patent be revoked if these requirements are not met;

as first auxiliary request,

that the following question be referred to the Enlarged Board of Appeal:

"Can the legal certainty required for the interpretation of amended claims be achieved by references in the description to the board's findings of fact that caused these claims to be amended."

and, as second auxiliary request,

that the following question be referred to the Enlarged Board of Appeal:

"Where the revocation of a dependent claim and the simultaneous maintenance of the main claim on which it is dependent are based on res judicata findings of fact by the board that the subject matter of the revoked dependent claim is not sufficiently disclosed and that

it cannot be stated that the same subject matter falls under the main claim, are these findings of fact to be inserted into the description to establish legal certainty when adapting the description ?"

XIV. Appellant V requested as main request

that the description be amended as suggested by the board, but

- without deletion of page 29, lines 17 to 26.
- with clarifications as per the handwritten inserts to claim 1 and to claim 26 (identical to Section XII Annex 1 above)
- with the insert "... but are not claimed herein." on page 43, line 58

and that otherwise the patent be revoked;

as first auxiliary request,

that the description be amended as suggested by the board, but with a "warning label" as requested by appellant II, and that otherwise the patent be revoked; and

as second auxiliary request,

that the legal question as formulated by appellant II be referred to the Enlarged Board of Appeal.

Reasons for the Decision

1. *Admissibility*

1.1 The appeals are admissible. Some of the requests by the appellants II to V seem to have no basis in the EPC, or to contravene the principle of *res judicata*, but as the outcome is not affected whether the requests are treated under the heading of admissibility or substantive allowability, they will be considered on the latter basis.

2. *Res judicata*

2.1 In the written decision T 412/93 the order and the reasons for the decision were silent on the question of what adaptation of the description, if any, was required. Such silence carries no necessary implication that no adaptation was required, but merely that the matter had not been considered and/or decided one way or the other. The point was thus not *res judicata*, and the opposition division was entitled to raise the matter of adaptation of the description. The main request of appellant I thus fails.

2.2 By way of explanation it should be stated that although the oral proceedings on T 412/93 had lasted some twenty-eight hours, the number of parties and the number of the documents and requests to be discussed meant that there had been no time to discuss the question of adaptation of the description during the oral proceedings. So for the board to have decided the question without affording the parties an opportunity to comment, would have been a violation of the right to be heard guaranteed by Article 113 EPC. The board,

mistakenly as it turns out, considered it a simple matter that could in this case be left to the opposition division, a procedure that has worked satisfactorily in the vast majority of run of the mill cases.

3. *Principles applicable to the adaptation of the description*

3.1 The principles applicable where in preceding appeal proceedings the scope of a patent has been limited by amendment of the patent claims have already been stated in decision T 113/92 of 17 December 1992, point 2, as being that the adaptation of the description must follow the dictates of legal certainty; that is the restriction has to be taken into account by deleting all statements which do not relate to the now more limited subject matter of the patent, and which are not necessary or useful for understanding the invention.

3.2 Also it should not be forgotten that Article 138(c) EPC allows the revocation of a European patent under the law of a Contracting State, with effect for its territory, on the ground that the subject-matter of the European patent extends beyond the content of the application as filed. Whereas as far as proceedings before the European Patent Office are concerned, the boards of appeal are the last instance, depending on the national law of a Contracting State, additional matter allowed by way of explanatory amendment by the board could be a ground of invalidity in later proceedings before a national court. Accordingly the board considers it appropriate that amendments be confined to the minimum necessary to avoid conflict between the description and the amended claims and to delete irrelevant or potentially misleading passages.

3.3 There are cases where amendment of the description is likely to be critical, or a disclaimer is necessary. In such cases the board would not wish to decide on a set of claims without at the same time already having an adapted description to consider. However even where, as here, there is a written decision on the claims considered allowable, the board sees no basis in the EPC for inserting into the description extracts from its decision on the allowable claims, nor is the description of an invention an appropriate place to reproduce extracts of a board decision. What needs to be done is to adapt the description to the allowable claims, not to add commentary on the interpretation of the claims. That the patent was amended will be apparent to the public from it being reprinted. The opponent appellants will be able to draw the attention of any national court to those passages of decision T 412/93 which they consider might help their case, even if that decision is not referred to in the amended description.

4. *Requests by Appellants II to V*

4.1 There is a practice (see Guidelines for Examination in the EPO, Part C, Chapter VI point 5.7b) that a mention will be printed on the cover page of the patent specification notifying the public of supplementary technical information submitted by the proprietor after the filing date provided this is open to public inspection on the application file. This is, however, firstly **technical** information and not **legal** evaluation relating to amended claims, and secondly this is done with the proprietor's consent, in the proprietor's and the public's interest. In this way, the public's attention is drawn to material which it otherwise would not be aware of. This is a situation quite different from the insertion of a reference to a decision. The

reprint of an amended patent specification already is an indication to the public that there is a decision allowing amendments. The requests that the board impose on the proprietor a requirement to insert a reference to the decision are thus refused.

4.2 For a referral to the Enlarged Board of Appeal (EBA) to be appropriate under Article 112 EPC either uniform application of the law or an important point of law should be in question. The board is not aware of any case law that has allowed or required extracts of a board decision to be inserted into the description. No question of uniform application of the law thus arises. Nor is an important point of law involved. The necessary adaptation of the description is a matter of fact which must ultimately always be resolved by the technical board. In future it is, beyond doubt, to be recommended that boards take care to prevent any similar situation arising, by deciding simultaneously on the allowable claims and an appropriately adapted description, in particular in a case such as this, where what is at stake makes the parties fight on every conceivable point. The questions suggested for referral are thus not of the general importance that might justify a referral to the EBA even though to this board the answers are clear (see point 3.3 above).

4.3 Various opponent appellants have objected to the deletion of the passage on page 29, lines 7 to 26. This was acknowledged by the patentee in the oral proceedings on T 412/93 to be erroneous, and it has been the general practice of the boards to allow the deletion of erroneous passages. The passage can certainly not contribute anything to the clarity or understanding of the claims. For the board this is the reason why it should be deleted.

4.4 The requests that an insert be made "Not claimed are DNA sequences originating by reverse transcription from human mRNA" offend against the principle of res judicata as they conflict with the decision T 412/92 where claims were allowed without any such limitation. No claim specifically directed to DNA sequences originating by reverse transcription from human mRNA has been allowed.

4.5 For the board it is a fundamental principle of patent law that a claim can validly cover broad subject matter, even though the description of the relevant patent does not enable every method of arriving at that subject matter to be carried out. Otherwise no dominant patent could exist, and each developer of a new method of arriving at that subject matter would be free of earlier patents. In many cases in the field of biotechnology, patent protection would then become illusory. This is not to say that some claims might not be too broad in scope and not be enabled over their whole scope for the purpose of Article 83 EPC (see for example decisions T 409/91-3.3.1 (OJ EPO 1994, 653), or T 694/92-3.3.4 (OJ EPO 1997, 408)), but this was not considered to be the case in respect of Claim 1 by this board in T 412/93 on the evidence before the board and this is res judicata. The boards have considered this question of allowability of a broad claim versus the requirements of Article 83 EPC, strictly on a case by case basis, influenced by the extent to which the information in the patent could be used to develop further embodiments without a major conceptual leap. The question of the allowable width of claims in relation to sufficiency under Article 83 EPC, may be an important question of law which may at some stage have to be considered by the EBA, in the light of recent national case law which shows that the view of some EPC Contracting States national courts may not be the same as that expressed here (cf. House of Lords in Biogen v.

Medeva (1997 RPC 1)). Such a question cannot however be put in the context of adaptation of the description in the present case.

4.6 The requests by the appellants II to V thus all have to be refused.

5. *Amendments made to description*

5.1 In the **first** auxiliary request appellant I follows substantially the textual amendments suggested by the board. The board made these suggestions merely to speed up proceedings and the proprietor was free to take up these suggestions in a request. However Article 113(2) EPC states that the instances of the EPO shall consider and decide upon the European patent only in the text submitted to it, or agreed, by the proprietor of the patent. An amorphous request in the form of the **second** auxiliary request of appellant I, the proprietor, is inadmissible: the board is there to decide on requests, be it that these requests were proposed by the board and adopted by the proprietor, not to be requested to formulate them for the proprietor. The other parties must be put in a position to make submissions on the detailed wording of the proposed amended description.

5.2 The first auxiliary request of appellant I includes a full repetition of claims 1 to 31 as maintained by decision T 412/93 which replaces the statement of invention originally appearing on lines 25 to 41 on page 8 of the granted patent. This serves the purpose that the maintained claims are supported by the description as required by Article 84 EPC, and to indicate that any arguable conflict between other parts of the description and the claims can for the purposes of Article 69 EPC be resolved in favour of the wording of the claims. Most of the claims were maintained as

granted. Against such claims Article 84 EPC is not a basis for opposition, and clarity objections cannot be taken. When adapting the description the purpose is to avoid discrepancies between the claims as amended and the description: Furthermore clarity depends on the reader reading the text with the intention of coming to a sensible conclusion. Particularly in cases like the present one where the scope of claim 1 is at issue in many infringement suits, it is unlikely that any form of adaptation will satisfy both the proprietor and the opponents. Further, the appellants II to V did not object to this amendment.

5.3 Lines 17 to 26 on page 29 of the granted patent have been cancelled. During the appeal proceedings in case T 412/93 the patentee submitted that the information given there about a certain carbohydrate pattern of recombinant erythropoietin expressed in CHO cells and that of urinary erythropoietin was wrong. Appellants III to V requested that this wrong information has to be kept in the description (see sections XI to XIII above). This request seems to be in remarkable contrast to other submissions requiring a maximum of clarity. Thus, the board finds it appropriate to cancel from the description information which is wrong.

5.4 Secondly on page 8 of the granted patent the sentence starting in line 53 and ending in line 55 was cancelled. It related to the production of monoclonal and polyclonal antibodies against various erythropoietins, and has been cancelled as there are no longer claims directed to antibodies.

5.5 Thirdly the word "monkey" has been incorporated on pages 9, 10, 44 and 45 before the word "cDNA". The board finds this sufficient to correspond to claim 3 of the eleventh auxiliary request, which request no longer contains a claim to human cDNA.

5.6 It follows that this first auxiliary request of appellant I is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The requests by appellants II to V (opponents 2 to 5) including the requests for referral of questions to the Enlarged Board are refused.
3. The case is remitted to the first instance with the order to maintain the patent on the basis of claims 1 to 31 as referred to in the order of the board in decision T 412/93 of 21 November 1994, amended pages of the description numbers 8, 9, 10, 29, 44 and 45 and Annex A as submitted at the oral proceedings on 25 March 1998 and the remaining pages of the description and the drawings as granted.

The Registrar:

The Chairwoman:

D. Spigarelli

U. Kinkeldey