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Datasheet for the interlocutory decision of 18 October 2007

Case Number: T 0601/05 - 3.3.04

Application Number: 94102560.3

Publication Number: 0614984

IPC: C07K 16/24

Language of the proceedings: EN

Title of invention:
Anti-TNF alpha human monoclonal antibodies

Patentee:
Bayer Corporation

Opponents:
01: Centocor, Inc.
02: Abbott Laboratories

Headword:
Anti-TNF alpha human monoclonal antibodies/BAYER I

Relevant legal provisions (EPC 1973):
EPC Art. 54, 108, 123(2)(3)

Keyword:
"Admissibility of appeal (yes)"
"Admission of new main and auxiliary request (yes)"
"Main request: added subject-matter (no); extension of scope (no); novelty (yes)"

Decisions cited:
-

Catchword:

See points 1 to 1.6

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0601/05 - 3.3.04

I N T E R L O C U T O R Y D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 18 October 2007

Appellant: (Patent Proprietor)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 16 February 2005 revoking European patent No. 0614984 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: M. Wieser
Members: G. Alt
R. Moufang

Summary of Facts and Submissions

I. An appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division, whereby the European patent No. 0 614 984 was revoked pursuant to Article 102(1) EPC.

II. The patent, entitled "Anti-TNF alpha human monoclonal antibodies", had been granted with eleven claims, eight of them relating to a composition and three to the use of antibodies.

Claim 1 as granted read:

"1. A composition comprising human monoclonal antibodies that bind to human tumor necrosis factor alpha."

III. The patent had been opposed by two parties (opponents 01 and 02). The oppositions were based on Article 100(a) EPC, invoking lack of novelty (Article 54 EPC), lack of inventive step (Article 56 EPC) and lack of industrial applicability (Article 57 EPC), and on Article 100(b) EPC and Article 100(c) EPC.

IV. The opposition division decided that claims 1 and 3 of the main request before it (the claims as granted) lacked novelty (Article 54 EPC).

In addition, it decided that the claims of the first auxiliary request contravened the requirements of Article 123(3) EPC and that claim 1 of the second auxiliary request lacked novelty (Article 54 EPC). Finally, it decided that the subject-matter of the

claims of the third and fourth auxiliary request before it did not involve an inventive step (Article 56 EPC).

V. In the notice of appeal the appellant requested that the decision be set aside and the patent maintained as granted. In the statement setting out the grounds for appeal, reasons were given only as to why the opposition division was wrong in finding that the claims as granted (the main request before the opposition division) lacked novelty.

VI. One month before the day of the oral proceedings, the appellant replaced the sole request on file by a new main and an auxiliary request. The new main request was identical to the third auxiliary request before the opposition division, and the first auxiliary request was identical to the fourth auxiliary request before the opposition division, except that the term "inhibiting" in claim 1 had been amended to read "capable of inhibiting".

VII. Oral proceedings were held on 18 October 2007, in the course of which respondent II (opponent 02) submitted the following document: "The Journal of Immunology, vol. 148, no. 9, May 1992, pages 2690-2702, Kasaian, M. T. et al." (hereinafter referred to as document ID59).

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 6 of the main request or, in the alternative, claims 1 to 6 of the first auxiliary request, both submitted with letter dated 18 September 2007.

Opponents 01 and 02 (respondents I and II) both requested that the appeal be rejected as inadmissible or, in the alternative, dismissed. They furthermore requested that the case be remitted to the department of first instance for examination as to the requirements of Article 83 EPC. Respondent I, in addition, requested remittal also for examination as to Article 57 EPC.

IX. Claim 1 of the main request read:

"1. A pharmaceutical composition containing a human monoclonal antibody that binds to human tumor necrosis factor alpha."

Claim 1 of the auxiliary request read:

"1. A pharmaceutical composition containing a human monoclonal antibody that binds to human tumor necrosis factor alpha and is capable of inhibiting LPS-induced human tumor necrosis factor alpha secretion by human monocyte cells."

Dependent claims 2 to 6 of both requests referred to preferred embodiments of the pharmaceutical composition of claim 1.

X. The following documents are referred to hereinafter:

ID8: Scand. J. Immunol., vol. 30, 1989, pages 219-223, Fomsgaard, A. et al.

ID9: Bendtzen K. et al. in "The Physiological and Pathological Effects of Cytokines"; Eds. Dinarello, C. A. et al.; 1990, pages 447-452

XI. The appellant's arguments as far as they are relevant for the decision may be summarised as follows:

Admissibility of the appeal

The decision on the admissibility of an appeal had to be taken on the basis of the notice of appeal and the statement setting out the grounds of appeal, and could not therefore be influenced by later submissions.

Lack of novelty was the only reason why the opposition division rejected the main request, which corresponded to the sole request relied on in the notice of appeal and the statement of grounds of appeal. Therefore, lack of novelty was the only issue that had to be dealt with in the statement setting out the grounds for appeal.

Admission of a new main request and auxiliary request

The new requests were submitted after reconsideration of the claims in the light of the respondents' submissions in the appeal proceedings.

The claims of these new requests could not have come as a surprise, because they had already been dealt with by the opposition division in its decision.

Main request

Amendments

As to the term "pharmaceutical" in claim 1, it was clearly and unambiguously derivable from the application as filed as a whole that the composition containing the human monoclonal anti-TNF alpha antibodies was to be used for the purpose of medical treatment.

It was also clearly and unambiguously derivable from the application as filed that the pharmaceutical effect was achievable with a composition containing a single kind of antibody. Therefore, the expression "**a** human monoclonal antibody" did not add matter.

Extension of scope of protection

The respondents did not correctly interpret the claims, especially as far as the meaning of the terms "comprising" versus "containing" was concerned. There was no extension of the scope of protection.

Novelty

Documents ID8 and ID9 disclosed a polyclonal serum, i.e. a composition containing a mixture of different antibodies.

Human sera from apparently healthy donors may contain harmful agents like HCV or HIV. Thus, unpurified sera could not automatically be regarded as pharmaceutical agents.

A disclosure was only novelty-destroying if it was reproducible. It was not disclosed how the sera

described in ID8 and ID9 were obtained. Thus the teaching could not be reproduced.

Document ID59 filed at the oral proceedings should not be admitted into the procedure since it did not disclose that the antibody F2.2.34 had all the features required by the claim.

XII. The arguments of respondents I and II (hereinafter "the respondents") as far as they are relevant to the present decision may be summarised as follows:

Admissibility of the appeal

The third and fourth auxiliary requests, corresponding to the actual main and auxiliary request, were rejected by the opposition division for lack of inventive step, and reasons for this finding were given in the decision. Claims 1 of each of the third and fourth auxiliary requests before the opposition division were dependent claims in the main request on appeal.

The appellant could therefore have anticipated that inventive step was a potential issue with regard to the claims relied on in the statement of grounds of appeal, i.e. the claims as granted. Since the reasons given by the opposition division, although in the context of the third and fourth auxiliary request, clearly applied to claims of the main request as relied on in the statement of grounds of appeal, it was necessary to deal with the issue of inventive step in said statement. Since the appellant's submission related to the issue of novelty only, the appeal was not sufficiently reasoned and should therefore be held inadmissible.

Even if the appeal were considered admissible with regard to the claims relied on in the statement of grounds of appeal, the claims now on file differed considerably from those submitted originally and dealt with in the statement of grounds of appeal. Therefore, the appeal as now pursued should be held inadmissible.

Admission of a new main request and auxiliary request

The Rules of Procedure of the Boards of Appeal stipulated that the parties should present their full case at the outset of the appeal proceedings. Waiting until the last moment for filing new claims without the indication of any reason was a behaviour to be avoided. The appellant's claim requests should not be admitted into the procedure.

Main request

Amendments

The only antibody for which test results were given in the application as filed was the human monoclonal antibody B5. It was derivable from the application that this antibody had low affinity for TNF-alpha and did not neutralise TNF-alpha activity. In the light of his/her common general knowledge the skilled person would not consider such an antibody as pharmaceutically useful. Therefore, the application as filed did not support a "pharmaceutical" composition.

In the general description the application as filed referred to "monoclonal human antibodies", while "**a**

monoclonal human antibody" was only derivable from the examples, i.e. the specific antibody B5. Therefore, a composition containing "a" human monoclonal antibody was an unallowable generalisation from the examples.

Extension of scope of protection

The meaning of the term "containing" used in claim 1 was wider than that of the term "comprising" used in claim 1 as granted, in that it meant that the explicitly mentioned antibody simply had to be present, including its presence in any trivial amount.

Novelty

The antibodies in a polyclonal serum constituted in fact nothing else than a mixture of monoclonal antibodies of different specificities. Given that, due to the term "containing", the composition according to claim 1 could comprise human monoclonal antibodies of different specificity, the disclosure in documents ID8 or ID9 of human sera containing auto-antibodies to TNF-alpha was novelty-destroying for the subject-matter of claim 1.

Moreover, the polyreactive IgM monoclonal antibody F2.2.34 described in the patent, for example in paragraph [0031], took away the novelty of the subject-matter of claim 1. This antibody was disclosed in document ID59, also cited in paragraph [0031] of the patent. This document should be introduced into the proceedings.

XIII. Moreover, the parties presented their arguments with regard to inventive step (Article 56 EPC) of the claims of the main request and also with regard to the issue of remittal of the case for consideration as to Articles 83 and 57 EPC.

Reasons for the decision

Admissibility of the appeal

1. In order to be admissible, an appeal has to fulfil inter alia the requirement of Article 108, third sentence, EPC that a written statement setting out the grounds of appeal must be filed within four months of the date of notification of the decision. In relation to this requirement, it has been developed in the case law of the Boards of Appeal that arguments must be presented so clearly and concisely that the board and the parties are put in a position to understand why the decision is alleged to be incorrect (Case Law of the Boards of Appeal of the EPO, 5th Edition, VII.D.7.5.1). In other words, the grounds for appeal must be given in a sufficiently substantiated manner.

1.1 In the present case, the statement setting out the grounds of appeal was filed within the prescribed time limit. In the statement the appellant requested, as already before in the notice of appeal, the maintenance of the patent with the claims as granted. The statement further contained reasons why the appellant considered the opposition division's sole reason for refusing the main request, corresponding to the claims as granted, for lack of novelty of claims 1 and 3, to be incorrect.

The argumentation was clear - which has also not been denied by the respondents - thus putting the board in a position to review the opposition division's decision on this issue without the need for further investigation.

1.2 However, the respondents have argued that the grounds of appeal in the present case had to contain more than this in order to comply with the requirements of Article 108, third sentence, EPC. In their view, the appellant should not have neglected the fact that the opposition division also decided that claim 1 of the then third auxiliary request lacked an inventive step. Since the patent as granted contained a dependent claim 2, which corresponded to that claim, and independent claim 1, which was even broader, the appellant should have specified the reasons why the subject-matter of these claims was inventive in contrast to the findings of the opposition division made in the context of the then third auxiliary request.

1.3 With respect to this argument, the board firstly notes that, even if it might be assumed that the opposition division, had it not refused the main request for lack of novelty, would have refused it for lack of inventive step at least for the reasons given with respect to the third auxiliary request, it did not do so.

1.4 Furthermore, if an appellant were obliged to deal, in the statement setting out the grounds for appeal, with all the reasons for the appealed decision which, albeit made in the context of lower-ranking requests, might become relevant for the further examination of a higher-ranking request, this would, in the board's view,

in many cases amount to a very complex task to sort out from the reasons for the decision the possibly relevant ones, especially in cases with a high number of requests and/or claims dealt with in the decision. In addition, legal uncertainty would ensue, since the relevance of a reason might frequently become a matter for dispute. The board therefore comes to the conclusion that the interpretation of Article 108 EPC favoured by the respondents would generate too high a threshold for the substantiation of an appeal and thus for its admissibility.

1.5 The respondents have also made the argument that, even if the appeal had originally been admissible, it later became inadmissible when the appellant withdrew the sole request relied on in the grounds of appeal and submitted new requests with claims identical or corresponding to claims dealt with in the decision under appeal. However, the substantiation of an appeal is judged on the basis of documents submitted within the term indicated in Article 108 EPC. An appeal cannot therefore become inadmissible by subsequent submissions, including changes or replacements of requests.

1.6 Thus, the appeal fulfils the requirements of Article 108, third sentence EPC, and is admissible.

Admission of a new main request and auxiliary request

2. In accordance with the Rules of Procedure of the Boards of Appeal (Articles 10a(2) and 10b(1) RPBA), the statement of grounds of appeal is required to contain a party's complete case. Any amendments filed thereafter may be admitted at the board's discretion. The main

principles taken into consideration when exercising that discretion are the complexity of the new subject-matter submitted and its formal allowability.

2.1 Claim 1 of the new main request is generated by a combination of claims 1 and 2 of the claims as granted with dependent claims 2 to 6 corresponding to claims 3, 5, 6, 7 and 8 of the claims as granted. Moreover, the new main request is identical to the third auxiliary request considered by the opposition division. Claim 1 of the auxiliary request is generated by a combination of features of claims 1, 2 and 11 as granted with dependent claims 2 to 6 corresponding to claims 3, 5, 6, 7 and 8 as granted. This auxiliary request corresponds, moreover, essentially to the fourth auxiliary request considered by the opposition division.

2.2 Thus, the features of the new claims were already present in claim requests considered during grant and opposition proceedings, as well as in the main request originally filed in appeal proceedings. Moreover, the two requests were filed one month before the day of the oral proceedings. Under these circumstances the board comes to the conclusion that the newly submitted subject-matter cannot be considered too complex in the sense that the time for considering it would not be sufficient for the respondents to prepare an adequate response without postponement of the oral proceedings. Finally, in the opposition proceedings neither the opponents nor the opposition division had raised objections for formal reasons against corresponding claims.

2.3 Therefore, the board decides to admit the new main and auxiliary request into the procedure.

Amendments - Article 123(2) EPC

In the following the term "application" means "application as filed".

"pharmaceutical" composition

3. The relevant question in assessing whether an amendment adds subject-matter extending beyond the content of the application is whether or not the amended subject-matter would be directly and unambiguously derived by the skilled person from the application. This determination takes account of the whole content of the document as understood by the skilled person when reading the document with common general knowledge.

3.1 The application does not explicitly mention the expression "pharmaceutical composition". Therefore the question arises whether the skilled person would implicitly derive that the disclosure of the application relates to a "pharmaceutical" composition.

3.2 The application, in its introductory part, when reviewing the prior art, inter alia, describes the activities of tumour necrosis factor (TNF) alpha: "Among the many activities of secreted TNFα are thymocyte growth factor, B cell growth and maturation factor, production in vivo of hemorrhagic necrosis, weight loss, cardiovascular collapse and multiple organ failure." This enumeration ends with the statement: "Naturally, these latter activities are the source of

the clinical interest in TNFα." In the next paragraph it is stated that: "During septic shock, as well as inflammatory diseases, synthesis and secretion of TNFα, IL-1, IL-6 and IL-8 have been documented". It is further disclosed that low-affinity auto-antibodies to TNFα have been detected in the human body. The introductory part closes by stating that: "... we are unaware of the disclosure of any monoclonal human antibodies specifically binding to TNFα even though it is thought such antibodies may have significant clinical value."

3.3 Given the disclosure of pathological situations in which TNF-alpha is involved, the board considers that the skilled person would already have derived from the introduction of the application that the focus of the invention is on providing human TNF-alpha binding monoclonal antibodies for clinical use.

The remainder of the application - which essentially discloses the human monoclonal TNF-alpha binding B5 antibody and some of its properties, such as binding affinity and specificity, competition ability, binding to surface TNF-alpha on a variety of cells or inhibition of secretion of TNA-alpha - would, in the board's view, not be in contrast to the skilled person's primary perception.

3.4 Among the claims as originally filed, claim 3 is directed to a composition comprising the antibodies in a pharmaceutically acceptable carrier, and claim 4 requires that the antibodies are suitable for intravenous administration. The board agrees that, when considered in isolation, the expression "in a

pharmaceutically acceptable carrier" does not necessarily qualify an agent as pharmaceutically useful. Likewise it is imaginable that an intravenous administration may be made for reasons other than a treatment. However, these are meanings that the skilled person would have ruled out in the context of the application, especially in the light of its introductory part (see point 3.2 above). Thus, in the board's view, the claims as filed unambiguously convey to the skilled person that the main intended use of the human monoclonal antibody-containing composition is in the pharmaceutical domain.

Hence, the board concludes that the application document as a whole provides an implicit basis for the introduction of the term "pharmaceutical" in claim 1.

3.5 The respondents argue that the skilled person would derive from the application that the human monoclonal TNF alpha-binding antibody B5 is not pharmaceutically useful in view of certain **results** presented in the application, especially the low affinity and the lack of neutralising capacity, and therefore that the application related to pharmaceutically useless compositions. Consequently, claiming a "pharmaceutical" composition would extend the content of the application.

3.6 The board observes that a distinction is to be made between the **disclosure** of subject-matter in a document, i.e. the information conveyed by the document, and the **actual or perceived effectiveness or usefulness** of the subject-matter. For example, a compound may in reality not have a property that a document discloses it to have. However, the evaluation as to Article 123(2) EPC

adheres, as explicitly stated in said provision, to the "content of the application as filed".

"a" human monoclonal antibody

3.7 Claim 1 relates to "a pharmaceutical composition containing **a** human monoclonal antibody that binds to human tumour necrosis factor alpha"(emphasis added by the board). The board considers that, in view of the term "a" in combination with the term "binds", the wording of claim 1 indicates that a single kind of antibody is present in the composition. Further, given the term "containing", the presence of other constituents, for example also other antibodies, is not excluded (for the extent of the presence of such further constituents, see point 6.1 below). Therefore, in other words, the claim must be construed as relating to a composition containing **at least one single kind** of a human monoclonal antibody that binds to human TNF alpha.

3.8 The respondents submit that this amended claim contravenes the requirements of Article 123(2) EPC because a composition containing a single kind of a human monoclonal antibody is only disclosed in the context of specific compositions, for example, the composition containing the monoclonal antibody B5. The other parts of the description refer to "human monoclonal antibodies", i.e. a plurality of monoclonal antibodies.

3.9 In view of the principles explained in point 3 above, in order to determine whether or not a composition containing at least a single kind of a human monoclonal

antibody that binds to human tumour necrosis factor alpha is an amendment contravening the requirements of Article 123(2) EPC, account has to be taken of the disclosure in the application as a whole, as understood by the skilled person.

3.10 The application's objective of providing a composition containing a single kind of monoclonal antibody, i.e. a monospecific composition, may, in the board's view, implicitly be derived from the statement on page 3: "Thus, there has remained a need for monospecific monoclonal antibodies to TNFα." Moreover, the specifically mentioned examples also relate to monospecific compositions. Taking together these disclosures and taking also the skilled person's common general knowledge into account, on the basis of which he/she would be aware that monospecificity is usually perceived as the main advantage of a monoclonal antibody composition in a clinical situation, leads the board to the conclusion that the skilled person would clearly and unambiguously derive from the application that it in particular relates to pharmaceutical compositions containing one single kind of antibody. By the same token, the board is also convinced that the skilled person would understand the plural of the expression "human monoclonal antibodies" as referring to the number of entities of a single kind of antibody present in the composition, rather than to the number of kinds.

Consequently, the board considers that the application provides a basis for a composition containing "a" human monoclonal antibody.

3.11 Accordingly, the amendments to claim 1 fulfil the requirements of Article 123(2) EPC.

Extension of scope of protection - Article 123(3) EPC

4. The claims as granted comprise eleven claims, eight thereof relating to a composition and three to the use of antibodies. Claim 1 as granted is directed to "a composition comprising human monoclonal antibodies that bind to human tumor necrosis factor alpha". In claim 2 as granted the composition is qualified as "pharmaceutical". Therefore, claim 1, the claim with the broadest scope, must be interpreted as relating to compositions suited for any use, including pharmaceutical use.

4.1 The set of claims of the present main request consists of six claims directed to a composition. Claim 1 of this request, the claim with the broadest scope, relates to "a pharmaceutical composition containing a human monoclonal antibody that binds to human tumor necrosis factor alpha". A comparison of the scope of granted claim 1 with that of present claim 1 reveals that the latter is limited with regard to the former, insofar as it is restricted to compounds suited for pharmaceutical use.

4.2 Regarding the respondents' suggested interpretation of the terms "containing" and "comprising", the board considers them to be equivalent in meaning. Moreover, the board is convinced that the term "human monoclonal antibodies" in granted claim 1 had the meaning of a plurality of entities of a single kind of human monoclonal antibody (see point 3.10 for the

corresponding interpretation of the term in the application as filed). Despite the singular "a human monoclonal antibody", the same meaning is implicit in present claim 1, because the pharmaceutical effect of antibodies cannot rely on the reactivity of a single molecule. Thus, this difference in wording between claim 1 of the main request and claim 1 as granted does not result in a difference in the meaning of the claim.

4.3 Hence, the scope of protection conferred is not extended by the amended claim 1 (Article 123(3) EPC).

Article 84 EPC

5. The respondents did not raise objections under Article 84 EPC and the board sees no reason to do so of its own motion.

Novelty - Article 54 EPC

Documents ID8 or ID9

6. Documents ID8 and ID9 disclose that normal sera and sera of patients with gram-negative bacterial sepsis or chronic inflammatory diseases contain antibodies of IgG (ID8 and ID9), IgM (ID8) and IgA (ID8 and ID9) classes binding to TNF-alpha.

6.1 Since claim 1 defines the composition as "containing" a human monoclonal antibody, the subject-matter is not restricted to a composition containing only the one kind of such antibodies; there may be further constituents. Therefore the argument has been made that claim 1 encompasses compositions including so many

further compounds as to result in a polyclonal serum as disclosed in documents ID8 and ID9. It is, however, the opinion of the board that a claim using the word "containing" should generally not be construed as covering subject-matter that would manifestly contradict the advantages brought forth by the invention. In the board's view, in the present case the term "monoclonal antibody" implies a certain degree of purity and specificity. Thus, despite the open-ended term "containing", the skilled person would not construe the claim such that, in addition to one kind of monoclonal antibody, the composition as claimed could contain further antibodies or other constituents to an extent that the composition equals a polyclonal serum.

Therefore, the board considers the polyclonal sera disclosed in documents ID8 and ID9 not to deprive the subject-matter of claim 1 of novelty.

Human monoclonal antibody "F2.2.34"

6.2 Respondent II argued for the first time at the oral proceedings that the antibody F2.2.34 which is mentioned in the patent, for example in paragraphs [0031] and [0050], bound to TNF-alpha according to Figure 4F of the patent and therefore destroyed the novelty of the subject-matter of claim 1. In order to show the public availability of this antibody before the priority date of the patent, respondent II submitted document ID59 and requested the board to admit it into the proceedings. The document is also cited in paragraph [0031] of the patent as a reference

for the production and characterisation of the antibody F2.2.34.

6.3 However, the board notes that document ID59 discloses neither the binding of the F2.2.34 antibody to TNF-alpha nor any pharmaceutical use of this antibody. Even if, as a technical reality, the F2.2.34 antibody could be used pharmaceutically, the disclosure of this antibody in document ID59 would only destroy the novelty of the subject-matter of claim 1, if the document also described its pharmaceutical usefulness, since, as it follows from Article 54(5) EPC, a composition, although it is comprised in the state of the art, is patentable for its first medical use. The board considers therefore that respondent II's argument fails. Thus, document ID59 cannot be relevant and is not admitted into the proceedings.

6.4 The subject-matter of claim 1 and of all of the dependent claims 2 to 6 fulfils the requirements of Article 54 EPC.

Order

For these reasons it is decided that:

1. The appeal is admissible.

2. Claims 1 to 6 of the main request filed with letter dated 18 September 2007 comply with the requirements of Articles 123(2) and (3), 84 and 54 EPC.

3. The debate with respect to the issue of inventive step of the main request is closed.

4. The procedure is continued in writing.

The Registrar: The Chair:

P. Cremona M. Wieser