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Datasheet for the decision of 14 October 2009

Case Number: T 0725/05 - 3.3.04

Application Number: 95105609.2

Publication Number: 0682040

IPC: C07K 16/46

Language of the proceedings: EN

Title of invention:
Production of Humanized Immunoglobulins and Corresponding Polynucleotiodies

Patentee:
PDL BioPharma, Inc.

Opponents:
(02) Boehringer Ingelheim GmbH
(03) Medimmune, Inc.
(04) Schering Corporation
(05) CELLTECH R & D LIMITED
(06) XOMA(US)LLC
(07) Novartis AG
(08) IDEC Pharmaceuticals Corpn

Headword:
Humanized Immunoglobulins II/PDL

Relevant legal provisions:
EPC Art. 76(1), 111(1), 112, 114(1)
EPC R. 103(1)(a)
RPBA Art. 12, 13

Keyword:
"Substantial procedural violation, remittal, reimbursement of the appeal fee, referral of questions to the EBA - (no)"
"First auxiliary request - added subject-matter - (yes)"
"Second auxiliary request - admissibility - (no)"

Decisions cited:
T 0011/82, T 0473/98, T 0500/01, T 0900/02

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0725/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 14 October 2009

Appellant: (Patent Proprietor)
PDL BioPharma, Inc.
1400 Seaport Blvd.
Redwood City
CA 94063 (US)

Representative:
Bizley, Richard Edward
HLBBshaw
Merlin House
Falconry Court
Baker's Lane
Epping
Essex CM16 5DQ (GB)

Respondent I: (Opponent 02)
Boehringer Ingelheim GmbH
D-55216 Ingelheim (DE)

Representative:
-

Respondent II: (Opponent 03)
Medimmune, Inc.
One Medimmune Way
Gaithersburg
Maryland 20878 (US)

Representative:
Walcher, Armin
Louis, Pöhlau, Lohrentz
Merianstrasse 26
D-90409 Nürnberg (DE)

Respondent III: (Opponent 04)
Schering Corporation
2000 Galloping Hill Road
Kenilworth
N.J. 07033-0530 (US)

Representative:
Adams, Harvey Vaughan John
Marthys & Squire LLP
120 Holborn
London EC1N 2SQ (GB)

Respondent IV: (Opponent 05)
CELLTECH R & D LIMITED
208 Bath Road
Slough
Berkshire SL1 3WE (GB)

Representative:
Mercer, Christopher Paul
Carpmaels & Ransford
43-45, Bloomsbury Square
London WC1A 2RA (GB)

Respondent V: (Opponent 06)
XOMA(US)LLC
2910 Seventh Street
Berkeley
CA 94710 (US)

Representative:
Armitage, Ian Michael
Mewburn Ellis LLP
33 Gutter Lane
London EC2V 8AS (GB)

Respondent VI: (Opponent 07)
Novartis AG
Patent and Tradmark Dept.
Klybeckstrasse 141
CH-4002 Basel (CH)

Representative:
Weiss, Wolfgang
Weickmann & Weickmann
Patentanwälte
Postfach 86 08 20
D-81635 München (DE)

Respondent VII: (Opponent 08)
IDEC Pharmaceuticals Corpn
11011 Torreyana Rd
San Diego, CA 92121 (US)

Representative:
Daniels, Jeffrey Nicholas
Page White & Farrer
Bedford House
John Street
London WC1N 2BF (GB)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 11 March 2005 revoking European patent No. 0682040 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
D. S. Rogers

Summary of Facts and Submissions

I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European Patent No. 0 682 040 was revoked pursuant to Article 102(1) EPC 1973 after the patent was opposed by eight parties under Articles 100(a), (b) and (c). The European patent, having the title "Production of humanized immunoglobulins and corresponding polynucleotides" was granted on the basis of divisional European application no. 95 105 609.2 (the "Divisional Application), divided from earlier application EP 90 903 576.8 (the "Parent Application"); the Parent Application was granted as EP 0 451 216.

II. Claim 18 of the Parent Application, published as WO 90/07 861, reads as follows:

"A method of designing a humanized immunoglobulin (Ig) chain having one or more complementarity determining regions (CDR's) from a donor Ig and a framework region from a human Ig, said method comprising: comparing the framework or variable region amino acid sequence of the donor Ig light or heavy chain with corresponding sequences in a collection of human Ig chains; and selecting to provide the human Ig light or heavy chain framework one of the about three most homologous sequences from the collection."

III. Claim 1 of the Divisional Application, which led to the patent in suit, as originally filed reads:

"A method of producing a humanized immunoglobulin (Ig) chain having one or more complementarity determining regions (CDR's) from a donor Ig and a framework region from a human Ig, said method comprising: comparing the framework or variable region amino acid sequence of the donor Ig light or heavy chain with corresponding sequences in a collection of human Ig chains; and selecting, to provide the human Ig light or heavy chain framework, a sequence from the collection which has at least about 65% homology with the donor framework."

IV. The patent in suit was granted with claims 1 to 6. Claim 1 reads as follows:

"A method of producing a humanized immunoglobulin (Ig) having complementarity determining regions (CDR's) from a donor Ig combined with a framework region from human Ig acceptor light and heavy chains, said method comprising:

1) comparing the framework or variable region amino acid sequences of the donor Ig light and heavy chains with corresponding sequences in a collection of human Ig chains;

2) selecting, to provide the human acceptor Ig light and heavy chain frameworks, sequences from the collection which have at least 65% homology with the respective donor framework sequences; and

3) combining CDR's from the donor Ig and frameworks from the selected acceptor sequences."

V. The description of the Divisional Application as originally filed contains the following text on page 4, line 9 to page 5, line 7 (page 3, lines 8 to 25 of the granted patent; paragraph [0012] and parts of paragraph [0013]):

"*The hypervariable regions (also called Complementarity Determining Regions, abbreviated to "CDRs") of immunoglobulins were originally defined by Kabat et al., ("Sequences of Proteins of Immunological Interest" Kabat, E., et al., U.S. Department of Health and Human Services, (1983)) based on extent of sequence variability, to consist of residues 24-34 (L1), 50-56 (L2) and 89-97 (L3) in the light chain variable domain (V_L) and 31-35(H1), 50-65 (H2) and 95-102 (H3) in the heavy chain variable domain (V_H), using Kabat's standard numbering system for antibody amino acids. The CDRs are believed to contact the target antigen of an antibody and to be primarily responsible for binding. More recently Chothia et al (Chothia and Lesk, J. Mol. Biol., 196:901-917 (1987)) have given an alternate definition of the hypervariable regions or CDRs as consisting of residues 26-32(L1), 50-52 (L2), 91-96 (L3) in V_L and residues 26-32 (H1), 53-55 (H2), 96-101 (H3) in V_H. The Chothia definition is based on the residues that constitute the loops in the 3-dimensional structures of antibodies. It is particularly important to note that for each of the six CDRs the Chothia CDR is actually a subset of (i.e. smaller than) the Kabat CDR, with the single exception of H1 (the first heavy chain CDR), where the Chothia CDR contains amino acids 26-30 that are not in the Kabat CDR.*

Riechmann et al ("Reshaping human antibodies for therapy", Nature, Vol. 332, pp 323-326, (March 1988)) describe work in which precisely the Kabat CDRs were transferred to a pre-determined human framework (NEW again for the heavy chain and REI for the light chain). However, they found that an antibody containing the humanized heavy chain lost most of its binding affinity and ability to lyse target cells. They therefore made a new humanized antibody containing the Kabat CDRs from the mouse antibody and two amino acid changes in Chothia CDR H1, but no other mouse amino acids."

This passage was not contained in the Parent Application as filed.

VI. The Opposition Division decided that the main request before them, claims 1 to 5 filed with letter dated 13 July 2001 (which were identical to claims 1 to 5 as granted), did not meet the requirements of Article 76(1) EPC. Moreover they decided that none of auxiliary requests 1 to 5 before them met the requirements of Article 123(2) and 123(3) EPC.

Auxiliary request 3 differed from the main request only in claim 1, wherein the term "complementarity determining regions (CDR's)" in the preamble had been changed into "Kabat complementarity determining regions (CDR's) and the term "CDR's" in item 3) had been changed into "Kabat CDR's".

VII. Following the reasons for their decision, the Opposition Division added in point (6) on pages 16 to 19 of the appealed decision their opinion with regard to the requirements of Article 83 EPC. This opinion

starts with an introductory remark (see point (3) below).

VIII. The Board expressed their preliminary opinion in a communication dated 20 May 2009 and summoned the parties for oral proceedings.

With letter dated 29 May 2009 the Appellant requested postponement of the oral proceedings. He was informed by the Board in a further communication dated 9 June 2009 that this request was not allowed.

Respondents I, III, V, VI and VII (Opponents 02, 04, 06, 07 and 08) did not attend the oral proceedings held on 14 October 2009.

Opponent 01 withdrew its opposition with letter dated 6 January 2009 and is no longer party to the proceedings.

IX. The Appellant (Patent Proprietor) requested:

That the decision under appeal be set aside due to a substantial procedural violation by the department of first instance and to remit the case to the department of first instance for further prosecution with the order that a different Opposition Division should hear the case; and

as a first auxiliary request, that the decision under appeal be set aside and the patent be maintained on the basis of the claims of the main request before the Opposition Division, that is claims 1 to 5 filed with

letter dated 13 July 2001 (identical to claims 1 to 5 as granted); and

as a second auxiliary request, that the Board sets aside the decision under appeal and accepts a further request upon the basis of claims 1 to 5 filed during oral proceedings, these claims being identical to claims 1 to 5 of auxiliary request 3 that were before the Opposition Division.

Respondents II to VI (Opponents 03 to 07) requested to dismiss the appeal. Respondents I and VII (Opponents 02 and 08) have not filed any request in the appeal procedure.

X. The following documents are mentioned in this decision:

(3) Riechmann L., et al., Nature, vol.332, March 1988, pages 323 to 327

(4) Kabat E., et al., extracts from "Sequences of Proteins of Immunological Interest", 1983 Edition, US Department of Health and Human Services

(5) Chotia C., et al., J.Mol.Biol., vol.196, 1987, pages 901 to 917

(15) EP-A-0 239 400

(29) Declaration C. Chotia, 18 October 1996

XI. The arguments of the Appellant as far as they are relevant for the present decision may be summarised as follows:

All pages of the papers constituting the written communication of the Opposition Division's decision were headed as "Grounds for the decision (Annex)". The fact that the Opposition Division on pages 16 to 19 of these papers came to certain views regarding issues other than added matter, the only EPC requirement discussed during oral proceedings, was to be seen as influencing the decision under appeal. Even the mere possibility of such influence or bias being publicly apparent, rendered the decision unreliable because it gave the impression that, whatever the outcome of the decision, justice had neither been done nor seen to have been done. Further, these additional statements although not apparently part of the "reasons for the decision" could lead to detrimental effects for the Appellant, for instance in proceedings before national courts who were aware of the decision under appeal.

Therefore, the Opposition Division's decision was vitiated by a substantial procedural violation requiring remittal to the department of first instance for further prosecution. The case should be remitted immediately with the order that a different Opposition Division should hear the case. Additionally the appeal fee had to be reimbursed.

Should the Board not remit the case to the department of first instance, questions concerning the inclusion of *obiter dicta* into a decision of an Opposition Division, which were prejudicial to a party's position, should be referred to the Enlarged Board of Appeal.

The Appellant argued that page 4, line 9 to page 5, line 7 of the application as originally filed, which was part of the Parent Application as originally filed, was part of the background discussion and analysed relevant prior art documents. As such these passages had no "dictionary function". The skilled reader, knowing that only Kabat (document (4)) gave a definition of CDR's would, at the best, have considered the teaching in these paragraphs as misleading and would not have been influenced in his understanding of the term "CDR" which had a clear definition in the art. Deciding that this would not be so would also stand in clear contradiction to decision T 500/01 of 12 November 2003, taken by this Board in a different composition, which was concerned with the patent granted on the basis of the Parent Application EP 90 903 576.8. If the Board, in case T 500/01 (supra) would have considered that the content of page 4, line 9 to page 5, line 7 of the present Divisional Application as originally filed, which was identically introduced in the Parent patent then under consideration, influenced the definition of the term "CDR", it could not have decided that a claim restricted to "[A] method for producing a humanized immunoglobulin light chain" met the requirements of Article 123(2) EPC (see decision T 500/01 (supra), points (20) to (23)).

Claims 1 to 5 which were intended to be introduced during the oral proceedings before the Board as Appellant's auxiliary request 2, were identical to claims 1 to 5 of auxiliary request 3 before the Opposition Division. Already in the letter setting out the grounds for appeal the Appellant reserved his right to rely on this and other requests in future. The

request could not have come as a surprise to the Board and to the other parties. The description could be adapted to this request at any time, once it was allowed into the procedure by the Board.

XII. The arguments of the Respondents, as far as they are relevant for the present decision, may be summarised as follows:

The *obiter dictum* on pages 16 to 19 of the papers containing the appealed decision was clearly designated as not being part of the reasons for the decision and could not therefore have any influence on the Opposition Division's decision which is concerned with the requirements of Articles 76(1), 123(2) and 123(3) EPC only. Any negative consequence of these passages on the attitude of a national court that at some future date would be concerned with the present case was not to be expected. The Opposition Division by expressing in this form its opinion on the requirements of Article 83 EPC, an issue comprehensively dealt with by all parties during the written procedure, did not commit a procedural mistake which would justify remittal of the case and reimbursement of the appeal fee. Moreover, none of the requirements mentioned in Article 112 EPC as being a prerequisite for the referral of questions of law to the Enlarged Board of Appeal were fulfilled in the present case.

The Parent Application as originally filed defined CDRs as was generally accepted in the art, namely according to Kabat in document (4). This was no longer the case in the Divisional Application as filed, since, in order to distinguish the claimed subject-matter from the

state of the art, especially from document (3), the Appellant had introduced a new definition for this technical term on pages 4 and 5. Contrary to the arguments presented by the Appellant, these newly introduced passages were not simply analysing the prior art and would not have been disregarded by the skilled reader as being misleading, they rather introduced a new definition of the technical term "CDR" valid for the Divisional Application. This new definition was not contained in the earlier application as originally filed and contravened the requirements of Article 76(1) EPC.

The Appellant, in the letter setting out the grounds for appeal, expressly stated that in appeal procedure "no current reliance" was placed on the auxiliary requests that were before the Opposition Division. Although it was evident for all parties from the present opposition/appeal procedure and from the opposition/appeal procedure in the case of Appellant's earlier application that the definition of the term "CDR" was the crucial point of the proceedings, no auxiliary request was filed by the Appellant during the entire written appeal procedure which lasted more than four years, not as a response to the Board's communication and not, at the latest, at the beginning of the oral proceedings.

Reasons for the Decision

Main Request

Substantial procedural violation - Remittal to the department of first instance (Article 111(1) EPC) - Reimbursement of the appeal fee (Rule 103(1)(a) EPC) - Referral of questions to the Enlarged Board of Appeal (Article 112 EPC)

1. The papers constituting the appealed decision consist of a cover sheet (EPO form 2331) and of two enclosures. The two enclosures are indicated on the bottom of EPO form 2331 which reads:

   "Enclosures(s):
   19 pages(s) reasons for the decision (Form 2916)
   Wording of Articles 106 - 108 (Form 2019)"

2. The Board notes that this statement is incorrect in so far as EPO form 2916 is not labelled as "Reasons for the decision" but as "Grounds for the decision (Annex)". The annex has the usual structure of decisions of the Opposition Divisions and contains a section "Facts and submissions" and a section "Reasons for the decision". This latter section deals on pages 5 to 15 with the requirements of Articles 76(1), 123(2) and 123(3) EPC in connection with Appellant's main request and auxiliary requests 1 to 5 and reads on page 15, point (5), under the heading "DECISION":

   "For the reasons discussed in items 2 - 4, none of the requests on file meets the requirements of the EPC, particularly of Art. 76(1), 123(2) and 123(3) EPC.

Consequently, the patent EP-B-0 682 040 is revoked pursuant to Art. 102(1) EPC."

3. This is followed by pages 16 to 19 of the Annex, wherein the Opposition Division expresses its opinion with regard to the requirements of Article 83 EPC, sufficiency of disclosure.

The introductory paragraph on page 16, point 6, reads:

"Although not being a reason for the decision, the opposition division wishes to express an opinion to other topics that had been discussed in extensio during the procedure in writing."

4. It is evident from the minutes of the oral proceedings before the Opposition Division, that the requirements of Article 83 EPC were not an issue discussed at the oral proceedings.

5. The Appellant infers from this situation that his right to be heard has been violated (Article 113(1) EPC). The addition of such considerations, which were not an issue at the oral proceedings, to a decision might be appropriate for the Boards of Appeal or another last instance court, but not for an Opposition Division. The Opposition Division's considerations on Article 83 EPC might have negatively influenced their decision with regard to added matter (Articles 76(1), 123(2) and 123(3) EPC). Finally, the content of pages 16 to 19 of the appealed decision could lead to detrimental effects for the Appellant, for instance in proceedings before national courts (see section (XV) above).

By referring to decision T 900/02 of 28 April 2004, the Appellant emphasised that justice must not only be done but must be seen to be done. Thus, the addition of these considerations to the written decision amounted to a substantial procedural violation.

6. With regard to the nature and the significance of pages 16 to 19 of the appealed decision (annexed as "Grounds for the decision" to EPO Form 2331) the Board notes that their content is marked as "not being a reason for the decision". Thus, the content of these pages forms an *obiter dictum,* a remark or observation made by a deciding body that, although included in the papers of the decision, does not form part of the actual decision.

On the other hand those parts of the appealed decision which are marked as "Reasons for the decision" and which end on the bottom of page 15 with the "Decision", exclusively refer to issues on which the parties had ample opportunity to comment at the oral proceedings before the Opposition Division (see minutes). Thus, the parties right to be heard, which in Article 113(1) EPC is defined as meaning that they had an opportunity to present their comments (in writing and orally) on all grounds or evidence on which a **decision** of the European Patent Office (here an opposition division) is based, has not been violated.

Decision T 900/02 (supra), referred to by the Appellant, is concerned with a suspicion of partiality, inevitably arising if a member of an Opposition Division first solicits and then accepts employment with a firm in which a partner or other employee is

conducting a case pending before that member. This situation has nothing to do with the situation underlying the present case. The findings in decision T 900/02 are therefore not considered to be relevant for the present case.

7. The Boards of Appeal, although in a procedurally different situation, have already examined whether or not a party to an inter partes proceedings can be adversely affected by an *obiter dictum* contained in a decision of an Opposition Division. The Board in decision T 473/98 (OJ EPO 2001, 231) decided that this is not the case and that moreover the inclusion of *obiter dicta* is appropriate for an Opposition Division as it may obviate the need for remittal in the event its decision (in this case revocation of the patent) is reversed on appeal (see point 2 of the reasons).

8. Article 76(1), 123(2) and 123(3) EPC all are concerned with the issue of "added matter". Article 83 EPC relates to sufficiency of disclosure.

The Board is convinced that all requirements that have to be met by a European patent application or a granted patent which are laid down in the different Articles and Rules of the EPC have to be seen and considered as an integral whole. However, in the absence of any specific reference by the Appellant to an aspect or argument in either the reasons for the decision or in the *obiter dictum,* the Board does not see that the Opposition Division's decision on added matter has been influenced by its opinion on sufficiency of disclosure. Moreover, the Board cannot duplicate Appellant's

suspicion that this could be seen differently by another deciding body, for instance a national court.

9. For all these reasons the Board comes to the decision that the Opposition Division by adding an *obiter dictum* at the end of the appealed decision had not made a substantial procedural mistake which would require remittal of the case to the department of first instance for further prosecution according to Article 111(1) EPC.

Appellant's main request is therefore refused. Consequently also the request for reimbursement of the appeal fee is refused.

10. With letter dated 14 August 2009 the Appellant, in case the Board should not remit the case to a reconstituted Opposition Division, submitted the following questions to be referred to the Enlarged Board of Appeal (EBA):

"1. In a case where an Opposition Division includes within the papers constituting its written communication of its decision obiter dicta which are prejudicial to the position of one of the parties, can this constitute a substantial procedural violation necessitating remittal to the First Instance?

2. If the answer to question 1 is "yes", under what circumstances is there a substantial procedural violation justifying such remittal?".

11. Article 112(1)(a) EPC stipulates that the Board of Appeal, following a request from a party to the appeal, shall refer any question to the EBA if it considers

that a decision is required in order to ensure uniform application of the law, or if an important point of law arises.

The questions proposed by the Appellant do not relate to a uniform application of the law, as this Board already answered them by taking a view of the law which does not deviate from earlier cases (see decision T 473/98, point (6) supra). Moreover, according to the relevant case law, questions which a Board can resolve itself without any doubt are not referred to the EBA (see Case Law of the Boards of Appeal of the EPO, 5th Edition 2006, Chapter VII.D.13.2; English version, page 639, third paragraph).

In view of the above, Appellant's request for referral of questions to the EBA is refused.

First auxiliary request

Added subject-matter in an European divisional application (Article 76(1) EPC)

12. The invention refers to a method for producing a humanized immunoglobulin (Ig) having CDRs from a donor Ig combined with a framework region from human Ig acceptor light and heavy chains (see claim 1).

13. In the Parent Application as originally filed the term "CDR" was defined according to the definition generally used and accepted by a skilled person working in the field of immunoglobulins at the filing date of the application, 28 December 1989, namely the definition of

Kabat, given in document (4) (see figure 1 and page 962, left column).

14. The passage bridging pages 9 and 10 of the Parent Application as originally filed reads as follows:

"*The variable regions of each light/heavy chain pair form the antibody binding site. The chains all exhibit the same general structure of relatively conserved framework regions joined by three hypervariable regions, also called CDRs (see, "Sequences of Proteins of Immunological Interest," Kabat, E., et al., U.S. Department of Health and Human Services, (1983); and Cholthia and Lesk, J. Mol. Biol., 196:901-917 (1987), which are incorporated herein by reference).*"

(The incorrect spelling of the name "Chotia" is contained in the original document).

The two references mentioned in this paragraph are document (4) (**Kabat**) and document (5) (**Chotia**).

It has to be established what the technical teaching of these citations is, when read in the context of the description, in particular whether each of them contains a separate definition of the term CDR.

Document (5) refers to hypervariable regions or loops, who's ".. limits are somewhat different from those of the complementary determining regions defined by Kabat et al. .." (document (5), page 904, left column). This is **not** a definition of CDRs. This conclusion is supported by the author of document (5), who declares in document (29), that there are no "Chotia CDRs". He

states that "the CDRs are regions in antibodies of sequence variation that were identified in 1970 by Kabat who predicted correctly that they would be the regions that bind antigen" (document (29), sentence bridging pages 6 and 7).

15. Besides a few minor amendments, which do not have to be considered in the context of Article 76(1) EPC, the present Divisional Application as originally filed is distinguished from the Parent Application as originally filed by the insertion of two paragraphs on page 4, line 9 to page 5, line 7 (see section IV above).

Firstly, by referring to the disclosure in document (4), the original definition of CDRs according to Kabat is described (page 4, lines 9 to 19). Then, starting on page 4, line 19, it is stated that "[M]ore recently Chotia et al (Chotia and Lesk, J. Mol. Biol., 196:901-917 (1987)) have given an alternate definition of the hypervariable regions or CDRs...". The term "Chotia CDR" is then introduced on page 4, line 27, and it is mentioned that for five of the six CDRs the "Chotia CDRs" are subsets of the Kabat CDRs. The single exception to this is the first CDR on the heavy chain (CDR H1) where the "Chotia CDR" contains amino acids 26 to 30 that are not part of the Kabat CDR (page 4, lines 26 to 30). The description goes on to discuss prior art document (3). It is said that therein a humanised antibody was disclosed wherein the Kabat CDRs were transferred from a donor (a mouse) to a pre-determined human framework. Additionally, in order to improve the humanised antibody's binding affinity and its ability to lyse target cells, two mouse amino acids were transferred which were positioned in "Chotia CDR

H1", but no other mouse amino acids (page 4, line 32 to page 5, line 7).

16. The Appellant argues, that this part of the description, not contained in the Parent Application as originally filed, has been introduced in the section headed "Background of the Invention", which was immediately followed by the section "Summary of the Invention". It referred therefore merely to the recognition of a disclosure in the state of the art, which according to the case law of the Boards of Appeal, e.g. decision T 11/82 (OJ EPO 1983, 479), cannot be regarded as added subject-matter. It was evident that the content of the introduced paragraphs had no "dictionary function" in the sense that a patent, being a legal document, may define technical terms and determine how a skilled person has to interpret a specific term when used in the description or in the claims. Rather the skilled reader, knowing from document (5), that Chotia gave no separate CDR definition, would have disregarded their teaching as being misleading and as having no impact on the definition of the term CDR.

In fact, according to the Appellant Representative's recollection of the oral proceedings in case T 500/01 (supra), concerning the patent granted on the basis of the Parent Application, before this Board in a different composition on 11 and 12 November 2003, this was exactly the opinion expressed by the Chair orally concerning the impact and significance of the newly introduced text passages, which were identically contained in the Parent Application as granted.

Moreover, the Board in decision T 500/01 has already examined the impact of the newly introduced parts of the description (Page 4, line 9 to page 5, line 7) and has reached the decision that they do not provide support or basis for a "combination definition" of CDRs which is both Kabat **and** Chotia. Deciding now differently not only would clearly contradict the decision T 500/01 in this point, but would also not be in line with the Board's decision in T 500/01 that a claim restricted to a method of producing a humanized immunoglobulin **light chain** met the requirements of Article 123(2) EPC (see points 20 to 23 of T 500/01).

The Appellant argued further, that the skilled reader after having reached the conclusion to disregard the teaching on page 4, line 9 to page 5, line 7 of the Divisional Application as originally filed, as being confusing and misleading, would have found evidence that the term CDRs had to be understood as referring to Kabat CDR's at several passages of the application as filed. He referred to page 17, line 24 to page 18, line 11 (paragraph [0046] of the patent as granted) and page 12, line 37 to page 13, line 7 (paragraph [0040] of the patent as granted).

17. Respondent II (Opponent 03) at the oral proceedings considered the introduced paragraphs of the description to disclose an **alternate** definition of CDRs. Respondent IV (Opponent 05) argued that the newly introduced passages of the description, although not explicitly stating it, have to be interpreted as referring to a definition of CDRs as meaning Kabat **together with** Chotia.

18. With regard to Appellant's recollection of an alleged statement of the Board during the oral proceedings in case T 500/01 (supra), neither those members of the present Board nor those representatives that were present at the oral proceedings in case T 500/01 and in the oral proceedings in the present case, share this recollection. Such a statement would be clearly contradictory to the gist of decision T 500/01.

19. Decision T 11/82 (supra), referred to by the Appellant, states, that the mere addition to the description of a reference to prior art cannot reasonably be interpreted as the addition of "subject-matter" contrary to Article 123(2) EPC. Nor is it inevitable that the addition of a discussion of the advantages of the invention with reference to such prior art would constitute a contravention of that Article. Whether it did so would clearly depend on the actual language used and the circumstances of the case (cf point 22 of the reasons).

20. However, the discussion of document (5) on page 4, lines 19 to 30 of the Divisional Application as filed is not "the mere addition to the description of a reference to prior art". In fact, by stating that it gives an **alternate** definition of the hypervariable regions or CDRs, it goes far beyond the disclosure in said document which expressly mentions on page 904, left column, that it refers to loops, whose "limits are somewhat different from those of the complementarity determining regions defined by Kabat". By immediately thereafter introducing the term "Chotia CDR" as being an alternate definition for "Kabat CDR", this new part of the description provides the public with the

instruction that the term "CDR" may be Kabat CDR or "Chotia CDR". This transpires also from the paragraph bridging pages 4 and 5 of the Divisional Application as originally filed, wherein the disclosure in prior art document (3) is acknowledged. The skilled reader is informed that document (3) describes a humanised antibody containing Kabat CDRs from a mouse and, additionally two mouse amino acids lying within "Chotia CDR H1".

As decision T 11/82 (supra) does not refer to a situation where the analyses and discussion of a prior art document goes far beyond the actual disclosure in said document, it is not relevant for the present case.

21. Although the added parts of the description have been introduced in the section "Background of the Invention" their content is considered by the Board to have an essential impact on the skilled reader's interpretation of the term CDR in the following parts of the application. The reader is provided with the technical teaching that, besides the generally accepted definition of CDRs according to Kabat, there is another, **alternate** definition of this term according to Chotia. He is moreover informed that five of the "Chotia CDRs" are subsets of the respective Kabat CDRs, while in one case (CDR H1) the Chotia CDR contains amino acids not contained in the Kabat CDR, and that accordingly document (3) does not teach to transfer amino acids from the mouse donor to the human acceptor which lie outside the CDRs, namely Kabat **or** Chotia CDRs.

Contrary to the opinion of Respondent IV (opponent 05) the Board sees no support or basis in these added parts

of the description that the term CDRs has to be interpreted as meaning Kabat **together with** Chotia.

22. The Board sees no reason why the skilled reader should disregard the clear information conveyed by the disclosure on page 4, line 9 to page 5, line 7 of the Divisional Application as filed.

23. The Appellant relied on page 12, line 37 to page 13, line 7 of the application as filed (paragraph [0040] of the patent as granted), which he considered to give a definition for CDRs and to be a basis for the assumption that the term CDRs in the application means Kabat CDRs only. This passage reads:

"*As used herein, the term "framework region" refers to those portions of immunoglobulin light and heavy chain variable regions that are relatively conserved (i.e., other than the CDRs) among different immunoglobulins in a single species, as defined by Kabat, et al., op. cit. As used herein a "human-like framework region" is a framework region that in each existing chain comprises at least about 70 or more amino acid residues, typically 75 or 85 or more residues, identical to those in a human immunoglobulin."*

The first sentence of this passage states that, according to Kabat, framework regions, other than CDRs, are relatively conserved. Thus, the information given does not concern the actual extent of framework regions, by disclosing those amino acid residues that are part thereof, but concerns their degree of conservation. The second sentence defines the term "human like framework regions".

Therefore, this passage does not provide a definition of the term CDRs.

24. The second paragraph referred to by the Appellant is on page 17, line 24 to page 18, line 11 of the application as filed (paragraph [0046] of the patent as granted).

This paragraph refers to document (15) and states on page 17, lines 27 to 28 that its disclosure is "excluded from coverage". The Appellant seems to argue that a reference to this document which itself refers to CDRs as being Kabat CDRs has to be considered as a basis for finding that the same term when used in the present application also means Kabat CDRs only.

The Board cannot agree. The acknowledgement of the disclosure in a prior art document is no basis for the allegation that a technical term defined in this document in a specific way has to be interpreted in an identical way in the present application, which on pages 3 and 4 contains an explicit statement that the term is defined in a different manner (see point (19) above).

25. In consideration of what has been said in points (18) to (20) above, the Board reaches the decision that according to the disclosure on page 4, line 9 to page 5, line 7, the application as originally filed refers to CDRs which are defined according to Kabat, **or** according to the alternate definition of Chotia.

Since the Parent Application as originally filed does not refer to CDRs according to Chotia, the Divisional

Application contains subject-matter going beyond the content of the earlier application as filed and does not meet the requirements of Article 76(1) EPC.

26. The Appellant has argued that this decision would contradict decision T 500/01 (supra), taken by this Board in a different composition and referring to the patent granted on the basis of the Parent Application.

He has put forward (see Appellant's letter dated 14 August 2009, section D.1.2), that the Board in decision T 500/01 (supra) has already performed an extensive analysis of the amendments to the description identical to page 4, line 9 to page 5, line 7 of the present Divisional Application as filed. The Appellant stresses that the Board, in decision T 500/01 (supra) came to the conclusion that these passages did not provide support or basis for a definition of CDRs which is both Kabat **and** Chotia.

27. It has to be emphasised that the patent that was the subject of the Board's decision in case T 500/01 contained an explicit statement that the term CDRs was as defined by **Kabat together with Chotia**, both in the description and in claim 1.

Whereas the situation underlying the present Divisional Application differs therefrom in so far as no such explicit definition of CDRs Kabat together with Chotia is present. However it is stated on page 4, starting in line 19, that Chotia provided an **alternate** definition of CDRs, which according to this decision (see point (24) above), that CDRs are **either Kabat CDRs or Chotia CDRs**. This passage, which was identically contained in

the Parent Application as granted was indeed examined by the Board in decision T 500/01 (supra) and it was decided, as correctly stated by the Appellant, that it did not provide support or basis for a "combination" definition of CDRs, Kabat together with Chotia.

The issue before the Board in case T 500/01 was whether the expression "Kabat **together** with Chotia" had a basis in the Parent Application as filed. The issue before the Board in the present case is whether page 4, line 9 to page 5, line 7 of the present Divisional Application as filed provides support for an alternate definition of CDRs, that is for Kabat **or** Chotia, and, if the answer is yes, whether this has a basis in the Parent Application as filed.

Deciding in the present case that the definition of CDRs in the Divisional Application is Kabat **or** Chotia is not, therefore, contradictory to decision T 500/01.

For the same reason the Board's present decision is not contradictory to points (20) to (23) of the reasons of decision T 500/01, where it was decided that a claim restricted to a method of producing a humanized immunoglobulin **light chain** met the requirements of Article 123(2) EPC. As all three "Chotia CDRs" of the **light chain** are subsets of the respective Kabat CDRs, for this embodiment the term "Kabat **together** with Chotia" was identical to Kabat CDR as disclosed in the Parent Application as originally filed. Therefore the Board did not see a violation of Article 123(2) EPC.

This is a different situation compared to the present case where the Board has decided that the term CDRs as

defined by Kabat **or** Chotia adds subject-matter in the Divisional Application compared with the Parent Application as filed which is contrary to Article 76(1) EPC.

Second auxiliary request

Admissibility of Claims 1 to 5 filed at the oral proceedings (Article 114(2) EPC

28. After being informed by the Board at the oral proceedings late in the afternoon of 14 November 2009, that his first auxiliary request did not meet the requirements of Article 76(1) EPC, the Appellant requested that the Board accept a further request upon the basis of claims 1 to 5, which were identical to claims 1 to 5 of auxiliary request 3 before the Opposition Division.

29. In the letter setting out the Appellant's grounds for appeal, dated 20 July 2005, he wrote on page 2, item (d):

"Nonetheless, brief discussion is also provided of the Auxiliary Requests which were before the Opposition Division, although no current reliance is placed on these Auxiliary Requests. The right to rely on these Auxiliary Requests in future is reserved."

The "brief discussion" of auxiliary requests 3 to 5, which were found by the Opposition Division not to meet the requirements of Articles 123(2) and 123(3) EPC (see point 4 of the appealed decision), can be found in six

lines on page 18 of Appellant's letter dated 20 July 2005 and relates to Articles 123(2) and 123(3) EPC only.

No further comments or arguments with regard to auxiliary request 3 before the Opposition Division were filed by the Appellant during the entire written appeal procedure which lasted more than four years.

Accordingly, also the Respondents did not file any submission with regard to this request.

30. It was evident for all parties from the beginning of the opposition procedure (see communication of the Opposition Division dated 22 November 2002, pages 5 to 6) that the "redefinition" of the term CDR was an essential point of the present case in the light of the requirements of Article 76(1) EPC.

Also the Board of Appeal in their communication dated 20 May 2009, annexed to the summons to oral proceedings, highlighted in point 8 on page 3, that "[M]ost probably the crucial point to be decided will be the question of the definition of the term "CDR"."

31. The Appellant did not react to this point until he was informed at the oral proceedings that his first auxiliary request was not allowable. In the last submission before the oral proceedings, dated 14 August 2009, he informed the Board that he would be prepared to alter the word "homology" in claim 1 to read "identity". No amendments or auxiliary requests serving as a fallback position in case the Board decided that the definition of CDRs was detrimental to the requirements of Article 76(1) EPC were submitted.

32. According to Article 114(2) EPC, the EPO may disregard facts or evidence which are not submitted in due time by the parties concerned.

The statement of grounds of appeal and the reply shall contain a party's complete case. They shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the facts, arguments and evidence relied on.

All documents referred to shall be

(a) attached as annexes insofar as they have not already been filed in the course of the grant, opposition or appeal proceedings or produced by the Office in said proceedings;

(b) filed in any event to the extent that the Board so directs in a particular case (Article 12(2) Rules of Procedure of the Boards of Appeal (RPBA)).

Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA).

Amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties

cannot reasonably be expected to deal with without adjournment of the oral proceedings (Rule 13(3) RPBA).

33. In the present case the Appellant wanted to file a new claim request more than four years after submitting the statement of grounds of appeal. For this request essential issues of patentability, such as novelty (Article 54 EPC), inventive step (Article 56 EPC) or sufficiency of disclosure (Article 83 EPC) have never been argued during the entire opposition/appeal procedure.

Also the Respondents, who were confronted with the request for the first time at the oral proceedings, had not had any possibility to comment on these essential issues during the course of the proceedings.

Thus, the admission of this late filed request into the procedure would almost inevitably require remittal of the case to the department of first instance for further prosecution (Article 111(1) EPC).

34. Therefore, the Board decides, based on Article 114(2) EPC and the Rules of Procedure of the Boards of Appeal, not to admit Appellant's auxiliary request 2 into the procedure.

Order

For these reasons it is decided that:

The appeal is dismissed.

Registrar: Chair:

C. Eickhoff U. Kinkeldey