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Datasheet for the decision of 20 September 2016

Case Number: T 2440/13 - 3.3.04

Application Number: 05022104.3

Publication Number: 1616572

IPC: A61K39/395

Language of the proceedings: EN

Title of invention:
Chimeric anti-CD20 antibody, rituxan, for use in the treatment of chronic lymphocytic leukemia

Patent Proprietor:
Biogen Inc.

Opponents:
Althausen, Sonja
Teva Pharmaceutical Industries Ltd.
Gedeon Richter Pharma GmbH
Rumpold, Tino
Royle, Matthew Charles James
Sandoz AG
Merck & Co.

Headword:
Rituximab/BIOGEN

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 115(2)
RPBA Art. 12(4), 15(3)

Keyword:
Main request, auxiliary requests 1 to 3: amendments - allowable (no)

Decisions cited:
G 0002/10, T 0296/96

Catchword:

Europäisches Patentamt
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Case Number: T 2440/13 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 September 2016

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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 24 September 2013 revoking European patent No. 1616572 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	R. Morawetz
	L. Bühler

Summary of Facts and Submissions

I. The appeal of the proprietor (hereinafter "the appellant") lies against the decision of the opposition division revoking European patent No. 1616572.

II. The patent in suit entitled "*Chimeric anti-CD20 antibody, rituxan, for use in the treatment of chronic lymphocytic leukemia*" was granted in respect of European patent application No. 05022104.3 ("the application as filed"; see also below, point 8) which is a divisional application of European patent application No. 99960232.9 filed on 9 November 1999 and published as WO 00/27428.

Claim 1 as granted reads:

"1. Use of rituximab in the manufacture of a medicament for the treatment of chronic lymphocytic leukemia (CLL) in a human patient, wherein the medicament is for administration to the human patient at a first dose of 375 mg/m^2 and subsequent dosages of 500 to 1500 mg/m^2."

Claim 3 is a corresponding claim drawn up in the format allowable under Article 54(5) EPC.

III. Seven oppositions were filed, invoking *inter alia* the ground of Article 100(c), first half-sentence, EPC that the subject-matter of the European patent extended beyond the content of the application as filed.

IV. In the course of the opposition proceedings the patent proprietor filed an amended main request, consisting of claims 1 and 3 as granted, and 4 auxiliary requests.

V. The opposition division decided that all claim requests before it failed the requirements of Article 123(2) EPC and revoked the patent.

VI. The following documents are referred to in the present decision:

D3 WO00/27428, publication of the parent application

D55 First declaration of Dr. David Schenkein, dated 22 March 2012

D71 Second declaration of Dr. David Schenkein, dated 5 June 2013

D72 Link B.K. *et al.*, 1998 ASCO Annual Meeting, Abstract No: 7

D91 Declaration of Dr. Michael Wenger, dated 31 January 2014

D92 Declaration of Dr. Steven Edward Coutré, dated 3 February 2014

D93 Knospe W.H. *et al.*, Cancer (1974), vol. 33, pages 555-562

D94 Rodriguez G., Investigational New Drugs (1994), vol. 12, pages 75-92

D95 Wintrobe's Clinical Hematology (1998), G.R. Lee *et al.*, editors, Tenth Edition, volume 2, pages 2416-2419

VII. With its statement of grounds of appeal the appellant submitted documents D91 to D95, a main request and auxiliary requests 1 to 4. These requests were identical to the corresponding requests underlying the decision under appeal.

VIII. The parties were summoned to oral proceedings. The summons was accompanied by a communication pursuant to Article 15(1) RPBA.

IX. With letter dated 18 August 2016 the appellant provided a main request and auxiliary requests 1 to 3 which were identical to auxiliary requests 1 to 4 filed with the statement of grounds of appeal.

Claim 1 of the main request read:

"1. Use of rituximab in the manufacture of a medicament for the treatment of chronic lymphocytic leukemia (CLL) in a human patient, wherein the medicament is for administration to the human patient at a first dose of 375 mg/m^2 and subsequent weekly, bi-weekly or monthly dosages of 500 to 1500 mg/m^2."

The subject-matter of claim 1 of auxiliary request 1 differed from the subject-matter of claim 1 of the main request in that all of the subsequent dosages were further specified to remain the same.

The subject-matter of claim 1 of auxiliary request 2 differed from the subject-matter of claim 1 of the main request in that the subsequent dosages were limited to three.

The subject-matter of claim 1 of auxiliary request 3 differed from the subject-matter of claim 1 of the main

request in that the subsequent dosages were limited to three and were further specified to remain the same.

X. Oral proceedings were held on 20 September 2016. Respondents I, II and VII were not present or represented as announced beforehand in writing. At the end of the oral proceedings the chairwoman announced the board's decision.

XI. The arguments of the appellant may be summarised as follows:

Admission of documents D91 to D95

These documents provided the perspective of the skilled person on the disclosure of the application and in particular of example 3. They had been filed in response to arguments of respondent VII raised for the first time at the oral proceedings before the opposition division and could not have been filed earlier.

Main request

Article 123(2) EPC - claim 1

The applicable standard was the gold standard (see decision G 2/10, point 4.3 of the reasons).

The basis for the subject-matter of claim 1 was to be found in the general part of the description with the exception of the stepped-up dosage of 500 to 1500 mg/m^2 which found a basis in example 3 as follows.

The application was directed to the use of anti-CD20 antibodies for the treatment of malignancies other than

B-cell lymphomas, see page 2, lines 9 to 12. In particular, the application provided for the use of these antibodies in the treatment of CLL, see page 3, lines 4 to 5. The preferred anti-CD20 antibody for use in the invention was rituximab, referred to by its proprietary name RITUXAN®, see page 5, lines 14 to 15. Therefore, it was directly and unambiguously disclosed that the invention was directed to the use of rituximab for the treatment of CLL, which was the preferred embodiment.

The application disclosed on page 2, second paragraph, that the FDA had approved the therapeutic use of RITUXAN® for use in treatment of relapsed and previously treated low-grade non-Hodgkin's lymphoma (NHL). The skilled person was aware that the FDA-approved dosage was 375 mg/m^2.

With specific respect to treatment regimen and timing, the skilled reader was informed that rituximab could be administered at various intervals, e.g. weekly, bi-weekly and monthly, depending on dosage and patient response, see page 6, lines 15 to 16.

An example of one treatment regimen was provided at page 6, lines 21 to 22, comprising the same dosage provided weekly for about 2 to 10 weeks, or for about 4 weeks.

The application taught that other regimens were also contemplated and were even preferred, for example, stepped-up dosing schedules, see page 6, line 23.

Stepped-up dosing was not only disclosed for weekly administration because the application referred on page 6 to "*stepped-up dosing schedules*" in the plural,

explicitly indicating to the skilled reader that more than the exemplified schedule (weekly) was disclosed. Also, page 6 further referred to "*weekly, bi-weekly, or monthly*" protocols making it clear that schedules other than weekly were contemplated. Flexibility of timing was thus taught in the application.

Additionally the skilled reader was informed that the treatment regimen might also be combined with other therapies such as radiation and chemotherapy, see page 6, line 25 to page 7, line 13. In particular, at least one chemotherapeutic regimen disclosed, CHOP, was known to be administered with rituximab less frequently than weekly, see document D72.

The skilled person who read the application and example 3 would see that chemotherapy was a typical treatment for CLL and would adapt the stepped-up dosage regimen accordingly to include bi-weekly and monthly administration.

Stepped-up dosing was the gist of the invention.

Example 3 was a phase I/II study that provided proof of concept of the stepped-up dosing concept by specifying 375 mg/m^2, subsequently stepped up to 500 to 1500 mg/m^2.

Although the exemplified embodiment comprised weekly subsequent dosages, nothing in example 3 indicated that the weekly timing was in any manner critical to the observed therapeutic effect. What mattered was a higher dosage in the second round of treatment while weekly administration was not relevant.

Declarations D71, D91 and D92 explained that no functional relationship between the technical effect of the claimed regimen and the timing between the dosages was made clear to the skilled person in the application.

Therefore, the treatment regimen could be extracted from the timing parameter recited in the specific embodiment of example 3 without infringing Article 123(2) EPC.

The subject-matter of claim 1 was the common denominator of what was directly and unambiguously disclosed in the general description and in example 3.

The standard set by decision T 450/98 was met.

Auxiliary requests 1 to 3

Article 123(2) EPC - claim 1

The subject-matter of claim 1 of auxiliary requests 1 to 3 complied with the requirements of Article 123(2) EPC for the same reasons as given for the subject-matter of claim 1 of the main request.

XII. The arguments of respondents I, III, IV, V, VI and VII may be summarised as follows:

Admission of documents D91 to D95

These documents addressed comments made by respondent VII during the oral proceedings before the opposition division. However, respondent VII's objection - that a single declaration from an employee of a licensee of the patent with a personal interest in

seeing it maintained was not enough to establish common general knowledge - was not surprising. The documents should not be admitted into the appeal proceedings.

Main request

Article 123(2) EPC - claim 1

The applicable standard was the gold standard (see decision G 2/10, point 4.3 of the reasons). It followed from the gold standard and in particular from the requirement "*directly and unambiguously*", that the application as filed could not be treated as a mere reservoir from which individually disclosed features could be combined in the absence of a pointer to the combination (see also decision T 296/96).

Claim 1 added matter over the description as filed because the appellant had combined scattered features from the general part of the description without there being any pointer to the combination, and over example 3 because features disclosed in combination were omitted.

In view of the references on page 6 (see e.g. lines 3, 7, 25 and 26) and throughout the application to any anti-CD20 antibody, rather than only to "*rituximab*", the broad dosage ranges and various administration frequencies (e.g. "*monthly*") of page 6, lines 12 to 14 and lines 15 to 16 did not apply directly and unambiguously to the particular antibody rituximab or to the treatment of CLL with rituximab.

In the context of the entire paragraph, the reference to "*schedules*" on page 6, line 24 was understood by the skilled person to refer to the plurality of different

weekly schedules, recited in the same paragraph. There was no reason for the skilled person to go back to lines 15 to 16 of page 6. Stepped-up dosing was disclosed in the application exclusively in the context of weekly administration.

Any reference in document D3 to a combination of rituximab with chemotherapy was disclosed as a mere option, not in connection with the stepped-up dosage regimen. As was evident from example 3, the study described therein was a monotherapy using rituximab. Because of this, there was no linkage between the passages of document D3 dealing with such other therapies, and the stepped-up dosing schedule of example 3. The appellant could thus not rely on the combination of rituximab with chemotherapy to justify a dosing interval other than weekly.

The disclosure of document D72 did not belong to the common general knowledge of the skilled person and it disclosed administration of rituximab every 3 weeks at 375 mg/m^2 and administration of CHOP 48 hours later, not together.

There was also no disclosure in the application that chemotherapy should be given with the same frequency as rituximab or that if rituximab was combined with chemotherapy then rituximab should be administered bi-weekly or monthly.

There was no mention on page 6 that stepped-up dosing was the gist of the invention. There was also no basis in the claim set of the application as filed that would allow the skilled person to understand that stepped-up dosing was the essence of the invention and that therefore page 6 could be combined with example 3.

Claim 6 as filed was limited to weekly administration and claim 9 to a dosage of 375 mg/kg weekly for a total of four weeks.

The only disclosure relating to a first dose of 375 mg/m^2 followed by a subsequent dosage of 500 to 1500 mg/m^2 was to be found in example 3 of the application as filed. Example 3 explicitly referred to weekly administration and there was nothing in example 3 that taught the skilled person that the interval between subsequent doses was to be changed or that a longer interval than weekly administration was used or could be used.

Contrary to the arguments of the appellant and its experts, the passage in lines 15 to 17 of page 6 explicitly stated that the administration protocol depended on the dosage, hence the dosages disclosed in example 3 were inseparably linked with the weekly administration interval.

In claim 1, the amount from example 3 had been combined with the general feature of "*weekly, bi-weekly or monthly*" administration described in the general part of the description. However, the resulting combination was not directly and unambiguously disclosed in the application since there was no pointer to it.

In the case underlying decision T 450/98, unlike the present one, the specification disclosed to the skilled person that it was possible to alter the amino acid sequence of the polypeptide without affecting its activity. In the present case, the application did not disclose to the skilled person that it was possible to alter the administration frequency without affecting the efficacy of the treatment.

Auxiliary requests 1 to 3

Article 123(2) EPC - claim 1

Claim 1 of auxiliary requests 1 to 3 added subject-matter beyond the content of the application as filed, for the same reasons as given with respect to the subject-matter of claim 1 of the main request. In particular, there was no specific disclosure in the application of the combination of the indicated dosage and a bi-weekly or monthly administration.

XIII. Respondent II did not submit any arguments or requests in the appeal proceedings.

XIV. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the main request, or, alternatively, of one of auxiliary requests 1 to 3, all filed with letter of 18 August 2016.

Respondents I, III, IV, V, VI and VII requested that the appeal be dismissed.

Reasons for the Decision

The decision under appeal

1. The board notes that the opposition division decided, *inter alia*, that the originally disclosed term "RITUXAN®" could be replaced with the term "rituximab" (see decision under appeal, reasons, points 3.10.1.1 to 3.10.1.3) and that the originally disclosed unit "mg/m^3" could be corrected to read "mg/m^2" (*ibid.*, points 3.10.2.1 to 3.10.2.9). In these

appeal proceedings the board dealt with the appellant's appeal first. As the appeal has to be dismissed, the board did not deal with points which were decided in the decision under appeal in the appellant's favour and were contested by the respondents on appeal. Accordingly, for the purpose of this decision, the board has accepted that "*mg/m*^{3}" can be corrected to read "*mg/m*^{2}" and that the term "*RITUXAN*®" can be replaced with the term "*rituximab*", without infringing Article 123(2) EPC.

Oral proceedings - Rule 115(2) EPC and Article 15(3) RPBA

2. Respondents I, II and VII were neither present nor represented at the oral proceedings. The board considered it expedient to conduct the scheduled oral proceedings in their absence in order to reach a final decision in this appeal case (Rule 115(2) EPC and Article 15(3) RPBA).

The invention

3. The present invention relates to the use of RITUXAN® (generic name: rituximab), a chimeric murine/human monoclonal antibody that targets the B-lymphocyte restricted differentiation antigen CD20, for use in the treatment of chronic lymphocytic leukemia (CLL).

Admission of documents D91 to D95

4. The appellant filed documents D91 to D95 with its statement of grounds of appeal. It explained that declarations D91 and D92 had been submitted to provide the perspective of the skilled person on the disclosure of the application and in particular of example 3. They had been filed in response to respondent VII's

assertion that a single affidavit was insufficient to establish the common general knowledge or the understanding of the skilled reader. Documents D93 to D95 were supporting documents cited in D91 and D92.

5. Respondents I, V and VII requested that documents D91 to D95 not be admitted into the appeal proceedings because they had been filed too late. The appellant could not have been taken by surprise by respondent VII's above-mentioned assertion because this was long-standing jurisprudence.

6. Article 12(4) RPBA provides that the Board has the power to hold inadmissible facts, evidence or requests which could have been presented in the first instance proceedings.

7. The board accepts that the declarations are a good faith response to an issue not raised until the oral proceedings before the opposition division. Documents D91 to D95 reinforce the evidence filed with the opposition division, *i.e.* declarations D55 and D71 and the prior art cited therein. Accordingly, the board decided, in the exercise of its discretion under Article 12(4) RPBA, not to exclude documents D91 to D95 from the appeal proceedings.

Main request

Article 123(2) EPC - claim 1

8. Reference was made by the parties to either document D3, *i.e.* the publication of the parent application, or to the application as filed (see above, sections XI and XII). It is undisputed that these documents are identical. Since the issue to be decided

is whether or not the requirements of Article 123(2) EPC are fulfilled, the board will refer in the following to the application as filed (see above, section II; hereinafter "the application").

9. Claim 1 of the main request is drawn up in the "Swiss-type" format and is directed to a dosage regimen for treating CLL with rituximab wherein the medicament is for administration to a human patient at a first dose of 375 mg/m^2 and subsequent weekly, bi-weekly or monthly dosages of 500 to 1500 mg/m^2 (see section IX).

10. The appellant submitted that a basis for the subject-matter of claim 1 was to be found in the general part of the description, with the exception of the stepped-up dosing of 500 to 1500 mg/m^2 which found a basis in example 3.

11. The appellant's line of argument is based on the following propositions: (i) stepped-up dosing is disclosed in the generic part of the application in combination with weekly, bi-weekly and monthly administration, (ii) stepped-up dosing is the gist of the invention and (iii) the dosing of 500 to 1500 mg/m^2 can be extracted from example 3 which provides proof of concept for stepped-up dosing (see section XI).

12. As regards, the first proposition, the appellant submitted that stepped-up dosing was disclosed for weekly, bi-weekly or monthly administration because the application referred to "*stepped-up dosing schedules*" in the plural and alternative schedules including "*weekly, bi-weekly or monthly*" were expressly disclosed. Furthermore, regarding schedules other than the weekly schedule in example 3, the claims covered - and the application disclosed - combining the anti-CD20

antibody with chemotherapies and thus further disclosed schedules less frequent than weekly.

13. The passages in the application relied on by the appellant in support of its first proposition are reported below.

14. As to how often the anti-CD20 antibody is to be administered, the application discloses that "*such administration may be effected by various protocols, e.g. weekly, bi-weekly, or monthly, dependent on the dosage administered and patient response*" (see page 6, lines 15 to 17).

15. The possible combination of the anti-CD20 antibody with other treatments is disclosed in the application as follows "*also, it may be desirable to combine such administration with other treatments, e.g. radioactive therapy, both targeted and non-targeted, chemotherapy, and lymphokine or cytokine administration, e.g. interleukins, interferons, TNF's, colony stimulating factors, etc.*" (see page 6, lines 17 to 20), and further "*a particularly preferred chemotherapeutic regimen that may be used in conjunction with the subject antibody immunotherapy comprises CHOP immunotherapy*" (see page 7, lines 9 to 11).

16. The application also discloses that treatment of CLL, B-pro-lymphocytic leukemia (B-PLL) and transformed non-Hodgkin's lymphoma "*will comprise the administration of a therapeutically effective amount of an anti-CD20 antibody, which administration may be effected alone or in conjunction with other treatment(s), e.g.*

chemotherapy, radiotherapy (e.g. whole body irradiation, or treatment with radiolabeled antibodies)" (see page 4, lines 3 to 8).

17. Finally, the application discloses that "*typically, treatment will be effected weekly, for about 2 to 10 weeks, more typically about 4 weeks. A particularly preferred dosage regimen will comprise administration of about .375 mg/kg weekly for a total of four infusions. Also, stepped-up dosing schedules may be even more preferable*" (see page 6, lines 22 to 24).

18. According to the established case law the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments of the application can be combined in order to artificially create a particular embodiment. In the absence of any pointer to that combination, this combined selection of features does not, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (see Case Law of the Boards of Appeal, 8th edition 2016, section II.E.1.4.1 and decisions cited therein).

19. The question thus arises whether the application provides a pointer to the combination of stepped-up dosing with weekly, bi-weekly or monthly administration.

20. Stepped-up dosing is mentioned once in the generic part of the description, see point 17 above. And while the passage refers to "*stepped-up dosing schedules*" in the plural, it does not define these schedules. The board considers however that the skilled person reading the entire paragraph notes that it starts by stating that "*typically, treatment will be effected weekly*" and

also that the schedules disclosed subsequently merely differ in their duration as follows: "for *2 to 10 weeks, more typically about 4 weeks"* and "*weekly for a total of four infusions"*. The skilled person would thus understand "*schedules*" in the context of "*stepped-up dosing*" to refer to these different schedules in which administration is always weekly.

21. There is thus no reason for the skilled person to understand the term "*schedules*" in the context of the whole paragraph to refer to any other administration frequency than weekly. Accordingly, in the board's view, the use of the plural "*schedules*" does not directly and unambiguously imply for the skilled person a variation in the administration timing which would direct him to combine stepped-up dosing also with bi-weekly or monthly administration which is disclosed on page 6 in a generic context (see point 14 above).

22. As regards the appellant's argument which is based on the combination of the anti-CD20 antibody with chemotherapy (see point 12), the board takes the following view.

23. The application discloses that anti-CD20 antibody treatment of CLL can be combined *inter alia* with chemotherapy, but this possible combination is disclosed in a general context and not specifically in the context of stepped-up dosing (see points 15, 16 and 17). Also example 3 which, as the appellant submits, provides proof of concept for stepped-up dosing, discloses a monotherapy using rituximab but not a combination of rituximab with any other therapy, let

alone chemotherapy. Finally, none of the claims of the application relates to stepped-up dosing in combination with chemotherapy.

24. Therefore, in the board's judgement, the application's disclosure relating to chemotherapy does not direct the skilled person to adapt the administration frequency disclosed in the application in the context of stepped-up dosing, namely weekly (see points 20 and 21), to also include bi-weekly and monthly administration.

25. The appellant's further argument that the skilled person, aware through his common general knowledge of the disclosure of document D72, would adopt the stepped-up dosing regimen to also include bi-weekly and monthly administration, also fails, because the application does not disclose the combination of stepped-up dosing with chemotherapy in the first place (see point 23).

26. Likewise, the argument relied on by the appellant that "*in view of the disclosure on page 6, line 15-20 of D3 and the known use of less frequent dosing schedules for rituximab combined with chemotherapy, an oncologist would have used the alternative schedules as disclosed in D3*" (*see* document D71, point 18), and similar lines of argument in documents D91 and D92, fail for the reasons set out above in points 23 and 24.

27. The board concludes from the above that the skilled person would not derive from the application as filed, directly and unambiguously, using common general knowledge, the combination of stepped-up dosing with

bi-weekly or monthly administration. In view of this finding it is not necessary to consider the remainder of the appellant's lines of argument (see point 11).

28. The board concludes from the above that the subject-matter of claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

Auxiliary requests 1 to 3

Article 123(2) EPC - claim 1

29. The same objections as set out above for the subject-matter of claim 1 of the main request apply *mutatis mutandis* to the subject-matter of claim 1 of auxiliary requests 1 to 3, as none of these requests is limited to subsequent weekly dosages. Therefore, claim 1 of these requests does not meet the requirements of Article 123(2) EPC either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated