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**Datasheet for the decision
of 25 July 2023**

Case Number: T 1998/21 - 3.3.04

Application Number: 15808356.8

Publication Number: 3212667

IPC: C07K16/24, A61K39/395,
A61K47/10, A61K47/18,
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A61K47/26

Language of the proceedings: EN

Title of invention:
Pharmaceutical anti-TNF-alpha antibody formulation

Patent Proprietor:
Richter Gedeon Nyrt.

Headword:
anti-TNF α antibody formulation / RICHTER GEDEON

Relevant legal provisions:
EPC Art. 113, 123(2), 111(1)
RPBA 2020 Art. 13(2)
EPC R. 103(1)(a)

Keyword:

Appealed decision sufficiently reasoned (no)

Amendment after summons - taken into account (yes)

Amendments - added subject-matter (no)

Reimbursement of appeal fee (no)



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Case Number: T 1998/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 25 July 2023

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 1 October 2021
revoking European patent No. 3212667 pursuant to
Article 101(2) EPC**

Composition of the Board:

Chairman A. Chakravarty
Members: O. Lechner
 M. Blasi

Summary of Facts and Submissions

- I. The appeal of the patent proprietor ("the appellant") lies from the decision of the opposition division to revoke European patent 3 212 667 ("the patent").
- II. The patent was granted on European patent application No. 15 808 356.8 which was filed as an international application PCT/EP2015/074986 (the "application as filed"), published as WO 2016/066688.
- III. Oppositions were filed by opponents 1 and 2. During the opposition proceedings, opponent 3 filed a notice of intervention. The oppositions were filed against the patent as a whole on the grounds for opposition set out in Article 100(a), (b) and (c) EPC.
- IV. In its decision, the opposition division only dealt with the ground for opposition under Article 100(c) EPC and *inter alia* held that the subject-matter of the claims of the patent as granted (main request) and of the auxiliary requests extended beyond the content of the application as filed. It further stated that auxiliary requests 1 to 4, 4a to 4h, 5 to 12, filed with the letter of 6 May 2021, were "*deemed to be on time*" (see point 24 of the decision).
- V. With the statement of grounds of appeal, the appellant filed sets of claims of new auxiliary requests 4e(i) and 4e(ii) and provided arguments on why neither the claims of the patent as granted (main request) nor of any of auxiliary requests 1 to 4, 4a to f and 5 to 19 contained subject-matter extending beyond the content of the application as filed (Article 100(c) and

Article 123(2) EPC, respectively). The appellant further requested reimbursement of the appeal fee pursuant to Rule 103(1)(a) EPC and submitted that its right to be heard under Article 113 EPC had been violated by the opposition division.

- VI. Opponents 1 to 3 ("respondents I to III") replied to the statement of grounds of appeal with a joint letter and presented arguments regarding novelty and inventive step, sufficiency of disclosure of the claimed invention and added subject-matter. They also raised objections under Article 84 EPC regarding auxiliary requests 4 to 14 and 18 and under Article 123(3) EPC against auxiliary requests 4, 4c, 4d, 4f and 5 to 19.
- VII. The appellant and the respondents submitted further letters.
- VIII. The oral proceedings before the board, scheduled as requested by the parties, took place on 25 July 2023.

During the oral proceedings

- the appellant requested, as a further auxiliary request, that the patent be maintained in amended form based on the sets of claims of auxiliary requests 4g and 4h as filed during opposition proceedings and that they also be admitted into the appeal proceedings
- the respondents I, II and III withdrew their oppositions and subsequently left the oral proceedings, after which the oral proceedings were continued with the appellant as the sole party
- the appellant filed a new claim request and withdrew all other claim requests, i.e. the former

main request and auxiliary requests 1 to 4,
4a to h, including 4e(i) and 4e(ii), and 5 to 19.

- IX. At the end of the oral proceedings, the Chairman announced the board's decision.
- X. The set of claims as submitted during oral proceedings reads:

"1. A liquid aqueous pharmaceutical formulation for use in the treatment of an autoimmune disorder, wherein said formulation is free of a phosphate buffer and comprises a therapeutically effective amount of Adalimumab in a buffered solution comprising L-histidine and citrate, said formulation having a pH of 5 to 5.5 and selected from the group consisting of:

- (a) having a content of aggregated species of Adalimumab after storage at 5°C for 3 to 6 months of less than 5 %;
- (b) having a content of aggregated species of Adalimumab after storage at 25°C for 3 to 6 months of less than 5 %;
- (c) having a content of acidic species of Adalimumab after storage at 25°C for 3 to 6 months of less than 40 %;
- (d) having a content of aggregated species of Adalimumab under heat stress conditions for 10 minutes at 55°C of less than 5 %;
- (e) having a content of acidic species of Adalimumab under heat stress conditions for 10 minutes at 55°C of less than 40%; and
- (f) retaining TNF α neutralizing activity of at least 80% after storage of 6 months at a temperature of 5°C or 25°C, and/or after being subjected to heat stress for 10 minutes at 55°C, freeze-thaw

conditions at -20°C to 5°C and/or mechanical stress;

wherein the concentration of Adalimumab in the pharmaceutical formulation is 50 mg/mL and the formulation further comprises 5 to 20 mg/mL mannitol, 0.1 to 10 mg/mL polysorbate 80 and 5 to 7.5 mg/mL sodium chloride, and wherein the aggregated species are measured by Size Exclusion High Performance Liquid Chromatography (HP-SEC) and the acidic species are measured by Strong Cation Exchange (SCX) High Performance Liquid Chromatography (SCX-HPLC) and wherein the formulation is administered subcutaneously to the human subject in need thereof on a biweekly dosing regimen of every 13-15 days.

2. The formulation for use in accordance with claim 1, wherein the formulation is to be administered in combination with an additional therapeutic agent that inhibits TNF α production or activity, preferably methotrexate."

XI. The appellant's arguments, in so far as relevant to the decision, can be summarised as follows:

(a) Admittance of the new claim request filed during oral proceedings - Article 13(2) RPBA

The claim request addressed the board's objections raised at the oral proceedings. Its admittance was therefore justified.

(b) Amendments - Article 123(2) EPC - claims 1 and 2

Basis for the subject-matter of claims 1 and 2 could be found in claims 1, 3, 6, 10, 19, 25, 26, 27 and 29 of

the application as filed in combination with page 25, lines 6 to 8 and last sentence of the first paragraph of the application as filed.

The features HP-SEC and SCX-HPLC found basis on page 4, paragraph 2 and page 11, paragraphs 3 and 4 and page 12, paragraph 2; page 13, paragraph 1; and page 29, last paragraph of the application as filed.

(c) Reimbursement of the appeal fee -

Rule 103(1)(a) EPC - Violation of the right to be heard - Article 113 EPC

The appeal fee should be reimbursed pursuant to Rule 103(1)(a) EPC due to substantial procedural violations committed by the opposition division. The right to be heard had been violated by the opposition division because (i) the opposition division had not given the appellant an opportunity to present submissions on the allowability of the auxiliary requests at the oral proceedings and (ii) no reasoning was provided in the opposition division's decision regarding the alleged non-allowability of the auxiliary requests. Each of the above circumstances amounted to a substantial procedural violation.

In more detail: The decision under appeal confirmed that all auxiliary requests had been admitted into the proceedings (see point 24). Nonetheless, the decision to revoke the patent was based only on the main request (see point 20). In relation to the auxiliary requests it was merely stated that the opposition division only considered claims to be allowable under Article 123(2) EPC which contained all limitations of the formulations from Table 1 of the Examples and that none of the auxiliary requests "*appear to comply*" with

the requirements of Article 123(2) EPC (see point 27 of the decision under appeal). The expression "appear to comply" conveyed the preliminary nature of the opposition division's view on the auxiliary requests and was a clear indication that the opposition division had not taken a decision on the auxiliary requests.

The appellant had, during the oral proceedings, asked the opposition division whether auxiliary requests IVe and IVf, which aimed to address the opposition division's objections explained in sections 26.2 and 26.4 of the decision under appeal, met the requirements of Article 123(2) EPC. In response, the chair had only asked whether these requests corresponded to one of the formulations in Table 1 of Example 1 (see point 11 of the minutes). After the appellant had denied this, the chair announced the decision to revoke the patent for failure of the main request to meet the requirements of Article 123(2) EPC (see point 15 of the minutes), without giving the appellant the chance to discuss the allowability of the auxiliary requests. Especially auxiliary requests IV, IVa to IVf, V, IX to XII which had been filed on 6 May 2021 had not been subject to discussion at all.

Moreover, the opposition division's decision provided no reasons for the alleged non-allowability of the auxiliary requests, which violated the appellant's right to be heard and constituted a procedural deficiency.

- XII. The appellant's requests relevant to the decision were as follows:
- that the decision of the opposition division be set aside and that the patent be maintained in amended

form based on the set of claims filed during the oral proceedings before the board

- that the board deals only with the issue of added subject-matter and that the case be remitted to the opposition division for further prosecution of the other issues under Article 100(a), (b) and (c) EPC and, furthermore
- that the appeal fee be reimbursed.

Reasons for the Decision

1. During the oral proceedings before the board, respondents I to III withdrew their oppositions. This means that they ceased to be party to the appeal proceedings as regards the substantive issues. The submissions of the former respondents may, nevertheless, be considered by the board in the appeal proceedings..

Admittance of claim request filed during oral proceedings before the board - Article 13(2) RPBA

2. Under Article 13(2) RPBA, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.
3. The board decided to admit the claim request filed during the oral proceedings before the board under Article 13(2) RPBA, because it was submitted to address objections under Article 84 EPC in relation to auxiliary request 4e(ii), raised *ex officio* by the board at the oral proceedings. The late filing of the

auxiliary request was therefore justified by exceptional circumstances.

Amendments - Article 123(2) EPC

4. In the board's view, the subject-matter of claim 1 is not directly and unambiguously disclosed in the application as filed because at least two selections from different lists in the application as filed are needed to arrive at the claimed formulation, i.e. i) the selection of the L-histidine citrate buffer from the three buffers of claim 1 of the application as filed and ii) the selection of polysorbate as surfactant from page 25, paragraph 2 of the description. The claims of the application as filed mention "a surfactant" and "Polysorbate 80" but not "polysorbate". Moreover, NaCl is not present in the formulation of claim 1 as granted. However, no disclosure of a corresponding formulation lacking NaCl can be found in the application as filed.
5. In contrast, only one selection from a single list is needed to arrive at the formulation of present claim 1, i.e. the selection of the L-histidine citrate buffer from the list of three L-histidine buffers provided in claim 1 of the application as filed. The 50 mg/mL antibody concentration in the formulation (claim 3 of the application as filed) and the specific combination of excipients and their concentration ranges (claim 6 of the application as filed) are disclosed in dependent claims and do not require further selections from lists.
6. The limitation to the treatment of an autoimmune disorder (disclosed in claim 26 of the application as filed) does not affect the formulation and represents a

restriction of the therapeutic goals. The feature of subcutaneous administration to a human subject in need thereof on a biweekly dosing regimen of every 13 to 15 days (claim 27 of the application as filed) is also directly disclosed via the dependencies of claim 27.

7. Claim 2 finds basis in claim 29 of the application as filed.
8. In view of the above considerations, the board concludes that the subject-matter of claims 1 and 2 does not extend beyond the content of the application as filed. Thus, claims 1 and 2 meet the requirements of Article 123(2) EPC.

Remittal - Article 111(1) EPC

9. The primary object of the appeal proceedings is to review the decision under appeal in a judicial manner (see Article 12(2) RPBA). In the case at hand, the decision under appeal was based solely on the issues of added subject-matter (Article 100(c) and Article 123(2) EPC, respectively), which have been addressed by the amended set of claims. No other ground for opposition initially raised in opposition was dealt with in the decision under appeal. Furthermore, independent claim 1 of this request (see point X. above) is directed to a formulation specifically defined by a combination of excipients contained therein and their concentration ranges, which were not present in any of the independent claims considered by the opposition division during the opposition proceedings, either in the decision under appeal or in one of its communications. Moreover, the appellant has requested that the case be remitted to the opposition division for further prosecution of the other issues

under Article 100(a), (b) and (c) EPC. In these circumstances, the board considers that special reasons for remitting the case to the examining division within the meaning of Article 11, first sentence, RPBA, exist. Thus the board decided to remit the case to the opposition division for further prosecution (Article 111(1) EPC).

*Reimbursement of the appeal fee - Rule 103(1)(a) EPC -
substantial procedural violations - Article 113(1) EPC*

10. A reimbursement of the appeal fee is ordered when an appeal is allowable, if such reimbursement is equitable by reason of a substantial procedural violation (Rule 103(1)(a) EPC).

11. The appellant submitted that its right to be heard had been violated in two ways, i) because it had not been given the opportunity to discuss the allowability of the auxiliary requests at the oral proceedings before the opposition division and ii) because in the decision under appeal, the opposition division did not give any reasons for the alleged non-allowability of the auxiliary requests. Both of these procedural defects amounted to substantial procedural violations.

Right to be heard during oral proceedings

12. The appellant did not request a correction of the minutes of the oral proceedings before the opposition division, thus, it must be assumed that the minutes properly reflect the course of events at oral proceedings.

13. According to point 11 of the minutes, the auxiliary requests were addressed at the oral proceedings: the appellant put questions in relation to specific auxiliary requests, the chair of the opposition division asked questions to the appellant, to which the appellant replied in the negative. Hence, at this stage of the oral proceedings, there had been opportunity for the appellant to make oral submissions on any of the auxiliary requests.
14. Moreover, according to the minutes, the appellant did not request the discussion of any of the auxiliary requests. Instead, it stated that no new claim request would be filed (see points 11 and 13 of the minutes). At the latest when the chair of the opposition division asked whether the hearing had been satisfactory from a technical point of view (see point 14 of the minutes), i.e. at a point at which it must have been apparent to the appellant that the discussion on substance was over, the appellant could have requested a discussion of the auxiliary requests.
15. In summary, the board cannot establish that the appellant did not have an opportunity to present its arguments on the auxiliary requests at the oral proceedings before the opposition division and that the appellant's right to be heard was violated during the oral proceedings.

Written reasoned decision

16. Pursuant to Rule 111(2) EPC decisions of the European Patent Office which are open to appeal must be reasoned. Adequate reasoning requires that there is a logical chain of arguments from which it can be derived why a request has been rejected. Moreover, due respect

of the right to be heard under Article 113(1) EPC requires not only that the party concerned be given an opportunity to present comments, but also that those comments be taken into consideration by the deciding body.

17. It had been submitted by the respondents, but was contested by the appellant, that all auxiliary requests filed in the course of the written proceedings in opposition had been withdrawn by the appellant at the oral proceedings before the opposition division. However, this is not derivable from the minutes of the oral proceedings before the opposition division. According to point 11 of the minutes, the appellant stated that "*no new [claim] request would be filed*" and there is no indication that any of the previously filed auxiliary requests was withdrawn. It is to be expected that such a withdrawal of one or more requests, i.e. a relevant statement within the meaning of Rule 124(1) EPC, would have been expressly recorded in the minutes.
18. Had the appellant made an unclear statement in relation to one or more auxiliary requests, it would have been for the opposition division to clarify it and in so doing clarify the procedural status of the auxiliary requests, or alternatively for the respondents, for whom withdrawal of the claim requests would have been beneficial, to request clarification.
19. As the auxiliary requests filed in written proceedings in opposition had not been withdrawn by the appellant they should have been and considered and decided upon by the opposition division in its decision.

20. In relation to the auxiliary requests, it is stated in point 24 of the reasons of the decision under appeal that they "*are deemed to be on time*" without however indicating whether or not this means that they were admitted into the proceedings or not.

21. In point 27 of the decision it is stated that the opposition division "*only saw compliance with Art. 123(2) EPC for the buffer compositions actually tested, as found in Table 1*". The subsequent wording used by the opposition division "[a]ccordingly, none of the auxiliary requests on file appear to comply with the requirements of Art. 123(2) EPC" is of the character of a preliminary opinion rather than a decision, because of the use of the word "appear". Also, these two sentences are mere statements and no further explanation was given.

22. Finally, as explicitly stated in point 20 of the facts and submissions of the decision under appeal, the "*decision is based on the Main Request (MR) being the claims as granted*", implying that it is actually not based on the auxiliary requests. This is also confirmed by the opposition division's order referring solely to a revocation of the patent under Article 101(2) EPC (see point III of the decision under appeal and EPO Form 2331).

23. Thus, the decision under appeal did not contain a written reasoned decision on the auxiliary requests, which must therefore be regarded as insufficiently reasoned, contrary to the requirements of Rule 111(2) EPC. It must also be concluded that the appellant's right to be heard under Article 113(1) EPC has been infringed.

Reimbursement of the appeal fee

24. As set out above, the decision under appeal lacks any reasoning on the auxiliary requests. As these auxiliary requests were the appellant's fallback positions in relation to a revocation of the patent, the lack of reasoning and the associated violation of the right to be heard amount to a substantial procedural violation within the meaning of Rule 103(1)(a) EPC.
25. According to Rule 103(1)(a) EPC, the appeal fee shall be reimbursed in full, where the Board of Appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation. However, in the present case, the board does not consider the reimbursement of the appeal fee equitable.
26. No causal link between the substantial procedural violation and the decision that necessitated the filing of an appeal exists because the procedural violation did not affect the opposition division's decision on the main request (patent as granted) and in the appeal the appellant also challenged the opposition division's decision on this request. Thus, the appellant would have had to file an appeal to have the opposition division's decision on the main request reviewed.
27. Reimbursement is also not considered equitable because none of the auxiliary requests filed before the opposition division and maintained by the appellant in the appeal was held allowable by the board, prior to the withdrawal of those requests by the appellant at the oral proceedings before the board.

28. The fact that the appeal is allowable, i.e. that the decision under appeal is set aside and the case is remitted for further prosecution, is the consequence of the board's decision to admit the claim request filed at the oral proceedings before it and to hold that claim request as compliant with Article 123(2) EPC. That claim request was admitted as a reaction to objections raised by the board *ex officio* against a claim request that had been presented on appeal for the first time and was admitted by the board.

29. In these circumstances, the board does not consider the reimbursement of the appeal fee to be equitable. Thus, the request for reimbursement of the appeal fee under Rule 103(1)(a) EPC is rejected.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:



I. Aperribay

A. Chakravarty

Decision electronically authenticated