

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 23 May 2017**

Case Number: T 2072/14 - 3.3.07

Application Number: 07842914.9

Publication Number: 2068822

IPC: A61K9/00, A61K47/02, A61K47/10,
A61K47/26

Language of the proceedings: EN

Title of invention:

SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

Patent Proprietor:

Alcon Research, Ltd.

Opponents:

Pohlman, Sandra M.
ALLERGAN, INC.

Relevant legal provisions:

EPC Art. 108, 100(b)
EPC R. 99(2)
RPBA Art. 12(4), 13

Keyword:

Admissibility of appeal - appeal sufficiently substantiated
(yes)

Request filed with the grounds of appeal- request could have
been filed in first instance proceedings (no)

Grounds for opposition - insufficiency of disclosure (no)

Late-filed argument - admitted (no)



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2072/14 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 23 May 2017

Appellant: Alcon Research, Ltd.
(Patent Proprietor) 6201 South Freeway, Mail Code TB4-9
Fort Worth, TX 76134-2099 (US)

Representative: Kingsbury, Oliver William
Elkington and Fife LLP
Prospect House
8 Pembroke Road
Sevenoaks, Kent TN13 1XR (GB)

Respondent: Pohlman, Sandra M.
(Opponent 1) df-mp Dörries Frank-Molina & Pohlman
Patentanwälte Rechtsanwälte PartG mbB
Theatinerstraße 16
80333 München (DE)

Representative: Greiner, Elisabeth
df-mp Dörries Frank-Molnia & Pohlman
Patentanwälte Rechtsanwälte PartG mbB
Theatinerstraße 16
80333 München (DE)

Respondent: ALLERGAN, INC.
(Opponent 2) 2525 Dupont Drive
Irvine CA 92612 (US)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 13 August 2014**

revoking European patent No. 2068822 pursuant to
Article 101(3) (b) EPC.

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	Y. Podbielski

Summary of Facts and Submissions

I. Two oppositions had been filed against European patent No. 2 068 822 on the grounds that its subject-matter lacked novelty and inventive step and it was not sufficiently disclosed. The following documents were among those cited during the first-instance proceedings:

D1: WO 2005/097067

D21: declaration of Dr Reichl

II. By decision posted on 13 August 2014 the patent was revoked. The decision was based on the patent as granted as main request and on six auxiliary requests.

Claim 1 of the granted patent read as follows:

"1. A multi-dose, self-preserved ophthalmic composition, comprising zinc ions at a concentration of 0.04 to 0.4 mM, wherein the concentration of anionic species present in the composition is less than 15 mM".

Claims 2 to 12 depended on claim 1. Claim 13 was an independent claim relating to a method of enhancing the antimicrobial activity of an ophthalmic composition. Claims 14 to 20 depended on claim 13.

III. In the decision under appeal, the opposition division considered that the skilled person would have not understood which anionic species had to fulfil the requirement of being present in an amount below 15 nM. Accordingly, he would have not been able to work out the invention defined in claim 1 of the patent since he would not have understood which anionic species were to be measured and therefore which method to use.

Furthermore, the results disclosed in examples 6 and 18 of document D1 suggested that the compositions of claim 1 of the opposed patent were not "self-preserved". Therefore, the patent did not fulfil the requirement of sufficiency of disclosure. Auxiliary requests 1 to 5 were likewise considered to be insufficiently disclosed for the same reasons as that of the patent.

Claim 3 of auxiliary request 6 was not entitled to the priority date and was anticipated by the public prior use of the product Travatan® Z. Auxiliary request 6*, which the patent proprietor expressed the intention to file during the oral proceedings, was not admitted into the proceedings.

IV. The patent proprietor (hereinafter: the appellant) filed an appeal against that decision. With the statement setting out the grounds of appeal filed on 19 December 2014 it submitted a main request and eight auxiliary requests.

The main request corresponded to the patent as granted, with the deletion of claims 7 to 9 and 17 to 19. Auxiliary request 1 corresponded to the patent as granted, with the deletion of claims 7 to 9 and 13 to 20.

V. Opponents 1 and 2 (hereinafter: respondents 1 and 2) filed their replies to the patent proprietor's appeal respectively on 4 May 2015 and 5 March 2015.

VI. In the course of the oral proceedings held on 23 May 2017 the appellant withdrew the main request submitted on 19 December 2014. Auxiliary request 1 filed on the same date became the new main request.

VII. Concerning the requirement of sufficiency of disclosure the appellant argued that the skilled person would have understood the term "anionic species" to encompass all anions within the composition. Analytical techniques for determining anion concentrations were known to the skilled person as part of the common general knowledge. The concentration of any buffering anion could be estimated using the Henderson-Hasselbalch equation or the method described in paragraph [0024] of the patent. None of the compositions exemplified in D1 had a concentration of anions below 15 mM. Thus, the opposition division was wrong in inferring from the data of D1 that the compositions of claim 1 were not "self-preserved". As to the respondent-2's argument concerning the analytical method described in paragraph [0024] of the patent, this was presented for the first time during the oral proceedings. Hence, it was not to be admitted into the appeal proceedings.

Concerning the possibility of remitting the case for further prosecution to the opposition division, the appellant observed that for the assessment of novelty and inventive step only a few documents were relevant. Accordingly, a remittal did not appear necessary.

VIII. The respondents' arguments can be summarised as follows:

(a) Admissibility of appeal - Respondent-2's objection

In the statement setting out the grounds of appeal the appellant did not address the issue of novelty over the public prior use of the product Travatan® Z. Thus, the appeal of the patent proprietor was not admissible.

(b) Admissibility of requests submitted for the first time during appeal

During the first instance proceedings the appellant ignored the objections of lack of priority and lack of novelty and did not file until the oral proceedings any request addressing these issues. Hence, the new requests filed during the appeal phase, in which the priority and novelty issues were addressed, were not to be admitted since they should have been submitted during the first instance proceedings.

(c) Sufficiency of disclosure

The term of claim 1 "anionic species" was not be considered in isolation. From paragraph [0024] of the patent it appeared that only the concentration of the buffering anions was critical. Paragraph [0029] and various examples suggested that the salts did not contribute the amount of anionic species. The general teaching of the patent did not give any clear guidance on which species were covered by the term of claim 1. Thus, the skilled person would have not been able to ascertain with certainty whether a given ophthalmic composition had a concentration of less than 15 mM of anionic species.

Furthermore, there was no teaching in the patent on how to determine the amount of anionic species other than the amount of buffering anions, let alone how to differentiate between the buffering anionic species and other anionic species of the solutions. Thus, determining the concentration of the anionic species amounted to an undue burden.

Additionally, the compositions of the patent in suit were not "self-preserved" as required by claim 1. This was evident from the data disclosed D1 in relation to the compositions of examples 6, 13-15 and 8 which contained low amounts of anionic species that were within the range of claim 1, namely about 2.09 mM of buffering anions. Only the solution of example 8 passed the preservative efficacy test. Thus, the results of D1 cast doubts on the antimicrobial efficacy of the compositions of the patent.

(d) Sufficiency of disclosure - Line of argumentation presented by respondent 2 during the oral proceedings

The method disclosed in paragraph [0024] of the patent was a rough estimation of the concentration of buffering anions which did not qualify as an analytical method for determining the amount of anionic species. Furthermore, this method could provide different results from the calculation based on the Henderson-Hasselbalch equation. Hence, the skilled person would have not been able to determine the amount of buffering anions.

(e) Remittal to the department of first instance

The decision of the opposition division did not cover all the grounds of opposition. The case was therefore to be remitted to the department of first instance if one of the requests were considered to meet the requirement of sufficiency of disclosure.

IX. The final requests of the parties at the end of the oral proceedings before the Board on 23 May 2017 were the following:

- (a) The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the request filed with the statement setting out the grounds of appeal as auxiliary request 1. The appellant furthermore requested that the line of argumentation presented by respondent 2 during the oral proceedings on the issue of sufficiency of disclosure not be admitted into the proceedings as it was submitted late.
- (b) Respondent 1 requested that the appeal be dismissed, that the requests submitted in appeal proceedings not be admitted and that the case be remitted to the opposition division if one of the requests were considered to meet the requirement of sufficiency of disclosure.
- (c) Respondent 2 requested that the appeal be rejected as inadmissible or, alternatively, that the appeal be dismissed. Respondent 2 furthermore requested that none of the requests in the form of amended claims submitted with the grounds of appeal be admitted.

Reasons for the Decision

Admissibility of the appeal

1. In the opinion of respondent-2, the conclusion of the opposition division that claim 3 of auxiliary request 6 was not entitled to priority and therefore lacked of novelty over the public prior use of the product Travatan® Z was relevant also in respect of the higher ranking requests pending before the opposition division since all these requests included a claim identical to

claim 3 of auxiliary request 6. In particular claim 3 of auxiliary request 6 was identical to claim 17 as granted.

Respondent-2's request not to admit the appeal of the patent proprietor is based on the argument that in the statement setting out the grounds of appeal the appellant did not disagree with the (implicit) finding of the opposition division that claim 17 as granted is not entitled to the priority date and lacks of novelty over the public use of Travatan® Z.

1.1 The Board does not share the position of respondent-2.

The opposition division refused the patent as granted because it was not sufficiently disclosed. In the statement setting out the grounds of appeal, the appellant clearly indicates that it does not agree with this conclusion and it explains why, in its opinion, the requirement of sufficiency of disclosure is met (see section 5 of the statement setting out the grounds of appeal).

As to the "implicit" finding of the opposition division that claim 17 as granted was not novel, the Board observes that according of the case law of the boards of appeal, an appeal by the patent proprietor is to be considered as sufficiently substantiated even if some reasons of the decision are not contested provided that these reasons are no longer relevant in view of the filing of amended claims with the statement setting out the grounds of appeal (see Case law of the boards of appeal of the EPO, 8th edition 2016; IV.E.2.6.5 b)).

All the new requests filed during the appeal phase, have been limited to claims which should be entitled to

the earliest priority date, in that the claim contested in this respect by the opposition division has been deleted. In particular, the main request no longer contains a claim corresponding to granted claim 17. In respect of these requests, it is not necessary for the appellant to take position with regard to the conclusions of the opposition division as to the issues of priority and novelty.

- 1.2 The appellant has maintained a request identical to auxiliary request 6 of the first instance proceedings (request filed with the grounds of appeal as auxiliary request 7). However, in respect of this request it has taken position in the statement setting out the grounds of appeal in respect of the issue of novelty over the prior use of Travatan® Z (see section 7 starting from page 13).
- 1.3 In view of the above, the Board concludes that the appeal meets the requirements of Article 108 and Rule 99(2) EPC and is therefore admissible.

Main request (filed with the statement setting out the grounds of appeal as auxiliary request 1)

2. Admissibility

- 2.1 The respondents argue that in the course of the first instance proceedings the appellant substantially ignored the objections of lack of priority and lack of novelty against claim 17 as granted and did not file until the oral proceedings any request addressing these issues. The only request dealing with these objections (auxiliary request 6*) was filed during the oral proceedings and was not admitted by the opposition division. Thus, in their opinion, the current main

request in which these issues are addressed is not admissible since it should have been submitted already during the first instance proceedings.

- 2.2 In order to assess the admissibility of the main request pursuant to Article 12(4) RPBA it is important to examine the factual circumstances of the first instance proceedings.

The Board notes in this respect that in the notice of opposition of respondent-2, the objection against the entitlement to priority of granted claim 17, is limited to the following sentence:

"Opposed claims 16-20 are also not entitled to priority, as these claims recite feature combinations which are not disclosed in either of the two priority documents".

The second letter submitted by respondent-2 during the first instance proceedings (letter of 2 October 2013) does not contain any further argument specifically relating to the issue of priority of granted claim 17.

- 2.3 Respondent-1 in its written submissions during the first instance proceedings has never contested the entitlement to priority of granted claim 17.

- 2.4 In the preliminary opinion issued on 28 May 2013, the opposition division considered that the patent was entitled to priority (paragraph 15).

- 2.5 During the oral proceedings, the discussion on the validity of the priority claims was made only with respect to auxiliary request 6 since the higher ranking requests were refused for insufficiency of disclosure.

From the minutes of the proceedings, it can be deduced that this discussion started only after 15:45 (see point 23). After the chairman announced that claim 3 of auxiliary request 6 was not entitled to priority the appellant proposed to submit a new request in which this claim was deleted. Said request was however not admitted by the opposition division (point 37 of the decision).

- 2.6 In the Board's view the priority objection against claim 17 raised by respondent-2 in the notice of opposition was not properly substantiated. Having regard to this, and also considering that the opposition division gave a positive preliminary opinion as to the validity of the priority claim, the Board considers that there were no compelling reasons for the appellant to file before the oral proceedings amended claims addressing the priority issues. Indeed there is no obligation for a patent proprietor to address each objection of the opponents by filing amended claims. This applies in particular when the objections are poorly substantiated and the opposition division provides a preliminary opinion in favour of the patent proprietor.
- 2.7 The fact that during the oral proceedings the first six requests were rejected without any discussion on the validity of the priority prevented the appellant from deleting from these requests the claims possibly affected by priority issues and therefore also from filing a request substantially corresponding to the current main request. This is however a circumstance that cannot be ascribed to the appellant.
- 2.8 For the above reasons, the Board decides to admit the main request into the appeal proceedings.

3. Sufficiency of disclosure

3.1 The opposition division considered that claim 1 of the patent was not sufficiently disclosed mainly for the following reasons:

(a) It was unclear to the skilled person which anionic species were covered by claim 1. As a consequence he would have not understood which species were to be measured and which analytical methods to be used.

(b) The composition were not self-preserved as required by claim 1.

The respondents' line of arguments substantially follows the position of the opposition division (with the exception for the argument mentioned in point VIII (d) above, which is treated in point 4 below). As explained in the following section, the Board considers that neither reason (a) nor reason (b) justifies the conclusion that the subject-matter of claim 1 is not sufficiently disclosed.

3.2 Reason (a)

3.2.1 The Board agrees with the appellant that the feature of claim 1 "*wherein the concentration of anionic species present in the composition is less than 15 mM*" expresses a condition which concerns all the anions of the composition. The Board considers that claim 1 in this respect is clear and unambiguous. Respondent-1 maintained that a patent specification may be its own dictionary which means that a technical term may be defined and used therein with a meaning different from

its normal one. However, this principle does not apply here since the patent does not provide a definition of the expression "anionic species". Hence, the skilled person would have no reason to consider that, in the context of the patent in suit, this feature is to be understood in a manner which deviates from its usual meaning.

Moreover, the general teaching of the patent supports the conclusion that the feature "anionic species" covers any anion. This is clear in particular from paragraph [0024] of the description, wherein it is stated that "*...it is preferred that the total concentration of anionic species, particularly buffering anions, should be limited to an amount of less than 15 mM...*". This passage suggests that controlling the concentration of the buffering anions is a key aspect of the invention. However, at the same time, the wording "*the total concentration of anionic species, particularly buffering anions*", clearly indicates that the upper limit of 15 mM does not apply only to this subgroup of anions. In line with this teaching, in paragraph [0045] of the patent it is explained that also the concentration of anionic therapeutic agents should be controlled, in paragraph [0051] it is reported that the compositions of the invention should be substantially free of anionic excipients and in paragraph [0054] it is affirmed that if a conventional antimicrobial preservative is present, this should not be anionic.

3.2.2 The respondents observed that according to paragraph [0029] of the patent the concentration of the "ionized salts" (e.g. NaCl) should be preferably less than 50 mM. This statement would be in conflict with the condition expressed in claim 1 that the total

concentration of anionic species present in the composition is less than 15 mM. Furthermore, some examples of the patent, which are stated to represent the invention (e.g. example Z) contain more than 15 mM of anions.

However, in the Board's view, the presence of some examples or embodiments that can easily be recognised as being outside the scope of claim 1 cannot have a negative impact on the assessment of sufficiency of disclosure, i.e. on the assessment of the question whether the skilled person would be able to carry out the invention defined in claim 1. The skilled person carrying out the invention would simply ignore information included in the description but concerning the preparation of compositions not covered by the claims. In this respect it is also observed that the description discloses various compositions which are covered by claim 1 (e.g. compositions A-C and K-N). In the Board's view, in the context of the patent in suit, the presence in the description of information which may be irrelevant for the assessment of the enablement of the disclosure does not have the effect of canceling out the information which is relevant.

- 3.2.3 Therefore, the opposition division's conclusion that the skilled person would not have understood which anionic species were to be measured and therefore which analytical method was to be used is not tenable.

As discussed above, claim 1 unambiguously indicates that the upper limit of 15 mM is a condition which concerns all the anions of the composition. The skilled person trying to reproduce the invention would have therefore to keep under control the concentration of

all the anionic species, a task which is well within his normal capacity, in the Board's view.

In particular, the concentration of anions which originate from compounds which are fully ionized can be easily calculated from the amounts of these compounds. As to the concentration of the buffering anionic species, in paragraph [0024] of the patent it is explained that this is equivalent to the concentration of monovalent cations that are present or needed to bring the pH to the specified value. The amount of buffering anionic species can also be calculated using the Henderson-Hasselbach equation as explained in paragraph 16 of D21.

3.3 Reason (b)

3.3.1 Claim 1 indicates that the ophthalmic compositions are self-preserved. According to the description (paragraph [0012]) a self-preserved composition is a composition that does not require conventional antimicrobial components.

The opposition division observed that some compositions disclosed in D1 were not self-preserved despite the fact of containing an amount of anions below 15mM. In view of this it was not credible that the compositions of the invention were self-preserved as required by claim 1.

3.3.2 However, as observed by the appellant, the compositions of D1 referred to in the decision (Tables 9 and 10) contain 38 mM of sodium chloride. Thus, these compositions are outside the scope of claim 1 because alone the concentration of the anion chloride exceeds the upper limit of 15 mM for the anionic species.

Hence, the conclusion of the opposition division must fail for this simple reason.

Moreover, the Board observes that the patent discloses various compositions included in claim 1 which fulfil the requirement of being self-preserved (e.g. compositions K to N).

3.4 In the light of the considerations set out in points 3.2 and 3.3 above, the Board concludes that the patent meets the requirement of sufficiency of disclosure.

4. Admissibility of new arguments on sufficiency of disclosure

4.1 In the course of the oral proceedings, when the issue of sufficiency of disclosure of the main request was discussed, respondent 2 argued that the method disclosed in paragraph [0024] of the patent for determining the amounts of buffering anions was only a rough estimation that could provide different results from the calculation based on the Henderson-Hasselbalch equation. Respondent 2 attempted to show this by reference to hypothetical examples.

The appellant requested that this line of argumentation ("the new line of argumentation") should not be admitted into the proceedings as it was submitted late. The appellant indicated that it had no chance to properly prepare to answer the new line of argumentation. Respondent 2 submitted that the new line of argumentation was already introduced into the proceedings by virtue of the sentence "*The argumentation presented in the first instance proceedings is maintained*" on page 7 of the Reply to the grounds of appeal. If the new line of argumentation

had been cut and paste into the submissions from the submissions made in the course of the proceedings before the opposition division then it would undoubtedly have been introduced into the appeal proceedings - a reference did effectively the same.

4.2 The Board takes the view that the new line of argumentation has not been introduced into the appeal proceedings and therefore constitutes an amendment to the case of respondent 2. In its reply to the statement setting out the grounds of appeal respondent 2 focused on three lines of argumentation: one concerned the inadmissibility of the appeal, the second the inadmissibility of the requests filed with the statement of grounds, and a third concerned insufficiency. The new line of argumentation presented during the oral proceedings on insufficiency had not been presented in the reply to the grounds of appeal and no other written submissions were made by respondent 2 on this issue. Respondent 2 itself acknowledged this by referring only to the sentence that "*The argumentation presented in the first instance proceedings is maintained*" as the reason why the new line of argumentation was already introduced into the appeal proceedings.

4.3 The mere reference to "*argumentation presented in the first instance proceedings*" in the reply to the grounds of appeal is too vague to enable the other parties and the Board to identify what is supposedly argued in response to the grounds of appeal. Therefore, this reference cannot serve to introduce the new line of argumentation into the appeal proceedings. The Board also does not regard it as equitable to permit the new line of argumentation into the proceedings. In doing so, it exercises its discretion under Article 13 RPBA,

taking in particular the late stage of the procedure into account as well as the fact that allowing the line of argumentation into the proceedings would not have given the appellant an adequate chance to fully answer to the new line of argumentation in the course of the oral proceedings.

The new line of argumentation of respondent-2 is therefore not admitted into the appeal proceedings.

5. Remittal

5.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

5.2 In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon some issues which are decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

5.3 The observations made above apply in full to the present case. The opposition division decided that the

claimed subject-matter did not meet the requirements of sufficiency of disclosure and that auxiliary request 6 was anticipated by a public prior use. However, it did not consider further issues, including inventive step. These issues, however, formed *inter alia* the basis for the request that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

5.4 Thus, the Board considers that in the circumstances of the present case, it is appropriate to remit the case to the opposition division for further prosecution on the basis of the claims of the main request.

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.

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated