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**Datasheet for the decision
of the Enlarged Board of Appeal
of 22 November 2013**

Case Number: R 0006/13
Appeal Number: T 0977/09 - 3.3.02
Application Number: 01994654.0
Publication Number: 1335706
IPC: A61K 9/16, A61K 38/46
Language of the proceedings: EN

Title of invention:

Process for the production of microspheres of pancreatic enzymes with high stability

Patentee:

Aptalis Pharma S.r.l.

Opponent:

Abbott Products GmbH

Headword:

Fundamental violation of Article 113 EPC/APTALIS PHARMA

Relevant legal provisions:

EPC Art. 112a(c), 113(1)
EPC R. 106

Keyword:

"Non-admittance of a document - Violation of right to be heard - no"
"Petition for review - clearly unallowable"
"Causal link between the procedural defect and the final decision - no"

Decisions cited:

R 0001/08

Catchword:

-



Case Number: R 0006/13

D E C I S I O N
of the Enlarged Board of Appeal
of 22 November 2013

Petitioner: Aptalis Pharma S.r.l.
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Decision under review: **Decision of the Technical Board of Appeal
3.3.02 of the European Patent Office of
30 November 2012.**

Composition of the Board:

Chairman: W. van der Eijk
Members: G. Weiss
M. Harrison

Summary of Facts and Submissions

- I. The petition for review concerns decision T 977/09 of the Technical Board of Appeal 3.3.02 of 30 November 2012, by which European No. 1335706 was revoked. The petitioner is the patent proprietor.
- II. The proceedings in case T 977/09 can be summarized as follows:
- (a) During the written phase of the appeal proceedings the appellant-opponent challenged, for the first time with letters dated 5 August 2010 and 30 September 2011, Example 4 of the patent with respect to Article 83 EPC 1973 and provided an expert opinion of Prof. Steffens [in the following referred to as D23] which had concluded that the instructions in paragraphs [0044] and [0045] of the patent could not be carried out, because the mixer-granulator Zanchetta Rotolab P-50 could not be run at the indicated 900 rpm but only at a maximum of 315 rpm. When using this maximum speed of rotation, Prof. Steffens was unable to arrive at microspheres as defined in claim 1 of the patent but rather at a product comprising powder particles of irregular shape.
- (b) In response to these letters the respondent-proprietor argued (with letter dated 27 June 2012) that the appellant-opponent's criticism of Example 4 was unjustified. The contested paragraphs [0044] and [0045] referred to two distinct experiments, performed with different machines, indicated as "*high energy mixer granulator Zanchetta Rotolab*"

and "*mixer Zanchetta Rotolab P-50*" respectively. An extract of the "*Zanchetta catalogue*" was filed as D24 and mentioned, on the same page, both models and evidently different machines. Concerning the experiment of paragraph [0044], the "Rotolab" granulator which was used had been available at the filing date, as supported by the catalogue. This document, bearing the date of 15/2/2009 showed that the "Rotolab" model was perfectly capable of reaching the indicated speed of 900 rpm, since it had a maximum working speed of 1194 rpm. Therefore, there was no justification to perform this experiment at 315 rpm. The experiment according to paragraph [0044] could and should have been repeated at the prescribed speed of 900 rpm.

- (c) After the written phase of the appeal proceedings, Board of Appeal 3.3.02 summoned the parties to oral proceedings which, after rescheduling, were set to take place on 30 November 2012. No annex to the summons to oral proceedings was issued.
- (d) No further substantive submissions were filed by the parties.
- (e) Oral proceedings were held on 30 November 2012 before the Board. During those oral proceedings, the respondent-proprietor requested that D23 not be admitted into the proceedings. Moreover it filed new auxiliary requests 1 and 2 replacing auxiliary request 1 filed on 27 June 2012.

During the oral proceedings the appellant-opponent- requested that D24 (extract of the "*Zanchetta catalogue*") not be admitted into the proceedings. In the course of the oral proceedings the Board announced that D23 (expert opinion) was admitted into the proceedings and that D24 was not, and further that the new auxiliary requests 1 and 2 were also not admitted into the proceedings.

(g) The written decision in case T 977/09 concerning the revocation of the patent was notified to the parties by registered letter with advice of delivery on 6 March 2013.

III. On 6 May 2013 the respondent-proprietor (hereafter "the petitioner") filed a petition for review of this decision by the Enlarged Board of Appeal pursuant to Article 112a EPC. The petition was based on the ground referred to in Article 112a(2)(c) EPC. Three complaints were made in the petition: (1) the lack of any discussion concerning the reasons leading to the non-admittance of D24; (2) the unbalanced state of evidence caused by the admittance of D23 and the non-admittance of D24 and (3) the non-admittance of the new auxiliary requests.

IV. In a communication in preparation for the oral proceedings, sent to the parties on 17 September 2013, the Enlarged Board identified certain issues of admissibility and allowability and gave its provisional and non-binding opinion. In response to this communication the petitioner filed as Annex 1 a full copy of the Installation, Use and Maintenance Manual dated 03/02/1998 of the Zanchetta "*Rotolab*" and as

Annex 2 a picture of this apparatus with an enlargement of the machine identification plate.

V. Oral proceedings before the Enlarged Board of Appeal in its composition pursuant to Rule 109(2) (a) EPC took place on 22 November 2013.

VI. The petitioner's arguments on the admissibility and the allowability of the petition, as presented in its written submissions and at the oral proceedings, may be summarized as follows:

The three complaints should not be considered as independent complaints, in the sense that the filing of D24 by the petitioner was a reaction to the filing of D23 by the appellant-opponent and that the non-admittance of D24 during the oral proceedings before the Board contributed to the complication of the procedural situation with the immediate effect that new auxiliary requests had to be filed due to the unbalanced state of evidence which had resulted.

(1) *The non-admittance of D24*

D24 was not admitted into the proceedings, whereas D23 was. No reasons for this decision were given at the oral proceedings. Only in the written reasons for the decision did the Board give its reasons for the non-admittance of D24 (i.e. lack of clarity as to whether all pages belonged to the same document and uncertainties as to the publication date). The petitioner was never requested to comment on, or be heard on, issues concerning the publication date of D24 or the layout of the catalogue. Declarations of

Mr Parker, Mrs Bertocchi and Mr Fabiani who attended the oral proceedings confirmed this point. Thus, for reasons / objections which had never been raised prior to the closure of the debate, D24 was not admitted. The petitioner was thus deprived of the possibility to be heard on these issues. A fundamental violation of Article 113 EPC had therefore occurred. Since the reasons for non-admittance of D24 only became known to the petitioner with the notification of the written decision, it was not possible to raise a Rule 106 EPC objection during the oral proceedings.

(2) The unbalanced state of evidence caused by the admittance of D23 and the non-admittance of D24

D23 concerned the reproduction of Example 4, and had been filed more than two years after the filing of the statement setting out the grounds of appeal. It also related to a new objection under Article 83 EPC, which objection had not been considered in the decision under appeal. This was in violation of the requirement that the statement setting out the grounds of appeal had to be exhaustive and that the appeal procedure was mainly of a judicial nature, not being the forum for a new opposition case. The overall nature of the appeal procedure was therefore unduly altered by the late submission of D23. The admission of D24 was then appropriate for re-establishing a fair balance of evidence.

Concerning the causal link between the non-admittance of D24 and the revocation of the patent, the non-admittance of D24 in the presence of D23 was directly linked to the revocation of the patent. After

considering D23 filed by the appellant-opponent, the Board made full use of the information contained in D23 to conclude that the granulator mentioned in paragraph [0045] could only reach 315 rpm instead of the 900 rpm required by paragraph [0044]. Based on this discrepancy the Board jumped directly to the conclusion that Example 4 was not enabling (see decision, page 9, lines 14-27). However, a proper and fair assessment of the skilled person when considering reproducibility of the invention as disclosed in particular in Example 4, would have resulted in the conclusion being reached that D23 was incomplete. If the skilled person initially assumed that the P-50 granulator should be used in Example 4 due to the information in paragraph [0045], it would then immediately be understood that the required rpm could not be reached. The skilled person would necessarily conclude that either the rpm indicated was incorrect, or the apparatus was incorrect. If Example 4 were carried out with the P-50 granulator at 350 rpm and (as indicated by D23) the result not achieved, the only logical conclusion would be that the apparatus should not be the P-50 granulator, but another one. Any skilled person would then necessarily consult Zanchetta literature and would immediately become aware of D24. This would have led to the conclusion that the correct apparatus should be used which immediately fulfilled all the requirements of Example 4. The correct way in which a skilled person, exercising due care, would resolve any possible conflict arising out of paragraphs [0044] and [0045] would thus have led the Board to a different conclusion. The admittance of D24 was thus causal and absolutely necessary for a fair reproduction of the invention in view of Example 4, not least since the

knowledge and information which the Board should rightfully have accredited to the skilled person when carrying out Example 4 would have been different.

As soon as D24 was not admitted, the respondent-proprietor was unable to defend its case properly in this regard, since it had no supporting evidence to back up any such submissions.

(3) The non-admittance of the proprietor's new auxiliary requests filed at the oral proceedings

The auxiliary requests filed at the oral proceedings were considered late-filed and not admitted by the Board. The reasons given under point 2 of the Board's decision for not admitting the auxiliary requests were however not complete: a further reason had been raised at the oral proceedings, namely that, in view of the unbalanced consideration of evidence by the Board, a major restriction of the process conditions became necessary in order to avoid the risk of a final revocation of the patent. The refusal to admit both D24 and the new requests thus synergized in depriving the petitioner of the due right to provide a defence against late-filed D23, which lay at the heart of the Board's reason for revocation.

IV. The petitioner requested that the decision to revoke European patent No 1335706 be set aside and the proceedings before Board 3.3.02 be re-opened.

Reasons for the decision

1. *Admissibility of the petition for review*

1.1 The petitioner is adversely affected by the decision T 977/09 revoking the European patent. The petition for review was filed on the ground referred to in Article 112a(2)(c) EPC. The petition therefore complies with the provisions of Article 112a(1) and (2) EPC.

1.2 The written decision was notified to the parties by registered letter with advice of delivery posted on 6 March 2013. The two month period for filing the petition for review expired on 16 May 2013 (Thursday) (Rules 126(2) and 131(4) EPC). As the petition was filed and the fee was paid on 6 May 2013, it also complies with Article 112a(4) EPC.

1.3 No objection under Rule 106 EPC was raised during the appeal proceedings. This poses also the question of whether the exception in Rule 106 EPC applies.

The two complaints: the unbalanced state of evidence caused by the admittance of D23 and the non-admittance of D24, and the non-admittance of the new auxiliary requests referred to above as complaints (2) and (3)

1.3.1 The petitioner did not raise an objection under Rule 106 EPC based on these complaints and has not forwarded in its petition arguments as to why it could not have made such an objection. The Enlarged Board noted that the admission of D23 took place during the oral proceedings before the discussion on the substance of the case in relation to Article 83 EPC 1973. This is

clear in particular from the chronological sequence of events set out in the minutes of the oral proceedings. As a result, when the Board of Appeal announced that D24 was not going to be admitted, the petitioner could - at that time or later before the debate was closed - have raised an objection, for example on the grounds of lack of procedural fairness in admitting D23 and not D24. Moreover, the petitioner does not assert that no discussion on "admittance" took place before the Board's decision not to admit the document was taken, which suggests that a discussion did indeed take place and that, consequently, the right to be heard on this issue was respected. The same reasoning applies to the non-admittance of the new auxiliary requests.

- 1.3.2 The Enlarged Board taking note of the fact that a correction of the minutes was not requested, considers that for the complaints (2) and (3) it was indeed possible to make such an objection and therefore that these complaints are clearly inadmissible pursuant to Rule 106 EPC. The Enlarged Board has also noted that the petitioner, during the oral proceedings before the Enlarged Board, did not pursue the admissibility of these two complaints and made no further submissions on this issue.

Non-admittance of D24

- 1.3.3 The present petition is based on the allegation that the reasons for not admitting D24 and cited for the first time in the decision are based on new issues to which no objection had been made either by the opponent or by the Board during either the written or the oral proceedings. Assuming this to be correct, therefore it

seems that the petitioner could not have raised any objection pursuant to Rule 106 EPC during the appeal proceedings. It seems also that the petitioner only become aware of the reasons for non-admittance of D24 when reading the decision, since nothing in the decision or the minutes indicates that any comments on the Board's reasons were made by any party, or that the petitioner was even made aware of these issues by the Board or the other party (which could have allowed it a possibility to address these).

1.3.4 The Enlarged Board thus considers that it was not possible for the petitioner to make an objection under Rule 106 EPC during the oral proceedings against reasoning of which it was not aware at that time. Therefore, the Enlarged Board judges that this complaint is not clearly inadmissible.

2. *Allowability of the petition for review*

Non-admittance of D24

2.1 Following R 1/08 dated 15 July 2008, item 3 and subsequent decisions, the Enlarged Board of Appeal finds that a petitioner, to succeed with this objection, has to establish

- (a) that the contested decision was based on an assessment or on reasoning relating to grounds or evidence which the petitioner was not aware of and had no opportunity to comment upon and
- (b) that a causal link existed between this procedural defect and the final decision, otherwise the

alleged defect could not be considered decisive and hence not fundamental.

2.2 In the petition for review and during the oral proceedings before the Enlarged Board, the petitioner stated that a direct causal link existed between the non-admission of D24 and the revocation of the patent (see item 7 of the petition: the Board has *"made fully use of the information contained in D23, to the effect that the granulator mentioned in paragraph [045] reaches only 315 rpm instead of the 900 rpm required by paragraph [0044],; based on this discrepancy the Board jumped directly to the conclusion that the Example 4 is not enabling....Regretfully, this conclusion was reached by ignoring the document D24 which, showing the existence of the cited "Rotolab" granulator reaching the 900 rpm, was cited by the Patentee exactly to address this issue. It is therefore evident that the above discussed unbalanced frame of evidences is directly linked with the revocation of the patent."* - page 7 of the petition).

2.3 In the present case, however, the Enlarged Board finds that a causal link between the decision and the lack of admittance of D24 does not exist.

D24 was filed to show that two types of Rotolab device existed (see summary of the respondent-proprietor's arguments in the written decision, "Summary of facts and submissions", item X). The decision under review (see paragraph bridging pages 8 and 9) identifies in paragraphs [0044] and [0045] of the patent (which refer to the process in question) that *"... The skilled person, reading example 4 as a whole, **would necessarily***

assume that the same mixer-granulator is used [emphasis added], *in the sense that the high-energy mixer-granulator Zanchetta Rotolab according paragraph [0044] is a generic denomination of the apparatus which is then specifically defined as mixer-granulator Zanchetta Rotolab P-50 in paragraph [0045].*" Thus, in the Board's decision, it was emphasised that the skilled person would only understand that one type of mixer-granulator is present and that two different mixer-granulators cannot be read from these paragraphs. Therefore, even if D24 had been admitted, the Board would not have decided differently concerning lack of disclosure of the invention.

Although the petitioner argued that a skilled person carrying out Example 4 would necessarily have come to a different conclusion had D24 been admitted, the Enlarged Board is not persuaded by this argument. The Board of Appeal's statement as to the use of one and the same mixer when reading paragraphs [0044] and [0045] in relation to Example 4, is notably not made against a background of the presence or absence of documentation in this regard, but simply on the wording of the paragraphs as they stand. The argument that another type of Rotolab mixer-granulator from Zanchetta capable of reaching 900 rpm might indeed have existed thus lacks relevance when reading the Board's unequivocal statement. Indeed, the Board even acknowledged at the end of the first paragraph on page 9 of the decision that either the rotation speed of 900 rpm was incorrect or that the designation of the P-50 mixer-granulator was incorrect; the Board had thus already taken into account that (as argued by the

petitioner) a different mixer-granulator might have been meant.

2.4 Under these circumstances, the request on the basis of this complaint is clearly unallowable.

3. In this context the Enlarged Board of Appeal would like to point out that the substantive correctness of a decision's findings and conclusions is not reviewable - even indirectly - under Article 112a EPC. That is a matter not for the Enlarged Board but solely for the boards of appeal, e.g. after the decision has been set aside and the proceedings re-opened under Article 112a(5) EPC.

Order

For these reasons it is decided that:

The petition for review is rejected as clearly unallowable.

The Registrar:

The Chairman:

P. Martorana

W. van der Eijk