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Datasheet for the decision of the Enlarged Board of Appeal of 29 May 2017

Case Number:	R 0005/15
Appeal Number:	T 1938/09 - 3.3.02
Application Number:	98906678.2
Publication Number:	0964677
IPC:	A61F13/00, A61K31/485, A61K9/70

EN

Language of the proceedings:

Title of invention:

Sustained analgesia achieved with transdermal delivery of buprenorphine

Patent Proprietor:

EURO-CELTIQUE S.A.

Opponents:

Hexal AG Luye Pharma AG

Headword: Right to be heard II/EURO-CELTIQUE

Relevant legal provisions:

EPC Art. 112a(2)(c), 112a(2)(d), 113(1) EPC R. 104(b); 106

Keyword:

Right to be heard - fundamental violation (no) Omission to decide on a relevant request (no) Other fundamental procedural defect (no)

Decisions cited:

G 0009/91, R 0001/08, R 0010/09, R 0012/09, R 0016/09, R 0013/12, R 0001/13, R 0002/14, R 0013/14, T 2362/08

Catchword:

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Große Beschwerdekammer Enlarged Board of Appeal Grande Chambre de recours

9 March

Case Number: R 0005/15

DECISION of the Enlarged Board of Appeal of 29 May 2017

Petitioner: (Patent Proprietor)	EURO-CELTIQUE S.A. 2, avenue Charles de Gaulle 1653 Luxembourg (LU)
Representative:	Maiwald, Walter Maiwald Patentanwalts GmbH Elisenhof Elisenstrasse 3 80335 München (DE)
Other Party: (Opponent 01)	Hexal AG Industriestrasse 25 83607 Holzkirchen (DE)
Representative:	ter Meer, Nicolaus Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburgerstraße 4 80335 München (DE)
Other Party: (Opponent 02)	Luye Pharma AG Am Windfeld 35 83714 Miesbach (DE)
Representative:	Best, Michael Lederer & Keller Patentanwälte Partnerschaft mbB Unsöldstrasse 2 80538 München (DE)
Decision under review:	Decision of the Technical Board of Appeal 3.3.02 of the European Patent Office of 9 2015.

Composition of the Board:

Chairman:	R. Moufang
Members:	MB. Tardo-Dino
	F. van der Voort
	E. Dufrasne
	T. Bokor

Summary of Facts and Submissions

- I. The petition for review concerns decision T 1938/09 of Technical Board of Appeal 3.3.02 (hereinafter: "the Board") announced orally at the end of the oral proceedings on 9 March 2015 and despatched to the parties in writing on 3 July 2015. By this decision the Board dismissed the appeal filed by the patent proprietor against the decision of the opposition division to revoke European patent No. 0 964 677.
- II. The petition was filed and the corresponding fee paid by the appellant/patent proprietor (hereinafter: "the petitioner") on Monday, 14 September 2015. The petition was based on the grounds that fundamental violations of the right to be heard had occurred and that the proceedings had been fundamentally defective (Article 112a(2)(c) and (d) in combination with Rule 104(b) EPC).
- III. On the second day of first oral proceedings held on 1 and 2 October 2014, the Board, in an alternate composition according to Article 24(4) EPC, had rejected the objections of suspected partiality raised by the petitioner against the Board's chairman. This decision gave rise to a separate petition for review (R 2/15), which was unanimously rejected by the Enlarged Board of Appeal as clearly unallowable at the end of oral proceedings held on 21 November 2016.
- IV. On 2 October 2014, the oral proceedings were then resumed before the Board in its original composition, under protest of the petitioner. The petitioner's pending substantive requests comprised a main request

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(maintenance of the patent as granted), first to fourth auxiliary requests, all filed with the statement of grounds of appeal, and auxiliary requests I to IV, filed in reply to the submissions of the respondents/opponents (hereinafter: "the opponents"). In reply to a new objection under Article 123(2) EPC raised during the oral proceedings by opponent 2, the petitioner filed auxiliary request V, which was admitted into the proceedings by the Board. At the end of the oral proceedings the chairman closed the debate on the question of whether claim 1 of the main request and claim 1 of the first to fourth auxiliary requests as well as the single claims of auxiliary requests I to IV met the requirement of Article 123(2) EPC and announced the Board's decision to continue the proceedings in writing.

v. With a communication of 28 October 2014, the Board issued a preliminary opinion prior to second oral proceedings scheduled to take place from 9 to 13 March 2015. It pointed out issues to be discussed regarding auxiliary request V, which inter alia included issues under Article 123(2) EPC. The petitioner was requested to demonstrate original disclosure of each of the features of the current claim of auxiliary request V in its context. In particular, the Board indicated that the specific meaning of the newly introduced passage "wherein at 72 hours after initiation of the dosing interval the dosing of buprenorphine during the at least next 48 hours is maintained in accordance with zero order kinetics" (hereinafter "zero order kinetics feature") would have to be discussed. The parties were informed that they should also be prepared to discuss issues under Articles 84, 54, 56 and 83 EPC based on

and starting from the arguments communicated during the procedure before the opposition division and so far before the Board.

- VI. With two submissions of 23 December 2014 the petitioner requested (i) that the oral proceedings be postponed until after all proceedings relating to the objection against the chairman of the Board in its current composition had been finally decided, (ii) that certain questions of law be referred to the Enlarged Board of Appeal, and (iii) that any objections the Board or the opponents might have against auxiliary request V on the basis of Article 123(2) or 84 EPC be clarified and substantiated in writing well in advance of the second oral proceedings.
- VII. In its communication of 29 January 2015 the Board informed the parties that the dates scheduled for oral proceedings would be maintained and that it would decide on the request for postponement at those oral proceedings, after having heard the parties. The Board noted that a petition for review had no suspensive effect. According to its preliminary view, it followed from Article 112a(3) and (6) EPC that it was the intention of the legislator that the interest of the petitioner should not prevail over the interest of the other parties to the proceedings and the general public.
- VIII. On 3 and 6 February 2015 opponents 1 and 2 filed submissions comprising objections under Article 123(2) EPC against auxiliary request V. These submissions also addressed the zero order kinetics feature and referred to Article 84 EPC.

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IX. The petitioner filed further submissions on 26 February and 2 March 2015 in reply to the Board's communication and the opponents' arguments and filed two auxiliary requests (VI and VII) in respect of a new objection raised by the Board regarding the term "system". It reiterated its request for postponement of oral proceedings.

X. Oral proceedings took place on 9 March 2015. The sequence of events at the oral proceedings as reported in the minutes was as follows:

> - The request for postponement was refused; in reaction the petitioner indicated that it would participate in the proceedings under protest.

- The request for referral of questions of law to the Enlarged Board of Appeal was refused.

- Auxiliary requests VI and VII filed with the letter of 2 March 2015 were admitted.

- A discussion on the requirements of Article 84 EPC took place with respect to auxiliary requests V, VI and VII.

- Auxiliary requests VIIIa and VIIIb were filed by the petitioner and their admissibility was discussed.

- Auxiliary requests VIIIa and VIIIb were not admitted and the debate on whether auxiliary requests V, VI and VII met the requirements of Article 84 EPC was closed. - The parties confirmed their requests, and the petitioner raised the following objection under Rule 106 EPC:

"Appellant Patentee hereby objects under Rule 106 EPC in combination with Art. 112a (2) c) and Art. 113 EPC to the non-admittance of Auxiliary Requests VIIIa and VIIIb filed during oral proceedings of March 9, 2015.

In the oral hearing on March 9, 2015 new objections under Art. 84 EPC were raised by the Opponents as regards the understanding of the feature `wherein at 72 hours after initiation of the dosing interval the dosing of buprenorphine during the at least next 48 hours is maintained in accordance with zero order kinetics', which feature was introduced for the first time with Auxiliary Request V filed during oral proceedings on October 2, 2014.

Appellant Patentee filed the above two Auxiliary Requests VIIIa and VIIIb in an attempt to overcome the newly raised objections. The Auxiliary Requests VIIIa and VIIIb were not admitted into the proceedings.

Thus, Appellant Patentee had no adequate opportunity to respond to the objections newly raised during the oral proceedings on March 9, 2015.

Against this background, Appellant Patentee considers the non-admittance of the two Auxiliary Requests VIIIa and VIIIb a fundamental violation of its right to be heard."

- The Board dismissed the objection under Rule 106 EPC and announced that the appeal was dismissed.

XI. The decision under review to the extent that it deals with the issues at stake in the petition for review may be summarised as follows:

> Regarding the request for postponement of the oral proceedings the Board noted that, although adjournment of oral proceedings might be justified in some cases as apparent from the notice of the Vice-President DG 3 dated 16 July 2007, even in those cases the proceedings were normally not adjourned indefinitely. Even if the Board had the discretion to generally adjourn the oral proceedings for an undefined period, in the case at issue this would not be in line with Article 112a EPC because the legislator's intention was that petition for review proceedings had no suspensive effect. The Board stated that it had to take into account not only the parties' interests but also the interest of the public at large in having clarified as soon as possible the question of whether an exclusive right has to be respected. Regarding the argument that the Enlarged Board of Appeal was likely to set aside the interlocutory decision on the objection of suspected partiality, the Board considered that this was mere speculation and that it could not postpone the proceedings on such a basis. The decision of the Board in its alternate composition was res judicata and could not be ignored.

Regarding the request for referral to the Enlarged Board of Appeal, which was linked to the request for postponement, the Board took the view that questions 1 and 3 raised points of law that the Board was able to answer itself, and question 2 was no longer relevant given that the alternate Board's decision on the objection of suspected partiality had already been issued and a petition for review against that decision had already been filed.

With respect to the petitioner's substantive requests, the decision under review firstly dealt with the admissibility of all the auxiliary requests. As to auxiliary request V, the Board explained the genesis of this request, which justified its admission. It had been filed during the oral proceedings on 2 October 2014 in reaction to a new objection under Article 123(2) EPC raised by opponent 2. The Board noted in points 6.2.2 and 6.2.3 of the reasons for its decision that before the oral proceedings opponent 2 had made no specific comments about the absence of the zero order kinetics feature with respect to auxiliary requests I to IV, thereby creating the impression that the feature was of minor interest. So when it was argued that the omission of this feature was in breach of Article 123(2)EPC, the Board gave the petitioner an opportunity to react by introducing the feature, which was taken from the description, into the claim and thus admitted auxiliary request V filed at the oral proceedings of 2 October 2014.

Auxiliary requests VIIIa and VIIIb were filed at the second oral proceedings in an attempt to overcome objections under Article 84 EPC raised against auxiliary request V. The Board exercised its discretion under Article 13 RPBA not to admit them into the proceedings, taking into account in particular the complexity of the new subject-matter and the current state of the proceedings. The Board referred to its communication of 28 October 2014, in which it had mentioned that the meaning of the zero order kinetics feature needed to be discussed and that the parties should be prepared to discuss issues under Articles 84, 54, 56 and 83 EPC. The Board emphasised (see points 6.4.1 and 6.4.2 of the reasons) that this communication made it clear that auxiliary request V had not been admitted as "clearly allowable" but as a bona fide attempt to remedy the last deficiency under discussion in the oral proceedings of 1 and 2 October 2014. The Board also referred to the opponents' written submissions of 3 and 6 February 2015, where this feature was objected to under Article 84 EPC, and concluded that the Board and the opponents had already raised in writing the issue that this feature was potentially not in line with the requirements of Article 84 EPC. The petitioner's attempts to clarify the definition of the litigious feature by introducing a further passage from the description was however not considered by the Board to overcome the objection, as it did not introduce the precise and full definition given in this passage of the description.

The Board then examined the merits of the pending requests. It concluded that auxiliary request V lacked clarity (Article 84 EPC). It found that the claim as amended by the newly introduced zero order kinetics feature could be given different interpretations (see point 9.1.2 of the reasons). The skilled person, acquainted with a certain usual definition of "constant plasma concentration" and trying to opt for one of those interpretations, would find in the description possible different meanings of the feature other than the one on page 39, lines 8 to 12, which indirectly linked this feature to the constant plasma concentration (see points 9.1.3 and 9.1.4 of the reasons).

- XII. On page 24 of the petition, the petitioner summarised the alleged violations of the right to be heard and the alleged fundamental procedural defect (Article 112a(2)(c) and (d) in combination with Rule 104(b) EPC) as follows:
 - The reasoning for the decision on not admitting auxiliary requests VIIIa and VIIIb into the proceedings was a clear breach of Article 113 EPC and constituted a fundamental violation of the right to be heard in accordance with the jurisprudence of the Enlarged Board of Appeal.
 - Not admitting auxiliary requests VIIIa and VIIIb was itself a fundamental violation of the right to be heard and in particular also constituted a fundamental procedural defect: a decision on a relevant request was missing.
 - Relevant arguments of the petitioner had not been taken into account in the decision on the request for postponement.
 - The chairman who had been objected to participated in the final decision in contradiction with

Article 6 ECHR and thus gave rise to a fundamental violation of the right to be heard.

The petitioner requested:

- that the decision under review be set aside and the appeal proceedings reopened;
- that all members of the Board who had participated in the decision under review be replaced;
- that reimbursement of the fee for the petition for review be ordered;
- that, in case the Enlarged Board of Appeal intended not to allow the first two requests above, oral proceedings be scheduled;
- that several persons who had attended the oral proceedings and were listed on page 3 of the petition be heard in case the Enlarged Board of Appeal questioned the facts on which the petition was based; and
- that the petition for review be treated in an accelerated manner.
- XIII. The Enlarged Board of Appeal in its three-member composition decided on 13 December 2016 to remit the petition for review to the Enlarged Board of Appeal in its five-member composition (in the following "the Enlarged Board) in accordance with Rule 109(2)(b) EPC and Article 17 RPEBA.
- XIV. The opponents filed written submissions on 23 February 2017, both requesting the rejection or dismissal of the petition.

- XV. With a communication sent on 13 March 2017 the Enlarged Board expressed its preliminary opinion, to which the petitioner reacted in a letter dated 2 May 2017.
- XVI. Oral proceedings took place on 29 May 2017.
- XVII. The petitioner's arguments in its written submissions and as presented during the oral proceedings may be summarised as follows:
 - (a) Violations of its right to be heard in relation to and resulting from the non-admittance of auxiliary requests VIIIa and VIIIb

(1) The first violation concerned the lack of opportunity to comment on grounds and evidence for not admitting auxiliary requests VIIIa and VIIIb. The petitioner learnt the reasons why these requests were not admitted only in the written decision. This violation was twofold:

(i) Although new clarity objections under Article 84 EPC were raised against the zero order kinetics feature during the oral proceedings on 9 March 2015 for the first time (and in contradiction with the written submissions of the opponents who endorsed the Board's view only at the oral proceedings), the Board considered in its decision that they had already been made in writing (point 6.4.2 of the reasons). The petitioner had no opportunity to argue against this allegation, which formed the first part of the Board's reasoning for not admitting auxiliary requests VIIIa and VIIIb. (ii) The objection that the additional feature in auxiliary requests VIIIa and VIIIb did not represent a precise reproduction of the definition in the description had never been raised by the opponents or by the Board, either in the written submissions or in the oral proceedings; therefore the petitioner had had no opportunity to comment on this argument. Any remaining doubts as to the factual situation had to be resolved to the affected party's benefit (see R 2/14).

(2) The second violation concerned the lack of opportunity to deal with what was effectively a fresh case in the second oral proceedings, i.e. the new arguments forming the basis for the decision rejecting auxiliary request V. By not admitting auxiliary requests VIIIa and VIIIb in this situation, the Board had infringed the petitioner's right to be heard.

During the oral proceedings on 2 October 2014 opponent 2 raised a new Article 123(2) EPC objection which prompted the petitioner to file auxiliary request V, in which the zero order kinetics feature was introduced into the claim. While the Board allowed this late objection although opponent 2 could, and should, have submitted it much earlier, the petitioner was not given sufficient opportunity to properly overcome the objection. The petitioner had repeatedly asked for clarification of possible objections even before the second oral proceedings. The opponents explained for the first time during the oral proceedings what their objection under Article 84 EPC was. Then the rapporteur intervened. His question regarding the meaning of dosing and his opinion that "zero order kinetics" had no link to the plasma concentration were ex officio

objections, which had not been mentioned before in the Board's preliminary opinion and were in direct contradiction with the opponents' own understanding as apparent from their previous written and oral submissions. The opponents then took over the objection raised *ex officio* by the Board only in the oral proceedings and were thus allowed to bring a late fresh case, whereas the petitioner was denied an adequate defence. This infringed its right to be heard (see also T 2362/08).

The only possibility left to the petitioner to deal with the new case after auxiliary request V had been found not to comply with Article 84 EPC on the basis of this late *ex officio* objection was the filing of auxiliary requests VIIIa and VIIIb, where zero order kinetics was defined by introducing a passage from the description: "wherein zero order kinetics means that the plasma concentration does not decrease more than 30% over a 48 hours time period".

However, the Board dismissed the requests without any further discussion than the formal discussion regarding the admissibility issues. The Board revoked the patent without letting the petitioner know the outstanding objections and therefore depriving the petitioner of an adequate opportunity to comment. It sacrificed the right to be heard to efficiency considerations, it being noted that the oral proceedings had been scheduled for five days and were terminated on the first day. The patent was revoked for reasons which had nothing to do with the first-instance proceedings or the written procedure during the appeal proceedings.

(b) Wrong decision regarding suspected partiality

The lawful composition of a court was a prerequisite for any correct procedure and a guarantee of the right to be heard. The petitioner referred to its submissions in case R 2/15 and argued that the decision on suspected partiality was wrong. It was also a violation of its right to be heard (see point 4 of the summary on page 24 of the petition).

(c) Lack of consideration of an argument regarding the request for postponement and the corresponding referral questions

With respect to the requests for postponement and for referral of corresponding questions of law, the Board had completely ignored the petitioner's arguments, which were based on Article 112a(6) EPC and referred to the irreparable damage which might be caused to the petitioner.

(d) Lack of a decision on a request relevant for the decision (Article 112a(2)(d) and Rule 104(b) EPC)

The Board had in fact not decided on auxiliary requests VIIIa and VIIIb. No proper discussion of admissibility had been allowed, which might have had an influence on the outcome of the proceedings. (e) Petition for review against the interlocutory decision

In case the petition for review against the interlocutory decision regarding the objection of suspected partiality were to be found inadmissible as a whole in R 2/15, the present petition should be considered as again also filed against the interlocutory decision.

- XVIII. The opponents' arguments in their written submissions and as presented during the oral proceedings may be summarised as follows:
 - Opponent 1 requested that the petition be rejected as inadmissible in so far as it was based on Article 112a(2)(d) EPC because the petitioner had not raised any objection under Rule 106 EPC in that respect. The Board decided upon auxiliary requests VIIIa and VIIIb after the petitioner had had an opportunity to discuss the admissibility issue, as the written notes by the petitioner's representatives themselves showed (see annexes to the petition, Pet12 and Pet13). If the petitioner had been of the view that it had not had sufficient opportunity to discuss the issue, it ought to have made this clear and/or could have requested the Board to reopen the debate.
 - Opponent 1 further contended that the petition should be rejected as unallowable for the following reasons:

As to the request for postponement denied by the Board, this issue was moot, since the petition for review filed against the interlocutory decision had been rejected and therefore the composition of the Board would not have changed.

As to the allegedly wrong interlocutory decision, there was nothing to add, since there was a separate review of the decision rejecting the objection of suspected partiality.

The petitioner made wrong factual statements in support of its petition. It was not understandable how the petitioner had come to the view that the subject-matter of auxiliary request V was clear for the opponents. Opponent 1 referred to its own submissions dated 6 February 2015 and to those of opponent 2 dated 3 February 2015. Also, the Board in its communication dated 28 October 2014 had pointed out that the meaning of the zero order kinetics feature should be discussed. It was the petitioner's duty to explain what this feature meant, and it had an opportunity to present its case in this respect. In an inter partes case, the petitioner could not expect the Board to specify which arguments and problems the Board considered relevant with respect to auxiliary request V. The parties had an active obligation to take initiatives (see R 12/09). Furthermore, the Board had no obligation to inform the parties of all foreseeable reasons for its decision (R 12/09).

 Opponent 2 reversed the petitioner's argument concerning the participation of the chairman objected to. The Enlarged Board of Appeal had dismissed the petition for review against the interlocutory decision. If the chairman who was entitled and obliged to participate in the final decision had not done so, the opponents' right to their lawful judge would have been violated. In any case, the composition of the Board was a moot point after the petition for review against the interlocutory decision had been rejected.

As to the refusal of the request for postponement, opponent 2 argued that, even if the Board had not taken into consideration all the petitioner's arguments, this did not change the result that the decision was made by the Board in its lawful composition. If the request had been successful, the same Board of Appeal would have had to decide on the appeal. In addition, it was not correct to say that the Board had not taken the relevant arguments into account. After listening to the petitioner's arguments, it had explained which the decisive reasons were.

As to the alleged violations of the right to be heard, opponent 2 argued that it had always objected to the claims of the main request and auxiliary requests I to IV under Article 123(2) EPC. It had been generous of the Board to admit auxiliary request V at the end of the second day of the first oral proceedings in view of the fact that Article 123(2) EPC had been the ground for the revocation of the patent by the opposition division and all the requests during the appeal proceedings had been objected to on that ground.

It was within the petitioner's responsibility to make sure that the very late-filed request met the requirements of the EPC. It was not understandable how the petitioner came to the view that opponent 2 had considered the zero order kinetics feature to be clear. Opponent 2 referred to its written submissions, where it clearly argued that interpreting the zero order kinetics feature as being related to the plasma concentration contradicted other parts of the description. In those circumstances the petitioner should have been expecting the claims to be under scrutiny, and it should have submitted claims overcoming the objections. Instead, it had waited until the oral proceedings before filing further auxiliary requests. It was established case law of the boards of appeal that such late-filed requests were admitted only if they were clearly allowable without a need for further investigation by the Board. In this particular case, oral proceedings had already taken place, and it was the filing of auxiliary request V which had made second oral proceedings necessary.

- XIX. The petitioner's final requests were:
 - that the decision under review be set aside and the appeal proceedings reopened;
 - that all members of the Board who had participated in the decision under review be replaced;
 - that reimbursement of the fee for the petition for review be ordered.

XX. The opponents' requests were that the petition for review be rejected as inadmissible or unallowable.

Reasons for the Decision

1. Admissibility of the petition

- 1.1 The petition was filed and the relevant fee paid in due time. The petition was also substantiated. The requirements under Article 112a(4) EPC are therefore met.
- 1.2 Before filing the present petition, the petitioner had already filed a separate petition for review of the Board's interlocutory decision. Nevertheless, it requested, "as a safeguard measure" in case a petition against an interlocutory decision were considered inadmissible as a whole in R 2/15, that the interlocutory decision be reviewed in the context of the present petition (see section XVII(e) above).

In its decision R 2/15, announced at the end of oral proceedings on 21 November 2016, the Enlarged Board of Appeal, in a different composition, unanimously rejected the first petition as clearly unallowable (see section III above). This implies that the first petition was not held inadmissible as a whole for being directed against an interlocutory decision. What was decided in R 2/15 became *res judicata* and can no longer be challenged in the context of the present petition directed against the Board's final decision ("*ne bis in idem*"). Thus, insofar as the petition aims at a second review of the interlocutory decision – the petitioner

neither explicitly withdrawing the issue nor further commenting on it -, it is inadmissible.

1.3 The petition is furthermore based on the ground that the Board was wrongly composed when it took its final decision, since the interlocutory decision incorrectly rejected the objection of suspected partiality. The petitioner argues that such unlawful composition directly affects the right to be heard with regard to the decision on the merits of the case (see section XVII(b) above).

> The Enlarged Board acknowledges that an interlocutory decision dealing with objections of suspected partiality unquestionably has consequences of utmost importance for the proceedings as a whole. Nevertheless, as has been made abundantly clear in the established case law, review proceedings cannot serve as a means to review the merits of a decision (see e.g. R 1/08 of 15 July 2008, Reasons 2.1, and R 13/12 of 14 November 2012, Reasons 2.5). In the present case, the Board decided in its alternate composition on the lawfulness of the composition in accordance with Article 24(4) EPC. The separate petition for review against this interlocutory decision was rejected as clearly unallowable. The lawfulness of the Board's composition thus remains res judicata. It falls outside the competence of the Enlarged Board to reassess the correctness of the composition in the framework of the present petition directed against the Board's final decision. The petition is therefore inadmissible in that respect. There is no need to discuss the hypothetical question of what the legal consequences for the present review proceedings would have been if

the Enlarged Board of Appeal had allowed the petition for review against the interlocutory decision.

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- According to Rule 106 EPC, a petition under 1.4 Article 112a(2)(a) to (d) EPC is only admissible where an objection in respect of the procedural defect was raised during the appeal proceedings and dismissed by the board of appeal, except where such objection could not be raised during the appeal proceedings.
- The alleged deficiency set out in section XVII(c) above, 1.4.1 namely that the Board omitted to take into consideration an essential argument made by the petitioner in relation to the request to postpone the oral proceedings, only became apparent from the written decision. It could therefore not be objected to earlier, and thus the exception provided for in the last halfsentence of Rule 106 EPC applies.
- 1.4.2 During the oral proceedings the petitioner raised an objection under Rule 106 EPC when the Board decided not to admit auxiliary requests VIIIa and VIIIb (for details see section X above). This objection covers the alleged deficiencies set out above in section XVII(a), i.e. violations of the right to be heard, and in section XVII(d), i.e. the omission to decide on a relevant request following from the refusal to admit auxiliary requests VIIIa and VIIIb. Accordingly, the petition is admissible in those respects.

2. Allowability of the petition

2.1 Violations of the right to be heard in relation to and resulting from the non-admittance of auxiliary requests VIIIa and VIIIb

> The petitioner maintains that it had no opportunity to argue on two essential reasons on which the Board based its decision not to admit auxiliary requests VIIIa and VIIIb (see section XVII(a)(1)(i) and (ii) above) and that in addition the non-admittance in itself constituted a violation of its right to be heard (see section XVII(a)(2) above).

2.1.1 According to the petitioner, the statement in the written reasons of the decision that the Board and the opponents had already raised in writing the issue that the zero order kinetics feature was potentially not in line with the requirements of Article 84 EPC was both wrong and surprising. The petitioner could not expect such a reasoning, since it was evident that the decisive reason for which the Board found the feature to lack clarity was put forward for the first time only in the second oral proceedings.

> There is no need to try to reconstruct the course of the oral proceedings before the Board in all details. The right to be heard does not hinge exclusively on the oral proceedings. When assessing whether or not it has been infringed, the Enlarged Board also has to take into account the written submissions of the parties and the communications of the Board (R 16/09 of 19 May 2010, Reasons 2.2.17). Considering the written part of the proceedings in the present case, it is apparent that

the different possible meanings of the litigious feature (as presented in points 9.1.1 to 9.1.4 of the decision under review) had not been so exhaustively presented prior to the oral proceedings.

Nevertheless, the Enlarged Board does not share the petitioner's view that the Board's above-mentioned statement was incorrect. It is a statement of a general nature reflecting the opponents' written submissions of 3 February 2015 (point II.3.2.2) and 6 February 2015 (point 5, pages 5 and 6). In these submissions clarity objections were raised, one of them relating to the zero order kinetics feature. It was submitted by opponent 1 that the usual understanding of this feature would be that it was connected to the constant plasma concentration, but that this usual interpretation was inconsistent with passages of the description (Tables 1 and 2, Figure 1 and example 1). There was even an explicit reference to Article 84 EPC on page 7 of opponent 2's submission of 3 February 2015. Assuming that zero order kinetics corresponds to a stable plasma concentration, opponent 2 pointed out that this was inconsistent with Figure 1, which showed that after four days the concentration decreased, and concluded that there were a lot of questions regarding the admissibility of this new feature in view of Articles 84 and 123(2) and (3) EPC. Although opponent 1 did not explicitly refer to Article 84 EPC, its submission also emphasised that the normal understanding of zero order kinetics was not consistent with Figure 1 of the patent.

It follows from the above that the Board's statement in the written reasons that clarity objections against the zero order kinetics feature had already been raised in the written proceedings was correct and could, from an objective point of view, not have surprised the petitioner. The Enlarged Board is unable to identify any violation of the right to be heard in that respect.

2.1.2 The petitioner furthermore argues that it only learned from the written reasons why the Board considered that the claims of auxiliary requests VIIIa and VIIIb did not comply with the clarity requirement, namely for not fully and precisely introducing the definition from the description. According to the petitioner, this objection amounted to a non-communicated *ex officio* consideration. There was no opportunity to comment on the objection, since it was evident that the petitioner believed itself to have included the full and precise definition.

> According to the established case law of the Enlarged Board of Appeal, the right to be heard enshrined in Article 113(1) EPC does not oblige the boards to provide the parties in advance with all reasons for a decision in detail or even to engage in an interactive discussion until one of the parties finds a solution to a problem caused by an objection.

> In the present case, the petitioner had been made aware of the reasons why the zero order kinetics feature contained in auxiliary request V was considered not to be clear. It then submitted auxiliary requests VIIIa and VIIIb in an attempt to clarify the feature by inserting a further passage from the description. In this situation, the petitioner could not be certain that the amendments overcame the objection under

Article 84 EPC and that they did not raise additional concerns. As emphasised by the opponents and as reflected in the minutes (see section X above), the admissibility of these requests was then discussed. Even if the Board did not provide the petitioner in advance with details of the view it later expressed in the written reasons, i.e. that the amendment did not fully and precisely reproduce the definition in the description, the petitioner was not prevented from arguing its case that the amendment overcame all pending objections and did not raise new ones.

Thus, no fundamental violation of the right to be heard can be established in that respect.

2.1.3 Moreover, the petitioner considers that its right to be heard was infringed by the course of events in the proceedings leading to the non-admittance of auxiliary requests VIIIa and VIIIb. Auxiliary request V had been filed in the first oral proceedings to overcome a late objection under Article 123(2) EPC. The clarity issue which turned out to be decisive for the non-allowance of auxiliary request V, i.e. the existence of different possible meanings of the zero order kinetics feature, had not been indicated in the written proceedings by the Board or the opponents. The issue was only raised in the second oral proceedings ex officio by the Board and contradicted previous submissions of the opponents. In this situation, the petitioner should have been given sufficient opportunity to defend its patent. In particular, auxiliary requests VIIIa and VIIIb should have been admitted in order to allow a full substantive discussion of all relevant issues. Even the admissibility discussion was fundamentally defective in that the petitioner was not informed of any alleged prima facie objections and thus could not present its response properly in the context of admissibility. The Board barred the petitioner from the sole opportunity to deal with what was effectively a new case. Although the oral proceedings had been scheduled for five days, they were terminated immediately after the nonadmittance of auxiliary requests VIIIa and VIIIb. The patent was finally revoked for something that had nothing to do with the appealed decision or the written submissions.

Although the objection under Article 123(2) EPC which caused the petitioner to file auxiliary request V in the first oral proceedings was raised only at a late stage, the petitioner does not claim that its right to be heard was infringed by the mere fact that the Board admitted this objection into the proceedings. Rather, it accepts that the Board had taken a balanced decision regarding auxiliary request V, since it allowed a late new objection and a full response including arguments and a new request, such that there was a full and adequate chance to overcome the late new objection (see petition, page 17).

When the petitioner prepared for the second oral proceedings, it had to be aware that objections under Article 84 EPC might be discussed with respect to auxiliary request V. In view of the opponents' submissions dated 3 and 6 February 2015, the petitioner was also aware of their contention that an inconsistency existed between the usual understanding of the litigious feature and certain passages in the description (see point 2.1.1 above). It thus had to be expected that the Board would ask for an explanation of the meaning of this feature. Even if it could not be anticipated at this point in time what position the Board would take and why, the petitioner had ample opportunity to prepare itself for a thorough discussion of the clarity requirement and to consider the submission of further auxiliary requests in order to overcome any possible concerns in that respect.

During the discussion of auxiliary request V in the second oral proceedings, the petitioner learned where precisely the problem of clarity arose from. Hence, at this stage the petitioner knew the concerns the Board had and was given a further chance to amend the request. This was sufficient for the purposes of Article 113(1) EPC to permit the petitioner to prepare its defence in respect of auxiliary request V. The petitioner was allowed to argue against the Board's position and to submit the further auxiliary requests VIIIa and VIIIb. As confirmed by the minutes of the second oral proceedings, the petitioner was also heard on the admissibility of these auxiliary requests.

In the light of the course of events before and during the second oral proceedings, no fundamental violation of the petitioner's right to be heard can be established. The Board was not obliged to admit auxiliary requests VIIIa and VIIIb into the proceedings in order to allow a fully-fledged discussion of their allowability (for a detailed discussion of this issue, see decision R 1/13 of 17 June 2013, Reasons 9 to 17). According to the established case law on Article 114(2) EPC and Article 13 RPBA, the admission of new requests in appeal proceedings, the purpose of which is mainly to review the decision of the department of first instance, is a matter for the Board's discretion and not a right of any party (see also R 10/09 of 22 June 2010, Reasons 3.2).

The Board was also not obliged to point out during the discussion of admissibility that in its view the amended claim still lacked clarity for not containing the full and precise definition of the zero order kinetics feature. The Enlarged Board acknowledges that the situation of a patent proprietor who submits amendments in order to defend a patent in opposition proceedings and who is confronted with objections under Article 84 EPC may sometimes be quite difficult. Nevertheless, as already stated above in point 2.1.2, the right to be heard does not imply that a board of appeal needs to provide the parties in advance with all reasons for a decision in detail or to engage in an interactive discussion until a patent proprietor who attempts to amend its patent in order to overcome an objection finds an acceptable solution.

The fact that the oral proceedings had been scheduled for five days and were terminated immediately after the non-admittance of auxiliary requests VIIIa and VIIIb has no relevance. The right to be heard is not a mere matter of time but rather a matter of whether or not the petitioner had sufficient opportunity to comment on the decisive reasons, in the present case the nonfulfilment of the clarity requirement.

Finally, the argument that the patent was revoked for something that had nothing to do with the appealed decision or the written submissions disregards the fact that all the requests submitted by the petitioner in the appeal proceedings aimed at reversing the appealed decision by which the patent had been revoked. Since several of these requests, including auxiliary requests V, VIIIa and VIIIb, had not been presented in the first-instance proceedings, they brought up new issues which had not existed before. In particular, the zero order kinetics feature was new in that it resulted from an amendment introduced by the petitioner in an attempt to overcome an issue under Article 123(2) EPC. This made it necessary for the Board to decide whether the claims as amended during the appeal proceedings complied with the requirements of Articles 123(2) and 84 EPC (see G 9/91, OJ EPO 1993, 408, Reasons 19).

2.2 The omission of a decision on a relevant request

A fundamental procedural defect under

Article 112a(2)(d) EPC may occur if a board decides on an appeal without deciding on a request relevant to that decision (Rule 104(b) EPC). In the present case, the Board decided not to admit auxiliary requests VIIIa and VIIIb into the proceedings. The decision was reasoned and was made in the exercise of the Board's discretion after the petitioner had been given the opportunity to comment (see point 2.1.3 above). Accordingly, the Board did not overlook or ignore the request. Rule 104(b) EPC does not aim at providing a legal remedy in all situations where a board refuses to deal with a request in substance, either because it considers itself to lack competence (see R 13/14 of 15 January 2016, Reasons 2.2 to 2.4.6) or because - as in the present case - it does not admit the request into the proceedings. Thus no fundamental procedural defect

under Article 112a(2)(d) EPC in connection with Rule 104(b) EPC to the detriment of the petitioner can be established in that respect.

2.3 Infringement of the right to be heard due to failure to consider an essential argument

The petitioner asserts that the Board ignored an important argument regarding the request to postpone the oral proceedings (to which a request for referral of questions of law was linked). The written reasons of the decision did not deal with the petitioner's argument that a continuation of the case risked serious and irreparable harm to the petitioner, in particular in view of Article 112a(6) EPC. Ignoring this argument amounted to a fundamental violation of the right to be heard.

The right to be heard under Article 113(1) EPC requires not only that the parties are given an opportunity to present comments, but also that these comments are taken into consideration by the deciding body. However, it is not necessary to consider each and every argument of the parties in detail in a decision. The boards may also refute arguments implicitly, and may disregard irrelevant arguments.

The Board dealt with the petitioner's request for postponement of the second oral proceedings in point 4 of its decision (see section XI above). It considered that it was clear from Article 112a(3) EPC that the legislator did not want to attribute any suspensive effect to a petition for review. Even if the Board were to assume that it had discretion to generally adjourn

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oral proceedings for an undefined period, this provision would speak against exercising such discretion in the present case. Furthermore, in opposition proceedings, and thus also in opposition appeal proceedings, a decision should be reached as quickly as possible, not only in the interest of the parties, but also in the interest of the public at large. Although the petitioner had argued that it was likely that the Enlarged Board of Appeal would set aside the decision of the Board in its alternate composition and that proceedings would then have to be reopened, it was found not to be appropriate to base a decision on speculation. The interlocutory decision of the Board in its alternate composition was binding and had the force of res judicata. This force could not be ignored by the Board at the request of one of the parties.

In the framework of the present review proceedings, it is not a matter for the Enlarged Board to assess the correctness of the Board's reasoning. Rather, the decisive question to be addressed is whether, viewed from the legal standpoint which the Board took in its reasoning, the petitioner's argument that the continuation of the case could cause serious and irreparable harm in view of Article 112a(6) EPC was so relevant that it needed to be dealt with explicitly. This question is to be answered in the negative. It is apparent from the decision that the Board believed itself to have strong reasons (which it explained in some detail) for not postponing the oral proceedings. It can be implicitly deduced that in the Board's view these reasons outweighed all other considerations and arguments brought forward by the petitioner. There is

absolutely no indication that the Board overlooked or ignored the particular line of argument which highlighted the legal and economic consequences of continuing the procedure in view of Article 112a(6) EPC. Rather, it transpires from the decision that the Board was generally sceptical about the relevance of considerations of an economic nature: when dealing with the refusal of the request for referral, it stated that when taking their decisions the boards are only bound by the provisions of the EPC and not required to weigh up the economic implications (see Reasons 5.2).

The Enlarged Board is therefore unable to establish that a fundamental violation of the petitioner's right to be heard occurred in that respect.

3. Conclusion

It follows from the above that the petition is not well founded and, as a whole, not allowable. It also follows that the fee for the petition cannot be reimbursed. Order

For these reasons it is decided that:

The petition for review is rejected as unallowable.

The Registrar:

The Chairman:

C. Eickhoff

R. Moufang