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**Datasheet for the decision  
of the Enlarged Board of Appeal  
of 14 December 2011**

**Case Number:** R 0012/10  
**Appeal Number:** T 0232/08 - 3.3.04  
**Application Number:** 98911246.1  
**Publication Number:** 0918535  
**IPC:** A61K 38/16  
**Language of the proceedings:** EN

**Title of invention:**

Sustained-release composition of drugs encapsulated in microparticles of hyaluronic acid

**Patentee:**

LG Life Sciences, Ltd.

**Opponent:**

Quadrant Drug Delivery Limited

**Headword:**

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**Relevant legal provisions:**

EPC Art. 112a(2)c)d), 112a(4), 113  
EPC R. 111(2), 104

**Keyword:**

"Inconsistency in the decision (no)"  
"Petition for review as far as not rejected as clearly inadmissible, rejected as clearly not allowable"

**Decisions cited:**

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**Case Number:** R 0012/10

**DECISION**  
**of the Enlarged Board of Appeal**  
**of 14 December 2011**

**Petitioner:** LG Life Sciences, Ltd.  
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**Decision under review:** Decision of the Technical Board of Appeal  
3.3.04 of the European Patent Office of  
7 May 2011.

**Composition of the Board:**

**Chairman:** B. Günzel  
**Members:** M. J. Vogel  
P. Ranguis

## Summary of Facts and Submissions

- I. This petition for review concerns the decision dated 7 May 2010 of Technical Board of Appeal 3.3.04 in case T 232/08, by which the petitioner's European patent No. 0918535 was revoked due to lack of inventive step. The title of the patent is "Sustained-release composition of drugs encapsulated in microparticles of hyaluronic acid". The contested decision was posted on 17 June 2010. The petition was filed on 26 August 2010 and the prescribed fee paid on the same day.
- II. The petitioner requests that the decision under review be set aside and that the proceedings before the Board of Appeal be re-opened. As an auxiliary measure it requests oral proceedings.
- III. 1. According to the written grounds for its petition the petitioner submitted that in the proceedings before the Board of Appeal a fundamental violation of Article 113(1) EPC had occurred because the Technical Board based its decision on grounds on which the respondent had no sufficient and adequate time to provide comments. Furthermore, the contested decision contained in one fundamental respect at least one inconsistency, with the consequence that the decision is not reasoned within the meaning of Article 113(1) and Rule 111(2) EPC.
2. This only became obvious when the decision was notified. It was not discussed during the oral proceedings with the consequence that it was impossible for the petitioner (the patent proprietor) to raise an appropriate objection or to request to request the

Board to continue the proceedings in writing in order to give the petitioner the opportunity to present further experiments and arguments. Under these circumstances the petitioner could not raise any objection under Rule 106 EPC during the oral proceedings. In essence the petitioner argued as follows:

3. The opinion of the Technical Board of Appeal under points 15 to 17 of the contested decision that a beneficial effect over the prior art was not established was neither mentioned nor indicated in any way during the oral proceedings before the Board. Thus, it was completely surprising that the Board alleged that the different protein drugs delivered by the particles of the invention and the formulation of D2 were structurally too different to allow a direct comparison of that document and the patent.

4. Moreover the Board pointed out that in D2 a "water soluble protein injectable into body fluids without showing any substantial pharmacological activity" constituted a "mandatory constituent" of its formulation, whilst this constituent was not present in comparative example 2 of the patent. Therefore the results of figure 7 of the patent were considered not to be appropriate to establish a beneficial effect of the patent. On the contrary, under point 20 the Board later disregarded this alleged mandatory constituent when analyzing the differences between the patent and D2 for the analysis of inventive step and argued that the only question to ask with respect to inventive step was whether the skilled person would apply spray drying to make a composition according to D2. However, if the

mandatory constituent was substantial enough a direct comparison to be disregarded, this difference should also be of fundamental importance for applying the problem-solution analysis to assess inventive step over D2.

5. Consequently, according to the petitioner, there were two contradictory statements in the decision:

5.1 If the said feature was not relevant at all, a direct comparison of the results of comparative example 2 and the gel of D2 should be permissible. The statement under point 15.1 of the contested decision was then erroneous and figure 7 was indeed appropriate to demonstrate a beneficial effect over D2.

5.2 If, however, the opposite was true and the feature was mandatory for the formulation in D2, then the reasoning under point 15.1 was correct and no direct comparison of the data of the invention and D2 was appropriate. However, the statements under point 20 would be questionable. The closed list of constituents in claim 1 of the patent did, however, not contain the "mandatory constituent".

IV. By order of the Enlarged Board of 18 April and following a notice of postponement of 22 September 2011, the petitioner was summoned to oral proceedings on 14 December 2011. In a communication annexed to the summons the Enlarged Board expressed doubts whether the requirements of Rule 106 EPC had been met and whether the petitioner's right to be heard had been violated by the Technical Board.

V. 1. In a letter dated 29 August 2011 in response to the Enlarged Board's communication, the petitioner stated that in preparation for the oral proceedings before the Board of Appeal it had filed new experiments 7 and 8 showing a difference in the structure/shape of the particles over the teaching of D2, which did not, however, rule out the possibility of these structural differences bringing an improvement over D2 in terms of better solubility and, therefore, injection of the drug composition into a patient.

2. Furthermore, the petitioner repeated its arguments that the decision under review was based on arguments on which, contrary to Article 113(1) EPC, the parties had not had an opportunity to present their comments and that an illogical and contradictory decision amounts to a violation of the right to be heard just as much as if the Board had not considered the arguments put forward but only listened to them.

VI. During the oral proceedings before the Enlarged Board the petitioner underlined the arguments which it had submitted in the written procedure regarding the alleged inconsistency in the decision. However, it no longer relied on the argument that it could not have expected the Board to conclude that it would not recognize a beneficial effect over D2 (see point III.3 above). Furthermore, the petitioner pointed out that the Board had only discussed the differences between D2 and the patent with respect to the method of drying (spray and freeze drying) and the molecular weight of hyaluronic acid used for the gel formulation of D2 and for the microparticles of the patent. However, the questions whether "a water soluble protein injectable

into body fluids without showing any substantial pharmacological activity" in D2 constituted a "mandatory constituent" of its formulation and whether it was not present in the gel formulation in comparative example 2 of the patent, was only raised in the contested decision. Moreover, the question whether these constituents were in fact comparable or not was not considered during the oral proceedings. Thus, the petitioner had not been able to argue on that, with the consequence that its right to be heard according to Article 113(1) EPC was violated by the Board.

VII. At the end of the oral proceedings of 14 December 2011 the Enlarged Board announced its decision.

## **Reasons for the decision**

### *1. Admissibility of the petition for review*

1.1 The formal requirements with respect to the two-month time limits of Article 112a(4) EPC are met. The contested decision was posted on 17 June 2010 and deemed to be notified pursuant to Rule 126(2) EPC on 27 June 2010. As the prescribed fee was paid on 26 August 2010 and the petition was filed on the same day the petition is deemed to have been filed in good time.

1.2 Of the objections raised in the petition, the petitioner eventually only maintained the allegation that the contested decision contains in one fundamental respect an inconsistency, with the consequence that it is not reasoned within the meaning of Rule 111(2) EPC,

thereby showing that the petitioner's right to heard according to Article 113(1) EPC has been violated by the Board for further details see above point III.3 seq. above).

1.3 Furthermore, in its letter dated 29 August 2011 and in its presentation during the oral proceedings, as summarized under point V.1 and VI. of the Facts and Submissions above, and, hence, after expiry of the two-month time limit according to Article 112a(4) and Rule 107(2) EPC, the petitioner submitted new grounds for the petition. In particular, it relied on new facts regarding what was allegedly not discussed during the oral proceedings. Pursuant to Article 12(1) RPEBA the Enlarged Board may consider new submissions made by the petitioner after expiry of the time limit for filing the petition for review, if this is justified for special reasons. However, the petitioner not having given any reasons why these new objections were only submitted after expiry of the period for filing a reasoned petition, nor why they should nevertheless be taken into consideration, the Enlarged Board regards them as inadmissible.

1.4 Finally, as regards the admissibility of the petition, Rule 106 EPC requires that the petitioner should have raised an objection in respect of the alleged procedural defect during the oral proceedings and that this objection was dismissed by the Board of Appeal, except where the objection could not have been raised during the appeal proceedings. The Enlarged Board of Appeal agrees with the petitioner that indeed an objection with respect to the ground submitted in good time (see point 1.2 above) and maintained in the



petition proceedings could not have been raised in the oral proceedings, as this ground only became obvious when the decision was notified in writing.

2. *Allowability of the petition*

2.1 Hence, the Enlarged Board's examination of the allowability of the petition is restricted to the petitioner's allegation that the contested decision contains in one fundamental respect an inconsistency, with the consequence that it is not reasoned within the meaning of Rule 111(2) EPC (for further details see point III. above). More specifically, the petitioner argued that the inconsistency showed that relevant arguments submitted by the petitioner had not been considered by the Board and consequently Article 113(1) EPC had been violated by the Board.

2.2 The petitioner argued with respect to the alleged inconsistency that it was not logical on the one hand to deny the comparability of the results of the formulation of document D2 with those of comparative example 2 of the patent for the reason that the feature "water soluble protein injectable into body fluids without showing any substantial pharmacological activity" is a "mandatory constituent" of the formulation of D2, which is not present in the comparative example 2 of the patent (point 15.1 of the reasons), and on the other hand not to consider this "mandatory constituent" of the prior art when assessing the inventive step of the patent in suit (point 20 of the reasons).

2.3 In the view of the Enlarged Board of Appeal, however, these arguments are not convincing because they are based on a misunderstanding of the questions dealt with in the contested decision under points 13 to 20, and in particular under points 15.1 and 20.

2.3.1 The Board held under point 13 of the contested decision, with reference to the established case law of the boards of appeal, that if the problem arising in relation to the closest prior art document (to provide microparticles for sustained release based on hyaluronic acid or salts thereof having improved sustained-release properties) is formulated as an improvement over the teaching in that document, there should be evidence that the claimed subject-matter indeed achieves this beneficial effect of improved sustained-release properties, the burden of proof for this lying with the patentee. The Board reasoned clearly and in detail as follows:

2.3.2 Under point 14 it stated that, contrary to the submissions of the petitioner, such an improvement could not be established by the assay of which the results are given in Figure 6 of the patent (test example 5), because no comparison was provided with the sustained-release preparations disclosed in the closest prior art document D2.

2.3.3 Under point 15 the Board observed that the same was true with respect to comparative example 2 on page 9 of the patent, the results of which are summarized in Figure 7 (page 9). It stated that in addition to the preparation of this assay the invention pursuant to document D2 contains as a "mandatory constituent" a

"water soluble protein injectable into body fluids without showing any substantial pharmacological activity". As such a compound is not present in the gel formulation of comparative example 2 and Figure 7 of the patent, it is equally not appropriate to establish an advantage over D2.

2.3.4 Furthermore, the Board stated under point 16 that a direct comparison of the results presented in document D2 with those in the patent would not be appropriate either due to the different molecular weights of the hyaluronic acid and to the different size of the proteins in document D2 and the patent, both differences excluding a direct comparison of the assays presented in each of the documents.

2.4 Thus, the Board discussed under points 13 to 16 the question whether the examples in the patent and those of the closest prior art allowed a comparison between them in order to establish a beneficial effect of the patent over the prior art. As this beneficial effect was not proven by the petitioner due to a lack of comparable examples in the description of the patent, the Board came to the conclusion that it could not accept the problem indicated by the patent proprietor in the patent and that the problem to be solved had to be reformulated as the provision of an alternative, dry hyaluronic-acid based sustained-release preparation for the delivery of water-soluble drugs (point 18).

3. Contrary to what the petitioner appears to have presumed, the question of the existence of comparable examples in the patent proving a beneficial effect over the formulation of document D2 is different from the

question of whether, with regard to the reformulated problem of providing an alternative, the technical solution of the patent involves an inventive step over document D2 as the closest prior art. In order to prove a beneficial effect, the parameters of two assays have to be of a similar substance, whereas with respect to inventive step, when the problem to be solved is only that of providing an alternative, the question is whether or not the disclosed solution is obvious to the skilled person.

3.1 Apart from this, and contrary to the submissions of the petitioner, the Board of Appeal did not disregard the crucial feature "water soluble protein injectable into body fluids without showing any substantial pharmacological activity", which it referred to as a mandatory constituent, when assessing inventive step, as the petitioner seems to have assumed.

3.2 Indeed, the opposite is true. The Board of Appeal stated in the contested decision that neither of the parties had accorded any relevance to features in the claim relating to the particle size, the protein or peptide drug, or to the stabilizer, with the consequence that for the assessment of inventive step, the only question to consider was whether it was obvious with regard to the prior art to provide a composition by spray-drying (point 20). This passage of the decision makes it clear not only that the Board - contrary to the petitioner's submissions - actually discussed the relevance of the stabilizer (i.e. the "mandatory constituent") for the assessment of inventive step during the oral proceedings, but that

the parties and the Board were unanimous in their opinion on this point.

3.3 The reasoning of the Board does not involve an inconsistency but the clear and logical observation that the feature of a stabilizer, which is present in claim 1 of the patent in suit as well as in document D2 - there described in the form of the "mandatory constituent", could not be taken into account for assessing inventive step.

4. Thus, the Enlarged Board unanimously comes to the conclusion that the right to be heard pursuant to Article 113(1) EPC was observed by the Technical Board of Appeal, with the consequence that in so far the petition for review is not to be rejected as inadmissible, has to be rejected as clearly unallowable.

## **Order**

### **For these reasons it is decided that:**

To the extent that the petition for review is not rejected as clearly inadmissible, it is rejected as clearly unallowable.

The Registrar:

The Chairwoman:

P. Martorana

B. Günzel