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**Datasheet for the decision
of the Enlarged Board of Appeal
of 15 September 2015**

Case Number: R 0008/13
Appeal Number: T 1676/08 - 3.3.02
Application Number: 96102992.3
Publication Number: 722730
IPC: A61K 31/485, A61K 9/20,
A61P 25/04
Language of the proceedings: EN

Title of invention:

Controlled release oxycodone compositions

Patent Proprietors:

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Mundipharma Pharmaceuticals BV
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Opponent:

Lannacher Heilmittel Ges.m.b.H.

Headword:

-

Relevant legal provisions:

EPC Art. 112a

EPC R. 104

Keyword:

Violations of the right to be heard: no. Other procedural defects: no
Petition not allowable

Decisions cited:

G 0006/95, G 0002/10, R 0001/08, R 0013/09, R 0016/10,
R 0019/11, R 0015/12, R 0016/13

Catchword:

-



Case Number: R 0008/13

DECISION
of the Enlarged Board of Appeal
of 15 September 2015

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Decision under review:

**Decision of the Technical Board of Appeal
3.3.02 of the European Patent Office of
9 March 2012.**

Composition of the Board:

Chairman: W. van der Eijk
Members: M.-B. Tardo-Dino
E. DufRASne
I. Beckedorf
M. Poock

Summary of Facts and Submissions

- I. This petition for review concerns decision T 1676/08 of Technical Board of Appeal 3.3.02 (hereinafter: the board) dismissing the appeal filed by the patent proprietors (hereinafter: the petitioners) against the interlocutory decision of the opposition division (hereinafter: the decision under appeal), deciding that European patent No. 722 730 could be maintained in amended form. This patent had been granted on the basis of divisional application No. 96102992 originating from parent application WO 93/10765.
- II. The debate during the opposition proceedings and the appeal proceedings, insofar as the present petition is concerned, focused on claim 1 of the patent as granted, and more precisely on the admissibility and the allowability of the disclaimer introduced in order to avoid double patenting with respect to the parent application and, accordingly, on the issue of the disclosed subject-matter in view of Articles 100 (c) and 76 (1) EPC. The claim reads as follows:

"A controlled release oxycodone formulation for oral administration to human patients, comprising:
(a) oxycodone salt in an amount equivalent to 10mg to 160mg of the oxycodone hydrochloride salt, and
(b) a controlled release dosage matrix, other than an acrylic resin matrix selected so that the formulation provides pH-independent dissolution characteristics,
(c) wherein salt formulation provides at steady state after administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 240 ng/ml at 2 to 4.5 hours after administration and a mean

minimum plasma concentration of oxycodone of 3 to 120ng/ml at 10 to 14 hours after administration"

The decision under appeal

III. The opposition division had found that claim 1 did not comply with Article 76(1) and 100 (c) EPC since its subject-matter extended beyond the parent application as filed. It concluded that the logic of G 2/03 did not apply in the situation of parent and divisional applications (point 27.3 of the decision under appeal) and further that "It could be argued that the feature "except an acrylic resin matrix" is not an *undisclosed* disclaimer (in italics in the decision) in the strict sense because the feature "acrylic resin matrix" as such (although in a positive sense) is disclosed in the parent application as filed (see e.g. page 9 of P4), albeit not in combination with the other features of granted claim 1. However, no matter whether the amendment is called disclaimer or not the OD considers that its introduction leads to a specific scope that was not disclosed in the parent application... An amendment leading to claims being directed to all but an acrylic resin matrix in combination with the other claimed features is not directly or unambiguously derivable from the parent application" (point 27.4 of the decision under appeal).

Procedure before the board of appeal

The parties

IV. The petitioners remained the sole appellant after Opponents (interveners)/appellants 3, 4, 5 had

withdrawn their appeal during the appeal proceedings. Opponent 2 had already withdrawn its opposition during the opposition proceedings. A further intervener during the appeal proceedings (Opponent 6) finally withdrew its intervention.

Opponent 1 was a party as of right.

The appeal proceedings

- V. The different steps of the appeal proceedings, which constitute the background to the alleged deficiencies, are summarised below.

The board held three sets of oral proceedings: on 13 and 14 October 2009, 19 October 2010 and 7 to 9 March 2012.

Proceedings up to the first oral proceedings

- VI. The board sent a communication prior to the first oral proceedings (24 March 2009) setting out its preliminary opinion. On page 3 the board wrote that "the introduction of the disclaimer 'other than an acrylic resin matrix' in the definition of component (b) creates an artificial subgroup for the controlled release matrix which was not disclosed in the parent application as filed (P4). The claim further recites that the matrix should be 'selected so that the formulation provides pH-independent dissolution characteristics' (this condition applied to all kind of matrices and not in particular to the subgroup now defined). Hence this artificially created subgroup is limited by a certain functional definition which did

not appear to configure a subgroup of controlled release polymeric materials but was a condition to be attained by the formulation (page 9 of the parent application as filed (P4)...Moreover, in the parent application..., the generic group was defined in claim 5 and on pages 9 and 10 of the parent application...The definition in granted claim 1 introduces technically meaningful boundaries in the definition of the matrix component which were not defined or derivable from the content of the parent application as filed and thus granted patent is not allowable under Article 76(1) EPC."

In their reply by letter of 6 April 2009, the petitioners requested *inter alia* that the following question be referred to the Enlarged Board: "*Is an amendment to a claim made by the introduction of a disclaimer which has been introduced for the sole reason to delimit the subject matter of a divisional application from the subject matter of the (granted) parent case to avoid double patenting unallowable under Article 123(2) EPC and/or 76 EPC?*"

The oral proceedings did not put an end to the proceedings: the debate was closed for the main request and auxiliary requests I to Vb, (containing the disclaimer) and the board decided to stay the proceedings with regard to auxiliary requests VI to VIb which contained only medical use claims, until the decision in pending referral G 2/08 has been issued.

After the first oral proceedings

VII. After G 2/08 was issued on 19 February 2010 (published: OJ EPO 2010, 456), the board summoned for oral proceedings to be held on 19 October 2010.

In their reply (letter dated 22 July 2010) the petitioners requested that the proceedings be suspended until the decision on new referral G 2/10, which had meanwhile been filed on 25 June 2010 and which concerned the allowability of a disclaimer, was issued.

The board by a communication dated 26 August 2010 maintained the date of the oral proceedings and expressed its view that *"although a final decision will be announced at the oral proceedings on 19 October 2010, the board [was] disinclined to reopen the debate which was already closed in the oral proceedings of 13 and 14 October 2010(sic) with respect to the main request and auxiliary requests I to Vb"*.

The petitioners by a letter dated 5 October 2010 requested the enlargement of the board to five members, and reiterated their request to reopen the debate on the above mentioned requests and to stay the proceedings until the outcome of G 2/10 was known. They also requested an explanation from the board as to why the disclaimer did not fulfil the requirements of the EPC, and submitted that a refusal to provide such an explanation would be considered to be a violation of Article 113 EPC.

By a letter of 14 October 2010, Opponent 4 which, at that time, was still an appellant, raised several

objections to the petitioners' claims concerning their right to be heard, because the issue of the admissibility of the disclaimer had been fully discussed and the debate on the main request had been closed during the first oral proceedings. Should the board give any of the information required in order to assist in adjusting further auxiliary requests, this opponent would regard that as a breach of the principle of equal treatment of parties and it would raise an objection under Article 106 EPC.

Second oral proceedings took place as scheduled on 19 October 2010

VIII. At the end of the oral proceedings the board informed the parties that *"in view of the discussion during the oral proceedings, it, on its own motion, intended to refer questions to the Enlarged Board of Appeal concerning, inter alia, the allowability of a disclaimer in a claim wherein the subject matter was delimited by both, structural and functional features"*

After the second oral proceedings

IX. Opponent 4, by a letter dated 12 January 2011, requested further oral proceedings to permit a discussion of the point of law the board intended to be referred to the Enlarged Board.

Summons to oral proceedings to be held before the board extended to five members was sent on 3 May 2011. The board in a communication of 25 October 2011 in accordance with Article 15(1) RPBA drew the parties' attention to the fact that it *"envisage[d] to reopen*

the debate for all requests on file in view of the enlargement of the board to five members (Article 21(4)(b) EPC and of the Enlarged Board of Appeal decision G 02/10 of 30 August 2011".

Oral proceedings initially arranged for 14 to 16 November 2011 were re-scheduled, at the petitioners' request, to 7 to 9 March 2012. The board confirmed in a communication of 22 November 2011 the terms of its previous communication of 25 October 2011 and specified that as to the issue of the referral to the Enlarged Board, considering the parties' submissions so far, the board in its new composition, did not intend at this stage of the proceedings to make such a referral.

The petitioners in a letter of 5 December 2011 submitted that the procedural situation had changed since the parties had received the first and so far only communication (24 March 2009) from the board. In this communication the relevant issues were Article 76 and 123(2) EPC with respect to claim 1 as granted (main request). They requested that the board issue a preliminary non-binding opinion on:

- which issues were considered to be relevant for discussion, especially regarding Article 76 EPC,
- its intention no longer to refer questions of law to the Enlarged Board.

They also requested some guidance on the legal issues and the opposition grounds to be discussed during the hearing, and requested postponement of the oral

proceedings to enable them to prepare appropriate requests.

The board answered on 18 January 2012 that exercising its discretion under Article 15 (1) RPEBA it maintained the date for oral proceedings and would not issue a further preliminary opinion.

With a letter of 7 February 2012 the petitioners filed 117 auxiliary requests and annexed more than 1000 pages, explaining that the high number of requests was their only option, in view of the refusal by the board to communicate any information or guidance about the fundamental issues regarding the relationship between structural and functional features it had in mind and which were not addressed in G 2/10.

Oral proceedings on 7 to 9 March 2012

- X. Right from the beginning of the hearing the petitioners expressed their profound disapproval of the board's way of conducting the appeal proceedings.
- During these oral proceedings three objections under Rule 106 EPC were raised and two requests for referral to the Enlarged Board and two requests for taking evidence were filed.

On 7 March 2012:

- (a) "Objections Rule 106 EPC, Article 112a EPC":
- i. [The] "Board has failed to give proper and adequate or any notice as to what the fundamental legal issue as referred to by the 3-member Board and reaffirmed by the 5-member Board is";*

- ii. *"Failure to give proper and adequate notice of the board's changing position regarding the relevance and applicability of G 2/10"*

(b) Requests for referral:

"Referral suggestion 1":

"Does a disclaimer which exempts subject matter needs [sic] consideration in addition to G 2/10 for the mere fact that the claim comprises structural and functional features?"

If so, does it matter whether the exempted subject matter was originally in the application as originally filed or in the parent application?"

"Referral suggestion 2"

The questions under this heading concerned the decision to extend the board to five members and its change of position about the referral and the obligation for the board to give information in this regard (see annex of the minutes of oral proceedings of 7 to 9 March 2012).

On 8 March 2012:

The patent proprietors *"object under Rule 106 EPC/ Article 112a EPC against a fundamental violation of Article 113 EPC (as meant in Article 112a (2)(c)) and/or other any fundamental defect as defined in the implementing regulations (Article 112a (2)(d)), in particular the refusal by the Board to allow the Patentees to present expert evidence in support of their position that the remaining subject-matter in claim 1 of EP 722 730 is disclosed in the parent application (P4), by:*

-1 the refusal to admit D100;

-2 the refusal to admit the two requests made under Article 117 EPC (Annex A and B of the minutes);
-3 the refusal to allow the opinion of party expert Professor Lamprecht to be heard according to G 4/95..."

On 9 March 2012

The patent proprietors "object under Rule 106 EPC/ Article 112a EPC against a fundamental violation of Article 113 EPC (as meant in Article 112a (2) (c)) and /or any other fundamental defect as defined in the Implementing regulations (Article 112a(2)(d)), in particular the Board's refusal to:

-1 disclose the grounds and/or evidence upon which it intends to determine the question of whether the subject-matter of claim 1 of EP 0 722 730 B1 is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge in the parent application as filed (Document P4), as required by G 2/10 and
-2 give the parties concerned an opportunity to present their comments thereon."

XI. The final decision of the board was announced at the end of the oral proceedings and the parties were notified of the reasons in writing on 28 February 2013. It is analysed *infra* in point 3 ff. of the reasons. The minutes of the oral proceedings were sent to the parties on 3 August 2012.

Procedure before the Enlarged Board of Appeal

XII. The petition for review was filed and the corresponding fee paid on 8 May 2013, on the basis of Article 112a(2) (c) EPC.

The petitioner attached to their request, *inter alia*, the following documents:

- *Pet1*: "Verfassungsbeschwerde" (Deubner and Kirchberg), a constitutional complaint with the German Constitutional Court including a detailed analysis of the human rights and constitutional aspects and an opinion by Professor Broß;
- *Pet2*: Opinion of Professor van Nispen on the conformity of the proceedings before Board 3302 with Article 6 ECHR according to Dutch practice;
- *Pet3*: a joint opinion of Lord Lester of Herne Hill QC and Haniff Mussa;
- *Pet4*: claim analysis;
- *Pet5*: opponent's submissions dated 6 March 2012 before the board;
- *Pet6*: Opinion of Mr Kitzmantel;
- *Pet7*: minutes of oral proceedings of 7 and 8 March 2012 reviewed by the petitioners.

On 24 March 2014, oral proceedings were held before the Enlarged Board in the composition under Rule 109, (2) (a) EPC. At the end of the oral proceedings the Enlarged Board announced that, in compliance with Article 17 RPEBA, the petition was remitted to the Enlarged Board as composed under Rule 109(2) (b) EPC.

With its letter of 12 June 2014, the other party to the petition for review proceedings requested the dismissal of the petition for review.

After the petitioners' letter of 2 June 2014 raising an objection under Article 24(3) EPC against a member of the Enlarged Board, the proceedings were interrupted in

accordance with Article 4(3) RPEBA and were resumed after the decision of 20 March 2015 had been issued.

XIII. Oral proceedings in the five-member composition under Rule 109(2)(b) EPC were held on 15 September 2015. At the end of the oral proceedings the decision was announced.

The final requests were the following

The petitioners requested that:

- the decision under review be set aside and the case be remitted to the board in a different composition;
- the petition for review fee be reimbursed.

The petitioners confirmed that the other requests in the petition originally filed (hearing of the members of the board, and of the petitioners' representatives who attended the oral proceedings before the board) were auxiliary requests in the event that the Enlarged Board needed information about the facts underlying the petition.

The other party requested the rejection of the petition for review.

The petition

XIV. The petition is based on (i) violations of the right to be heard (Article 112a(2)(c) EPC) alleged to have occurred during the appeal proceedings. It also refers to (ii) other procedural defects (fair trial complaints, section VI of the petition). Specific arguments were

also put forward, based on decision R 16/13 and the notion of fair trial (iii).

The petitioners' entire arguments submitted in writing (8 May 2013 petition, 14 November 2013 information about the cases filed before national courts, 24 February, 2 June, 10 September 2014 and 28 July 2015) and presented during the oral proceedings may be summarised as follows:

(i) The decision came as a surprise because, in spite of several requests from the petitioners, the board had refused consistently to communicate the facts, grounds and evidence on which the decision would be based. More precisely, as summarised in the petitioners' submissions of 10 September 2014, pages 43 and 44, in reply to the opponent, the interpretation by the board that "a controlled release matrix" is "any matrix" (emphasis by the present Enlarged Board) other than an acrylic resin matrix which resulted in the specific blood curve range, had as a consequence that the blood curve range (also called the plasma feature) was no longer a selection criterion in itself for delimiting the suitable controlled release matrix. At variance with the petitioners' interpretation, the blood curve range according to the board's interpretation must be the direct result from any thinkable controlled release matrix, and therefore was not a limiting feature. This claim construction was the basis for the decision that claim 1 of the main request did not comply with Articles 76(1) and 100 (c) EPC. This new interpretation was in clear contradiction with the

teaching of the application as filed and appeared for the first time in the written grounds of the decision. None of the opponents had ever raised an objection based on such an interpretation; the only objection under Article 100 (c) EPC was from Opponent 1 in respect of the pH-independent feature.

The allowability of claim 1 and of the disclaimer therein was a moving and hidden target during the entire appeal proceedings: firstly the issue was considered under the case law established by decisions G 1/03 and G 2/03 concerning disclosed or undisclosed disclaimers. Then the board identified a legal issue to be referred to the Enlarged Board, but not known to the parties, and refused to unveil what this legal issue was. Finally, the disclaimer had to be analysed in view of G 2/10 which changed the legal background and created a *de novo* situation. However, the decision did not deal with G 2/10 and had nothing to do with the disclaimer. The decision was based on a specific construction regarding the interrelation of structural and functional features which the petitioners believed had been abandoned in view of the *de novo* situation.

The board had never issued a written communication except for the communication of 23 March 2009 prior to the first oral proceedings, nor answered the questions posed during the oral proceedings.

(ii) There were other procedural defects that the petitioners labelled fair trial complaints (section VI of the petition of 8 May 2013). Although these procedural defects were not listed in Article 112a EPC and Rule 104 EPC, they were based on the basic principle of a party's right to a fair trial and were

part of the petition for review, also in order to comply with the principle of subsidiarity governing the constitutional complaint pending before the Federal Constitutional Court of Germany and the human rights complaints before the EctHR.

These procedural defects were the following:

- (a) The enlargement of the board from three to five members without giving any reason.

Under this heading the petitioners complained that, although the board had started a new case after the enlargement of the board and decision G 2/10, it considered any attempt from the petitioners to file documents or requests in reaction to the new situation to be an amendment of the case and refused to admit them. This amounted to (i) an abuse of the discretionary power by the board, (ii) a denial of the rightful judge according to the constitutional law and (iii) a violation of the right to be heard to the extent that the petitioners were prevented from presenting their case before the board in its full composition.

- (b) There was no preliminary opinion before the third oral proceedings and the board consistently refused to indicate in which way functional features had to be interpreted differently from structural features.

The only argument brought forward by the opponent was not part of the decision. In addition the petitioners were denied the right to file any evidence or auxiliary requests. All

this resulted in a dual abuse of the discretionary power. The application of Articles 13 and 15 RPBA must not result in violation of the fundamental rights of the parties (Article 113 and Rule 116 EPC).

- (c) The minutes of the oral proceedings. Dispatched five months after the oral proceedings, they indicated nothing about the changed status of the proceedings regarding the enlargement of the board and the impact of G 2/10. They were evidence that the petitioners did not have any adequate opportunity to comment on the decisive issues. This lack of relevant information about the course of oral proceedings deprived the petitioners of a basis for the petition for review. The board of appeal had refused to allow transcripts.

- (d) The time between the decision and the provision of the written grounds: almost a year.

Given the inadequacy of the minutes, the "facts and submissions" of the written decision were the only information from the board of appeal regarding the statements made during the oral proceedings. Almost one year after the oral proceedings, the events which took place during these oral proceedings were more reconstructed than reproduced and the delay necessitated a retrospective reconstruction of the reasons. The petitioners also referred to German law in this respect, according to which a decision issued more than five months after oral

proceedings was considered to be not properly reasoned, amounted to a violation of the fundamental right to a fair trial (Article 6 ECHR) and resulted in a fundamental violation of the right to be heard.

(e) Requests for referral.

The interpretation given by the board of claim 1 was new and led to a contradiction with the established case law under Articles 123(2) and 76 EPC. This would have required at least a discussion and clarification by the Enlarged Board. Instead, the board had abandoned its intention to refer a question to the Enlarged Board and the reasons given to reject the petitioners' requests for referral (i.e. that there was no difference between functional and structural features) were in complete contradiction with the main reason for rejecting claim 1 relying on a claim construction that treated one functional feature differently i.e. not as a true limitation.

(f) Under the label of other procedural defects the petitioners also contended that although the board indicated that G 2/10 was the legal framework for the decision, the reasons of the decision did not relate to G 2/10 and nullified its gist. Since the board deviated from this decision it should have referred the issue to the Enlarged Board of Appeal. The refusal of a referral amounted to a denial of the rightful judge in accordance with the German constitution.

(iii) The decision did not fulfil the tests set out in R16/13 nor the requirements of a fair trial. A fair trial implied:

(g) an adversarial procedure. It was not enough to know that the construction of claim 1 was under discussion;

(h) the right to have any material relevant for the case considered. The board had refused to apply the case law: *Lawrence v The General Medical Council, High Court of England and Wales* case No: CO/11086/2010;

(i) the parties were the only ones who could decide which document was worth being discussed.

XV. The submissions of the opponent (other party) filed on 12 June 2014 and 17 August 2015 are summarised as follows.

It was not clear from the petition on which objection according to Rule 106 EPC the petitioners intended to base their petition regarding the violations of the right to be heard. It was also not clear which relationship the "fair trial complaints" in section VI had with the alleged violations of the right to be heard.

The parties to *inter partes* proceedings were not entitled to advance indications of the reasons for a decision before it is taken (R 12/09 of 15 January 2010, R 15/10). In the present case the parties were informed by the board that the main issue to be discussed during

the third oral proceedings was the new decision G 02/10 in relation to the assessment of added subject-matter, and this issue was discussed at length.

The petition for review was based on an incorrect interpretation of the decision of the board of appeal; when the petitioners read the construction of the claim by the board as meaning that the *blood plasma feature* was not a limiting feature or that this feature was said to be inherent to, or the unavoidable result of, the combination of the other features, they in fact read their own facts. This was an incorrect presentation of facts or construction of the decision. There was no violation of the right to be heard.

Reasons for the Decision

1. Admissibility

The requirements of Article 112a (4) EPC, regarding the time limit and payment of the fee, are met.

As to the requirement of Rule 106 EPC, three objections under this rule were raised during the oral proceedings (X *supra*) which cover the alleged violations of the right to be heard.

The grounds linked to reasoning in the written decision could not be known during the oral proceedings.

The present petition for review is admissible.

2. Allowability

The petitioners' grounds may be grouped in two categories which to some extent overlap:

- violations of their right to be heard (A); and
- other procedural defects (B).

Preliminary remarks about the principles to be applied:

Article 113 EPC/ fair trial

1. The Enlarged Board of Appeal subscribes to the petitioners' view that the right to be heard is not a mere formal concept for an opportunity to speak but a real right for a party to be aware of, and comment on, the decisive issue(s) on which the board is going to base its decision. In this respect the Enlarged Board fully endorses the analysis of decision R 16/13 of 8 December 2014 which in particular stated: "*Demnach ist das Recht, gehört zu werden, gewahrt, wenn eine Partei die Gelegenheit erhalten hat, sich zu den entscheidungserheblichen Gesichtspunkten des Falles... zu äußern, wenngleich die Kammer aus der Erörterung der vorgebrachten Gründe letztlich ihre eigenen Schlüsse ziehen können muss (R 15/12 vom 11 März 2013 Nr.5a der Gründe). Dies bedeutet, dass die Kammer ihre Entscheidung nur auf Gründe stützen darf, die im Beschwerdeverfahren angesprochen worden sind und deshalb die Parteien nicht überrascht haben konnten*" "So a party has been given the right to be heard, if it has had an opportunity to comment on the decisive aspects of the case..., even if, ultimately, the board must be able to draw its own conclusion from the discussion of the grounds put forward... This means that

the board may base its decision only on grounds which were addressed and thus could not come as a surprise to the parties" (Reasons point 3.3) (translation by the Enlarged Board).

The Enlarged Board also agrees that Article 13 RPBA which is to be applied in compliance with Article 114 EPC cannot thwart the application of Article 113 EPC.

2. On the other hand, according to established case law, the right to be heard does not go so far as to impose a legal obligation on a board of appeal (like any other judicial body) to disclose in advance to the parties, how and why, on the basis of the decisive issues under discussion - or at least those foreseeable as the core of the discussion (in this case: the different possible roles of the functional features) - it will come to its conclusion. This is part of the reasoning given in the written decision (R 1/08 of 15 July 2008, Reasons point 3.1; R 13/09 of 22 October 2009, Reasons point 2.6.3; R 16/10 of 20 December 2010, Reasons point 2.2.4; R 19/11 of 2 October 2012 Reasons point 2.2; R 15/12 of 20 December 2012 Reasons point 5; and also R 16/13 *supra*, Reasons point 3).

The Enlarged Board will first analyse the decision under review before examining complaints A and B

3. In point 8.3 of the reasons, the board indicated how it was applying the principles laid down in G 2/10. Starting from the Enlarged Board's answers to the questions referred, the board explained that it had to evaluate the disclosure of the parent application as filed in comparison with the subject matter remaining in the claim after amendment due to the disclaimer

- (point 4.6 of G 2/10). In point 8.4 it then noted that a disclaimer introduced in a divisional application to avoid double patenting had been considered legitimate by decision G 2/10 (point 4.5.5 of the Reasons), and thus concluded (point 8.5) that the construction of claim 1 was a necessary step in order to assess what the subject-matter claimed was.
4. The board considered that claim 1 was a product claim defined by structural and functional features (points 8.5.1 to 8.5.4) and stated that the pharmacokinetic plasma profiles (also called "plasma feature" in the discussion) were attainable by means of any controlled release dosage matrix, which was not an acrylic resin matrix, and which did not cause pH-dependent dose dumping (points 8.5.2 and 8.5.4).
 5. From point 8.6.1 to point 8.6.6 the board discussed different passages in the parent application which disclosed:
 - the general principle but not the claimed values of oxycodone salt nor the C_{min} and C_{max} (corresponding to the plasma feature),
 - a matrix which performed the required functions but *in vitro* (page 9 of the parent application),
 - the possible materials of the matrix (page 10 of the parent application; claims 5 and 6 of the parent application).
 6. The board concluded that it could not be derived from these passages that any of the controlled release matrices was able to provide the pharmacokinetic plasma profile required in claim 1 of the main request, or that any controlled release matrix could achieve the

plasma profiles without the occurrence of an acrylic resin (point 8.6.4, last sentence). The parent application did not disclose the combination of features (a) the oxycodone salt (the active ingredient), (b) a controlled release dosage matrix providing a pH independent dissolution which was not an acrylic resin matrix and (c) the desired plasma concentration. Accordingly the subject-matter of claim 1 remaining after the introduction of the disclaimer extended beyond the content of the parent application (point 8.6.7).

(A) The alleged violations of the right to be heard

7. The core of the petition is that the decision came as a surprise because the specific construction of claim 1 which turned out to be the decisive and crucial element, on which the decision was based, was in fact raised *ex officio* by the board and never communicated to the parties. More precisely, the board singled out a specific feature, namely the functional plasma profiles, feature (c) of claim 1, and gave it a very specific meaning in combination with the controlled release matrix feature (feature (b) of claim 1), the latter feature being both structural and functional. This amounted to raising *ex officio* a new ground of opposition, the petitioners contended.

8. The argument that this conclusion was the result of an unexpected specific construction of the claim has two aspects:

(a) Such a construction had never been present in the debate since the outset of the opposition

proceedings, as it had never been raised by any opponent. It was in contradiction with the previous construction of claim 1 by the opposition division and by the board in its first communication. It was not predictable. This line of argument requires looking into the file history.

- (b) This objection is coupled with the contention that the specific claim construction had nothing to do with the debate, which was to be expected about the disclaimer and decision G 2/10. While the debate had been reopened precisely in order to discuss the admissibility of the disclaimer in view of G 2/10, the board in fact, under cover of remaining subject matter and G 2/10, took a general approach to the claim and dealt with its compliance with Articles 76(1) and 100(c) EPC on the basis of the interplay of structural and functional features which the petitioners had thought no longer relevant. This second aspect no longer concerns the facts but rather is the petitioners' assessment of the merits of the analysis of the facts and of the correctness of the interpretation of the principles applied by the board.

As to the first aspect of the argument (a)

9. To determine which subject matter (grounds, facts and evidence) could have been expected to be discussed, and whether new facts and grounds were introduced *ex officio* by the board of appeal in its decision, the Enlarged Board has to check the file history.

- 9.1 The decision of the opposition division made clear that an amendment leading to claims being directed to all but an acrylic resin matrix in combination with the other claimed features was not directly or unambiguously derivable from the parent application (point 27.4 of the reasons and also *supra* point III). It is true that the decision was issued prior to G 2/10 but the construction of the claim expressed there was, in fact, irrespective of the principles developed by the case law. Furthermore, it anticipated the notion of "remaining subject matter" of G 2/10. ("*... no matter whether the amendment is called disclaimer or not, the OD considers that its introduction leads to a specific scope which was not disclosed in the parent application*").
- 9.2 It must be borne in mind that the task of the board of appeal was firstly to check whether the reasons supporting the decision of the opposition division under appeal were cogent (R 16/13, *supra*, point 5). Therefore the subject-matter of the appeal was determined by the content of the decision under appeal.
- 9.3 In its first communication (24 March 2009) prior to the first oral proceedings the board also made clear that the introduction of the disclaimer created an artificial subgroup (*supra* VI) not disclosed as such in the parent application.
10. In this respect the petitioners counter-argued that the reasoning in the decision of the opposition division and the opinion of the board of appeal were of no relevance because they did not concern the feature of the plasma concentration (Cmin, Cmax) but only the pH

independent feature and that for ten years the discussion had never concerned this feature. It is true, as appears from the file, that the relationship between the controlled matrix other than a resin matrix and the plasma profile feature had not been singled out, either by any opponent in their written submissions or by the board in its communication mentioned above.

It is also true that one cannot establish what exactly was discussed during the oral proceedings.

11. However, firstly, the general terms of the decision of the opposition division ("an amendment leading to claims being directed to all but an acrylic resin matrix in combination with the other claimed features") and in the communication ("Hence *this artificially created subgroup is limited by a certain functional definition which did not appear to configure a subgroup of controlled release polymeric materials but was a condition to be attained by the formulation*"... "The definition in granted claim 1 introduces technically meaningful boundaries in the definition of the matrix component..." *supra* point VI - emphasis by the Enlarged Board) excludes the petitioners' restrictive interpretation and leads to the conclusion that the scope of the appeal entailed a global evaluation of the claim. There was no reason for a non-biased reader to understand the functional features referred to as only the matrix defined by the pH-independent feature, and for not considering all the possible functional boundaries.

12. Secondly, even though no reasons were given at the end of the first oral proceedings, the logical conclusion to be drawn from the decision to close the debate on

auxiliary requests I to Vb which contained the disclaimer, while continuing in writing with respect to auxiliary requests VI to VIb, is that the board stuck to its analysis set out in the communication (*supra* point 9.3).

13. Thirdly, it must be borne in mind that the appeal procedure is mainly in writing; the written submissions have also to be taken into account. In this respect the petitioners in their written submissions of 7 February 2012 in preparation of the oral proceedings, page 24 ff., referred expressly to the passage of G 2/10 where it was explained that the disclaimed subject matter should not lead to a particular meaning of the remaining subject-matter which was not originally disclosed. They contended that the remaining group of matrices was only a generic group limited in size, and the removal of the acrylic resin matrix did not lead to the combination of specific meanings attached to the remaining group of retardants created by the removal of acrylic resins from this group, and that specific retardants as such were not connected with the effects associated with the invention (paragraph bridging pages 26 and 27). The Enlarged Board reads these arguments, which were not limited to the pH-independent feature, as a rebuttal of the foreseeable analysis of the board, i.e. the petitioners obviously had in mind the possible combinations of structural and functional features referred to so far by the opposition division in its decision and by the board in its communication, even if each of the possible combinations between structural and functional features had not been expressly addressed. It was indeed within the normal understanding of any qualified party to identify which

kinds of combinations were at stake and needing to be interpreted, particularly bearing in mind the known concern of the board about the relationship between the different features (structural and functional). The declaration from Mr Van Nispen (Pet2) who, prior to the oral proceedings, tried to foresee the possible interpretations the board might come to, one of them being that the functional features played a role in the definition of the claim, and the request for referral to the Enlarged Board submitted by the petitioners during the appeal proceedings (Referral suggestion 1, *supra* point X(b)), are further evidence that the petitioners were aware of the issue related to the interplay of all the features.

14. Therefore the Enlarged Board cannot see anything in the decision of the opposition division, or in the first communication of the board and the whole proceedings, which could have caused the petitioners to think that the debate would be restricted to the "ph-independent feature" only, or that the interrelationship of the different structural and functional features was no longer a relevant issue.

15. Lastly it appears from the decision that the board was aware of the petitioners' position and considered it (facts and submissions of the decision under review *LIII* under heading d) "*the appellants' claim requests*" pages 39 ff.; and points 8.7 ff. of reasons). As reported by the board, the petitioners explained at length why the material of the matrix was irrelevant, what the core subject-matter of the invention was, and that any matrix could be taken provided it had all the required functionality. The petitioners also filed an

- auxiliary request 2a in response to the objection that the teaching in relation to the pharmacokinetic profile could not be combined (page 52, end of paragraph e) of the facts and submissions of the decision under review).
16. The Enlarged Board is aware of the petitioners' objections that the facts and submissions summarised by the board in its decision are not all supported by the minutes of the oral proceedings, which, in the petitioners' view, renders the board's summary not reliable. However, the arguments brought forward by the petitioners during the review proceedings against the construction of the claim by the board - in line with the petitioners' written submissions referred to *supra* point 13 - tally with the arguments taken into consideration in the decision and corroborate the correctness of the facts and submissions part of the decision in this respect. The board discussed these arguments, gave its own construction of the claim, which was indeed at variance with the petitioners' position, and explained why, in view of G 2/10, the petitioners' arguments were not accepted (8.7 ff.).
17. It follows from the above that the Enlarged Board cannot accept the contention that the claim construction and the consequences drawn from it came as a surprise, or that the petitioners were left in the dark. The board did not accept the petitioners' analysis. While they contended that the matrix was necessarily limited by the functional plasma feature and the skilled person would know which matrices to choose, the board reasoned in terms of mere disclosure of the combination of all features, applying its interpretation of the principles of G 2/10 as shown

- below. It is indisputable that the petitioners, like the other parties (see the letter of opponent 4 of 14 October 2010; VII *supra*), were aware of what the crucial issues were, namely the disclosure of the combination of features (a), (b) and (c) wherein the controlled release dosage matrix was defined by functional features.
18. To conclude on this point, the Enlarged Board notes that what the petitioners expected from the board was that, after considering their arguments about the limiting effect of the plasma profiles feature (see the passage under facts and submissions paragraphs (d) and (e)) (already quoted in point 15 *supra*), it would explain to the parties how it had come to the conclusion that the combination was not disclosed and why it was not persuaded by the petitioners' arguments. That is however beyond the right to be heard or the requirements of adversarial proceedings, and concerns the intellectual process of substantiating the decision, as explained in R 16/13 (*supra* 2)
19. In R 16/13, referred to by the petitioners, the Enlarged Board noted that the board, *ex officio*, had given an evaluation of the comparative tests, filed in order to show an improvement compared with the closest prior art which was at variance with the evaluation made hitherto by the examining division, the opposition division and both parties, and without giving the parties any opportunity for being acquainted with this evaluation nor for commenting on this new approach.
20. That situation is not comparable with the present one, where the interpretation of the combination claimed in

claim 1 and the admissibility of the disclaimer with respect to Articles 76(1) and 100(c) EPC had been central to the case since the proceedings before the opposition division. The creation of a non-disclosed subgroup of matrices resulting from the introduction of the disclaimer had first been pointed out by the opposition division and was also mentioned by the board. From both the decision under appeal and the communication of the board drawing attention to the definition of the matrix component by functional features, a representative with normal experience and training could foresee what the crucial issues were for the board, and which features and possible combinations were at stake (R 16/13 point 3, last sentence).

21. It results from the above that the contention that the debate should have been limited to the pH-independent feature and that the discussion concerning the disclosure of the other features in the decision under review came as a surprise is belied by the file history.

As to the second aspect of the argument (b)

22. The petitioners also expressed their objection by saying that there were two periods in the appeal proceedings and two legal bases: at the beginning the board only considered G 1/03 and G 2/03 and later, once decision G 2/10 became known, the board changed its approach of the claim. In the end, instead of dealing with the subject-matter in the light of G 2/10, it went for the specific construction, based on a particular relationship between structural and functional features. The petitioners have repeatedly claimed that this specific construction corresponded to the particular

legal issues the board had had in mind since announcing on 19 October 2010, in its three member composition, its intention to refer of its own motion a question to the Enlarged Board (*supra* point VIII).

23. As suggested by the other party, the petitioners have a reading of the decision which is not objective.

Without of course attempting any assessment of the substantive issues, it results from an objective reading of the decision (*supra* point 3) that the logic of the reasoning revolved around the application of Article 76(1) EPC: the board, according to the method taught in case G 2/10, construed claim 1 found not allowable by the opposition division in a way which did not deviate from its first communication and checked whether this claim was disclosed in the parent application (*supra* points 9.2,11 and 14).

24. The petitioners' assertion that this analysis had nothing to do with G 2/10 is factually incorrect as shown below.

- 24.1 As analysed above in point 8 a distinction (that was not clear in the petitioners' arguments) is to be made, between, on the one hand, the construction of the claim without the disclaimed subject matter (*supra* points 9 to 14) and, on the other hand, the legal approach under Articles 76(1) and 100(c) EPC to the subject-matter thus construed. Decision G 2/10 may have made it clear, adding to the existing case law, that a disclaimer in a divisional application is not inadmissible merely because it was introduced solely to avoid double patenting with the parent application. But this

decision did not change the basic requirements of Articles 76(1) and 100(c) EPC in line with G 1/03 and G 2/03 (point 4.6 of G 2/10).

- 24.2 Furthermore, considering the history of the case and the issues under discussion so far (*supra* points 9 to 14), the Enlarged Board cannot see that G 2/10 started a *de novo* construction of the claim in the light of the notion of remaining subject matter which had always been present in the debate (see earlier the opposition division's decision). The allegation that under the principles set out in G 2/10 the feature of Cmin and Cmax was immaterial is a personal view of the petitioners. The Enlarged Board sees in the decision under review no more than the application of G 2/10, particularly points 4.5.4 about the need for a technical assessment of the case and 4.6 about divisional applications and Article 76(1) EPC. Reference is also made to pages 8 and 9 of the minutes as reviewed by the petitioners, according to which the respondent-opponent stated that the disclaimer always generated remaining subject matter which was a new subgroup, relying on the statement of the board in the communication issued in 2009 in its three-member composition (page 3).

The petitioners' additional arguments in respect of the alleged procedural deficiencies (b), (e), and (f) of (ii) in point XIV supra are rendered moot by the conclusion above that no de novo construction has occurred (point 24.2 supra):

25. Ground (b) of (ii) in point XIV: The petitioners did not obtain further communications after the one issued

prior to the first oral proceedings, despite their requests in writing (of 5 December 2011 and during the oral proceedings) and orally. This complaint fails because (i) apart from the fact that there was no obligation on the board to issue a communication (G 6/95, OJ EPO 1996, point 5, page 657), (ii) the communication of 18 January 2012 in reply to the petitioners' request implicitly meant that the board had the same analysis about the scope created by the disclaimer, and (iii) the reasons set out in points 9 to 14 above apply.

26. The petitioners further complained that the board had withheld the technical information about this specific interpretation, despite their repeated requests for clarification, for hearing a technical expert (Pr. Lamprecht) or for referral to the Enlarged Board.

26.1 The petitioners criticised the board because it applied to the facts, grounds and evidence the principle set up by the Enlarged Board, in particular in R 6/11, according to which *"the parties are not entitled to advance indications of the reason or reasons for a decision before it is taken...If that principle applies to the reasons for a decision generally, it must apply to a comment forming only a part of such reasons"* (point 7.1 of the reasons).

26.2 In fact, in point 7.2, the board merely explained why it did not need an external expert to interpret the claim; a claim is construed by reference to the common general knowledge of the skilled person and does not need the competence of an expert (point 4.5.4 of G 2/10); in the board's analysis, construing claim 1

did not go beyond the expertise of the three technical members of the board. It cannot be said that the board refrained from giving any information, since everything necessary to interpret the claim was clearly open to discussion (*supra* points 9 to 14). The Enlarged Board does not see any possible relevance here of *Lawrence v The General Medical Council, High Court of England and Wales*, case No. CO/11086/2010 cited. The general point made in this judgement was the need to avoid taking a decision on the basis of an expert opinion that has not been submitted to the parties as evidence or argument. In the present case the "evidence" boiled down to the disclosure of the combination of features and the choice between two claim constructions: the petitioners' construction or, if that were not accepted, the construction hitherto found non-compliant with Articles 76(1) and 100(c) EPC by the opposition division and the board. Once again, there is nothing to support the petitioners' complaint that they had no idea that the possible combination of features (a), (b) and (c) could result in the undisclosed subgroup according to a possible interpretation by the person skilled in the art.

26.3 The Enlarged Board therefore does not see that the board withheld technical information. So the refusal of all the requests in this respect does not amount to a procedural violation. Therefore there is nothing that might infringe Article 6 ECHR. This is different from the situation that was considered in R 16/13 to be a violation of the right to be heard (*supra* points 19 and 20).

27. *Grounds (e) and (f) of (ii) under point XIV supra:*

As to the refusal of the requests for referral to the Enlarged Board and the alleged refusal by the board to reveal the point of law regarding the interrelation of the structural and functional features it had previously intended to refer to the Enlarged Board, the Enlarged Board notes (i) that the board gave its reasons (points 10ff. of the reasons) and (ii) that it does not fall within the ambit of the petition for review proceedings to evaluate their merits, (iii) it results from the decision that the "point of law" applied was the interpretation of Articles 76(1) and 100(c) EPC in view of G 2/10 (*supra points 22 to 24*). Lastly the reasons set out under (A) *supra*, in particular in points 22 to 26, apply here.

(B) Other procedural defects (a), (c) and (d) of (ii) under point XIV *supra*

28. The petitioners cited the adage that "justice delayed is justice denied". The delay in issuing the minutes and the written decision amounted to an unreasoned decision, according in particular to German case law, in the sense that the facts had to be reconstructed. This alleged defect is not however one of those that can give rise to a petition for review. In any case, the delays in sending both the minutes and the decision, a consequence of the length of proceedings and the quantity of submissions (see the facts and submissions), have no causal link with the decision issued at the end of oral proceedings. Nor has any procedural deficiency been identified as a consequence of this, admittedly, unsatisfactory situation.

29. The change of composition of the board and the abandonment of its intention to make a referral to the Enlarged Board are not per se procedural deficiencies. The petitioners themselves had requested an enlargement of the board, by letter of 5 October 2010. The fact that the board decided to enlarge later "for complexity of the case" does not change the background to the case, and this administrative measure had no detrimental consequences, in the light of the reasons given *supra* in points 9 to 14).

As to the change of mind regarding the referral to the Enlarged Board, the board explained the reasons and the present Enlarged Board cannot, in the light of the analysis *supra*, see any breach of the right to be heard or any violation, let alone a violation that might justify a petition for review.

30. The reasons set out in points 9 to 21 and 28 *supra* also apply to grounds (iii) of point XIV *supra* about the adversarial character of the proceedings, which overlapped with the grounds dealt with in these points.
31. It results from the above that the grounds for the petition based on the violations of the right to be heard are ill-founded because the petitioners relied on an overly broad definition of the right to be heard and (ii) the petitioners' strong disagreement with the board's construction of the claim in itself and with the whole decision (Pet6, analysis by Mr Kitzmantel), which, according to the petitioners, "nullified the gist of decision G 2/10" and is at odds with the

established case law does not fall within the ambit of the petition for review procedure.

(i) The right to be heard, or the party's rights in an adversarial litigation, does not encompass giving the parties the reasons why the board does not accept their arguments; that is part of the reasoning of the decision based on the arguments of the parties (*supra* point 18).

(ii) As made clear by the *travaux préparatoires* for Article 112a EPC, under no circumstances should the petition for review be a means to review the application of substantive law. A review of the application of the substantive law would mean adding a third instance to the procedure before the EPO (CA/PL 17/00 of 27 March 2000, point 11). Consequently the Enlarged Board cannot be requested to evaluate the construction of the claim and the application G 2/10.

32. It results from the above that the petition for review is unallowable.

Order

For these reasons it is decided that:

The petition for review is rejected as unallowable.

The Registrar

The Chairman

Mr Martorana

Mr Van der Eijk