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Datasheet for the decision of 9 March 2015

Case Number: T 1938/09 - 3.3.02

Application Number: 98906678.2

Publication Number: 0964677

IPC: A61F13/00, A61K31/485, A61K9/70

Language of the proceedings: EN

Title of invention:
SUSTAINED ANALGESIA ACHIEVED WITH TRANSDERMAL DELIVERY OF BUPRENORPHINE

Patent Proprietor:
EURO-CELTIQUE S.A.

Opponents:
Hexal AG
Acino AG

Headword:
TRANSDERMAL DELIVERY OF BUPRENORPHINE / EURO-CELTIQUE

Relevant legal provisions:
EPC Art. 24, 84, 116(4), 112a(2)(c), 112a(3), 123(2), 114(2)
RPBA Art. 3(2), 13, 15(2)
Basic proposal for the revision of the EPC MR/2/00

Keyword:

Admissibility of objection of partiality (yes) -
No delay and sufficient substantiation
Admissibility of auxiliary requests (yes) -
Bona fide attemps to remedy newly raised deficiencies
Admissibility of auxiliary requests (no) -
Not clearly allowable and raising complex problems at late stage
Postponement of oral proceedings because of pending petition for review of a decision rejecting an objection based on suspected partiality (no) - No suspensive effect
Referral of questions to the Enlarged Board of Appeal (no)
Amendments -
extension beyond the content of the application as filed (yes)
Claims - clarity after amendment (no)

Decisions cited:

G 0002/04, R 0012/09, R 0017/09, R 0019/12

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 1938/09 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 9 March 2015

Appellant: (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)
Respondent: (Opponent 1)	Hexal AG Industriestrasse 25 83607 Holzkirchen (DE)
Representative:	ter Meer, Nicolaus Ter Meer Steinmeister & Partner Patentanwälte mbB Mauerkircherstrasse 45 81679 München (DE)
Respondent: (Opponent 2)	Acino AG Carl-Feichtner-Ring 1 83714 Miesbach (DE)
Representative:	Best, Michael Lederer & Keller Patentanwälte Partnerschaft mbB Unsöldstrasse 2 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 24 July 2009 revoking European patent No. 0964677 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	U. Oswald
Members:	H. Kellner
	R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 964 677, based on application No. 98 906 678.2 and on international application No. PCT/US1998/003584 published as WO 1998/036728, was granted with sixteen claims.

Independent claim 1 as granted reads as follows:

"The use of buprenorphine in the preparation of a transdermal delivery system for treating pain in a human patient for a dosing interval of 7 days,
said transdermal delivery system being suitable for administering buprenorphine transdermally to a human patient by applying the transdermal delivery system to the skin of a patient,
and having a mean relative release rate of 0.3 µg/hr to 9 µg/hr from 72 hours until 168 hours after the initiation of the dosing interval

such that mean plasma concentrations are provided as follows:
a mean plasma concentration from 0.3 to 113 pg/ml at 6 hours after initiation of the dosing interval;
a mean plasma concentration from 3 to 296 pg/ml at 12 hours after initiation of the dosing interval;
a mean plasma concentration from 7 to 644 pg/ml at 24 hours after initiation of the dosing interval;
a mean plasma concentration from 13 to 753 pg/ml at 36 hours after initiation of the dosing interval;
a mean plasma concentration from 16 to 984 pg/ml at 48 hours after initiation of the dosing interval;
a mean plasma concentration from 20 to 984 pg/ml at 60 hours after initiation of the dosing interval;

a mean plasma concentration from 20 to 1052 pg/ml at 72 hours after initiation of the dosing interval;
a mean plasma concentration from 23 to 1052 pg/ml at 96 hours after initiation of the dosing interval;
a mean plasma concentration from 23 to 1052 pg/ml at 120 hours after initiation of the dosing interval;
a mean plasma concentration from 22 to 970 pg/ml at 144 hours after initiation of the dosing interval; and
a mean plasma concentration from 19 to 841 pg/ml at 168 hours after initiation of the dosing interval."

II. Oppositions were filed against the granted patent under Article 100(a) EPC, lack of novelty and inventive step, Article 100(b) EPC, insufficiency of disclosure, and Article 100(c) EPC, added subject-matter.

III. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

Expert opinion of Mr. Broß dated 7 September 2012, and filed by appellant's fax of 6 May 2014; filed for the first time to the EPO by letter of 8 May 2013 in review case R 8/13

Statement of a former chairperson of a technical board of appeal, dated 6 May 2014, and filed by appellant's fax of the same day

Excerpts from the OJ EPO showing the composition of the Presidium of the Boards of Appeal in the years 2004 to 2014, filed by letter of 28 August 2014

(E29) Driscoll, C.E., "Pain Management", Primary Care Vol. 14 (1987), No. 2, 337-352

IV. By its decision posted on 24 July 2009, the opposition division revoked the patent under Articles 101(2) and 101(3)(b) EPC.

The opposition division held that claim 1 of the patent as granted contained subject-matter extending beyond the content of the application as originally filed (Article 100(c) EPC).

Additionally, the subject-matter of the first auxiliary request was not inventive (Articles 100(a) and 56 EPC).

A second auxiliary request submitted during the proceedings was not admitted because it was held to be not suitable to overcome the objections against the patentability of the subject-matter of the first auxiliary request.

V. The patent proprietor lodged an appeal against that decision and filed grounds of appeal together with a request to maintain the patent as granted according to its main request or in amended form according to any of the first to fourth auxiliary requests. The first auxiliary request was identical to the first auxiliary request before the opposition division.

As a reply to the submissions of the respondent-opponents, the appellant filed auxiliary requests I to IV with letter of 19 December 2012.

VI. Both respondents had filed a response to the grounds of appeal, both dated 14 June 2010. They did not comment on auxiliary requests I to IV.

VII. Claim 1 of the first auxiliary request is derived from claim 1 as granted by adding the feature regarding a

mean relative release rate of 3 µg/hr to 86 µg/hr **until 72 hours** after the initiation of the dosing interval to the claim (emphasis by the board).

Claim 1 of the second auxiliary request is worded like claim 1 of the first auxiliary request, but it concerns buprenorphine base instead of buprenorphine.

In claim 1 of the third auxiliary request, besides the amendments in the foregoing auxiliary requests, the passage "wherein the transdermal delivery system comprises a polymer matrix layer which comprises the buprenorphine base" is added at its end.

In claim 1 of the fourth auxiliary request, besides the amendments in the foregoing auxiliary requests, the passage "and wherein the T_{max} occurs from 3 to 5 days after application of said transdermal delivery system" is added at the end of claim 1.

The single claims of auxiliary requests I to IV are derived from claims 1 of the first to fourth auxiliary requests in that in each of them "moderate to severe" is introduced before the word "pain".

VIII. After the summons to oral proceedings had been dispatched on 30 September 2013, the appellant requested the recording of a transcript of the oral proceedings with letter of 7 April 2014.

By letter of 6 May 2014 it filed an objection under Article 24(3) EPC to the members of the board on the ground of suspected partiality "in the event that any member of this appeal board has acted or is acting as the appointed substitute of VP3 in the course of these appeal proceedings".

The oral proceedings originally scheduled for 8 May 2014 were thereupon cancelled.

IX. By letter dated 15 May 2014 the board summoned the parties to oral proceedings to be held on 1 and 2 October 2014 and issued a communication pursuant to Article 15(1) Rules of Procedure of the Boards of Appeal (RPBA). It questioned the admissibility of the objection, and stated that at the oral proceedings it would decide on that issue in its original composition.

X. Observations on the admissibility of the objection were filed by the appellant in its letter of 20 June 2014 and by respondent 01 in its letter of 6 August 2014. The appellant, by letter of 28 August 2014, restricted its objection under Article 24(3) EPC to the Chairman of the board. The objections to the other members of the board were not maintained.

By fax of 19 September 2014 the appellant filed *inter alia* conditional requests for the referral of questions to the Enlarged Board of Appeal (EBA) and for a stay of the proceedings. The board issued a further communication on 24 September 2014 in which it expressed the preliminary view that the objection now restricted to the Chairman of the board was admissible.

Further, it indicated that it intended to reject the appellant's request for recording of a transcript of the oral proceedings and making it available to the parties.

XI. On 1 and 2 October 2014, oral proceedings took place before the board.

As far as the Article 24 EPC-related issues were concerned, the board decided in accordance with Article 116(4) EPC that they were not public.

XII. After hearing the parties and then deliberating, the board rejected the appellant's request for recording of a transcript of the oral proceedings and making it available to the parties.

XIII. After the board in its original composition had heard the parties and deliberated on the matter, the Chairman announced that the board had decided that the objection under Article 24(3) EPC against him was admissible.

XIV. The Chairman was replaced by an alternate to decide on the objection according to Article 24(4) EPC. The board in its alternate composition refused the objection by decision of 2 October 2014.

XV. The Chairman resumed the public oral proceedings before the board in its original composition on the same day. The board took notice of a written statement of the appellant filed "for inclusion in the minutes" (see attachment to the minutes of oral proceedings of 2 October 2014).

XVI. During the oral proceedings the appellant filed auxiliary request V, which was admitted into the proceedings.

The wording of its single claim is as follows (amendments to claim 1 of the main request, which is claim 1 as granted, are shown in bold by the board):

" The use of buprenorphine in the preparation of a transdermal delivery system for treating **moderate to**

severe pain in a human patient for a dosing interval of 7 days,
said transdermal delivery system being suitable for administering buprenorphine transdermally to a human patient by applying the transdermal delivery system to the skin of a patient,
and having a mean relative release rate of 3 µg/hr to 86 µg/hr until 72 hours after the initiation of the dosing interval and a mean relative release rate of 0.3 µg/hr to 9 µg/hr from 72 hours until 168 hours after the initiation of the dosing interval

such that mean plasma concentrations are provided as follows:
a mean plasma concentration from 0.3 to 113 pg/ml at 6 hours after initiation of the dosing interval;
a mean plasma concentration from 3 to 296 pg/ml at 12 hours after initiation of the dosing interval;
a mean plasma concentration from 7 to 644 pg/ml at 24 hours after initiation of the dosing interval;
a mean plasma concentration from 13 to 753 pg/ml at 36 hours after initiation of the dosing interval;
a mean plasma concentration from 16 to 984 pg/ml at 48 hours after initiation of the dosing interval;
a mean plasma concentration from 20 to 984 pg/ml at 60 hours after initiation of the dosing interval;
a mean plasma concentration from 20 to 1052 pg/ml at 72 hours after initiation of the dosing interval;
a mean plasma concentration from 23 to 1052 pg/ml at 96 hours after initiation of the dosing interval;
a mean plasma concentration from 23 to 1052 pg/ml at 120 hours after initiation of the dosing interval;
a mean plasma concentration from 22 to 970 pg/ml at 144 hours after initiation of the dosing interval; and
a mean plasma concentration from 19 to 841 pg/ml at 168 hours after initiation of the dosing interval

wherein at 72 hours after the initiation of the dosing interval the dosing of buprenorphine during the at least next 48 hours is maintained in accordance with zero order kinetics."

XVII. After admission of this auxiliary request at the end of the second day of the oral proceedings the Chairman announced that the proceedings would continue in writing.

XVIII. On 17 October 2014 the board summoned to oral proceedings to be held on 9 to 13 March 2015 and sent a communication pursuant to Article 15(1) RPBA. With its communication the board indicated *inter alia* that the parties should be prepared to discuss the single claim of auxiliary request V with respect to all requirements of the EPC.

XIX. With letter of 23 December 2014 the appellant requested that the oral proceedings be postponed because it intended to file a petition for review with respect to the decision to refuse the objection under Article 24(3) EPC against the Chairman of the board. It further requested that the following questions 1 to 3 be referred to the EBA unless the board agreed to the postponement.

The questions read as follows:

"1) Where one member of the Board of Appeal before which the case is pending has been objected to and where the rejection of the objection is or will be the subject of a petition for review under Article 112a EPC, is a stay of the appeal proceedings on the merits justified until after the petition for review and any subsequent

proceedings relating to the objection have been finally decided?

2) May an alternate Board of Appeal which does not include the member who has been objected to delay the notification of the decision rejecting that objection until after the appeal proceedings on the merits have been progressed and/or decided with the result that a petition for review of the decision rejecting the objection cannot be filed before the appeal proceedings on the merits have been concluded?

3) May a Board of Appeal knowingly take procedural steps which may have the result of irreparably damaging a party to appeal proceedings pending before it?"

XX. The board issued a further communication and expressed its view that a decision concerning the newly filed procedural requests could only be taken after having heard the parties at the scheduled oral proceedings.

With respect to the request to postpone the oral proceedings the board indicated its preliminary opinion that according to Article 112a(3) EPC a petition for review had no suspensive effect and that the parties should be prepared to deal also with the substance of the case at the scheduled oral proceedings.

XXI. By letters of 6 February 2015, 26 February 2015 and 3 March 2015 the appellant reiterated its request for postponement. Furthermore, it requested that the oral proceedings be recorded and the recording made available to the parties.

XXII. With letter of 2 March 2015 the appellant submitted auxiliary requests VI and VII.

The single claim of auxiliary request VI is derived from claim 1 of auxiliary request I, dated 19 December 2012; the word "system" has been replaced by "device".

The single claim of auxiliary request VII is derived from the claim of auxiliary request V, dated 2 October 2014; the word "system" has been replaced by "device" (for the wording of auxiliary request V see the minutes of oral proceedings on 2 October 2014).

XXIII. Oral proceedings took place on 9 March 2015.

The board took notice of another written statement of the appellant filed "for inclusion in the minutes" (see attachment to the minutes of oral proceedings of 9 March 2015).

During these proceedings the appellant sought to file auxiliary requests VIIIa and VIIIb.

The single claim of auxiliary request VIIIa is derived from the claim of auxiliary request V, dated 2 October 2014, with the following passage ", wherein zero order kinetics means that the plasma concentration does not decrease more than 30% over a 48 hours time period" added at its end.

The single claim of auxiliary request VIIIb is derived from the claim of auxiliary request VIIIa with the word "system" being replaced by "device".

Auxiliary requests VIIIa and VIIIb were not admitted into the proceedings.

XXIV. The appellant further filed an objection under Rule 106 EPC in conjunction with Articles 112a(2)(c) and 113 EPC:

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

In the oral hearings on March 9, 2015 new objections under Art. 84 EPC were raised by the Opponent 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."

XXV. The appellant's submissions, as far as relevant for the present decision, may be summarised as follows:

Arguments presented at the oral proceedings of 1 and 2 October 2014

Record of transcript
A record of a transcript of the oral proceedings was appropriate since the proceedings concerning the objection of partiality were of far-reaching importance. Moreover, the transcript could help in potential petition-for-review proceedings.

Admissibility of the objection of partiality
The objection of partiality against the Chairman of the board was not based on the expert opinion of Mr. Broß but on interlocutory decision R 19/12 of 25 April 2014 together with the further information contained in the statement of a former chairperson of a technical board of appeal, dated 6 May 2014. Mr. Broß had based his expert opinion purely on provisions contained in the EPC while decision R 19/12 related to activities of VP3 and consequently also its "elected" deputy which were not specifically laid down in the EPC. Accordingly, even if the latest procedural action had occurred in the knowledge of the expert opinion of Mr. Broß (Article 24(3) EPC, second sentence) the objection was not belated.

Sufficient substantiation followed from the evidence on file that the Chairman objected to was member of the presidium and according to Rule 12(5) EPC, these members potentially had to replace VP3. Additionally, the statement of a former chairperson of a technical board of appeal was on file that prior to the year 2010 chairpersons of technical boards of appeal deputised for the VP3 then in office, and took part in managerial meetings as the deputy of VP3.

Added subject-matter; main request and first to fourth auxiliary requests
The subject-matter of claim 1 as granted represented the full set of features that defined an independent embodiment of the invention on pages 16 and 17 of the application as originally filed. The textual connection of the mean relative release rate after 72 hours with ";and" to the mean relative release rate up to 72 hours after the initiation of the dosing interval and the introducing word "preferable" meant that these two release rates were alternatively eligible.

As buprenorphine was a strong analgesic with considerable side-effects and had never been intended to be used for treating slight pain with the characteristics of headache, the introduction of the adjectives "moderate to severe" to describe the pain to be treated was self-evident. For the skilled person it was indisputable that treatment of pain using buprenorphine was restricted to moderate to severe pain *per se* and, consequently, replacing "moderate to severe pain" by "pain" did not add subject-matter.

Admissibility of auxiliary requests I to IV
Auxiliary requests I to IV should be admitted into the proceedings, as they had been filed in reaction to the responses of the respondents to the grounds of appeal and moreover since no objections to these requests had been filed by the respondents until the oral proceedings of 1 and 2 October 2014.

With regard to their *prima facie* allowability under Article 123(2) EPC, the introduction of the wording "moderate to severe pain" overcame all the objections brought forward by the respondents in writing. In addition, this wording was not unclear in the sense of

Article 84 EPC since it was used for instance in an international context and thus the skilled person knew what it meant.

Added subject-matter; auxiliary requests I to IV
Concerning all requests filed before the oral proceedings of 1 and 2 October 2014, the necessity to introduce the feature relating to zero order kinetics was discussed for the first time in this context. However, the structure of the wording on pages 16 and 17 of the application as originally filed revealed that lines 10 to 12 represented a block of special information that could be separated from the rest because of the terms "in further preferred embodiments" before the sentence containing "zero order kinetics" and a simple "preferably" starting the further text (instead of a "most preferably"). Therefore, the feature relating to zero order kinetics represented additional information not necessarily linked to the other characteristics of the claims in suit.

Admissibility of auxiliary request V
Since the alleged necessity to introduce the feature relating to zero order kinetics was discussed for the first time at the oral proceedings, auxiliary request V was to be admitted into the proceedings. The request constituted a reaction to this discussion.

The feature was now introduced in view of Article 100(c) EPC in connection with Article 123(2) EPC. It had not been possible to submit this request earlier in the proceedings because the respondents had withheld the appropriate arguments up to now.

Arguments presented with respect to the oral proceedings of 9 March 2015

Postponement of oral proceedings
The oral proceedings should be postponed until after a final decision relating to the objection against the Chairman of the board under Article 24(3) EPC had been reached. A petition for review pursuant to Article 112a EPC had already been filed and only a relatively short time would be necessary to see if it was likely to succeed. The patentee might suffer an irreversible loss of rights and irreparable commercial harm, whereas the opponents had not shown that they had a particular interest in an early decision, and there was also no reason to assume the general public would have such interest. Article 112a(3) EPC did not impose a positive obligation upon the board to continue in the substantive prosecution of the case, and did not deprive the board of the discretion to postpone, particularly as the situation was rather complex. Moreover, there were real prospects that the EBA would set aside the decision taken on the objection, given that Article 6(1) of the European Convention on Human Rights (ECHR) had been breached by the refusal of the Chairman to comment on the partiality objection. There was a body of case law of the European Court of Human Rights (ECtHR) and the European Court of Justice (ECJ) to the effect that a board had a positive duty to investigate partiality and to provide full and frank disclosure, irrespective of whether or not the final decision depended on this investigation.

Referral of questions to the EBA
The question of whether oral proceedings on the merits of a case should be stayed because of a pending petition for review concerning an interlocutory decision with

respect to a suspicion of partiality in the same case, was of fundamental importance not only for the outcome of the present proceedings but also for the administration of justice in proceedings under the EPC, and thus legitimised the request to refer to the EBA the questions submitted with letter of 23 December 2014.

Admissibility of auxiliary requests VI and VII
Auxiliary requests VI and VII were to be admitted into the proceedings, since they represented a direct response to the respondents' submissions of 3 and 6 February 2015 and therefore could not have been filed earlier.

Clarity
The subject-matter of auxiliary request V and especially 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" was clear to a person skilled in the art. Zero order kinetics was understood to mean a relatively constant plasma concentration, as reflected in example 1 of the patent, in particular table 1 and figure 1, representing the statistic mean results of a study with 24 patients. This understanding of the feature zero order kinetics was supported by the definition found in paragraph 107 of the patent (corresponding to page 39, lines 8 to 14 of the application as published). The data of table 2 related to different pharmacokinetic parameters, which did not contradict the data of table 1.
Moreover, the features of the claim of auxiliary request V had to be read in connection with each other. A dosing regimen for a 7-day interval was claimed, split into the first 3 days or up to 72 hours after the initiation of the dosing interval and the next 4 days or

from 72 hours to 168 hours after the initiation of the dosing interval. For each of these two parts of the 7-day dosing interval, the first 3 days and the next 4 days, two groups of features, namely the mean relative release rate and the mean plasma concentrations, were claimed. The mean relative release rate was more pronounced in the first 3 days, which resulted in an increase of the mean plasma concentration and for the next 4 days the mean relative release rate was at a lower level, which resulted in a relatively constant plasma concentration. In other words, the mean relative release rate of the second part of the dosing interval (day 4 to 7) caused the zero order kinetics evidenced by the constant plasma concentration. In this context the skilled person would understand that the wording "the dosing of buprenorphine" was identical to "mean relative release rate" and that "kinetics" related to "pharmacokinetics" which was linked to plasma concentrations. Again, this understanding was supported by the description for instance on page 39, lines 8 to 14, page 45 last paragraph to page 46 first paragraph and page 68 last paragraph.

Regarding various types of curves and kinetics fitting into the ranges of plasma concentrations as claimed, the person skilled in the art would understand the features of the claim and would consequently exclude illogically fluctuating plasma curves.

The term "moderate to severe pain" was a generally accepted term in the art and thus clear to a skilled person. As evidenced by document E29, pain management was divided into three levels, i.e. level 1 for mild pain, level 2 for moderate pain and level 3 for severe pain (see E29, page 343, third and fifth paragraphs and page 345, first paragraph).

Admissibility of auxiliary requests VIIIa and VIIIb
Auxiliary requests VIIIa and VIIIb should be admitted into the proceedings as a fair attempt to overcome the new objection under Article 84 brought forward by the respondents for the first time during the oral proceedings of 9 March 2015. In the written procedure the respondents had linked the term zero order kinetics to the plasma concentration.

XXVI. The respondents' arguments, as far as relevant for the present decision, may be summarised as follows:

Arguments presented at the oral proceedings of 1 and 2 October 2014

Record of transcript
The request for recording a transcript of the oral proceedings had no basis in the EPC and should therefore be rejected.

Admissibility of the objection of partiality
The objection for suspected partiality was belated because it was based on facts that were all known from the expert opinion of Mr. Broß. Thus, procedural actions had been taken after the date on which the grounds for the suspicion of partiality had become known. Decision R 19/12 only reinforced the basically known suspicions and added no new matter of law.

Added subject-matter; main request and first to fourth auxiliary requests
The mean relative release rate during the first 72 hours after the initiation of the dosing interval was missing because, in the context of transdermal delivery devices aimed at obtaining the effective plasma concentrations

over time, the application as originally filed consistently disclosed the relevant range for the initial mean release rate in close association with the relevant range for the mean release rate after 72 hours of the dosing interval. Mentioning the definition of the relevant mean release rate after 72 hours in claim 1 of the patent as granted, whilst omitting the relevant mean release rate during the initial 72 hours, therefore introduced subject-matter extending beyond the content of the original disclosure (see decision of the opposition division, page 15, second paragraph).

The wording "moderate to severe pain" was missing in the claim as granted, because the definition of the claimed subject-matter was to be derived from features set out in this context and stemming solely from two subsequent pages in the whole description as originally filed. Throughout the description, there was no passage that provided for these features in their totality and referring to the treatment of pain in general.

Admissibility of auxiliary requests I to IV
Auxiliary requests I to IV should not be admitted into the proceedings as the feature "moderate to severe pain" was *prima facie* unclear and, thus, these requests provoked new objections.

Added subject-matter; auxiliary requests I to IV
The necessity for introducing the feature relating to zero order kinetics had already been indicated in the response to the grounds of appeal of respondent 02. The wording "preferably" on line 12 of page 17 of the application as originally filed meant that it concerned a narrower teaching based on and including the teaching directly before this term. Moreover, there was also no other feature present in the claim that could inherently

provide the same information with regard to the dosing of buprenorphine in accordance with zero order kinetics.

Admissibility of auxiliary request V
Auxiliary request V should not be admitted into the proceedings because it raised questions that could not be treated at such a late stage of the proceedings (without adjournment of the proceedings) and since it was *prima facie* not allowable.

Arguments presented with respect to the oral proceedings of 9 March 2015

Postponement of oral proceedings
The request for postponement of the oral proceedings was late-filed. The EPC made no provision for such a postponement; on the contrary, Articles 112a(3) and (6) EPC clearly stated that a petition for review had no suspensive effect. Moreover, there was no prospect of success for the petition of review given the fact that Article 3(2) RPBA provided that there was a duty to ask the member objected to to give comments, but no duty to comment. The objection of suspected partiality was not part of these proceedings. It had been decided upon by the board in its alternate composition and the board in its current composition was bound by that interlocutory decision. Moreover, first the EBA had to decide if the appellant's right to be heard had been breached, but not on the objection of suspected partiality as such. Not only the opponents had a clear interest in having a fast procedure; the general public too had an interest in lower-priced medicaments entering the market. Consequently, a postponement was only in the interest of the patentee.

Referral of questions to the EBA

The request for referral of the questions submitted with letter of 23 December 2014 should be rejected as these questions were not essential to ensure a uniform application of the law and also did not relate to a point of law of fundamental importance. Moreover, the referral would unduly postpone the proceedings. Question 3 could in principle not be followed as it was the duty of a board to decide its cases, which would inevitably result in damaging the interests of one of the parties.

Admissibility of auxiliary requests VI and VII
Auxiliary requests VI and VII were late-filed representing an attempt to overcome objections that had been known for months whereas the requests had been filed one week before the date of these oral proceedings. Moreover, the scope of auxiliary request VI was even broader than that of auxiliary request V instead of being narrower. Auxiliary requests VI and VII should therefore not be admitted into the proceedings.

Clarity
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" was unclear in view of the definition given in paragraph 107 of the patent (corresponding to page 39, lines 8 to 14 of the application as published), disclosing that "*a relatively constant plasma concentration is defined as a concentration which does not decrease more than about 30% over a 48 hour time period*". Hence, the definition of zero order kinetics found in the description, allowing up to a 30% decrease in the plasma concentration, was in clear contrast to the generally accepted meaning of this term in the art. Moreover, the data of table 1 and table 2 contradicted the definition

of paragraph 107 of the patent, since there was even a clear increase in the plasma concentration in the time period from 72 to 168 hours after initiation of the dosing interval.

Moreover, it was not apparent if the "zero order kinetics" related to the measurement of the mean relative release rate, the plasma concentrations or both, let alone a disclosure of how these measurements were to be done by the person skilled in the art.

Even taking all the features of claim 1 together, it was not evident what was actually claimed, given the fact that the ranges of mean relative release rates and plasma concentrations claimed allowed not only first order kinetics in the first 72 hours and zero order kinetics in the next 120 hours, but on the contrary the claim encompassed all kinds of kinetics for the two time periods.

The terminology used in the patent was not consistent but rather related to pain, chronic pain and moderate to severe pain, without giving a proper definition. The sensation of pain was subjective and would consequently differ from one patient to another. Accordingly, the term "moderate to severe pain" was unclear and had no well-defined meaning in the art.

Admissibility of auxiliary requests VIIIa and VIIIb
Auxiliary requests VIIIa and VIIIb had been proposed to remedy deficiencies in auxiliary request V, itself introduced and admitted at a very late stage of the proceedings, with regard to objections under Article 84 EPC. Auxiliary request V, however, had already been objected to under Article 84 EPC during the written proceedings, and due to its late filing it was

clear that it had to be discussed in full during the oral proceedings. It was not appropriate to concede further chances to correct defects in such requests now, in these oral proceedings.

In addition, these requests *prima facie* gave rise to new objections under Articles 84 and 123(2) EPC. In particular, the new feature did not represent a precise reproduction of the passage of page 39, lines 8 to 14, disclosing the application's definition of zero order kinetics.

Consequently, auxiliary requests VIIIa and VIIIb should not be admitted into the proceedings.

As a further consequence, the appellant's objection under Rule 106 EPC also had to be rejected.

XXVII. The appellant requested

- that the oral proceedings be postponed until after all proceedings relating to the objection against the Chairman of the Board in its current composition have been finally decided,
- that if oral proceedings were not postponed the Board refers the questions filed with letter of 23 December 2014 to the Enlarged Board of Appeal,
- that the oral proceedings be recorded and the recording be made available to the parties.

The appellant further requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or alternatively be maintained in amended form on the basis of one of the sets of claims of the first to fourth auxiliary request filed with the statement of grounds of appeal, or on the basis of one of the single claims filed as auxiliary requests

I to IV with letter of 19 December 2012, or on the basis of the single claim filed as auxiliary request V at the oral hearing of 2 October 2014, or on the basis of one of the single claims filed as auxiliary requests VI and VII with letter of 2 March 2015, or as a further alternative on the basis of one of the single claims filed as auxiliary requests VIIIa and VIIIb at the oral hearing of 9 March 2015.

XXVIII. The respondents (opponents) requested

- that the request for postponement be refused,

- that the request for referral of the questions filed with letter of 23 December 2014 to the Enlarged Board of Appeal be refused and

- that the appeal be dismissed.

Respondent 02 further requested that auxiliary requests VI and VII not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. Recording of oral proceedings

Whether or not a sound recording of oral proceedings is made is a matter of discretion for the board (R 17/09 of 1 October 2010, Reasons for the decision No. 9). The board did not consider the present case to involve such exceptional circumstances that a sound recording of the proceedings would have been justified. Even if such a

sound recording were made, there would have been no legal basis for making it available to the parties.

Consequently, the request for recording the oral proceedings was refused.

3. Admissibility of the objection of partiality

3.1 If, in an admissible appeal, an objection under Article 24(3) EPC is made in respect of a board member by one of the parties, the board in its original composition must first decide on the admissibility of the objection (interlocutory decision R 12/09 of 3 December 2009, Reasons for the decision No. 2). An objection is inadmissible if, for example, the party has taken a procedural step while being aware of a reason for objection, or bases the objection on the nationality of the board member (Article 24(3) EPC, second and third sentences). Furthermore, the objection must be sufficiently substantiated in order to be admissible (R 12/09, Reasons for the decision No. 2).

3.2 The Chairman objected to was a member of the presidium and, according to Rule 12(5) EPC, all members of the presidium are potential deputies for VP3. Interlocutory decision R 19/12 of 25 April 2014 addressed for the first time the dual role of VP3 as Chairman of the EBA on the one hand, and as a member of EPO management on the other hand, as a basis for a perceived suspicion of lack of impartiality.

3.3 As the objection under Article 24(3) EPC is based on the link between decision R 19/12 and the member objected to being eligible for deputising for VP3, and the objection was filed directly after the publication of decision R 19/12, the objection has been sufficiently

substantiated and the appellant has not taken a procedural step while being aware of the reason for objection.

3.4 The board is thus convinced that the objection under Article 24(3) EPC against the Chairman of the board is admissible.

4. Request for postponement of oral proceedings scheduled for 9 to 13 March 2015

The appellant's request is based on the assumption that the board had a general discretionary power to postpone proceedings at the request of one of the parties. The board recognises that, once oral proceedings have been fixed, serious reasons may arise which justify the fixing of a new date (Article 15(2) RPBA). Examples are given in the notice of the Vice-President of Directorate-General 3 dated 16 July 2007 (OJ EPO 2007, Special edition No. 3, 115). Also, in the present case the board cancelled the oral proceedings originally scheduled for 8 May 2014 in view of the objection under Article 24(3) EPC filed on 6 May 2014, to enable the board and the other parties to properly prepare for the discussion of the objection at oral proceedings. In these cases proceedings are normally not adjourned indefinitely; rather a new date is fixed (see the wording of Article 15(2) RPBA - "change of date" - and of the Notice of VP3 - "fixing of a new date").

Even if the board were to assume that it had a further-reaching discretion and could generally adjourn oral proceedings for an undefined period, Article 112a(3) EPC would speak against exercising such discretion in the case at issue. It is clear from Article 112a(3) EPC that

the legislator did not want to attribute any suspensive effect to a petition for review.

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 in having clarified as soon as possible the question of whether an exclusive right has to be respected (G 2/04, OJ EPO 2005, 549, Reasons for the decision, point 2.1.4).

The appellant has furthermore argued that proceedings should be postponed as it was likely that the EBA would set aside the decision of the board in its alternate composition, and that proceedings would have to be re-opened. It is however not the task of the present board to speculate on what the EBA may or may not decide, and it cannot base its decisions on such speculation.

The decision of the board in its alternate composition on the objection under Article 24(3) EPC is binding for the board in its present composition and has the force of *res judicata* (see "Basic proposal for the revision of the EPC" MR/2/00 dated 13 October 2000, page 139, point 11). This force cannot be ignored by the board on the request of one of the parties.

In view of the above considerations the board is not only entitled but also obliged to continue with the examination of the substance of the appeal.

5. *Referral of questions to the EBA under Article 112(1)(a) EPC*

The appellant requested that three questions be referred to the EBA.

5.1 According to Article 112(1)(a) EPC, if a point of law of fundamental importance arises, the board must refer questions to the EBA if it considers that a decision is required. It is then within the discretion of the board to decide whether a question is referred, and a board will usually not decide to refer a question if it is in no doubt that it can resolve the point of law itself.

5.2 Question 1 involves a point of law that the board was able to deal with without any doubt (see point 4 above). The same applies to Question 3. Additionally, when taking their decisions the boards are bound only by the provisions of the EPC and are not required to weigh up the economic implications.

Question 2 is no longer relevant in the current proceedings because the alternate board's decision on the objection against the Chairman under Article 24(3) EPC was issued on 27 February 2015, which is in advance of this decision on the merits announced on 9 March 2015. Moreover, given the fact that a petition for review has already been filed, the underlying cause also no longer has any factual basis from this point of view.

6. Admissibility of the auxiliary requests

6.1 Auxiliary requests I to IV

These requests have been filed in reaction to the responses of the respondents to the grounds of appeal and especially in a *bona fide* attempt to overcome an objection under Article 123(2) EPC, by adding of the

feature "moderate to severe". The respondents had argued that all pending requests were deficient under Article 123(2) EPC, because the feature "moderate to severe" was missing from their claims 1.

The board therefore exercised its discretion, pursuant to Article 13 RPBA in conjunction with Article 114(2) EPC, to admit auxiliary requests I to IV into the proceedings.

6.2 Auxiliary request V

6.2.1 Amended auxiliary request V filed during the first oral proceedings on 2 October 2014 is considered a *bona fide* attempt to respond to respondent 02's arguments set out during those oral proceedings.

6.2.2 In its response to the grounds of appeal, respondent 02 had argued that claim 1 of the main request contravened Article 123(2) EPC for **several reasons** even if, for the sake of argument, it accepted that it was not essential to introduce into claim 1 the preferred embodiments of the transdermal therapeutic systems on page 17, line 8 to page 17, line 12. The "several reasons" mainly related to the wording "moderate to severe pain" and to the mean relative release rate in the first 72 hours after the initiation of the dosing interval (see respondent 02's letter of 14 June 2010, page 4, second paragraph, ff).

After the appellant had introduced the latter two features into the claims according to auxiliary requests I to IV, respondent 02 did not submit any further comments, thus creating the impression that the feature relating to "zero order kinetics" contained in

the cited passage of the original description was of minor interest with respect to added subject-matter.

6.2.3 In contrast thereto, respondent 02 argued at the oral proceedings that the claim without the feature relating to "zero order kinetics" was in breach of Article 123(2) EPC. Consequently, the appellant had to be given the opportunity to react to the arguments now demanding that it introduced the feature relating to "zero order kinetics" into the single claim of the new request.

6.2.4 Under the circumstances of the present case, the board, exercising its discretion pursuant to Article 13 RPBA in conjunction with Article 114(2) EPC, saw no reason to hold auxiliary request V inadmissible.

6.3 Auxiliary requests VI and VII

These requests have been filed in direct reaction to the objection under Article 123(2) EPC raised by the board in its communication dated 28 October 2014, shortly after the summons to the second oral proceedings, and complemented by the respondents by letters of 3 and 6 February 2015.

The claims of these auxiliary requests are derived from auxiliary requests I and V respectively, with the word "system" replaced by "device".

These amendments are straightforward and simple; they raise no additional problems to be considered.

The board therefore exercised its discretion pursuant to Article 13 RPBA in conjunction with Article 114(2) EPC

and admitted auxiliary requests VI and VII into the proceedings.

6.4 Auxiliary requests VIIIa and VIIIb

6.4.1 The appellant filed these requests at the oral proceedings on 9 March 2015 in an attempt to overcome objections under Article 84 EPC with regard to the single claim of auxiliary request V, which had been filed and admitted at the end of the oral proceedings of 2 October 2014.

6.4.2 After discussion of issues relating to Article 123(2) EPC particularly with regard to auxiliary request I, the feature "wherein at 72 hours after the initiation of the dosing interval the dosing of buprenorphine during the at least next 48 hours is maintained in accordance with zero order kinetics" (hereafter "the zero order feature") had been introduced from the description to arrive at auxiliary request V.

The board's communication pursuant to Article 15(1) RPBA issued on 28 October 2014 indicated that "*the specific meaning*" of "the zero order feature" in the claim of auxiliary request V needed to be discussed under Article 123 EPC. Additionally, the parties should be prepared to also discuss issues of Articles 84, 54, 56 and 83 EPC. On this basis, the appellant was given an opportunity to explain why it thought that the late-filed auxiliary request V was a basis for maintaining the patent in suit. In addition, the communication thus served to make 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 respondents' submissions of 3 and 6 February 2015 contained arguments under Article 84 EPC, especially directed against "the zero order feature".

Hence, the board and the respondents had already raised in writing the issue that "the zero order feature" was potentially not in line with the requirements of Article 84 EPC.

6.4.3 The appellant has neither provided counterarguments nor submitted a further auxiliary request in the course of the written proceedings in order to take account of the clarity objection.

6.4.4 During oral proceedings, it has sought to amend auxiliary request V by introducing at the end of the single claim the passage ",wherein zero order kinetics means that the plasma concentration does not decrease more than 30% over a 48 hours time period". Further taking account of the device/system problem, auxiliary requests VIIIa and VIIIb resulted from the amendment to auxiliary request V. The passage introduced relates to the description as originally filed (see WO 98/36728 publication) on page 39, lines 8 to 12.

6.4.5 Yet the appellant has not introduced the precise and full definition of "zero order kinetics" given in this paragraph, but only a part of it.

With its amendment, the appellant has therefore not clearly overcome the clarity objection brought forward against the previous request and, additionally, the amendment gives rise to new considerations concerning Article 123(2) EPC.

6.4.6 Consequently, taking into account the provisions of Article 13 RPBA, in particular the complexity of the new subject-matter submitted and the current state of the proceedings, and exercising its discretion, the board saw no room for admitting auxiliary requests VIIIa and VIIIb into the proceedings.

7. For the same reasons, applied *mutatis mutandis*, the objection under Rule 106 EPC, including the considerations given in the paper submitted during oral proceedings (see point XXIV. of this decision), was also to be rejected.

8. Articles 100(c) and 123(2) EPC

8.1 Main request (the patent as granted), first to fourth auxiliary requests and auxiliary requests I to IV and VI

8.1.1 The subject-matter of claim 1 of the main request is in a Swiss-type format and comprises the following features:

i. The use of buprenorphine in the preparation of a transdermal delivery system
ii. for treating pain in a human patient
iii. for a dosing interval of 7 days,
iv. said transdermal delivery system being suitable for administering buprenorphine transdermally to a human patient by applying the transdermal delivery system to the skin of a patient,
v. having a mean relative release rate of 0.3 µg/hr to 9 µg/hr from 72 hours until 168 hours after the initiation of the dosing interval
vi. such that mean plasma concentrations are provided as follows ...

vi./part 1

until 72 hours after the initiation of the dosing interval and
vi./part 2
from 72 hours until 168 hours after the initiation of the dosing interval

8.1.2 The subject-matter of claim 1 of the first to fourth auxiliary requests additionally contains at least the following feature:

vii. the mean relative release rate of 3 µg/hr to 86 µg/hr until 72 hours after the initiation of the dosing interval

8.1.3 The subject-matter of each of the single claims of auxiliary requests I to IV and VI is further restricted (apart from possible other modifications) to at least:

viii. for treating **moderate to severe** pain in a human patient (emphasis added)

8.1.4 The subject-matter of claim 1 of each of the main request, first to fourth auxiliary requests and auxiliary requests I to IV and VI **does not contain** the following feature:
"wherein at 72 hours after the 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: the "zero order feature"; see point 6.4.1 of this decision).

8.2 The sole part of the application as originally filed (reference is made to the WO 1998/036728 publication) that constitutes a conceivable basis for the subject-matter claimed is the passage on page 16, line 24 to page 17, line 25.

The remaining parts of the application, including the claims, relate to different embodiments of the invention and can therefore not qualify as a basis for the claimed features in their entirety.

8.3 The cited passage on page 16 to 17 discloses a group of embodiments of the invention, as substantiated by the wording at its beginning "*In certain preferred embodiments of the present invention where the patient(s) is being treated for moderate to severe pain... .*"

All the features of this group of embodiments, including features vi (see page 17, lines 20 to 22) and vii (see page 16, line 25) are to be read together and, consequently, in order not to extend beyond the content of the application as filed under Articles 100(c) or 123(2) EPC, the claimed subject-matter needs to include all of them and cannot arbitrarily omit one or another.

Nevertheless, in the following it is particularly evaluated if the "zero order feature" in fact is a compulsory feature for the group of embodiments disclosed on pages 16 to 17.

8.4 With regard to the "certain preferred embodiments", the mean plasma concentrations to be achieved until 72 hours after initiation of the dosing interval (part 1 of feature vi) are disclosed from page 16, line 27 to page 17, line 8.

Directly thereafter, there is a disclosure that the mean plasma concentrations are maintained from about 19 to about 1052 pg/ml over at least the next 48 hours.

This range of mean plasma concentrations setting out the overall range for the at least next 48 hours is automatically not exceeded by the provisions of part 2 of feature vi to be fulfilled, with the disclosure of the mean plasma concentrations from 72 hours until 168 hours after initiation of the dosing interval to be found directly adjacent to the "zero order feature" starting with the word "Preferably" (page 17 of the original description, lines 12 to 19).

Due to this wording, the specific mean plasma concentrations from 72 hours until 168 hours (part 2 of feature vi) are necessarily disclosed as part of the "Further preferred embodiments" (group of embodiments, see page 16, line 24) which are additionally inextricably linked to the "zero order feature".

8.5 The argument that the "zero order feature" represented a block of special information that could be separated from the remaining features therefore cannot succeed.

The further argument brought forward that the mean plasma concentrations (features vi) as claimed would inherently provide for "zero order kinetics" does also not hold true. The plasma concentrations at the different points of time are claimed as ranges with a certain breadth, which allow not only for zero order but also for at least first order kinetics.

For these reasons it is concluded that the "zero order feature" forms part of the specific group of embodiments disclosed on pages 16 to 17.

The subject-matter as claimed - without this feature - therefore extends beyond the subject-matter of the application as originally filed.

8.6 Consequently, the subject-matter of claims 1 of the main request, the first to fourth auxiliary request and auxiliary requests I to IV and VI extends beyond the content of the application as filed under Articles 100(c) and 123(2) EPC.

9. Article 84 EPC

9.1 Auxiliary request V

9.1.1 The missing "zero order feature" having been introduced, the single claim of auxiliary request V is derived from auxiliary request I with the addition of the wording *"wherein at 72 hours after the 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 is taken word for word from the consistent source of the claimed features on pages 16 and 17 of the description as originally filed, and in particular lines 10 to 12 on page 17.

9.1.2 The board notes that the wording of the new feature on its own leaves room for differing understandings. "Dosing" *prima facie* means anything concerning an amount of buprenorphine per time unit. It might be the release rate from the device, the rate of transport into the body to be treated concerning any tissue to be penetrated or the rate of change of plasma concentration. Assuming for the sake of argument (as the appellant did) that "dosing" in the claim of auxiliary request V meant the release rate from the buprenorphine device, there are at least three possible ways of reading the inserted passage, namely that

- the dosing of buprenorphine, understood as the release rate from the buprenorphine device, is itself maintained according to zero order kinetics,
- the dosing/release rate of buprenorphine is maintained in such a way as to achieve mean plasma concentrations according to zero order kinetics, or
- the dosing/release rate of buprenorphine itself and the mean plasma concentrations are maintained according to zero order kinetics.

Each of these understandings represents a different, technically meaningful teaching. Thus, the board cannot see on what basis a person skilled in the art would be able to rule out two of the three possible understandings as being less plausible leaving the third as the only true meaning of the "zero order feature".

9.1.3 The same is true if the skilled person tries to understand the meaning of the "zero order feature" by reading all the features of the claim together:

- Zero order kinetics linked to the "**release rate**", seen to be equivalent to the term "dosing" used in the claim language, is understood by the skilled person as a constant release rate. Such an understanding is not contradicted by the further features of the claim for the period of time from 72 hours to at least 120 hours after initiation of the dosing interval. In fact, the claim stipulates that the mean relative release rate is 0.3 µg/hr to 9 µg/hr, which is open for a constant release rate in this time interval.

- Again seeing the wording "release rate" and the wording "dosing" as equivalent, but despite this context connecting the word kinetics directly to

plasma concentrations, because the terms kinetics or pharmacokinetics usually relate to plasma concentrations (according to the submissions of the appellant), the understanding that the zero order kinetics is linked to the **plasma concentrations** prevails. Plasma concentrations following zero order kinetics would then be seen by the skilled person as constant plasma concentrations.

The mean plasma concentrations at 96 hours and 120 hours after initiation of the dosing interval are claimed to be uniformly from 23 to 1052 pg/ml (same upper and lower limit), hence constant plasma concentrations "within the at least the next 48 hours" are within the scope claimed.

- Lastly, for the above reasons, the overall view of the features of the single claim of auxiliary request V also allows linking of "zero order kinetics" to **both parameters in parallel**, the release rate and the plasma concentration. This would mean that a constant flow from the buprenorphine device would induce a constant level of plasma concentration.

9.1.4 Under such conditions, the skilled person would try to resolve the problem of different understandings of the added feature by taking into account the whole content of the claims and the description.

However, although the application provides a definition of the term "zero order" pharmacokinetics on page 39, lines 8 to 12, which indirectly links this term to a constant plasma concentration, other teachings are found in the description too.

On the same page, lines 13 to 14, "zero order kinetics" is linked to a constant amount released per area unit relating to membrane-controlled devices. Also on page 9, lines 20 to 23, on page 10, line 28 to page 11, line 2, on page 24, lines 5 to 14 and on page 68, lines 24 to 25, zero order kinetics is linked to the release of buprenorphine and not to a constant mean plasma concentration.

Taking in addition the skilled person's normal view of the term constant plasma concentration, "constant" in the classical sense would mean a level of buprenorphine fluctuating around a particular value at most to an extent limited by the possibilities of "exact" measurement under *in vivo* conditions. An increase as seen in figure 1 and a later decrease of "less than 30%" as defined on page 39 would *prima facie* not be within the scope of his considerations.

Consequently, even trying to define the meaning of the "zero order feature" in the claim of auxiliary request V in the light of an overview of all features contained in the claim, and in the light of the description, is not sufficient to deduce that one of the possible understandings is the only correct one and thus to overcome the problems relating to Article 84 EPC.

The board therefore concludes that the subject-matter of the single claim of auxiliary request V does not fulfil the requirements of Article 84 EPC.

9.2 Auxiliary request VII

The single claim of auxiliary request VII is derived from the claim of auxiliary request V which comprises

the "zero order feature". The word "system" is replaced by the word "device".

Because of the presence of the "zero order feature", the line of argument provided under point 9.1 above applies *mutatis mutandis* and the claim is also in breach of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Kiehl U. Oswald

Decision electronically authenticated