BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 12 May 2009

Case Number: T 0064/06 - 3.3.02

Application Number: 95114527.5

Publication Number: 0699436

IPC: A61K 31/135

Language of the proceedings: EN

Title of invention:
Controlled release formulation

Patentee:
EURO-CELTIQUE S.A.

Opponents:
SMB S.A.
Hexal Aktiengesellschaft
Zentiva a.s.

Headword:
Controlled release formulation of tramadol/EURO-CELTIQUE S.A.

Relevant legal provisions:
EPC Art. 100(b), 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request, first auxiliary request, new main request, new first auxiliary request - sufficiency - no: non workable embodiment"
"Second auxiliary request - inventive step - yes: combination based on ex post facto analysis"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0064/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 12 May 2009

Appellant: (Opponent 01)
SMB S.A.
Rue de la Pastorale 26-28
BE-1080 Bruxelles (BE)

Representative:
ter Meer, Nicolaus
TER MEER STEINMEISTER & PARTNER GbR
Patentanwälte
Mauerkircherstrasse 45
D-81679 München (DE)

Appellant: (Opponent 03)
Hexal Aktiengesellschaft
Industriestr. 25
D-83607 Holzkirchen (DE)

Representative:
Wibbelmann, Jobst
Wuesthoff & Wuesthoff
Patent- und Rechtsanwälte
Schweigerstrasse 2
D-81541 München (DE)

Appellant: (Opponent 04)
Zentiva a.s.
U Kabelovny 130
CZ-10237 Praha 10 (CZ)

Representative:
Teipel, Stephan
Lederer & Keller
Patentanwälte
Prinzregentenstrasse 16
D-80538 München (DE)

Appellant: (Patent Proprietor)
EURO-CELTIQUE S.A.
2, avenue Charles de Gaulle
LU-1653 Luxembourg (LU)

Representative:
Maiwald Patentanwalts GmbH
Elisenhof
Elisenstrasse 3
D-80335 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 5 December 2005 concerning maintenance of European patent No. 0699436 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J.-P. Seitz

Summary of Facts and Submissions

I. European patent No. 0 699 436, based on application No. 95 114 527.5, was granted on the basis of 20 claims.

Independent claim 1 as granted read as follows:

1. An oral controlled release preparation of tramadol or a pharmaceutically acceptable salt thereof, effective for the treatment of moderate to severe pain for 12 hours or more, wherein:
(A) the oral controlled release preparation comprises the tramadol or a salt thereof incorporated in a controlled release matrix which includes one or more materials selected from (a) digestible C8-C50 substituted or unsubstituted hydrocarbons such as fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral or vegetable oils or waxes and (b) polyalkylene glycols; or
(B) the oral controlled release preparation comprises the tramadol or salt thereof in a controlled release matrix and in the form of multiparticulates, the matrix including a hydrophobic fusible carrier or diluent having a melting point of 35 to 140°C or a tablet obtained by compressing said multiparticulates; or
(C) the oral controlled release preparation comprises the tramadol or a salt thereof incorporated in a normal release matrix which is a spheroid comprising the tramadol or a pharmaceutically acceptable salt thereof and a spheronising agent, the spheroid having a controlled release coating chosen from water insoluble waxes, water insoluble polymethacrylates and water insoluble celluloses.

II. Notices of opposition were filed against the granted patent by appellant-respondents 1 to 4 (opponents 1 to 4).

The patent was opposed for lack of novelty and an inventive step under Article 100(a) EPC, insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

The documents cited during the proceedings before the opposition division and the board of appeal included the following:

(9) US 5,073,379
(11) Arzneim. - Forsch. 36(II), Nr. 8 (1986), 1278-1283
(13) EP-A-248548
(15) EP-A-271193
(18) DE-A-3810343
(19) EP-A-147780
(20) WO-A-9318753
(32) Affidavit of Ben Oshlack dated 19 November 1997
(33) Statutory Declaration of Sandra Therese Antoinette Kite-Malkowska dated 26 July 1995.

III. The appeal lies from the decision of the Opposition Division maintaining the patent in amended form under Article 102(3) EPC pronounced at the oral proceedings held on 8 November 2005.

Independent claim 1 of the main request on which the Opposition Division's decision is based is identical to claim 1 as granted.

Independent claim 1 of the first auxiliary request on which the Opposition Division's decision is based reads:

1. An oral controlled release preparation of tramadol or a pharmaceutically acceptable salt thereof, effective for the treatment of moderate to severe pain for 24 hours, wherein:
(A) the oral controlled release preparation comprises the tramadol or a salt thereof incorporated in a controlled release matrix which includes one or more materials selected from (a) digestible C8-C50 substituted or unsubstituted hydrocarbons such as fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral or vegetable oils or waxes and (b) polyalkylene glycols; or
(B) the oral controlled release preparation comprises the tramadol or salt thereof in a controlled release matrix and in the form of multiparticulates, the matrix including a hydrophobic fusible carrier or diluent having a melting point of 35 to 140°C or a tablet obtained by compressing said multiparticulates; or
(C) the oral controlled release preparation comprises the tramadol or a salt thereof incorporated in a normal release matrix which is a spheroid comprising the tramadol or a pharmaceutically acceptable salt thereof and a spheronising agent, the spheroid having a controlled release coating chosen from water insoluble waxes, water insoluble polymethacrylates and water insoluble celluloses
and wherein the in vitro release rate of tramadol when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm is:

time (h)	% released
1	10-30
2	17-37
4	27-47
8	40-60
12	49-69
16	57-77

The Opposition Division took the view that the set of claims of the main request submitted with letter dated 13 August 2003 did not meet the requirements of inventive step.

It considered that document (11), which disclosed an immediate release form of tramadol, represented the closest prior art and defined the problem as the provision of a formulation suitable for achieving a release of the drug over an extended period of time.

The Opposition Division held that the desirability of a controlled release analgesic appeared in that respect self-evident and argued that the skilled man would then be in a position to find suitable sustained release preparations to achieve this result.

In fact, such preparations were disclosed for instance in document (13).

As document (13) described compositions of the present claim which can be used to delay the release of "any active ingredient", it submitted that it would therefore be clear to the skilled man that tramadol could be used. By doing so he would arrive at a composition within the broad scope of the main

request's claim 1. In its opinion, the fact that document (13) did not mention tramadol did not indicate that it was not obvious. This merely indicated that the claim was novel. Furthermore the differences between tramadol and the analgesics listed in document (13) would not deter the skilled man, as "any" agent could be used.

The Opposition Division was however of the opinion that claim 1 and claims 4 and 10 of this set of claims did not infringe the requirements of Article 123 EPC.

It moreover concluded that the claims met the requirements of Article 100(b) EPC because the skilled man, with the use of common knowledge, would be able to reproduce claim 1 part (C). In that respect, it did not accept the result of the test provided by opponent 1 to that end because the chosen criteria used to reproduce part C of claim 1 were outside those recommended by the coating manufacturer.

As to the other points raised in relation to Article 100(c) EPC, the Opposition Division was of the opinion that they related in fact to objections under Article 84 EPC.

It also considered that claim 1 was novel over the disclosure in document (9) and (18) because the skilled man would be required to make multiple selections to possibly arrive at the subject-matter of claim 1.

Concerning auxiliary request 1, the Opposition Division held that the comments for the main request as to

Articles 123, 100(b) and 54 EPC applied to this set of claims as well.

It was however of the opinion that the above comments on inventive step could not be applied to this request as claim 1 here referred to a composition with a specified release profile, which enabled it to be used on a once-a-day basis.

In its view, when combining document (11) with document (13), the skilled man not would have expected a once-a-day preparation and would not have been in a position to limit the release profile to that as claimed in order to provide such a preparation.

IV. The appellant-patent proprietor and the appellant-opponents 1 to 4 (opponents 1 to 4) lodged an appeal against the said decision and filed arguments.

The appellant-patent proprietor filed a main request and auxiliary requests 1 to 4 together with its grounds of appeal.

V. With its letter dated 27 December 2007, appellant-opponent 2 withdrew its opposition.

VI. In the communication of 5 May 2009, the Board expressed its preliminary opinion as to inventive step.

VII. Oral proceedings were held before the board on 12 May 2009.

During the oral proceedings, the respondent filed five requests, namely a main request, a first auxiliary

request, a new main request, a new first auxiliary request and a second auxiliary request.

Claim 1 of the main request reads:

1. An oral controlled release preparation of tramadol or a pharmaceutically acceptable salt thereof, effective for the treatment of moderate to severe pain for 24 hours, wherein:
1.1 the oral controlled release preparation comprises the tramadol or salt thereof in a controlled release matrix and in the form of multiparticulates, the matrix including a hydrophobic fusible carrier or diluent having a melting point of 35 to 140°C or a tablet obtained by compressing said multiparticulates; or
1.2 the oral controlled release preparation comprises the tramadol or a salt thereof incorporated in a normal release matrix which is a spheroid comprising the tramadol or a pharmaceutically acceptable salt thereof and a spheronising agent, the spheroid having a controlled release coating chosen from water insoluble waxes, water insoluble polymethacrylates and water insoluble celluloses,
and wherein the in vitro release rate of tramadol when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm is:

time (h)	% released
1	10-30
2	17-37
4	27-47
8	40-60
12	49-69
16	57-77

Claim 1 of first auxiliary request reads:

1. An oral controlled release preparation of tramadol or a pharmaceutically acceptable salt thereof, effective for the treatment of moderate to severe pain for 24 hours, wherein:
the oral controlled release preparation comprises the tramadol or salt thereof in a controlled release matrix and in the form of multiparticulates, the matrix including a hydrophobic fusible carrier or diluent having a melting point of 35 to 140°C or a tablet obtained by compressing said multiparticulates;
and wherein the in vitro release rate of tramadol when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm is:

time (h)	% released
1	10-30
2	17-37
4	27-47
8	40-60
12	49-69
16	57-77

Claim 1 of the new main request and of the new first auxiliary request differs from claim 1 of the main request and of the first auxiliary request only in that the word "or" before the expression " a tablet obtained by compressing said multiparticulates" has been replaced by "in".

The single claim of the second auxiliary request reads:

1. An oral controlled release preparation of tramadol hydrochloride effective for the treatment of moderate to severe pain for 24 hours, wherein:
the oral controlled release preparation comprises the tramadol hydrochloride in a controlled release matrix in the form of multiparticulates, the matrix consisting of tramadol hydrochloride and hydrogenated vegetable oil having a melting point of 35 to 140°C, wherein said multiparticulates are admixed with tabletting excipients and compressed into a tablet;
and wherein the in vitro release rate of tramadol hydrochloride when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm is:

time (h)	% released
1	10-30
2	17-37
4	27-47
8	40-60
12	49-69
16	57-77

VIII. The submissions of the appellant-opponents (opponents O1, O2 and O4) in relation to the above requests and which remain relevant for the present decision can be summarised as follows:

In their grounds of appeal (respectively on pages 3 and 4 and on page 4, paragraph 3), appellant-opponents 01 and 04 raised an objection pursuant Article 100(b) EPC against the contested patent because an essential element was missing in the claim in order to achieve

the claimed release preparation and also because the description did not provide information on how any hydrophobic carrier of diluent could achieve said release preparation.

As to inventive step, the appellant-opponents argued that the claimed subject-matter was not inventive since it was the result of an obvious combination of the closest prior art document (11) with either document (20) or (13) or (15).

IX. The submissions of the appellant-patent proprietor in relation to the above requests and which remain relevant for the present decision can be summarised as follows:

In its view, the appellant-opponents did not provide concrete evidence that the description did not disclose all the required technical information necessary to produce release preparation according to the claims.

Concerning inventive step, it held that the document combinations opposed by the appellant-opponents were based on *ex post facto* analysis.

X. The appellant-patent proprietor requested that the impugned decision be set aside and that the patent be maintained on the basis of either on of the 5 requests filed during the oral proceedings held before the Board of Appeal respectively as: main request, first auxiliary request, new main request, new first auxiliary request and second auxiliary request.

The appellant-opponents requested that the impugned decision be set aside and that the patent be revoked. Auxiliary, they all requested the remittal of the case to the first instance for further prosecution on the basis of the second auxiliary request.

Reasons for the decision

1. The appeal is admissible.

2. Admissibility of the requests filed during the oral proceedings.

2.1 Main request and first auxiliary request

Claim 1 of these requests corresponds to claim 1 of the first auxiliary request maintained by the Opposition Division wherein alternative A (main request) and alternatives A and C (first auxiliary request) respectively have been deleted.

Thus, these amendments amount merely to the deletion of independent alternatives in claim 1. They are therefore admitted into the proceedings since they greatly simplify them.

2.2 New main request and new first auxiliary request.

These requests differ from the above requests merely in that the word "or" before the expression "a tablet obtained by compressing said multiparticulates" has been replaced by "in" in claim 1, which restricts the

subject-matter of the embodiment relating to multiparticulates to the tablet formulation.

As these auxiliary requests were filed as a direct response to the board's observation made during the oral proceedings that an objection under Article 100(c) EPC arose in the light of document (32), these sets of claims are admitted into the proceedings.

2.3 Second auxiliary request.

This request, which consists of a single claim restricted to a single embodiment wherein the controlled release matrix is in the form of a tablet, the matrix consisting of multiparticulates of tramadol hydrochloride and hydrogenated vegetable oil having a melting point of 35 to 140°C, was already filed on 12 March 2009, i.e. two months before the oral proceedings.

Under these circumstances, the Board considers that its evaluation could have been easily undertaken by the appellant-opponents. Accordingly, it is admitted into the proceedings.

3. Main request

Article 100(b) EPC

3.1 According to the patent in suit, (page 5, lines 47 to 49) an oral controlled release preparation of tramadol effective for the treatment of moderate to severe pain for 24 hours can be prepared simply by using a controlled released matrix in the form of matrix

particulates including a hydrophobic fusible carrier or diluent.

This teaching is repeated in claim 1 of the main request, wherein the hydrophobic fusible carrier or diluent is further required to have a melting point of 35 to 140°C.

In document (32), the appellant-patent proprietor has submitted an experiment showing that a controlled release preparation of tramadol in the form of matrix particulates containing a hydrophobic fusible carrier or diluent having a melting point of 35 to 140°C, namely stearyl alcohol (melting point: 59°C), does not have the controlled release properties required in claim 1.

Under these circumstances, the Board considers that the broad teaching of claim 1 and the description, i.e. to use any matrix in the form of multiparticulates provided it contains any hydrophobic fusible carrier or diluent having a melting point of 35 to 140°C is not sufficient to produce the desired controlled release profile for the treatment of moderate to severe pain for 24 hours as required in claim 1.

3.2 The appellant-patent proprietor did not deny that the structural technical features of claim 1 covered the embodiments of document (32), but contended that the skilled person would not consider these formulations of tramadol as a formulation according to the contested patent because the matrix in document (32) was not hydrophobic since it contained a hygroscopic polymer (i.e. NVP-vinyl acetate copolymer).

The Board cannot however accept this line of argument since, firstly, claim 1 does not require the matrix to be hydrophobic since it merely indicates that a hydrophobic fusible compound must be present in the matrix, and, secondly, the description of the patent in suit even foresees the addition in the matrix of a "hydrophilic release modifier" (page 5, paragraph 35, first sentence).

The Board agrees with the appellant-patent proprietor that the description, in particular example 8 in connection with the disclosure on page 7, paragraph 59, enables the skilled person to prepare a formulation according to claim 1, namely with the desired release profile.

In the light of document (32), this disclosure and in particular example 8 cannot, however, be representative for the whole scope of claim 1. This has been moreover confirmed during the oral proceedings since the appellant-patent proprietor himself conceded during the oral proceedings that, in order to obtain the desired release profile, the matrix is required to be hydrophobic and not just to contain a hydrophobic fusible compound. This teaching is clearly not present and/or derivable from the contested patent since as mentioned above the addition in the matrix of a "hydrophilic release modifier" is even foreseen (page 5, paragraph 35, first sentence), and this technical feature, namely a "hydrophobic matrix", is also not in claim 1.

Accordingly, this set of claims has to be rejected because the subject-matter of claim 1 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Under these circumstances, there is no need to examine the dependent claims.

4. First auxiliary request, new main request and new auxiliary request

First auxiliary request

The above fully applies to this set of claims as well since claim 1 contains the same subject-matter.

New main request and new auxiliary request

These two requests differ from the above requests merely in that the subject-matter relating to a matrix in the form of multiparticulates is now restricted to tablet formulation.

This however does not change the above analysis and conclusions since document (32) relates also to tablet formulation (see experiment 2).

5. Second auxiliary request

5.1 Remittal

Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances. It is however well recognised that any party

should where possible be given the opportunity to have two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In the present case, the subject-matter of the second auxiliary request, which consists of a single claim restricted to a single embodiment wherein the controlled release matrix is in the form of a tablet, the matrix consisting of multiparticulates of tramadol hydrochloride and hydrogenated vegetable oil having a melting point of 35 to 140°C, is essentially the result of a combination of an embodiment of claim 1 and one embodiment of dependent claim 9 of the set of claims maintained by the Opposition Division.

Accordingly, the observations and comments made above do not apply to the present case since the subject-matter of claim 1 formed, inter alia, the basis for the examination of the Opposition Division, so that the Board does not consider remittal of the case necessary.

5.2 Article 100(b) EPC

During the oral proceedings the appellant-opponents did not raise any objections under Article 100(b) EPC against this request and the Board sees no reason to differ.

In fact, this claim is based on example 8 of the description, which is fully representative for the restricted scope of the claim.

5.3 Article 123 EPC

The board is satisfied that the restricted subject-matter of this request is disclosed in the original description on page 10, second and fourth paragraphs, page 11, third paragraph, page 13, seventh paragraph and page 4, table.

Moreover, during the oral proceedings the appellant-opponents did not raise any objections under Article 100(c) EPC against this request.

5.4 Clarity (Article 84 EPC).

The Board observes that none of the appellant-opponents objected that the terms or the overall meaning of the claim was unclear or not understandable.

The only objection raised was in substance that it was not clear how to select the tabletting ingredients and the various amounts of ingredients in order to achieve the desired release profile.

This objection, which is in fact an objection relating to Article 100(b) EPC, cannot however be followed by the Board in the absence of any experimental data and/or detailed argumentation, since, on the one hand, example 8, which is fully representative for the restricted scope of the claim, shows an in vitro and in vivo release profile according to the invention, and,

on the other hand, the description provides information on how to adjust the release profile (page 7, paragraph 7, lines 35 to 39).

5.5 Novelty

No novelty objection was raised against this subject-matter and the Board sees no reason to differ.

5.6 Inventive step

5.6.1 The contested patent relates to a once-a-day controlled release preparation for oral administration of tramadol having a specific release profile (page 2, paragraph 1; page 3 paragraph 13).

The Board considers that document (11), which disclosed a conventional release preparation of tramadol in the form of a capsule having an efficacy in the treatment of pain for about 9 +/- 2,2 h., represents the closest prior art (summary).

Vis-à-vis document (11), the technical problem may therefore be formulated as the provision of a means which enables a once-a-day administration of tramadol for the treatment of pain.

5.6.2 This problem is solved by the use of an oral controlled release preparation having the technical features of the claim.

In the light of the description, in particular example 8 and figure 2, of the patent in suit, the Board is satisfied that the problem has been solved.

5.6.3 Thus the question to be answered is whether the proposed solution would have been obvious to the skilled person in the light of the prior art.

In that respect, the Board notes that three documents, namely documents (9) (column 5, line 15), (18) (column 3, line 20) and (19) (page 7, line 30) disclose, among a list of other active agents, tramadol in combination with controlled release preparations.

The matrix of the controlled release preparations of documents (9) and (18) is similar and contains polymers such as NVP/vinyl acetate (respectively, column 3, lines 1 to 22; column 1, line 59 to column 2, line 17).

The controlled release preparations of document (19) are coated with polyvinyl alcohol (page 3, line 26 to page 4, line 33).

Thus, these disclosures appear to be suitable candidates to solve the problem as stated above.

In fact, the controlled release preparations of these documents are disclosed as being useful for almost any drugs, among which tramadol is mentioned *expressis verbis*.

The Board has therefore no doubt that the skilled person would indeed combine the teaching of these documents with document (11) since these disclosures appear to be *prima facie* suitable candidates to solve the problem as stated above.

The Board observes however that the controlled release preparations of these documents are structurally very different from the system disclosed in the contested patent which consists of multiparticulates made of hydrogenated vegetable oil and tramadol further compressed into a tablet with tabletting excipients.

The appellant-patent proprietor has moreover shown in documents (32) and (33), wherein controlled release formulations according to respectively documents (9) and (19) were reproduced, that the controlled release preparations according to these documents are not suitable for achieving a controlled release of tramadol, contrary to the teaching of said prior-art documents.

As none of the available prior-art document contains any hints as to how to modify these controlled release formulations so as to end up with the claimed formulations, the subject-matter of the claim fulfils the requirements of inventive step.

5.6.4 The appellant-opponents have mainly argued that the controlled release preparations as claimed were disclosed in documents (13) (page 2, under item (b)), (15) (page 5, under item (b)) and (20) (page 4, lines 14 to 24, and page 6, lines 33 to 38), so that the combination of document (11) with any of these documents would render this claim obvious.

Firstly, the Board agrees that the claimed pharmaceutical compositions have compositional

features, which are similar to those mentioned in the prior-art documents.

This is however not sufficient to establish that a person skilled in the art would indeed have a motivation to adapt these features so as to end up with the features of the claim to solve the stated problem.

It is indeed a key condition for assessing inventive step using the problem-solution approach that the prior art must be considered without the knowledge of the solution provided in the patent in order to avoid insight analysis.

In the present case, the skilled person had no reason to consider these documents since their only link to the patent is the similarity with the features of the controlled release described in the contested patent, i.e. the solution of the problem, which it is supposed to ignore when looking for a solution.

Accordingly, these combinations are the result of an *ex post facto* analysis since, contrary to documents (9), (18) and (19), tramadol is not mentioned in these prior-art documents.

Secondly, the Board observes that none of these documents disclosed a tablet made from a matrix **consisting of hydrogenated vegetable oil**.

Indeed, **hydrogenated** vegetable oils are even not mentioned in documents (13),(15) and (20), and the matrix disclosed in document (13) requires moreover the presence of a polydextrose (claim 1).

Accordingly, none of the above combinations would lead to the claimed subject-matter.

The Board also does not agree with the appellant-opponents' submission that the claimed controlled release preparations are merely the result of an arbitrary choice among the available controlled release preparations, since documents (32) and (33) show that not all available controlled release preparations would be suitable for tramadol.

Finally, the Board also does not follow the unrealistic argument that the claimed subject-matter is not inventive because the skilled person would find the claimed controlled release formulation of tramadol just by systematically and routinely trying tramadol in all existing controlled release formulations.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the sole claim of auxiliary request 2 filed during the oral proceedings held on 12 May 2009 before the Board of Appeal and a description to be adapted.

The Registrar The Chairman

N. Maslin U. Oswald