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D E C I S I O N
of 1 August 2002

Case Number: T 0592/99 - 3.3.2

Application Number: 94303128.6

Publication Number: 0624366

IPC: A61K 31/135

Language of the proceedings: EN

Title of invention:
Controlled release formulation containing tramadol

Patentee:
Euro-Celtique S.A.

Opponent:
Krewel-Meuselbach GmbH
Nycomed DAK A/S
Bioglan Laboratories Ltd
Lannacher Heilmittel Ges.m.b.H.
Hexal Aktiengesellschaft
Arzneimittelwerk Dresden GmbH

Headword:
Matrix-formulation/EURO-CELTIQUE

Relevant legal provisions:
EPC Art. 100(c), 84, 112(1), 123(2),(3)

Keyword:
"Subject-matter of claim 1 of the patent in suit as granted extends beyond the application as filed - claimed subject-matter covers products not originally disclosed - technical contribution according to G 0001/93"

Decisions cited:

Headnote:
In the view of the Board, in the typical example given in point 16 of the decision G 0001/93, the expression "inventive selection" in the phrase "where the limiting feature is creating an inventive selection not disclosed in the application as filed or otherwise derivable therefrom" cannot mean anything other than a **potential** (inventive) selection - obviously, an opponent cannot be requested to demonstrate the potential character of the selection without making or preventing itself from making a further selection invention (Reasons No. 2.5)

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Case Number: T 0592/99 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 1 August 2002

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 9 June 1999 revoking European patent No. 0 624 366 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 624 366, based on European patent application No. 94 303 128.6 was granted on the basis of 7 claims.

Claim 1 reads as follows:

"A controlled release, oral pharmaceutical preparation suitable for dosing every twelve hours containing 50 to 400mg of tramadol or pharmaceutically acceptable salt thereof (calculated as hydrochloride) in a controlled release matrix, the matrix containing between 1 and 80% w/w of one or more hydrophilic or hydrophobic polymers, preferably a cellulose ether, and having the following dissolution rate in vitro when measured using the PH. Eur. Paddle Method at 100rpm in 900ml 0.1 N hydrochloric acid at 37EC and using UV detection at 270nm ;
between 5 and 50% (by weight) tramadol released after 1 hour,
between 10 and 75% (by weight) tramadol released after 2 hours,
between 20 and 95% (by weight) tramadol released after 4 hours,
between 40 and 100% (by weight) tramadol released after 8 hours,
more than 50% (by weight) tramadol released after 12 hours,
more than 70% (by weight) tramadol released after 18 hours,
more than 80% (by weight) tramadol released after 24 hours."

II. Seven Oppositions were filed against the granted patent.

In addition to the grounds of opposition under Article 100(a) EPC an objection under Article 100(c) EPC was raised on the grounds that the feature "...the matrix containing between 1 and 80% w/w...polymers", extends beyond the content of the application as filed.

III. By a decision announced on 27 April 1999, and posted with written reasons on 9 June 1999, the Opposition Division revoked the patent under Article 102(1) EPC.

In the Opposition Division's view the subject-matter of the main request (the set of claims as granted) and the first and second auxiliary requests did not comply with Article 123(2) EPC.

More particularly, it was pointed out that the term "...the matrix containing between 1 and 80% w/w...polymers" in claim 1 of the main request was a clear technical feature but found no basis in the application as originally filed. The application as originally filed disclosed a preparation containing 1 to 80% polymer not excluding other ingredients in the final preparation. Accordingly, the amendment relating to a polymer content in the matrix instead of the preparation changed the polymer content. There was also no contradiction between claim 1 and dependent claim 5 defining a dosage form of the preparation.

The same reasoning applied to the first auxiliary request which included in line 4 of claim 1 as granted (page 11, line 46 of the specification) after the wording "...preferably a cellulose ether...", the

further amendment *"the w/w basis being weight of the polymer per weight of the preparation".*

The amendment to the second auxiliary request implying that the terms "matrix" and "preparation" should mean the same product was also not derivable from the application as originally filed.

The description including the examples as originally filed left no doubt that the matrix should be regarded as something like a container which together with the other ingredients made up the preparation.

IV. The Appellant appealed against this decision.

On the 2 July 1999 Respondent 03 (Opponent 03) withdrew as a party to the opposition and appeal proceedings.

With its grounds of appeal filed on 11 October 1999, the Appellant filed two auxiliary requests. The first auxiliary request corresponded as regards content to the first auxiliary request before the first instance and was presented as a correction under Rule 88 EPC. The wording of claim 1 of the second auxiliary request corresponded to claim 1 as granted with the additional words *"...provided that the preparation must contain between 1 and 80% w/w of the one or more hydrophilic or hydrophobic polymers."*

Oral proceedings took place on 1 August 2002 during which the Appellant withdrew its first auxiliary request filed with the grounds of appeal. During the oral proceedings the Appellant presented the following question to be referred to the Enlarged Board of Appeal:

"Where an amendment is made to a claim by reducing a stated range in the claim and where

(A) that reduced range is not identified in the application as filed, and

(B) the reduction does not provide a technical contribution to the subject-matter of the claimed invention

does that amendment extend the content of the application as filed within the meaning of Article 123(2) EPC ?"

V. The arguments of the Appellant, both during the written procedure and at the oral proceedings, may be summarised as follows:

The limitation regarding the 1 to 80% of one or more hydrophilic or hydrophobic polymers was introduced into claim 1 as a result of an interview with the first Examiner during the examination procedure. The choice of the wording regarding the allegedly wrong weight basis for the polymers, however, was accidentally introduced. The Examiner did not object to the wording introduced.

To read claim 1 in isolation, as was done by the Opposition Division could not be correct particularly having regard to the requirements of Article 69 EPC and the outcome of decision T 860/93. The patent as a whole made it clear that the weight per weight (w/w) basis is weight of the polymer per weight of preparation rather than weight of polymer per weight of matrix. This was

supported by reference to claim 5 in which the product might contain as little as 1% of alkyl-celluloses with a w/w basis polymer/preparation. The bottom limit of 1% w/w in claim 1 must therefore be read as weight of polymer per weight of preparation since otherwise claim 5, which was dependent on claim 1, claimed a product outside the scope of claim 1.

In the alternative, if claim 1 was indeed to be read in isolation as specifying a w/w basis of polymer per matrix, reference was made to decision G 1/93 of the Enlarged Board of Appeal and in particular to the general guidance it provided on the underlying principles of equity. The overall purpose of Article 123(2) and (3) EPC was to create a fair balance of interests, as explained in paragraphs 8 and 9 of G 1/93, and having regard also to the effect of Article 69(2) EPC as explained in paragraph 10.

As for the requirement that the feature in claim 1 "...the matrix containing 1 to 80% of one or more hydrophilic or hydrophobic polymers..." should be an undisclosed feature only limiting the scope of protection, it was only an undisclosed feature to the extent that the weight basis is that of the matrix and not that of the preparation. This change did not provide a technical contribution in the sense for example of creating an inventive selection but merely excluded protection for a small part of the original subject-matter and accordingly did not adversely affect the interests of third parties as also required by decision G 1/93.

It was particularly to be noted that an upper limit of 80 wt% polymer/matrix was not greater than an upper

limit of 80 wt% polymer/preparation. Considering for instance the product of Example 1, the matrix had a film coating which amounted to about 3 wt% of the product and typically the matrix amounted to 97 wt% of the product. As such, an upper limit of 80 wt% polymer/matrix approximated to an upper limit of 77,6 wt% polymer/preparation. Moreover, for a product which consisted solely of the matrix (film coating being optional), the figures were the same regardless of how the weight basis was expressed. Similarly a lower limit of 1 wt% polymer matrix was not greater than a lower limit of 1 wt% polymer preparation. For a film coated product a typical lower limit of 1 wt% polymer/matrix approximated to a lower limit of 0.97 wt% polymer/preparation. The amount of 0.97 wt% was within the limits of what is meant by 1 wt% since clearly an experimental determination of value of 0.97 wt% is within the rounded meaning of 1 wt%. On the basis of the proposed wording of claim 1 of the second auxiliary request it was in any case certain that there was no extension of the protection at the bottom end of the range. Considering an imaginary product weighing 100 mg with a coating of 3 mg, the figures for polymer per preparation were 1 mg in comparison with 0.97 mg polymer per matrix for the lower limit of 1 wt% and 80 mg polymer per preparation in comparison with 77,6 mg polymer per matrix for the upper limit of 80 wt%.

Regarding the overall composition of the preparation including the amount of tramadol, it was necessary to take into account both the clear technical information on page 2, line 46 of the specification that "the active ingredient in the preparation ... may suitably be incorporated in a matrix ... that affords controlled

release tramadol ..." and also the fact that "alternatively, normal release matrices having a coating which provides for controlled release ... may be used."

Having regard to example 1 of the patent in suit, it was clear that the accidental change of weight basis disclaimed not only a negligible part of the composition but also only a small part of the release profile and thus merely excluded protection for a small part of the subject-matter of the claimed invention as covered by the application as filed. The adding of such feature could not reasonably be considered to give any unwarranted advantage to the Patentee (Appellant). Nor did it adversely affect the interests of third parties.

It was emphasised that the burden on proof was on the Respondents to show what was the technical contribution resulting from an accidental change of the weight basis.

Finally, it was strongly denied that the alleged change in the claimed release profile resulting from the change in the weight basis for the polymer content of the preparation formed part of the common general knowledge in the art.

Therefore, in the light of Headnote 2 of the decision G 1/93 the ground for opposition under Article 100(c) did not prejudice the maintenance of the patent in suit which included the feature in question.

VI. The Respondents' arguments may be summarized as follows:

In the circumstances of the present case none of the criteria set out in decision G 1/93 were fulfilled, particularly since the change of the weight basis in the present case had a drastic effect on the bottom end of the range of polymer content of the preparation and the matrix.

Contrary to the Appellant's assertion the following points had to be to taken into account:

(i) The patent in suit did not provide any technical information as to the meaning of the term matrix in claim 1;

(ii) claim 1 as granted did not relate to preparations containing exclusively 97 wt% of matrix material and 3 wt% of a coating;

(iii) the active ingredient tramadol did not form part of the matrix (-material) as such;

(iv) a change of the matrix composition caused a change of the release profile;

(v) the application as originally filed allowed a matrix in the form of a component consisting 100% of polymer material whereas claim 1 as granted necessarily required a minimum of 20 % of other components of the matrix material.

Points (iv) and (v) alone showed that the weight basis for the polymer content in claim 1 provided a technical contribution to the subject-matter of the claimed invention in the form of a functional effect on the preparation as such.

Moreover, the 100 mg tablet forming the basis for the Appellant's calculation but containing 26 wt% of matrix material of the total preparation instead of the Appellant's 97 wt%, would then contain **0.26 mg polymer** at the bottom end range of 1% polymer per matrix material, an amount much lower than the **1 mg** polymer calculated on the basis of the originally disclosed weight basis in relation to the total preparation.

The figures produced on the basis of simple calculation also clearly demonstrated that the feature in claim 1 as granted relating to the weight basis of the polymer content provided a technical contribution to the subject-matter of the claimed invention in the form of a limiting but originally undisclosed feature which cannot be deleted without offending Article 123(3) EPC.

Further, there was neither a lack of clarity nor a contradiction between the wording of independent claim 1 and dependent claim 5 which could give rise to the Appellant's interpretation of the weight basis of the polymer in the preparation. Claim 5 in fact represented a preferred embodiment of a dosage form of the preparation of claim 1 by limiting the type of polymer and polymer content such that the polymer content could not fall below the lower limit of 1% of polymer in the matrix.

VII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained either unamended or on the basis of claim 1 of the second auxiliary request filed with the grounds of appeal on 11 October 1999 and claims 2 to 7 as in the granted patent and dependent on that new claim 1 (the only auxiliary request: the first auxiliary request having

been withdrawn - see IV above).

The Respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Claim 1 of the main request with the set of claims as granted and claim 1 of the only auxiliary request both relating to a controlled release, oral pharmaceutical preparation containing tramadol in a controlled release matrix comprise the feature opposed under Article 100(c) EPC *"... the matrix containing between 1 and 80% w/w of one or more hydrophilic or hydrophobic polymers ..."*.

It was common ground between the parties that the only disclosure for the range of between 1 and 80% w/w of one or more hydrophilic or hydrophobic polymers is to be found on page 6, last full paragraph of the application as originally filed. Having regard to the exact wording *"The preparation may conveniently contain between 1% and 80% (by weight) of one or more hydrophilic or hydrophobic polymers*", this passage, however, clearly discloses that the preparation as such forms the basis for the said range of percentage by weight

2.1 Furthermore, the Board notes that page 6, third paragraph and the worked examples of the application as originally filed also clearly disclose that the active agent tramadol is incorporated in a matrix and therefore does not form part of the matrix material as

such.

Moreover, as the Respondents argued, the worked examples of the patent in suit clearly show the inclusion of other ingredients than polymer and tramadol, inter alia magnesium stearate and talc, in tablets of the claimed pharmaceutical preparation.

By the use of the wording "A...preparation...containing..." claim 1 as granted is clearly open as to the inclusion of additional ingredients besides the matrix.

Accordingly, there is no room for the assumption that the matrix as such and the claimed preparation represent the same composition expressed in percentage per weight of each of the components in the composition, nor is it possible to equate the specific functionality of a *"controlled release matrix"* as claimed and the overall functionality of the oral pharmaceutical preparation comprising the active agent tramadol incorporated in the matrix and other possible ingredients making up the preparation eg suitable for oral administration.

2.2 Further taking into account that claim 1 as granted does not contain any limitation as to the proportion of the matrix to the total preparation composition, the Board sees no reason to doubt the Respondents' calculation (see point VI above) made to exemplify compositions defined by the upper and lower limit of the range of polymer content in the matrix and the final preparation in the form of a tablet. This calculation clearly demonstrates that, by the change of weight basis from matrix to preparation, claim 1

defines new preparation compositions as exemplified by a tablet of 100 mg which may contain 0.26 mg polymer instead of 1 mg.

2.3 Finally, the Board is satisfied that the change of the weight basis of the polymer content not only causes a change of the overall composition expressed as a percentage but also changes the release profile as defined in claim 1.

This was strongly contested by the Appellant. However, claim 1 clearly relates to a pharmaceutical preparation containing the active agent tramadol in a controlled release matrix and therefore a change of the matrix content in relation to the unchanged total mass of the preparation (tablet) with a fixed amount of the active agent must influence the release profile.

2.4 Accordingly, **the feature as originally disclosed having been replaced by the feature objected to under Article 100(c) EPC, the claim as such relates to different products** and the Board can only conclude that in keeping with "Order 1" of decision G 1/93 (OJ 1994, 541) the patent in suit contains subject-matter which extends beyond the content of the application as filed which is prohibited by Article 123(2) EPC. Thus, the patent cannot be maintained unamended, because the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent. On the other hand, it cannot be amended since, as shown above, deleting the limiting subject-matter from the claims would extend the protection conferred, which is prohibited by Article 123(3) EPC.

2.5 In the case of a product claim concerning a composition

defined by its components and their relative amounts given in terms of ranges, it cannot be accepted that such ranges, which constitute essential features, do not provide a technical contribution to the subject-matter of the claimed invention, as suggested by the Appellant. Any amendment to the ranges must have the effect of modifying the claimed subject-matter, and thus also provide a technical contribution.

If the newly claimed limited range were, although unsupported, allowed, any subsequent selection invention based on this new range would have to be refused as not novel, which would otherwise not necessarily be the case. To allow this would, of course, give an unwarranted advantage to the patentee, contrary to the purpose of Article 123(2) EPC. In the view of the Board, this is exactly what was meant in the "typical example" given in point 16. of the decision G 1/93 "where the limiting feature is creating an inventive selection **not disclosed** in the application as filed or otherwise derivable therefrom" (emphasis added). Obviously, in the quoted text, such an "inventive selection" cannot mean anything other than a **potential** (inventive) selection.

Obviously the Respondents cannot be requested to demonstrate the potential character of the selection without making, or preventing themselves from making a further selection invention. Thus, the burden of proof cannot reasonably be shifted to them, as demanded by the Appellant.

Therefore, the new feature constitutes added subject-matter.

2.6 The Appellant's calculation described in point V (7th paragraph) above, is based on one particular matrix content of the preparation. Claim 1 as granted does not in fact relate to such preparations containing exclusively 97 wt% of matrix material and 3 wt% of a coating. Moreover, contrary to the Appellant’s view, the results of these calculations demonstrate that the change of weight basis in question leads to an unallowable potential selection within the meaning of point 16 of the reasons for the decision G 1/93, particularly regarding the upper limit of the percentage range (see point V above).

2.7 The Board does not agree with the Appellant’s submission regarding the application of Article 69(1) EPC as proposed in decision T 860/93 (OJ EPO 1995, 047). Neither claim 1 as granted shows a lack of clarity regarding the subject-matter for which protection is sought, nor is there any contradiction between the composition of the preparation of claim 1 and the composition of the dosage form according to dependent claim 5 as granted. The Board agrees with the Respondents' submission that dependent claim 5 relates to a preferred embodiment of a dosage form of the preparation of claim 1 by limiting the type of polymer and polymer content such that the polymer content could not fall below the lower limit of 1% of polymer in the matrix.

2.8 Finally (as regards the main request), the Appellant’s argument that the excision of parts of the range of polymer content in the preparation, or the excision of parts of the release profile of the drug caused by the accidental introduction of the undisclosed weight basis, simply represents the exclusion of subject-

matter in the same way as an allowable disclaimer over prior art, is unacceptable. There is clearly a substantial difference between an amendment to disclaim an "accidental" anticipation and an amendment which affords protection for something not disclosed in the application as filed.

2.9 Having regard to claim 1 of the only auxiliary request which is formulated in the following way:

A controlled release, oral pharmaceutical preparation ... containing ... tramadol ... in a controlled release matrix, *the matrix containing between 1 and 80% w/w of one or more hydrophilic or hydrophobic polymers* ... and having the following dissolution rate in vitro ... ***"...provided that the preparation must contain between 1 and 80% w/w of the one or more hydrophilic or hydrophobic polymers."***

the Board sees no reason to deviate from its conclusion as set out under point 2.4 above.

The application document as originally filed neither expressis verbis nor implicitly discloses a combination of different weight bases for the content of one or more hydrophilic or hydrophobic polymers in the total composition of the preparation, nor does such a combination avoid the selection of new upper values of the polymer content in the preparation in comparison with the granted version of the claim.

2.10 Moreover, in the present case the application of two different weight bases for the overall polymer content is contradictory and therefore causes a lack of clarity within the meaning of Article 84 EPC.

2.11 Since each of the Appellant's requests fails to meet the requirements of the EPC, there is no reason to set aside the decision of the first instance.

2.12 As regards the Appellant's requested referral of a question to the Enlarged Board of Appeal, the Board considers Decision G 1/93 provides adequate guidance as to when an amendment which adds an undisclosed limiting feature provides a technical contribution and whether such an amendment gives a patentee an unwarranted advantage or not and, as appears from the reasons above, the Board has without difficulty followed that guidance in the present case. Therefore, the Board cannot see this case as raising a new important point of law or any question of ensuring uniform application of the law, the conditions for a referral to the Enlarged Board of Appeal (Article 112(1) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend P. A. M. Lançon