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**Datasheet for the decision  
of 11 October 2018**

**Case Number:** T 1209/15 - 3.3.07

**Application Number:** 06708567.0

**Publication Number:** 1855657

**IPC:** A61K9/28, A61K31/485, A61P25/04

**Language of the proceedings:** EN

**Title of invention:**  
DOSAGE FORM CONTAINING OXYCODONE AND NALOXONE

**Patent Proprietor:**  
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**Opponents:**  
Hexal AG  
Actavis Group PTC ehf  
ETHYPHARM  
Teva Pharmaceutical Industries Ltd.  
G. L. Pharma GmbH  
Acino Pharma AG

**Headword:**  
Oxycodone/ EUROCELTIQUE

**Relevant legal provisions:**  
EPC Art. 123(2)

**Keyword:**

Amendments - added subject-matter (no)



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Case Number: T 1209/15 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 11 October 2018**

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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 8 April 2015  
revoking European patent No. 1855657 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** J. Riolo  
**Members:** A. Usuelli  
P. de Heij

## **Summary of Facts and Submissions**

- I. European Patent 1 855 657 based on European patent application 06708567.0 was granted on the basis of 3 claims. Claim 1 related to a sustained release formulation comprising oxycodone and naloxone for use in the treatment of moderate to severe pain and other conditions.
- II. Six oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed. By decision posted on 8 April 2015 the patent was revoked. The decision was based on the patent as granted as main request, and on 8 auxiliary requests.
- III. In the appealed decision, the opposition division essentially considered that the combination of features recited in claim 1 of the patent had not been disclosed as such in the application as filed. In particular, starting from the disclosure on page 15, line 21 to page 16, line 4, several selections had to be made in order to arrive at the subject-matter of claim 1. Hence, the patent did not comply with the requirements of Article 123(2) EPC. The auxiliary requests did not meet the requirements of Article 123(2) EPC for essentially the same reasons as the main request.
- IV. The patent proprietor (hereinafter: the appellant) filed an appeal against that decision. In the statement setting out the grounds of appeal filed on 10 August 2015, the appellant submitted a main request and 11 auxiliary requests.

Claim 1 of the main request read as follows:

"1. A sustained release pharmaceutical dosage form comprising 40 mg of oxycodone or a pharmaceutically acceptable salt thereof and 20 mg of naloxone or a pharmaceutically acceptable salt thereof with oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof being present in a ratio of 2:1 by weight for use in the treatment of moderate to severe pain and opioid bowel dysfunction syndromes occurring during pain therapy, wherein said opioid bowel dysfunction syndrome is constipation, and adverse events, wherein said adverse event is the elicited naloxone typical adverse event diarrhea."

- V. In the replies to the appeal the opponents (hereinafter: respondents) submitted their arguments on Article 123(2) EPC and contested the admissibility of several requests. Some respondents further argued against the possibility of remitting the case to the opposition division for further prosecution.
- VI. In a communication pursuant to Article 15(1) RPBA issued on 13 August 2018 the Board expressed, *inter alia*, the opinion that claim 1 of the main request met the requirements of Article 123(2) EPC. It furthermore considered that it appeared appropriate to remit the case for further prosecution if one of the requests were considered to comply with Article 123(2) EPC.
- VII. Oral proceedings were held on 11 October 2018. They were not attended by respondents 2 and 6 as announced by letters dated 14 March 2018 and 4 August 2017, respectively.

VIII. The appellant's arguments, as far as they are relevant for the present decision, can be summarised as follows:

(a) Article 123(2) EPC

Claim 1 of the main request was disclosed in the passage of page 15, line 21 to page 16, line 4. This passage was not an isolated statement detached from the remainder of the application. In fact, it was clear from the clinical trial disclosed in example 1 that the application as filed considered the therapeutic areas of pain, opioid bowel dysfunction (OBD)/constipation and adverse events (AE)/diarrhea together. Thus, contrary to the opposition division's conclusions, combining the treatments of moderate to severe pain, constipation and diarrhea was not an artificial combination. The expression "treatment" used in claim 1 was to be regarded as an "umbrella" term that also covered prophylactic treatment. The fact that some features disclosed in the passage of pages 15/16 had not been incorporated into claim 1 did not result in an intermediate generalization, since these features were described as optional. Moreover, the original application disclosed a generic sustained release preparation on page 50 that was not restricted by the optional features disclosed on page 16. For instance, there was no indication on page 50 that the dosage form had to release the active ingredients in an invariant and independent manner.

(b) Remittal

The opposition division did not decide on the issues of novelty and inventive step. It was therefore appropriate to remit the case for further prosecution.

IX. The respondents' arguments, as far as they are relevant for the present decision, can be summarised as follows:

(a) Admissibility

The main request should not be admitted into the appeal proceedings under Article 12(4) RPBA. The appellant had ample opportunity during the first instance proceedings to address the objection under Article 123(2) EPC. Since it chose not to file this request during first instance proceedings it should not be permitted to file it on appeal. In addition, the modification of claim 2 and the deletion of claim 3 do not appear to comply with Rule 80 EPC.

(b) Article 123(2) EPC

The passage starting from page 15 of the original application did not provide a clear and unambiguous disclosure of the subject-matter of claim 1 of the main request. It referred simultaneously to the treatment and/or reduction and/or prevention of several conditions. It was not a valid basis for isolating the "treatment" feature and combining this feature with the specific conditions mentioned in claim 1. In addition, it made no sense to treat diarrhea and constipation at the same time. Furthermore, claim 1 of the main request did not specify that the active ingredients were released in an invariant and independent manner from a substantially non-swellable diffusion matrix. However, these features were disclosed in the passage starting from page 15. Moreover, this passage referred to "the dosage form according to the present invention". This form was the one defined in claim 1 of the original application which was characterised, *inter alia*, by a specific Tmax. The omission of the Tmax in claim 1 of



the main request resulted in an addition of subject-matter. The introduction in claim 1 of the "salt thereof" feature also had no clear basis in the original application. The clinical trial described in example 1 did not relate to the use of a single-dosage form containing oxycodone and naloxone. For this reason alone this example could not be used as the basis for the subject-matter of claim 1.

(c) Remittal

Remitting the case to the opposition division for further prosecution was contrary to the need for legal certainty. Moreover, the decision included an *obiter dictum* concerning the requirements of sufficiency of disclosure, novelty and inventive step. Accordingly, the remittal to the department of first instance should be avoided.

(d) Remittal - Arguments of respondent-4

Remittal would lead to further delay in the handling of the case, which should be avoided. In case of remittal, the Board should order that the appellant not be allowed to submit new sets of claims or data.

X. The appellant requested:

- that the decision under appeal be set aside and the patent be maintained on the basis of the set of claims of the main request or, alternatively, that the patent be maintained on the basis of the set of claims of auxiliary requests I, IIa, IIb, IIIa, IIIb, IVa, IVb, V, VI, VII or VIII, all submitted with the grounds of appeal;

- that the case be remitted to the opposition division for discussion of the requirements of novelty and inventive step and sufficiency of disclosure.

XI. The respondents requested that the appeal be dismissed, that all the requests, with the exception of auxiliary request I, not be admitted into the proceedings and that the case not be remitted to the opposition division.

## **Reasons for the Decision**

### Main request

1. Admittance

1.1 The appellant's main request was filed with the statement setting out the grounds of appeal. Accordingly, it forms part of the basis of the appeal proceedings, unless it is concluded that it should have been submitted during the first instance proceedings (Article 12(4) RPBA).

1.2 Claim 1 of the main request differs from claim 1 as granted in that the adverse events have been limited to diarrhea (deletion of abdominal pain and cramping). This amendment addresses the conclusion made by the opposition division on page 8 of the decision (lines 8 to 10), according to which the reference to "diarrhea" on page 15 of the original application could not serve as a basis for claiming any naloxone typical adverse events. The deletion of claim 3 and the modifications in claim 2 constitute an adaptation of the entire set of claims to new claim 1.

1.3 Thus, the submission of the main request is a legitimate attempt on the part of the appellant to overcome the objections leading to the revocation of the patent. In the Board's view, there were no compelling reasons for the appellant to file this request at an earlier stage. Hence, the Board decides to admit the main request into the appeal proceedings.

2. Article 123(2) EPC

2.1 Claim 1 relates to the use of an oxycodone/naloxone formulation in the treatment of:

- (i) moderate to severe pain
- (ii) opioid bowel dysfunction syndromes (OBDs), wherein said OBD is constipation, and
- (iii) adverse events (AEs), wherein said adverse event is the elicited naloxone typical AE diarrhea.

Since both the OBDs and AEs are restricted to single diseases, claim 1 relates to the treatment of three specific conditions, namely moderate to severe pain, constipation and diarrhea.

2.1.1 The passage of the original description relied upon by the appellant as a possible basis for the subject-matter of claim 1, i.e. the paragraph linking pages 15 and 16, refers to these three conditions without mentioning any other specific disease.

This paragraph describes a method of treating moderate to severe pain by the use of an oxycodone/naloxone dosage form and states that by this method constipation and diarrhea are reduced and/or prevented and/or treated. Claim 1 of the main request refers instead

only to the treatment of pain, constipation and diarrhea.

- 2.1.2 The Board considers that the deletion of the terms "reducing and or/preventing" does not result in the addition of new information. Constipation and diarrhea are side effects caused by the oxycodone/naloxone medication itself. It is clear that the patent in suit addresses the problem of providing a therapy that provides an analgesic effect and is safe, i.e. it reduces these side effects (see, e.g., page 8, second paragraph and page 9, lines 16 to 18 and 25 to 26). In the Board's view, a clear distinction between reduction/prevention and treatment (of constipation and diarrhea) cannot be made in the present case. Indeed, it appears difficult to establish whether the safety of a specific oxycodone/naloxone dosage form is due to the fact that this dosage form prevents or reduces or treats these side effects. Therefore, using the term "treatment", which also covers the concept of prophylactic treatment, correctly reflects the teaching of the patent in suit, which is to provide a pain therapy that does not result in excessive discomfort in terms of side effects. In this context, it is observed that in the first paragraph of page 98 the term "treatment" is used in relation to the reduction of pain, improvement of BFI (i.e. bowel functionality) and avoidance of diarrhea.

- 2.2 The above interpretation of the passage linking pages 15 and 16 is in line with the experiment disclosed in example 1.

This example describes a study aimed at investigating whether an oxycodone/naloxone combination is effective in providing analgesia and decreasing constipation

(page 66, line 10 to 16). The incidence of diarrhea is also considered in the study (page 94, lines 24), and it is concluded that it is reduced when a 2/1 oxycodone/naloxone ratio is used. Thus, example 1 confirms that the patent in suit relates to the provision of a therapy for the treatment of pain, constipation and diarrhea.

Hence, the features defining the therapeutic application of the dosage form have a basis pursuant to Article 123(2) EPC in the paragraph linking pages 15 and 16.

2.3 As to the features defining the composition, claim 1 indicates that it is a sustained release dosage form comprising:

- (i) 40 mg of oxycodone or a pharmaceutically acceptable salt thereof and
- (ii) 20 mg of naloxone or a pharmaceutically acceptable salt thereof wherein
- (iii) oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof are present in a ratio of 2:1 by weight.

2.3.1 The appellant referred again to the paragraph linking pages 15 and 16 of the original application as a possible basis for the features concerning the composition.

Indeed, the Board notes that this paragraph indicates that oxycodone and naloxone are preferably administered in a 2:1 weight ratio (page 15, lines 25 and 26), and that the dosage form preferably comprises about 40 mg oxycodone and 20 mg naloxone (page 16, lines 2 to 4). The information that the composition is a sustained

release dosage form is disclosed in several parts of the original application (e.g. page 50, lines 14 and 15). The possibility of using salts as the active ingredients is disclosed for instance on page 27 (lines 17 to 19) and on page 59 (lines 7 to 11).

Thus, the description of the original application discloses the features of the dosage form referred to in claim 1 of the main request.

- 2.3.2 The respondents observed that the paragraph linking pages 15 and 16 of the original application contains additional features relating to the definition of the dosage form that have not been incorporated into claim 1 of the main request. In particular, they argued that claim 1 did not contain any limiting feature defining the amounts of active ingredients administered per day, whereas the original application did.

In this regard, the Board observes that the passage uses the 'per day' feature in the context of defining a dosage, i.e. in relation to the indication of the total amounts of naloxone and oxycodone administered per day. Claim 1 relates instead to a pharmaceutical form for use in the treatment of certain diseases. This form contains 40 mg of oxycodone and 20 mg of naloxone as disclosed on page 16, line 3. Obviously this is without the 'per day' feature because it is just mentioned how much active ingredient is in the pharmaceutical composition.

- 2.3.3 The same consideration applies with regard to the indication that the dosage form preferably releases the active agents in a sustained, invariant and independent manner from a substantially non-swellable diffusion matrix (page 16, lines 4-7). The word

"preferably" (page 16, line 4) unambiguously introduces features that define characteristics of the dosage form that are not compulsory. In line with this, the description discloses broad embodiments in which the composition is merely defined as a "sustained release preparation" (page 50 lines 14 and 15) or "sustained release oxycodone formulation" (page 8, lines 26 and 27). Thus, the fact that claim 1 is not restricted to compositions releasing the drugs in a sustained, invariant and independent manner from a non-swellable diffusion matrix does not violate Article 123(2) EPC.

- 2.3.4 Some respondents argued that "the dosage form according to the present invention" referred to on page 15 (line 25) is the dosage form defined in claim 1 of the original application that is characterised, *inter alia*, by the provision of a certain Tmax for oxycodone. In their view, the fact that claim 1 does not refer to the Tmax of the composition would offend against Article 123(2) EPC.

In this respect the Board notes that the original description also discloses general dosage forms that are not limited by the fact that this Tmax is provided (see also point 2.3.3 above). Furthermore, on page 10 of the description (lines 19 to 23), it is stated that the compositions providing the Tmax recited in claim 1 represent "one aspect of the present invention", i.e. the invention is not limited to these compositions. Therefore, the feature 'dosage form according to the invention' (page 15 line 25) cannot be read as a reference to claim 1. In the Board's view, it rather refers to the dosage form that is disclosed in the next part of the same paragraph, bridging pages 15 and 16. Thus, this argument is also not convincing.

2.3.5 To summarise, the original application refers to formulations defined in broad terms as "sustained release preparations of oxycodone and naloxone" (e.g. page 50) as well as to formulations that are more narrowly defined, e.g. by indicating that they release the active ingredient in a sustained, invariant and independent manner (page 16, lines 4 and 5). However, it is clear that the therapeutic applications remain the same for all these compositions. Thus, linking the diseases mentioned on page 15 with a dosage form that is not restricted by certain limiting features disclosed in the description does not add any new technical information.

2.4 On the basis of the above considerations, the Board concludes that claim 1 of the main request meets the requirements of Article 123(2) EPC.

### 3. Remittal

3.1 The primary function of an appeal is to consider whether the decision issued by the department of first-instance is correct. Hence, a case is normally remitted if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

3.2 These observations fully apply to the present case.

The opposition division considered that none of the requests on file complied with the requirement of Article 123(2) EPC and it did not decide on the other grounds for opposition. In the *obiter dictum* on page 12 of the decision, the opposition division referred to



its preliminary opinion issued on 9 July 2014. However, this communication does not provide any opinion on novelty and inventive step and is anyway not part of the reasons for the decision to revoke the patent.

In the Board's view, these circumstances justify a remittal for further prosecution to the opposition division.

- 3.3 Respondent-4 requested that the appellant be prevented from filing other requests or experimental data during the prosecution of the case before the opposition proceedings.

However, the Board has no power to limit the procedural steps of a party after remittal to the opposition division. Moreover, allowing this request would have the effect of restricting the possibility of the appellant to defend its case before the opposition division, and could therefore violate its right to be heard. For these reasons alone, the request of respondent-4 must be rejected.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated