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Datasheet for the decision of 5 July 2017

Case Number: T 1156/16 - 3.3.01

Application Number: 06111805.5

Publication Number: 1685839

IPC: A61K31/485, A61P25/36

Language of the proceedings: EN

Title of invention:
Pharmaceutical oral dosage form comprising a combination of an opioid agonist and opioid antagonist

Patent Proprietor:
EURO-CELTIQUE S.A.

Opponents:
Hexal AG
Teva Pharmaceutical Industries Ltd.
G. L. Pharma GmbH
Actavis Group hf.
Bachelin, Martin, Dr.
KRKA, d.d., Novo mesto

Headword:
Oxycodone sustained release dosage form/EURO-CELTIQUE

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - clarity after amendment (no)

Decisions cited:
G 0003/14

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 1156/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 5 July 2017

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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 8 March 2016 revoking European patent No. 1685839 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	G. Seufert
	L. Bühler

Summary of Facts and Submissions

I. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division revoking the European patent No. 1 685 839.

The present decision refers to the following documents:

(44) Expert Declaration by Dr Lars Hermann, signed and dated 24 September 2014, pages 1 to 11 plus CV and attachments 1 to 4
(48) OxyContin Total Appearances 1996, one page

II. Notices of opposition were filed by opponents 1 to 6 (respondents 1 to 6) requesting revocation of the patent in suit on the grounds of lack of novelty (opponents 1 and 3 to 6), lack of inventive step (opponents 1 to 6), insufficiency of disclosure (opponents 1 to 6) and added subject-matter (opponents 3 to 6) pursuant to Article 100(a), (b) and (c) EPC. Opponent 2 also requested revocation of the patent in suit on the ground of exclusion from patentability pursuant to Article 52(2) EPC.

III. The decision of the opposition division was based on a set of claims according to the main request filed with letter of 26 September 2014, sets of claims according to auxiliary requests Ia to Ic and IIa to IId filed with letter dated 24 September 2015 and sets of claims according to auxiliary request IIa' to IId' filed at the oral proceedings before the opposition division on 25 November 2015.

The opposition division decided that the main request and auxiliary requests Ia to Ic did not comply with Article 123(2) EPC, as the terms "usually prescribed

dose" in claim 1 as originally filed and "analgesically effective dose" in claim 1 as granted were not synonymous. Auxiliary requests IIa and IIa' were held to contravene Article 84 EPC. According to the opposition division, the newly introduced term "usually prescribed dose" into feature f) could be examined for lack of clarity, as it was made in a different context and had a different impact on the scope of the claims. The use of this term and the replacement of the term "physically dependent human subjects" by "physically dependent addict" were also held to contravene Article 123(3) EPC. The same conclusions with respect to lack of clarity applied to auxiliary requests IIb to IId and IIb' to IId'. In addition, auxiliary requests IIb to IIc were held to contravene Article 123(3) EPC for the same reason as auxiliary request IIa.

IV. With the statement setting out the grounds of appeal, the appellant maintained the set of claims according to auxiliary requests IIa to IId and IIb' to IId' underlying the decision under appeal and filed an amended auxiliary request IIa'. The main request and auxiliary requests Ia to Ic underlying the decision under appeal were not maintained.

Claim 1 of auxiliary request IIa reads as follows:

"*1. A sustained release oral dosage form for use in the treatment of pain while reducing the oral abuse potential of the dosage form by an addict who attempts to achieve euphoria by taking more than the usually prescribed dose at a time, the dosage form comprising in combination an orally analgesically effective dose of an opioid agonist and an opioid antagonist,*

the ratio of opioid antagonist to opioid agonist providing a combination product which is analgesically effective when the combination is administered orally to a non-physically dependent human subject, but which provides an aversive effect in physically dependent addicts when orally administered at a higher dose than the usually prescribed dose,
wherein said opioid agonist is oxycodone, wherein the oxycodone is included in an amount from 2.5 to 800 mg, further comprising a sustained release carrier, such that the dosage form is administrable on a twice-a-day or on a once-a-day basis."

Claim 1 of auxiliary request IIb differs from claim 1 of auxiliary request IIa in that the feature "**wherein the amount of antagonist included in the oral dosage form causes an aversive experience in the physically dependent addicts taking about 2 - 3 times the usually prescribed dose of the opioid**" has been added.

Claim 1 of auxiliary request IIc differs from claim 1 of auxiliary request IIb in that the feature "**and wherein the opioid antagonist is selected from the group consisting of naloxone, nalmephene, cyclazocine, levallorphan, naltrexone and mixtures thereof**" has been added.

Claim 1 of auxiliary request IId differs from claim 1 of auxiliary request IIc in that the opioid antagonist has been limited to **naloxone.**

Claims 1 of auxiliary requests IIa' to IId' essentially differ from claims 1 of auxiliary requests IIa to IId in that the expression "but which provides an aversive effect in physically dependent addicts ... " has been

changed to "but which provides an aversive effect in physically dependent **human subjects** ... ".

V. With letters dated 20 June 2017, 13 June 2017 and 2 June 2017, respondents 3, 4 and 5 informed the board that they would not be attending the oral proceedings scheduled for 5 July 2015.

VI. The appellant's arguments, as far as they relate to the decisive issues of the present decision, can be summarized as follows:

The term "usually prescribed dose" could not be examined for lack of clarity as it was present in feature c) and dependent claim 2 as granted and its meaning in feature e)/f) was the same. The opposition division's findings that the disputed term in feature e)/f) was used in a different context was based on a claim construction disregarding the teaching in the description.

Claim 1 of auxiliary request IIa was directed to a combination dosage form for use in the treatment of pain. The combination provided an analgesic effect for pain patients and aversive effects for addicts if multiple dosage forms - for example 2 or 3 tablets - were taken by an addict. The opioid agonist oxycodone was the active ingredient for pain relief and for this purpose it would be prescribed by the medical practitioner. No medical practitioner would prescribe a certain dose to an addict to induce aversive effects.

The opposition division had no problem in understanding that a usually prescribed dose in the context of a claim dealing with a pharmaceutical dosage form for pain relief had to refer to the pharmaceutical active

agent for pain treatment, in the present case, the opioid agonist oxycodone.

The ratio was the means to achieve the dual functionality (i.e. analgesia in pain patients and aversive effects in addicts), which was the key element of the invention (see page 6, lines 13 to 16 or page 6, line 30 to page 7, line 1 of the application as originally filed). However, this did not allow for the conclusion that the term "usually prescribed dose" had a different meaning in the context of the ratio feature (i.e. referring to the dose of oxycodone and opioid antagonist as alleged by the opposition division) than in the rest of the claims. The disputed term was always used in the context of the combination product, the purpose of which was the treatment of pain, and always referred to the opioid agonist as the active ingredient. The ratio was not affected and would be the same, whether the combination product was given to a pain patient or taken by an addict.

Granted claim 2 unequivocally set the amount of opioid antagonist in relation to the amount of opioid agonist and therefore must relate to the ratio feature. As this claim used the phrase "2-3 times the usually prescribed dose of the opioid", it was clear that the disputed term in the context of the feature e)/f) of claim 1 must also refer to the dose of opioid, i.e. oxycodone.

The term "usually prescribed dose" was the range of doses of opioid agonist commonly prescribed by medical practitioners to pain patients. This dose did not differ whether it was administered in the form of oxycodone alone or in the form of a combination product comprising oxycodone and an opioid antagonist. This also illustrated that the opposition division's

conclusion that the disputed term was used in a different context was flawed.

The terms "analgesically effective dose" and "usually prescribed dose" always referred to the opioid agonist and were related to the intended use as analgesic in patients suffering from pain. These patients required an analgesically effective dose, with the "usually prescribed dose" being the commonly administered analgesically effective dose prescribed by a medical practitioner.

The disputed term was also clear. It would be understood by the skilled person to refer to the range of doses of oxycodone, which would be used for the majority of pain patients. As was apparent from document (48), about 96% of all prescriptions for oxycodone were of a dosage strength up to 80 mg and about 79% were for dosage strength up to 40 mg. Moreover, in document (44), which conveyed the everyday knowledge of a medical practitioner, it was explained in point 6.5.1 that the commonly prescribed doses were in the range of 20 to 60 mg. This was well in line with the ranges derivable from document (48). Article 84 EPC was therefore complied with.

The arguments with respect to auxiliary requests IIa', IIb to IId and IIb' to IId' were the same as for auxiliary request IIa.

VII. The respondents' arguments, as far as they relate to the decisive issues of the present decision, can be summarized as follows:

The finding of the opposition division that the term "usually prescribed dose" was used in a different

context was justified. The replacement of the term "analgesically effective dose" by the term "usually prescribed dose" could therefore be examined for lack of clarity.

The disputed term was newly incorporated into feature f) and changed the ratio. None of the claims as granted included the feature that the ratio would be determined *inter alia* by the aversive effect in physically dependent human subjects or addicts, when the combination is orally administered at a higher dose than the usually described dose. With the introduction of the disputed term into the ratio feature, a lack of clarity was generated that had not been present in the claims as granted. Moreover, the introduction of the disputed term had a limiting effect on the claims.

In feature c) the same wording was used but in a different context. Feature c) was related to the underlying objective of the invention. It was not critical to the dosage form and there was no relationship between the disputed term and the ratio. In feature f) the disputed term had a direct effect on the amount of oxycodone and as a consequence the ratio. Granted claim 2 referred to the amount of opioid antagonist, not the ratio.

In feature f) the disputed term was related to the combination product, as was the expression "analgesically effective dose" (see page 6, lines 27 to 30; page 15, lines 22 to 27 of the application as filed). The appellant's assertion that it referred to the dose of oxycodone was based on the assumption that it did not matter whether the oxycodone was administered in combination with an opioid antagonist or not. This assumption was not justified, as was

apparent from the application as filed (see page 8, lines 27 to 30). In order to ensure effective analgesia in patients, the "usually prescribed dose" in a drug formulation containing an opioid agonist as well as an opioid antagonist would have to be higher in term of the opioid agonist as compared to the "usually prescribed dose" of a pure opioid agonist.

The disputed term was not defined in the patent in suit and did not have a well accepted meaning. It was *prima facie* unclear, as it could vary with time, patient group, severity of the illness etc. (see document (44), point 6.5.1). Furthermore, different practitioners might have different concepts of what was "the usual dose" for the patients they were treating. The prescribed dose could also vary in different countries. The different ranges mentioned in document (44) already showed that there was no clear understanding with respect to the limits of what was the "usually prescribed dose". With regard to document (48), it was also unclear whether it was the dose prescribed to 79% or 96% of the patients. As a consequence of the introduction of the disputed term into feature f), the ratio was unclear. The skilled person could not establish whether a particular sustained release dosage form would fall within the scope of the claims or outside. Article 84 EPC was therefore not complied with.

The same arguments applied with respect to auxiliary requests IIa', IIb to IId and IIb' to IId'.

VIII. The appellant requested that the decision under appeal be set aside, that the case be remitted to the opposition division should the board conclude that any of the auxiliary requests IIa to IId filed with letter

24 September 2015, auxiliary request IIa' filed with the statement of grounds of appeal or auxiliary requests IIb' to IId' filed on 25 November 2015 at the oral proceedings before the opposition division comply with Article 123(2) and (3) EPC, or, alternatively, that the patent be maintained on the basis on one of these requests.

IX. The respondents 1, 2, 6 requested that the appeal be dismissed. Respondents 3 and 5 had requested in writing that the appeal be dismissed. Respondent 2 further requested that the case not be remitted to the opposition division.

Respondent 4 did not file any requests and provided no arguments with regard to the substantive issues.

Reasons for the Decision

1. The appeal is admissible

2. Procedural matters

Respondent 3, 4 and 5 did not attend oral proceedings to which they had been duly summoned. The board decided to continue the proceedings pursuant to Rule 115(2) EPC and Article 15(3) RPBA.

3. Preliminary remark

In the decision under appeal (see point 9.1.1.1 of the Facts and Submissions), the opposition division provided the following feature analysis:

a) A sustained release oral dosage form
b) for use in the treatment of pain
c) while reducing the oral abuse potential of the dosage form by an addict who attempts to achieve euphoria by taking more than the usually prescribed dose at a time,
d) the dosage form comprising in combination an orally analgesically effective dose of an opioid agonist and an opioid antagonist,
e) the ratio of opioid antagonist to opioid agonist providing a combination product which is analgesically effective when the combination is administered orally to a non-physically dependent human subject,
f) but which provides an aversive effect in physically dependent human subjects (physically dependent addicts) when orally administered at a higher dose than the analgesically effective dose (the usually prescribed dose),
g) wherein said opioid agonist is oxycodone,
h) wherein the oxycodone is included in an amount from 2.5 to 800 mg,
i) further comprising a sustained release carrier, such that the dosage form is administrable on a twice-a-day or on a once-a-day basis."

For ease of reference the board adopts this analysis taking into account the amendments, which have been made (indicated in brackets).

The board also accepts the appellant's view that features e) and f) are to be considered as a single feature (hereinafter feature e)/f)).

Auxiliary request IIa

4. Clarity (Article 84 EPC)

4.1 In claim 1 of auxiliary request IIa the term "analgesically effective dose" in feature e)/f), which was the term in claim 1 as granted, has been replaced by the term "usually prescribed dose" to overcome an objection under Article 123(2) EPC. Although such a term was present in step c) of claim 1 as granted and in granted claim 2, the opposition division considered that its introduction into feature f) was made in a different context and had a different impact on the scope of the claims. The newly introduced term in feature f) could therefore be examined for compliance with Article 84 EPC. The opposition division also decided that this term was unclear.

This finding was challenged by the appellant, who argued that the term had the same meaning in feature e)/f) and feature c) and claim 2 as granted. It was not used in a different context and therefore could not be examined for lack of clarity.

4.2 Since lack of clarity is not a ground for opposition and only becomes an issue if it arises out of an amendment made during opposition or opposition appeal proceedings (see G 3/14, OJ EPO 2015 A102), it is first necessary to examine whether the opposition division's findings that the introduction of the term "usually prescribed dose" into feature e)/f) could be examined for lack of clarity was justified.

4.3 Claim 1 as granted uses the disputed term in the context of feature c), which defines the underlying objective of the presently claimed dosage form, that is the reduction of the oral abuse potential of a medicament by an addict, who in an attempt to achieve

euphoria takes more than the "usually prescribed dose". In this context, there is no explicit reference to the opioid agonist. However, taking into account that oral abuse and euphoria are associated with the opioid agonist, the board agrees with the opposition division and the appellant that the disputed term relates to the opioid agonist, i.e. to oxycodone, which is also the active ingredient for the treatment of pain. The disputed term is used to characterise the behaviour of an addict, who needs, or would take an opioid agonist containing medicament, which is commonly used for the treatment of pain, in an amount sufficient to achieve an excited mental state. This amount is in general much higher than the amount of opioid agonist a pain patient would usually take at a time (i.e. a medical practitioner would prescribe to a pain patient) for pain relief.

Feature c) is not linked or related to any feature or measurements suitable to reduce the abuse potential. It defines the underlying objective taking into account the behaviour of an addict and, unlike the ratio of ingredients or sustained release carrier, is not a critical feature of the dosage form as such.

4.4 In contrast, feature e)/f) in claim 1 as granted defines a compositional feature of the dosage form, that is the ratio of opioid antagonist to opioid agonist providing the combination product. This ratio is not defined by a numerical value or a range of numerical values, but solely by effects to be achieved when the combination is orally administered. In a non-physically dependent human subject the combination is analgesically effective. In a physically dependent human subject (who is not necessarily an addict (see

document (44), point 5.5) the combination provides aversive effects.

It was common ground that the ratio of opioid antagonist to opioid agonist is the key feature of the invention (see also paragraphs [0022] and [0025] of the patent in suit). Feature e)/f), unlike feature c), is therefore a critical feature of the dosage form. Any change in the definition of the dose of either opioid antagonist or opioid agonist directly affects the ratio.

4.5 The board agrees with the appellant that oxycodone is the analgesically effective compound in the dosage form. However, this does not mean that the term "at a higher dose than the analgesically effective dose" in feature e)/f) as granted refers to oxycodone or that the term "analgesically effective dose" and "usually prescribed dose" in feature c) are necessarily the same.

4.5.1 According to the wording of the claim as granted the term "at a higher dose than the analgesically effective dose" refers to the combination product. It is the combination product that is analgesically effective in a non-physically dependent pain patient and the combination product that provides the aversive effects in a physically dependent human subject/addict when it is taken or administered at a higher dose. This is also supported by the description of the patent in suit (see page 4, paragraph [0025] or page 7, paragraph [0046], which corresponds to the passages on page 6, lines 27 to 30 and page 15, lines 22 to 27 referred to by the respondents). The understanding that the term "usually prescribed dose", which replaces the term "analgesically effective dose" in feature e)/f),

relates to the combination product, is therefore not in contradiction to the specification, as asserted by the appellant.

4.5.2 The appellant's view that the term "at a higher dose than the analgesically effective dose" in feature e)/f) as granted was related to the dose of oxycodone is not accepted. It presupposes that the analgesic effect of the combination product is determined solely by the opioid agonist (i.e. by oxycodone). However, as was pointed out by the respondents, the level of analgesia can be significantly reduced by the opioid antagonist (see application as filed page 8, lines 28 to 30). As effective pain relief provided by the combination product is required to compensate for any interference of the opioid antagonist with the opioid agonist, the analgesically effective dose of oxycodone in the combination product may have to be higher than the dose of oxycodone, when administered alone, that is "usually prescribed" by a medical practitioner for the treatment of pain. The analgesically effective dose of oxycodone in combination with an opioid antagonist is therefore not necessarily identical to the dose of oxycodone, when administered alone, a medical practitioner would usually prescribe to a pain patient. It is immediately apparent that replacement of the former term, which is clearly defined by its function, by the latter, which is potentially unclear with respect to its boundaries, would have an impact on the ratio. Contrary to the appellant's view, it matters whether or not the "usually prescribed dose" of oxycodone is administered alone or in form of a combination product with an opioid antagonist.

4.6 In view of the above considerations, the board concurs with the opposition division that, despite the presence

of the potentially unclear term "usually prescribed dose" in feature c) of claim 1 as granted, its incorporation into feature e)/f) introduces a new ambiguity (i.e. of ratio) that did not exist before. Accordingly, the amendment made in feature e)/f) can be examined for lack of clarity.

4.7 This finding is not changed taking into account granted claim 2. This claim defines yet another feature, that is the amount of opioid antagonist included in the oral dosage form, which when taken by an addict - obviously to achieve euphoria - causes an aversive experience in the addict. Similar to feature c), claim 2 uses the disputed term in the context of an addict alone, while the ratio in feature e)/f) is defined in the context of effects achieved in pain patients and physically dependent human subjects/addicts. Furthermore, in feature c) and claim 2, the disputed term refers to the amount of oxycodone usually prescribed by a medical practitioner, while in amended feature e)/f) the disputed term is made in the context of a combination product.

4.8 Pursuant to Article 84 EPC in combination with Rule 43(1) EPC, the claims must be clear and define the matter for which protection is sought in terms of the technical features of the invention. These requirements serve the purpose of ensuring that the public is not left in any doubt as to which subject-matter is covered by a claim and which not. A claim cannot be considered clear in the sense of Article 84 EPC if it does not unambiguously allow this distinction to be made. A claim comprising an unclear technical feature, therefore, entails doubts as to the subject-matter covered by that claim. This applies all the more if the unclear feature is essential with respect to the

invention in the sense that it is intended to delimit the subject-matter claimed from the prior art, thereby giving rise to uncertainty as to whether or not the subject-matter claimed is anticipated (see decision T 728/98, OJ EPO 2001, 319; point 3.1 of the Reasons; T 226/98,OJ EPO 2002, 498, point 7.1 of the Reasons).

4.9 It was undisputed that the ratio of opioid antagonist to opioid agonist is the key feature of the present invention. The board therefore agrees with the opposition division that any feature that influences or partly defines this ratio has to be well defined for the claims to be clear. Accordingly, it has to be examined whether the disputed term "usually prescribed dose" is such a clear and well defined feature.

4.10 The board notes that the patent in suit does not provide a definition for the term "usually prescribed dose". According to the appellant, the person skilled in the art would understand this term as referring to the range of dosages of oxycodone that will be used for the treatment of the majority of pain patients. In this context, the appellant relied on documents (44) and (48).

4.11 However, these documents do not provide a generally applicable quantitative definition of the term "usually prescribed dose".

4.11.1 Document (44) is a declaration by the appellant's expert. In point 6.5.1 of said document, the expert explained that the initial average dose is 5 to 15 mg per day every 4 to 6 hours, that dosages of 30 mg are rarely needed and should be used with great caution, that in "non terminal" cancer patient the commonly prescribed dose is between 20 and 60 mg and that in

"terminally palliative" cancer patients, the dosage is 100 mg and more. This explanation already shows that what is "usually" prescribed can vary considerably, depending on the patient group and/or type and severity of the illness.

Other potential factors, which can have an influence on the meaning of the term "usually prescribed dose" include the knowledge and experience of the medical practitioner or new scientific findings.

4.11.2 Document (48) reflects IMS data on prescription of dosage strengths of OxyContin - an oxycodone containing formulation - from 1996. It does not refer or define a "usually prescribed dose" of oxycodone. Moreover, if, as argued by the appellant, the "usually prescribed dose" was identical to the range of dosages that would be used for the "majority" of pain patients, two ranges can be deduced from document (48) that fulfil this criterion: between 20 and 40 mg (79%) and 20 to 80 mg (96%) oxycodone. This also shows that there is no clear and unambiguous meaning of the disputed term, in particular with respect to the upper limit, which apparently depends on what the skilled person considers to be the majority of pain patients.

4.12 The board therefore concurs with the opposition division that no definite meaning can be attributed to the term "usually prescribed dose", which renders the ratio of feature e)/f) unclear. As a consequence, the person skilled in the art is not in a position to determine whether a particular sustained release dosage form falls within the scope of the claims or outside.

4.13 The board therefore concludes that claim 1 of auxiliary request IIa does not comply with the requirement of Article 84 EPC.

Auxiliary requests IIa', IIb to IId and IIb' to IId'

5. Clarity (Article 84 EPC)

5.1 The feature "usually prescribed dose" is present in feature e)/f) of claim 1 of all the auxiliary requests (see point IV above). Therefore, the same observations and conclusion as set out in point 4.1 to 4.13 apply. Indeed, the parties did not submit additional arguments specific to the auxiliary requests.

5.2 Hence, the board concludes that auxiliary request IIa', IIb to IId and IIb' to IId' must also be refused for failing to comply with Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated