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Datasheet for the decision of 23 September 2021

Case Number: T 3035/19 - 3.3.07

Application Number: 11177518.5

Publication Number: 2425821

IPC: A61K9/16, A61K9/20, A61K31/485

Language of the proceedings: EN

Title of invention:
Pharmaceutical preparation containing oxycodone and naloxone

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Headword:
Pharmaceutical preparations containing oxycodone and naloxone / EURO-CELTIQUE

Relevant legal provisions:
EPC Art. 100(c), 76(1), 123(2)

Keyword:
Amendments - extension beyond the content of the application as filed (yes)

Decisions cited:
G 0002/10, G 0001/05, G 0001/03, T 0783/09, T 0598/12, T 0012/81

Catchword:
Selections in two or more lists, see points 1.4 and 1.5 of the reasons

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European Patent Office
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Case Number: T 3035/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 23 September 2021

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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 September 2019 revoking European patent No. 2425821 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	Y. Podbielski

Summary of Facts and Submissions

I. European patent 2 425 821 (hereinafter "the patent") was granted on the basis of 6 claims. Claim 1 of the patent read as follows:

"Pharmaceutical oral preparations for use in treating pain and for use in concurrently reducing opioid induced obstipation, wherein each preparation comprises as the actives oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein oxycodone or a pharmaceutically acceptable salt thereof is present in said preparations in a range of usable absolute amounts and in a ratio of 2:1 to naloxone or a pharmaceutically acceptable salt thereof, characterized in that the actives are released from the preparations in a sustained, invariant and independent manner."

II. Eleven oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application and the earlier application as filed.

III. The appeal was filed by the patent proprietors (appellants) against the decision of the opposition division to revoke the patent.

The decision was based on the patent as granted as the main request, on auxiliary requests I-VIII filed on 5 July 2018, and on auxiliary requests IX-XII filed on 15 May 2019.

IV. In particular, the opposition division decided the following.

Regarding claim 1 of the main request, the earlier application as filed did not make directly and unambiguously available to the skilled person the teaching that in order to significantly reduce opioid induced obstipation without compromising analgesic activity for pain treatment, a fixed weight ratio oxycodone/naloxone 2:1 had to be used. Arriving at the combination of the features pertaining to weight ratio 2:1 and to reducing opioid induced obstipation required simultaneous selections from several independent lists. As a consequence, the requirements of Article 76(1) EPC, and, for the same reasons, those of Article 123(2) EPC, were not met.

Likewise, none of the auxiliary requests I-XII met the requirements of Articles 76(1) and 123(2) EPC.

V. The patent proprietors (appellants) lodged an appeal against the decision of the opposition division.

With their statement setting out the grounds of appeal, the appellants defended their case on the basis of the patent as granted as the main request, and filed auxiliary requests I-XIII, of which auxiliary requests I-XII had already been filed during the proceedings before the opposition division.

In comparison with claim 1 of the main request, claim 1 of auxiliary request I specified that the 2:1 ratio was a weight ratio.

In claim 1 of auxiliary request II, the expressions "oxycodone or a pharmaceutically acceptable salt

thereof" and "naloxone or a pharmaceutically acceptable salt thereof" were additionally replaced with "oxycodone hydrochloride" and "naloxone hydrochloride", respectively.

Claim 1 of auxiliary request III additionally specified that "the preparations comprise oxycodone hydrochloride in an amount range of 10 to 150 mg". The same range was amended to "10 to 80 mg" in claim 1 of auxiliary request IV.

Claim 1 of auxiliary request V-VIII corresponded to claim 1 of auxiliary request I-IV, where the preparations were "matrix preparations".

Claim 1 of auxiliary request IX-XII corresponded to claim 1 of auxiliary request I-IV, where the preparations were "storage-stable". Claim 1 of auxiliary request XIII was identical to claim 1 of auxiliary request IX.

VI. Oral proceedings were held before the Board.

VII. In the present decision, reference is made to the following documents:

D3: WO 03/084520 A2 (PCT publication of the parent application)
D70: Zenz, Jurna, "Lehrbuch der Schmerztherapie" 2nd Ed., 2001, pp. VII-XIV, 255-280, 457-473, 485-498 and 875-885
D73: Expert Report of Dr. Nigel Sykes (dated 23 June 2017)
D89: Second Expert Report of Dr. Nigel Sykes (dated 11 September 2017)

D115: Third Expert Report of Dr. Nigel Sykes (dated 10 May 2019)
D116: Novartis Pharmaceuticals UK Limited v Dr Reddy's Laboratories (UK) Limited [2019] EWHC 92 (Pat)
A123: Judgment of the Swiss Federal Patent Court dated 7 November 2019
A124: Judgment of the Swiss Federal Court dated May 11, 2020 to dismiss Mundipharma's appeal against the judgment of the Swiss Federal Patent Court of 7 November 2019 (Al24a: Order; Al24b: Reasoning)
Al26: Decision of the opposition division dated 6 April 2021 relating to EP 1 855 657

VIII. The arguments of the appellants, as far as relevant to the present decision, can be summarised as follows:

The earlier application directly and unambiguously disclosed pharmaceutical preparations for treating pain and concurrently reducing OIC with a fixed weight ratio combination of oxycodone to naloxone of 2:1 as claimed in the main request.

For the assessment of added subject-matter, the principles laid down in G 2/10 and phrased as the "gold standard" had to be applied. A strictly formalistic application of the concept of selection from lists, developed by the case law as an aid for assessing disclosure in certain situations, was not appropriate in the present case, because a skilled person would understand the condition to be treated and the medicament to treat said condition to be closely related. Following T 783/09, the absence of a direct and unambiguous disclosure for individualised subject-matter was not a mandatory consequence of its presentation as elements of lists.

But even if the concept of selection from lists was considered to be applicable in the present case, a skilled person equipped with his common general knowledge would still regard the claimed combination of a fixed oxycodone/naloxone weight ratio of 2:1 and the reduction of OIC while treating pain as clearly and unambiguously disclosed in the earlier application as filed.

OIC was one of three opioid side effects disclosed in the earlier application (see page 9, lines 13-17, and page 17, lines 13-21, of the earlier application). The skilled person, based on his common general knowledge as reflected in D70 and discussed in the declarations D73, D89 and D115, would have understood that OIC was the opioid side effect that the application was predominantly concerned with. In particular, of the opioid-induced side effects mentioned in the application, OIC was the most prevalent in real-world clinical practice. Furthermore, in contrast to the other mentioned side effects, OIC could not be addressed by the physician adjusting the dose, but was targeted by the oral administration of naloxone. The mentioning of oral administration as the most preferred route of administration thus confirmed the skilled person’s understanding that the invention disclosed in the earlier application primarily related to reducing OIC while treating pain. The expression "reduction" did not represent a selection from "suppressed, or at least significantly reduced" either, because the relevant feature was the reduction of OIC and not the actual degree to which the reduction was accomplished in the individual case.

Furthermore, in the earlier application, the oxycodone/ naloxone weight ratio of 2:1 was an especially

preferred weight ratio (see page 16, lines 20/21 or claim 7; see also examples 1, 2, 7 and 8, and the embodiments on page 11, line 27, page 12, line 9 and page 14, line 2). It was clear that any of the especially preferred weight ratios could equally be used in the disclosed therapeutic applications, in particular OIC. No new technical teaching was introduced by the choice of the 2:1 ratio.

This view was supported by the decision of the opposition division relating to EP 1 855 657 (document A126). In this decision, the earlier application of the present case was considered as prior art and was found to disclose the feature relating to the oxycodone/ naloxone weight ratio of 2:1 in connection with the feature relating to the reduction of OIC.

Hence no added subject-matter was introduced.

IX. The arguments of the respondents, as far as relevant to the present decision, can be summarised as follows:

The earlier application as filed considered several especially preferred ratios of oxycodone to naloxone ranging from 15:1 to 1:1, and contained no pointer to the weight ratio of 2:1. The application further indicated that the preparation could be used for the suppression or at least significant reduction of several side-effects, in particular OIC, addiction and breath depression, and cited prior art, including oral naloxone formulations, targeting not only OIC but also other side-effects. The application did not single out OIC among these side effects. Furthermore, "suppression" and "significant reduction" described the treatment of two different patient groups, namely patients with or without OIC. Consequently, the use of

the ratio of 2:1 for the reduction of OIC according to claim 1 of the main request represented new technical information.

The concept of multiple selections was a valuable tool for assessing whether or not a certain subject-matter was directly and unambiguously derivable from the earlier application for the skilled person using their common general knowledge, according to the "gold standard" of G 2/10. In this respect, the common general knowledge of the skilled person was to be used only to make a technically sensible reading of a disclosure, not to supplement it with additional information, let alone to interpret the application in contrast to what was explicitly disclosed therein.

Here the earlier application contained no information as to which ratio was to be used for which side-effect. Contrary to the appellants, the various ratios could not be expected to be equally effective for the treatment of the different side-effects, because orally administered naloxone had low systemic bioavailability and was almost exclusively active against peripheral side-effects (such as OIC) and much less against systemic side-effects. Thus the choice of the amount of naloxone depended heavily on the side-effect to be treated.

Additionally, the respondents disagreed with the approach of the appellants, according to which a skilled person would understand from the earlier disclosure that any and all of the especially preferred oxycodone/naloxone ratios would be equally suitable to treat each of the side effects, such that any of the resulting combinations was directly and unambiguously disclosed. Such an approach undermined the very idea

underlying Article 123(2) EPC that an applicant or proprietor should not be allowed to improve its position by adding subject-matter not disclosed in the application as filed.

This view was supported by the judgments of the Swiss Federal Patent Court and the Swiss Federal Court (see documents A123, A124a and A124b) finding that the combination of features, i.e. the weight ratio of oxycodone to naloxone of 2:1 in combination with the reduction of OIC, was not directly and unambiguously disclosed in the application as originally filed.

X. The appellants request that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, alternatively, that the patent be maintained on the basis of one of the auxiliary requests I-VIII filed on 5 July 2018, or auxiliary requests IX-XII filed on 15 May 2019, or auxiliary request XIII filed with the grounds of appeal.

XI. The respondents O1, O2, O3, O4, O5, O6, O7, O8, O10 and O11 each request that the appeal be dismissed.

Reasons for the Decision

1. Main request (patent as granted), Articles 100(c) and 76(1) EPC

1.1 The patent in suit was granted on a divisional application. The earlier application was published under the PCT as WO 03/084520 A2 (i.e. D3).

Claim 1 of the main request (the patent as granted) relates to pharmaceutical oral preparations defined, in particular, both by an oxycodone:naloxone ratio of 2:1 and in that the preparation is "for use in treating pain and for use in concurrently reducing opioid induced obstipation". "Opioid induced obstipation" is synonymous with "opioid induced constipation", abbreviated OIC.

The question is whether this subject-matter extends beyond the content of the earlier application as filed (Article 100(c) EPC in combination with Article 76(1) EPC).

1.2 The fundamental test for determining whether subject-matter meets the requirements of Article 76(1) EPC is the same adopted for assessing the requirement of Article 123(2) EPC, namely the "gold standard" disclosure test (see G 1/05 of 28 June 2007, point 5.1 of the reasons, and G 2/10, point 4.3 of the reasons). This standard requires that the subject-matter of a claim of a divisional application or patent remain within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the earlier application as filed. The skilled person may not be presented with new technical information (see G 2/10, point 4.5 of the reasons).

1.3 Here, the earlier application as filed discloses several oxycodone:naloxone ratios, including the ratio of 2:1 (see page 16, lines 19-21), and lists several side effects, one of which is OIC (see page 9, lines 15-17). However, the fact that each of these two features of claim 1 of the main request is,

individually, disclosed in the earlier application as filed is not sufficient to conclude that their combination is also derivable from the earlier application as filed.

In such a situation, it is established case law that the combination - unsupported in the application as filed - of one item from each of two lists of features means that although the application might conceptually comprise the claimed subject-matter, it does not disclose it in that particular individual form (see the Case Law of the Boards of Appeal, 9th edition, 2019, II.E.1.6.2).

1.4 While the notion of selection from two lists is not meant to take the place of the gold standard, it provides valuable guidance and finds wide application in case law for the assessment not only of added subject-matter but also of novelty (see the landmark decision T 12/81 and the Case Law of the Boards of Appeal, 9th edition, 2019, I.C.6.2). Consequently, in view of the importance of applying a uniform concept of disclosure for the purposes of Article 54 and 123(2) EPC (see G 2/10, point 4.6 of the reasons, referring to G 1/03, point 2.2.2 of the reasons), and by the same token Article 76(1) EPC, the Board considers that a departure from this established criteria for selection inventions in the assessment of added subject-matter is not appropriate.

1.5 The appellants generally criticise a strict application of the concept of selection from several lists, and cite in this respect T 783/09 (see point 5.5-5.6 of the reasons: "the absence of a direct and unambiguous disclosure for individualised subject-matter is not a mandatory consequence of its presentation as elements

of lists") and the judgment of the British Patents Court in Novartis Pharmaceuticals UK Limited v Dr Reddy's Laboratories (UK) Limited [2019] EWHC 92 (Pat) (D116, see in particular paragraph 29: "I do not accept that, as a general statement, it is true that a teaching which consists of a combination of two individualised lists, in other words two lists of individualised members, necessarily means that that combination is now to be treated as an un-individualised generic disclosure").

The Board emphasizes that the combination of features resulting from selections in two or more lists, or pertaining to separate embodiments, only introduces added subject-matter in the absence of a pointer to that particular combination. Thus, an amendment based on the combination of two items disclosed in the earlier application in two lists of some length, may still be considered to comply with the requirement of Article 123(2) EPC (or 76(1) EPC) if the earlier application contains a pointer towards this combination. In other words, the concept of selection from lists must be applied with due regard to the whole content of the earlier application as filed.

1.6 The Board concurs with the appellants that a skilled person may understand the condition to be treated and the medicament to treat said condition to be closely related. However, this consideration does not disqualify the present situation from being assessed using the concept of selection from lists. Indeed, the question is not whether the skilled person would generally read the oxycodone:naloxone ratios and the side effects together, but whether the earlier application as filed directly and unambiguously

discloses the individualised subject-matter combining the ratio of 2:1 with OIC.

1.7 Hence it must be examined whether the earlier application as filed contains a pointer to the claimed combination.

1.7.1 The weight ratio of 2:1 oxycodone to naloxone is shown on page 16 (lines 19-21) as one of seven "especially preferred" ratios, namely 15:1, 10:1, 5:1, 4:1, 3:1, 2:1 and 1:1. The ratio of 2:1 is also exemplified in examples 1, 2, 7 and 8 as well as on page 11, line 27, page 12, line 9 and page 14, line 2. However, these passages also disclose ratios other than 2:1 (e.g. 20:1 or 4:1, see the examples) and do not express any preference for the ratio of 2:1 over these other exemplified or listed ratios.

1.7.2 As to the feature relating to the reduction of OIC, the earlier application discloses that preparations according to the invention treat pain and that, at the same time, "common side effects such as obstipation, breath depression and development of addiction are suppressed, or at least significantly reduced" (see page 9, line 15; page 17, line 19, lists the same side effects).

However, the earlier application as filed does not point to the choice of OIC over the other side-effects. A focus on OIC cannot be derived from the above parts of the earlier application pertaining to the invention. Such a focus does not derive from the parts pertaining to the background art either, because the earlier application as filed discusses whether the cited prior art addresses not only OIC but also the other side-effects (see for instance page 5, lines 1-5 and 16-20).

1.7.3 According to the appellants, the skilled reader equipped with common general knowledge would understand the earlier application as being first and foremost about reducing OIC when treating pain. Out of the opioid-induced side-effects mentioned in the earlier application, OIC would be highly distressing and the most prevalent in real-world clinical practice, whereas the other side-effects mentioned were much less of a concern (as explained in the declarations D73, D89 and D115).

The Board does not agree with the appellants. The focus on OIC that the appellants seek to find in the common general knowledge is firstly entirely subjective, since it might equally be argued that the skilled person would focus on life-threatening side-effects such as breath depression. But more importantly, the argument of the appellants amounts to inferring from common general knowledge a pointer to this particular selection in the absence of any justification therefor in the content of the earlier application as filed. In this, the Board shares the position of the respondents that a reference to common general knowledge cannot compensate for the lack of disclosure in the application itself.

As explained in T 598/12 (see point 4.3.6 of the reasons), what has to be judged is whether the notional skilled person working in the field would consider something as directly and unambiguously implicitly disclosed in the light of his common general knowledge. The assessment of what information is implicitly disclosed in an application cannot go beyond the limits of what the skilled person would objectively understand to be a direct and unambiguous consequence of the

explicit disclosure in the particular case. Moreover, when performing this assessment, the common general knowledge cannot serve to enlarge or replace, in a subjective or artificial manner, the actual content of the specification.

1.7.4 The appellants sought to derive an implicit focus on OIC from the preference, expressed in the earlier application as filed (see page 15, lines 25-26), for an oral administration. Thus, according to the appellants, it was common general knowledge that, in contrast to the other mentioned side effects, OIC could not be controlled by the physician adjusting the dose, but could be addressed by the oral administration of naloxone, based on its local action on the opioid receptors in the gut (see D70, page 270 and 272). The skilled person would not consider that the other side effects could be addressed because of naloxone's low systemic availability due to its metabolism in the liver.

However, this alleged common general knowledge contradicts the earlier application as filed, according to which the pharmaceutical compositions of the invention, preferably for oral administration, comprising oxycodone and naloxone, suppress or at least significantly reduce all side effects (see page 9, lines 8-17 and page 15, lines 25-26). It also contradicts the mention of known preparations "which can be taken orally and comprise an opioid analgesic and the opioid antagonist, naloxone" "to avoid side effects such as obstipation and breath depression during pain therapy" (see page 5, lines 16-18). Thus, the appellants do not rely on common general knowledge to ascertain the direct and unambiguous teaching of the earlier application as filed, but seek to enlarge or

replace it. Accordingly, this reasoning does not demonstrate that a focus on OIC can be inferred from the earlier application as filed.

1.8 In conclusion, no specific preference for or pointer to the combination of the ratio of 2:1 with OIC can be discerned in the earlier application as filed. This combination in claim 1 of the main request thus represents a new teaching extending beyond the content of the earlier application as filed. It is accordingly not necessary to assess whether claim 1 introduces added subject-matter in other respects, for example the further alleged selection from of a significant reduction or a suppression of OIC mentioned in the earlier application as filed.

The Board's conclusion is not modified by the reasoning of the opposition division in a decision (document A126) taken on different case, where the disclosure of the earlier application D3 (numbered O4 in A126) was assessed as prior art in the context of inventive step. The reasoning in A126 relies on specific compositions disclosed in the examples of D3 and comprising 20 mg oxycodone and 10 mg naloxone (see A126, paragraph 28.2). This reasoning in A126 does not give any consideration to the issue of whether D3 contains a pointer to the general combination of the ratio of 2:1 with OIC.

1.9 Accordingly, the main request contravenes Article 76(1) EPC.

2. Auxiliary requests

Claim 1 of each of the auxiliary requests I-XIII also combine an oxycodone:naloxone ratio of 2:1 with the

choice of the reduction of OIC as side effect. Accordingly, none of the auxiliary requests I-XIII meet the requirements of Article 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated