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# Datasheet for the decision of 1 June 2022

**Case Number:** T 0043/18 - 3.3.02

**Application Number:** 10011792.8

**Publication Number:** 2305683

**IPC:** C07D489/00, C07D489/08, A61K9/00, A61K31/485

**Language of the proceedings:** EN

**Title of invention:**
Pharmaceutical dosage form comprising oxycodone hydrochloride having less than 25 ppm 14-hydroxycodeinone

**Patent Proprietor:**
EURO-CELTIQUE S.A.

**Opponents:**
Acino Pharma AG
James Poole Limited
Setna, Rohan P.
Hoffmann Eitle

**Headword:**

**Relevant legal provisions:**
EPC Art. 54
RPBA 2020 Art. 11

**Keyword:**
Novelty
Remittal

**Decisions cited:**
G 0002/88, G 0001/03, G 0002/10, T 0990/96, T 1085/13

**Catchword:**
Novelty – purity: decision T 1085/13 followed

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**Case Number: T 0043/18 - 3.3.02**

# D E C I S I O N
# of Technical Board of Appeal 3.3.02
# of 1 June 2022

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | EURO-CELTIQUE S.A.<br>1, rue Jean Piret<br>2350 Luxembourg (LU) |
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| **Representative:** | Lederer & Keller Patentanwälte<br>Partnerschaft mbB<br>Unsöldstraße 2<br>80538 München (DE) |
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted on 26 October 2017 revoking European patent No. 2305683 pursuant to Article 101(3)(b) EPC.**

**Composition of the Board:**

**Chairman** M. O. Müller
**Members:** P. O'Sullivan
P. de Heij

## Summary of Facts and Submissions

I. The appeal of the patent proprietor (hereinafter appellant) lies from the decision of the opposition division to revoke European patent 2 305 683.

II. Four notices of opposition were filed against the patent, invoking Article 100(a) (lack of novelty and inventive step), (b) and (c) EPC.

III. The following documents *inter alia* were cited in opposition proceedings and invoked by the parties in appeal proceedings:

D1: WO 2004/16618 A1
D2: US 5,266,331
D3: US 5,656,295
D15: US Pharmacopeia 23, pages 1129-1134

According to the contested decision, *inter alia,* the subject-matter of claim 1 of the "amended main request" (the main request in appeal proceedings) submitted during oral proceedings before the opposition division lacked novelty over D1-D3 and D15.

Specifically, the opposition division concluded that D1-D3 and D15 did not disclose a pharmaceutical dosage form comprising oxycodone hydrochloride and less than 25 ppm 14-hydroxycodeinone as recited in claim 1. Following decision T 990/96 however, the disclosure in D1-D3 and D15 of oxycodone hydrochloride made this compound available in all levels of purity before the effective date of the patent. The exceptional situation whereby, according to T 990/96, novelty could be acknowledged where all prior attempts to achieve the

claimed purity had failed, was not applicable to contested claim 1.

IV. With the statement of grounds of appeal, the appellant contested the conclusion of the opposition division on novelty, in particular the conclusion that the exceptional situation in T 990/96 did not apply to the claimed subject-matter. The appellant also submitted the following documents therewith:

D37: Experimental Report dated 5 March 2018
D38: USP 28 on oxycodone hydrochloride

V. With the letter dated 16 May 2019 the appellant submitted further observations, in particular in relation to decision T 1085/13, published subsequent to the filing of the statement of grounds of appeal.

VI. With the letters of 27 July 2021 and 4 August 2021 opponents (hereinafter respondents) 1 and 4 stated that they would not attend the scheduled oral proceedings. Respondent 2 was silent in appeal proceedings. With letter dated 9 August 2017 submitted during opposition proceedings, opponent 3 withdrew its opposition.

No requests were submitted by the respondents in appeal proceedings.

VII. In a communication pursuant to Article 15(1) RPBA, the board set out the view that the subject-matter of claim 1 of the main request was novel vis à vis documents D1-D3 and D15. The board also expressed the view that the case was to be remitted to the opposition division for further prosecution. Since such a remittal was not in line with the appellant's request to maintain the patent on the basis of the claims of the main request,

the question of whether to remit was to be addressed at oral proceedings. The board also indicated that if the appellant were to agree in writing to a remittal as set out above, oral proceedings could be cancelled.

VIII. With letter dated 13 June 2022, the appellant stated its agreement with a remittal of the case to the opposition division, as set out in the board's communication.

IX. Requests relevant to the present decision

The appellant requested:

- that the decision under appeal be set aside;
- that novelty be acknowledged for the set of claims of the main request submitted with the statement of grounds of appeal, which was identical to the main request submitted during oral proceedings before the opposition division (denoted "amended main request" in the contested decision, section 3).

The board understands that the appellant requested in addition that, in case novelty of the subject-matter of the main request is acknowledged and the decision under appeal is set aside, the case be remitted to the opposition division for further prosecution.

The respondents did not submit any requests in appeal proceedings.

X. Since none of the respondents requested oral proceedings, and the board was in a position to take a decision in the appellant's favour based on the written file, the scheduled oral proceedings were cancelled.

XI. The sole independent claim 1 of the main request reads as follows:

"*A pharmaceutical dosage form comprising oxycodone hydrochloride and less than 25 ppm 14-hydroxycodeinone as determined by the HPLC method of Example 6, and a pharmaceutically acceptable excipient*"

XII. The arguments of the appellant, insofar as relevant to the present decision, may be summarised as follows:

The subject matter of claim 1 of the main request was distinguished from D1-D3 and D15 in the recited purity of oxycodone relative to 14-hydroxycodeinone. Decision T 990/96 had been overruled by T 1085/13, which stated that a claim defining a compound as having a certain purity lacked novelty over a prior-art disclosure describing the same compound only if the prior art discloses the claimed purity at least implicitly.

## Reasons for the Decision

Main request

1. The opposition division acknowledged that the grounds for opposition under Articles 100(b) and (c) EPC did not prejudice the maintenance of the patent on the basis of the "amended main request" (main request in appeal proceedings). In the absence of any arguments from the respondents to the contrary, the board sees no reasons to diverge from the opposition division's conclusion.

2. Novelty - Article 54 EPC

2.1 Claim 1 is directed to a pharmaceutical dosage form comprising oxycodone hydrochloride and less than 25 ppm of an impurity, 14-hydroxycodeinone. According to the opposition division (contested decision, page 7, second paragraph), and unchallenged in appeal proceedings, this claim is to be interpreted such that the amount of 14-hydroxycodeinone in ppm is to be determined relative to the amount of oxycodone hydrochloride, and not to the amount of the pharmaceutical dosage form as a whole, i.e. including the pharmaceutically acceptable excipient.

2.2 According to the contested decision, *inter alia*, the subject-matter of claim 1 of the main request submitted during oral proceedings before the opposition division ("amended main request" according to the decision) lacked novelty over D1-D3 and D15. Specifically, the opposition division concluded that D1-D3 and D15 did **not** disclose a pharmaceutical dosage form comprising oxycodone HCl and less than 25 ppm 14-hydroxycodeinone as recited in claim 1 (contested decision, 3.3.1, final paragraph). The opposition division reasoned however, that following decision T 990/96, the disclosure in D1-D3 and D15 of oxycodone HCl made this compound available to the public in all desired grades of purity. The exceptional situation whereby, according to T 990/96, novelty could be acknowledged where all prior attempts to achieve the claimed purity by conventional purification processes had failed, was not applicable to claim 1.

2.3 The appellant submitted in appeal proceedings that according to decision T 1085/13, published after the contested decision was issued, the approach taken in

T 990/96 contravened the established standards for the assessment of *inter alia* novelty, set out in Enlarged Board of Appeal decisions G 2/10 and G 2/88. In view of T 1085/13, the decision of the opposition division was to be set aside, and novelty acknowledged.

2.4 The board agrees with the rationale and the conclusion of decision T 1085/13 in relation to the assessment of novelty. The claim at issue in that decision was directed to a specific compound in the amorphous form having a purity of at least 99.5% and containing less than 0.5% of the crystalline form. This situation is analogous to that of present claim 1, which as set out above, defines oxycodone hydrochloride as having less than 25 ppm of a specific impurity.

2.5 The rationale of T 1085/13 was based on the observation that T 996/90 was not consistent with the case law of the Enlarged Board of Appeal (T 1085/13, reasons 3.6). Specifically, in decision G 2/10 (reasons, 4.7), the Enlarged Board stated:

"*the overriding principle for any amendment to be allowable under Article 123(2) EPC is that the subject-matter of an amended claim must be at least implicitly disclosed to the skilled person, using common general knowledge, in the application as filed*".

The Enlarged Board (reasons, 4.6) further referred to decision G 1/03 stating:

"*the European Patent System must be consistent and the concept of disclosure must be the same for the purposes of Articles 54, 87 and 123 EPC*".

Therefore, to be in line with G 2/10, it was determined in T 1085/13, in the same way as for assessing compliance with Article 123(2) EPC, that in order to conclude a lack of novelty, there must be at least an implicit disclosure in the state of the art of subject-matter falling within the claimed scope. It was therefore concluded (T 1085/13, reasons, 3.7 and 3.8) that

"*A claim defining a compound as having a certain purity therefore lacks novelty over a prior-art disclosure describing the same compound* ***only if the prior art discloses the claimed purity at least implicitly****, for example by way of a method for preparing said compound, the method inevitably resulting in the purity as claimed.*

*Such a claim, however, does not lack novelty if the disclosure of the prior art* ***needs to be supplemented, for example by suitable (further) purification methods allowing the skilled person to arrive at the claimed purity.***

*3.8 The question of whether such (further) purification methods for the prior-art compound are within the common general knowledge of those skilled in the art and, if applied, would result in the claimed purity, is not relevant to novelty, but is rather a matter to be considered in the assessment of inventive step.*"
(emphasis added by the present board)

2.6 As stated above, it was accepted in the contested decision that D1-D3 and D15 did not, even implicitly, disclose the purity recited in claim 1. Furthermore, the opposition division concluded a lack of novelty despite accepting that the evidence on file

demonstrated, at the effective date of the patent, that there was "*no specific* [oxycodone hydrochloride] *preparation available on the market which would have met the claimed purity criteria*" (contested decision, 3.3.3, second paragraph, final sentence). It is abundantly clear therefore that in the present case, the prior art D1-D3 and D15 would need to be supplemented with suitable further purification methods in order to (potentially) arrive at the claimed purity, which, as stated in the second and third paragraph cited from T 1085/13 above, cannot lead to a lack of novelty of the claimed subject-matter, but is rather a matter to be considered in the assessment of inventive step.

2.7 It follows that the subject-matter of claim 1 of the main request is novel vis à vis documents D1-D3 and D15.

3. Remittal - Article 11 RPBA 2020

The appellant requested that should novelty of the claims of the main request be acknowledged, the case be remitted to the opposition division for further prosecution.

According to Article 11 RPBA 2020, the board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

The board notes that inventive step was not addressed in substance by the parties in appeal proceedings. Furthermore, inventive step was neither addressed during oral proceedings before the opposition division, nor in the contested decision. Therefore, it does not

form the basis of appeal proceedings in accordance with Article 12(1) RPBA 2020. These facts, in the view of the board, constitute sufficient "special reasons" within the meaning of Article 11 RPBA 2020 to justify remittal of the case to the opposition division.

Consequently, the board, in line with the appellant's request, decided to remit the case to the opposition division for further prosecution.

## 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:

N. Maslin M. O. Müller

Decision electronically authenticated