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**Datasheet for the decision
of 11 January 2019**

Case Number: T 0069/14 - 3.3.02

Application Number: 05730345.5

Publication Number: 1730151

IPC: C07D489/00, C07D489/08

Language of the proceedings: EN

Title of invention:

PROCESS FOR PREPARING OXYCODONE HYDROCHLORIDE HAVING LESS THAN
25 PPM 14-HYDROXYCODEINONE

Patent Proprietor:

EURO-CELTIQUE S.A.

Opponents:

Elend, Almut Susanne
Actavis Group PTC ehf
Acino Pharma AG

Headword:

EURO-CELTIQUE / OXYCODONE HYDROCHLORIDE

Relevant legal provisions:

EPC Art. 83, 123(2)
EPC R. 80

Keyword:

Main request - added subject-matter (no) - sufficiency of disclosure - (yes)

Decisions cited:

T 0225/93, T 0464/05, T 0608/07, T 2290/12

Catchword:



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Case Number: T 0069/14 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 11 January 2019

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 8 November 2013
revoking European patent No. 1730151 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman M. O. Müller
Members: M. Maremonti
 L. Bühler

Summary of Facts and Submissions

- I. The appeal by the patent proprietor (hereinafter "appellant") lies from the decision of the opposition division to revoke European patent No. 1 730 151.
- II. The contested patent contains twenty-six claims, independent claim 1 of which reads as follows:
- "1. A process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level of less than 25 ppm by reacting an oxycodone base composition having an 8,14-dihydroxy-7,8-dihydrocodeinone compound with hydrochloric acid, whereby 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydroxycodeinone, and reducing 14-hydroxycodeinone to oxycodone."*
- III. The opposition division came to the conclusion that none of the then pending claim requests were either allowable or admissible, in particular:
- the subject-matter of claim 1 as granted (main request) did not meet the requirements of Article 123(2) EPC, and
 - the subject-matter of claim 1 of auxiliary request III met the requirements of Article 123(2) EPC but it was insufficiently disclosed under Article 83 EPC.
- IV. In its statement setting out the grounds of appeal, the appellant maintained claim 1 as granted as the main request and filed auxiliary requests I, Ia-c, II, IIa-c, III and IIIa-c.
- V. In their replies to the statement of grounds of appeal, opponent 1 and opponent 3 (hereinafter "respondent 1" and "respondent 3") raised various objections against

the appellant's claim requests including objections under Rule 80 EPC and Articles 123(2) EPC and 83 EPC.

VI. In preparation for the oral proceedings, the board issued a communication, containing the preliminary opinion that the opposition ground under Article 100(c) EPC appeared to prejudice maintaining the contested patent on the basis of claim 1 as granted but that auxiliary request I seemed to be admissible and in compliance with Articles 83 and 123(2) EPC. The board also observed that the requirements of Rule 80 EPC appeared to be met.

VII. By letter of 17 December 2018, the appellant filed a new main request, which was identical to auxiliary request I as filed with the statement of grounds. This request contains a single claim, which reads as follows (amendments as compared to claim 1 as granted put in bold by the board):

*"1. A process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level of less than 25 ppm by reacting an oxycodone base composition having an 8,14-dihydroxy-7,8-dihydrocodeinone compound with hydrochloric acid, whereby 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydroxycodeinone, **and under reducing conditions, whereby 14-hydroxycodeinone is converted to oxycodone.**"*

VIII. Respondent 1, opponent 2 (hereinafter "respondent 2") and respondent 3 informed the board that they would not attend the oral proceedings.

IX. Oral proceedings before the board were held on 11 January 2019 in the absence of the respondents, pursuant to Rule 115(2) EPC and Article 15(3) RPBA.

X. Final requests

The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the claim of the main request filed by letter dated 17 December 2018 (VII, *supra*), or, alternatively, on the basis of the claims of auxiliary requests Ia-c, II, IIa-c, III, and IIIa-c, as filed with the statement of grounds of appeal.

Respondents 1 and 3 requested in writing that the appeal be dismissed.

Respondent 1 further requested in writing that none of the claim requests filed with the statement of grounds of appeal be admitted into the appeal proceedings.

Respondent 3 further requested in writing that the case be remitted to the opposition division for discussing novelty and inventive step, should the subject-matter of one of the requests be found to meet the requirements of Articles 123 and 83 EPC.

Respondent 2 did not take an active part in the appeal proceedings and did not file any requests.

XI. The arguments of the appellant, where relevant for the present decision, may be summarised as follows:

Article 123(2) EPC:

- The claimed subject-matter was limited to a "one-pot" process, wherein the reaction of the oxycodone base with hydrochloric acid was performed under reducing conditions. This process was based on paragraph [0019] of the application as filed. The

claimed subject-matter thus complied with Article 123(2) EPC.

Article 83 EPC:

- Example 3 of the contested patent showed that the claimed process could successfully be performed and levels of 14-hydroxycodeinone (hereinafter "14-OH") of less than 25 ppm were achieved.
- The fact that two methods for measuring the 14-OH level were described in the contested patent (examples 4 and 6) and that these methods could lead to different results might at most represent a clarity problem but not an insufficiency of disclosure.
- Moreover, the results in terms of the 14-OH level as reported in examples 4 and 6 were, even if different from each other, both well below the claimed threshold of 25 ppm. Thus, an objection under Article 83 EPC was not justified.
- The burden of proof was on the respondents, who had not provided any data showing that the claimed process was not able to achieve the claimed level of 14-OH.
- The claimed subject-matter was thus sufficiently disclosed in the patent in suit.

XII. The respondents essentially counter-argued in writing as follows:

Admittance of requests:

- According to respondent 1, none of the requests filed by the appellant were admissible, primarily

because the introduced amendments were not occasioned by a ground of opposition, thus infringing Rule 80 EPC.

- Moreover, the filed requests were based on subject-matter that was either withdrawn or not admitted by the opposition division or presented in the appeal proceedings for the first time. Therefore, all requests should not be admitted under Article 12(4) RPBA.

Article 123(2) EPC:

- Respondent 1 was of the opinion that claim 1 at issue could only be based on paragraph [0019] of the application as filed. However, process features disclosed in said paragraph were not included in claim 1, thus contravening Article 123(2) EPC.
- Respondent 3 argued that claim 1 at issue represented a non-allowable generalisation of claim 1 as filed, thus contravening Article 123(2) EPC.

Article 83 EPC:

- According to respondents 1 and 3, the contested patent disclosed two methods for determining the level of 14-OH giving substantially different results (100% variability). An undue burden was placed on the skilled person, who could not reliably determine whether he was operating within the ambit of the claim. Decisions T 0464/05 and T 0225/93 were referred to.
- Respondent 3 noted that no lower limit for the level of 14-OH was mentioned in claim 1. The claim thus covered 14-OH concentrations lower than e.g. 1 ppm, and the contested patent did not contain any

teaching as to how to reach such low concentrations.

- The claimed subject-matter was, therefore, not sufficiently disclosed.

Reasons for the Decision

Main request - admittance into the proceedings

1. The board observes that, contrary to what was submitted in writing by respondent 1 (XII, *supra*), the main request (VII, *supra*) is identical to auxiliary request III filed before the opposition division (see the annex to the minutes of the oral proceedings of 19 September 2013 before the opposition division). This request was dealt with in substance in the impugned decision (pages 8 and 9 under "5) *Third auxiliary request*") and thus formed part of the opposition proceedings.

The board sees no reason not to admit this request into the appeal proceedings. The main request is therefore admitted.

Main request - compliance with Rule 80 EPC

2. Respondent 1 objected to all claim requests filed by the appellant with its statement of grounds under Rule 80 EPC. It argued that the deletion of the dependent claims did not comply with Rule 80 EPC regardless of whether or not there was a deference to procedural economy as invoked by the appellant. In any case, lack of procedural economy was not an opposition ground under Article 100 EPC. The appellant's requests should thus be rejected under Rule 80 EPC.

3. The board notes that the dependent claims were already deleted in auxiliary request III filed by the appellant during oral proceedings before the opposition division and corresponding to the present main request. In the board's judgement, it is hardly possible to conceive of circumstances where the deletion of dependent claims cannot be seen as being occasioned by a ground of opposition, especially under Article 100(c) and/or (b) EPC. The board thus concludes that the deletion of the dependent claims in the main request at issue does not contravene Rule 80 EPC.

Main request - compliance with Article 123(2) EPC

4. The board is convinced that paragraph [0019] of the application as filed represents an adequate basis for the subject-matter defined in claim 1 at issue.
 - 4.1 Respondent 1 argued that this paragraph did not disclose that the oxycodone base composition contained 8,14-dihydroxy-7,8-dihydrocodeinone (hereinafter "8,14-diOH") as mentioned in claim 1 at issue.

In the board's view, however, the fact that according to paragraph [0019] of the application as filed, an oxycodone base composition is reacted with HCl "*under conditions suitable to promote dehydration of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone*" automatically implies that 8,14-diOH must be present. Otherwise, no reaction would take place.
 - 4.2 Respondent 1 further argued that said paragraph recited that the reaction with HCl was carried out **under conditions suitable to promote dehydration** of 8,14-diOH to 14-OH during salt formation. This requirement was not included in claim 1.

However, given the chemical formulae of 8,14-diOH and 14-OH (figure 1 of the contested patent), the conversion of 8,14-diOH to 14-OH referred to in claim 1 can only occur by means of a dehydration. Moreover, for the reaction to occur, suitable conditions must always be applied. Therefore, claim 1 does include the requirement referred to by respondent 1.

- 4.3 Respondent 3 argued that claim 1 as filed was limited to a hydrogenation process, whereas claim 1 at issue recited a reduction process. However, hydrogenation was a specific form of reduction. No basis for the extension to any form of reduction was present in the application as filed.

The board disagrees. The process defined in claim 1 is based on paragraph [0019] and not on claim 1 of the application as filed. Said paragraph [0019] discloses that the process occurs "*under reducing conditions*". Hence, there is no limitation to hydrogenation as argued by respondent 3.

- 4.4 The board thus concludes that claim 1 of the main request at issue is not objectionable under Article 123(2) EPC.

Main request - sufficiency of disclosure under Article 83 EPC

5. The opposition division rejected present claim 1 under Article 83 EPC. In particular (impugned decision, page 9), it agreed that example 3 of the contested patent resulted in a sample with a 14-OH level falling under the scope of claim 1 at issue (VII, *supra*). However, it observed that the measurement methods described in examples 4 and 6 resulted in a 100% deviation of the 14-OH level of the same sample. It argued that, in view of these differences, the skilled person would "*not*

know exactly when he works within the scope of the claim or not". It observed that this matter was not to be dealt with under Article 84 EPC and that this ambiguity established in examples 4 and 6 would indeed prevent the skilled person from carrying out the invention over the whole scope claimed. The same argument was submitted in writing by respondents 1 and 3 (XII, *supra*).

6. The board notes that claim 1 at issue is directed to a process for preparing an oxycodone HCl composition having a 14-OH level "*of less than 25 ppm*".
- 6.1 It is common ground that examples 4 and 6 of the contested patent disclose two methods for measuring the concentration of 14-OH. Example 3 of the contested patent discloses at least one way to carry out the claimed process such that the obtained oxycodone HCl composition has the required level of 14-OH, independent of the method used for determining the latter. In fact, by using the methods disclosed in examples 4 and 6, a 14-OH level respectively of 5 ppm and 10 ppm was determined as having been achieved in example 3 (patent in suit, paragraphs [0184] and [0185]). Both values are within the range of less than 25 ppm defined in claim 1.
- 6.2 The board is therefore convinced that the fact that the two measurement methods described in examples 4 and 6 furnish different results with respect to the 14-OH level could at most represent a clarity problem under Article 84 EPC, maybe affecting the upper limit of the claimed range of the 14-OH level. This problem, however, does not permeate the whole claim. Therefore, the different measurement results obtained in examples 4 and 6 do not support any insufficiency of

disclosure under Article 83 EPC (T 0608/07, reasons 2.5.1 and 2.5.2, T 2290/12, reasons 3.1).

- 6.3 The skilled person aiming at reproducing the process of claim 1 would find in example 3 clear guidance as to the operating conditions to be followed so that a 14-OH level as required by claim 1 at issue would be obtained. The respondents did not point out any technical difficulties that would pose an undue burden on the skilled person when reworking example 3.
- 6.4 Decisions T 0464/05 and T 0225/93 invoked by respondent 3 are not applicable to the present case. Both decisions concerned cases in which the contested patent did not disclose the method for measuring the parameter(s) included in the claim (T 0464/05, reasons, 3.2 and 3.4; T 0225/93, reasons, 2). In the present case, however, it is not in dispute that examples 4 and 6 of the patent in suit disclose in detail how the level of 14-OH is to be determined.
- 6.5 As to the argument of respondent 3 (XII, *supra*) that the claimed subject-matter was insufficient since no lower limit for the 14-OH level was mentioned in claim 1, the board observes that claim 1 is directed to a process for preparing a product and not to a product *per se*. A lower limit of the 14-OH level, even if not mentioned in claim 1, is imposed anyway by the claimed process. In other words, the protection conferred under Article 64(2) EPC to claim 1 would only extend to products having a 14-OH level which is the direct result of the claimed process. Example 3 of the contested patent clearly demonstrates that a 14-OH level below 25 ppm, i.e. in accordance with claim 1, may be achieved when carrying out the claimed process.

6.6 The respondents were not able to show on the basis of verifiable facts that an undue burden is needed to carry out the claimed process. The board comes therefore to the conclusion that the main request fulfils the requirements of Article 83 EPC.

Remittal

7. The primary function of an appeal is to give the losing party an opportunity to obtain judicial review of whether the decision appealed was correct. In the present case, the opposition division decided only on the questions of added matter under Article 123(2) EPC and sufficiency of disclosure under Article 83 EPC. Since as set out above, the present main request complies with both these requirements, the board considers it appropriate to remit the case to the opposition division for the assessment of other aspects of patentability (e.g. novelty and inventive step) not dealt with in the decision under appeal, in accordance with the request of the appellant and respondent 3 to this end.

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 on the basis of the main request filed with letter dated 17 December 2018.

The Registrar:

The Chairman:



N. Maslin

M. O. Müller

Decision electronically authenticated