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**Datasheet for the decision  
of 21 June 2024**

**Case Number:** T 1655/21 - 3.3.03

**Application Number:** 14742322.2

**Publication Number:** 3022231

**IPC:** C08B37/16, A61K47/40

**Language of the proceedings:** EN

**Title of invention:**

CYCLODEXTRIN

**Patent Proprietor:**

Curadev Pharma Pvt. Ltd.

**Opponent:**

Ligand Pharmaceuticals Incorporated

**Relevant legal provisions:**

EPC Art. 113(1)  
EPC R. 103(1)(a), 103(3)(a), 111(2), 116  
RPBA 2020 Art. 11, 12(8)

**Keyword:**

Decision in written proceedings  
Submissions central to the appellant's case dealt with (no)  
Appeal decision reasoned (no)  
Reimbursement of appeal fee - (yes)  
Remittal - fundamental deficiency in first-instance  
proceedings (yes)

**Decisions cited:**

T 0246/08, T 0337/17



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Case Number: T 1655/21 - 3.3.03

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.03**  
**of 21 June 2024**

**Appellant:**  
(Opponent)

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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
14 July 2021 concerning maintenance of the  
European Patent No. 3022231 in amended form.**

**Composition of the Board:**

**Chairman**            D. Semino  
**Members:**            F. Rousseau  
                              A. Bacchin

## Summary of Facts and Submissions

I. The appeals lie from the interlocutory decision of the opposition division according to which European patent No. 3 022 231 as amended according to the claims of the first auxiliary request submitted during the oral proceedings on 18 May 2021 and a description adapted thereto met the requirements of the EPC. The contested decision was also based on the patent as granted as the main request.

II. The following documentary evidence was among others submitted before the opposition division:

D1: WO 2013/123254 A1

D3: US 2009/270348

D4: D. Tyler Mcquade et al., J. Org. Chem., 78(13) (2013), 6384-6389

D5: Hartman et al., Angew. Chem. Int. Ed., 2011, 50 7502-7519

D6: Zannou et al., Pharmaceutical Research, 18(8) (2001), 1226-1231

D7: Zia et al., Pharmaceutical Research, 17(8) (2000), 936-941

D8: US 5,134,127

D11: Grard et al., J. Chromatog A, 925 (2001) 79-87

D21: Declaration of Mr. Jeff Duke dated 17 May 2019

D22: Declaration by Mr. Stephen Wicks dated 7 July 2016

D29: Declaration by Mr. Vincent Antle dated 14 February 2020

D30: US 6,153,746

D31: Szeman et al., 16th International Cyclodextrin Symposium, Tianjin, China (2012) (poster)

D32: Yang et al., Huaxue Shijie Chemical World, 54(2) (2013) 110-113, with confirmation of the 25 February 2013 publication date and an English language translation annexed thereto

D33: D. Penry et al., Chemical Reactor Analysis and Optimal Digestion, BioScience Vol.36, No.5 (1986) 310-315

D39: Declaration of Mr Jeff Duke dated 1 May 2020

D45: Savage et al. Int. J. of Pharmaceutics 495 (2015) 862-868

D47: Declaration of Mr Vincent Antle dated 16 March 2021

D48: Declaration of Mr Valentino Stella dated 5 March 2021

III. According to the reasons for the contested decision which are pertinent for the appeal proceedings:

*Main request (patent as granted)*

(a) The subject-matter of claim 1 as granted was entitled to the claimed priority and, consequently, D1 was prior art only under Article 54(3) EPC. Having regard to table 3 of D1, paragraphs [0099] and [0100] of that document and its examples 3 and 6, the subject-matter of granted claim 1 lacked novelty.

*Auxiliary request 1*

*Novelty*

(b) Documents D6, D7, D11, D31 and D32 disclosed the analysis of sulfobutyl ether  $\beta$ -cyclodextrin (hereafter SBE- $\beta$ -CD) samples, that were either purchased, donated to the authors, or prepared in

their laboratories but the description of the preparation was described elsewhere. The documents themselves were silent about the preparation methods. Only D32 described a method of preparation and disclosed an ADS of 8.6, but the analytical data were ambiguous and it was doubtful that SBE- $\beta$ -CD with a degree higher than 7.3 was obtained. Consequently, the subject-matter of claim 8 of auxiliary request 1 was considered new.

*Inventive step*

- (c) Claim 1 corresponded to granted claim 1 whereby it was specified that the activation reaction was carried out in a first reservoir vessel at a temperature between 50 and 95 °C. D3 represented the closest prior art. D3 disclosed alkaline activation and sulfoalkylation as batch processes. Claim 1 differed from the disclosure of D3 in that the sulfoalkylation was performed as continuous flow reaction.
- (d) Based on figures 6, 14, and 18-20 of the specification, the technical problem successfully solved over the closest prior art could be seen as the provision of a method to prepare sulphoalkyl ether cyclodextrin with an increased ADS. Paragraph [0062] of D3 did not suggest a continuous flow sulfoalkylation reaction but merely continuous addition of CD/NaOH to the substituent precursor solution. Although the general possibility of continuous flow reaction mode was known from D4, D5, or D33, the skilled person could not foresee an increase in ADS for the reaction referred to in claim 1 of the contested patent. Moreover, it would

have complicated the process. On that basis the subject-matter of claim 1 was inventive.

- (e) D3 was also considered to represent the closest prior art for the subject-matter of granted claim 8, which differed from D3 is that the latter did not disclose an ADS larger than 7.3. It could be agreed with the patent proprietor that the data provided by the opponent were not convincing and that no evidence was on file suggesting that an increase in butane sultone would increase the ADS of the resulting SBE- $\beta$ -CD over 7.3.

One conclusive experiment simply comparing (a) a batch process with increased amounts of butane sultone with (b) the process of the contested patent both analysed with the same chromatographic method was not presented. On the other hand, both the patent and D45, in particular its figure 6, provided data showing that unambiguous analysis of highly substituted SBE- $\beta$ -CD was possible. It could not be concluded from the data available to the opposition division that the skilled person following the suggestion of D3 would have automatically arrived at the subject-matter of claim 8. Moreover, the skilled person would have had no reasonable expectations of success when following the suggestions of D3. Therefore, it was not obvious to provide SBE- $\beta$ -CD with an ADS equal or larger than 7.3. The subject-matter of claim 8 was therefore inventive.

IV. An appeal was filed by both the patent proprietor and the opponent. Both parties filed a statement of grounds of appeal, a rejoinder and a reply to the rejoinder of the other party.



- V. With their statement of grounds of appeal (letter dated 23 November 2021), the patent proprietor had submitted 20 sets of claims as first to twentieth auxiliary requests.
- VI. In preparation of the oral proceedings, a communication pursuant to Article 15(1) RPBA conveying the Board's provisional opinion was issued.

The Board indicated reasons why in its preliminary view claim 1 of the main request lacked novelty over both example 3 and example 6 of D1. For this reason, the main request did not appear to be allowable. The same was valid for claim 1 of the first auxiliary request which was identical to claim 1 of the main request.

Concerning the second auxiliary request, identical to the first auxiliary request underlying the contested decision, the Board preliminary opinion was that

(i) the part of the contested decision dealing with novelty of claim 8 was not reasoned within the meaning of Rule 111(2) EPC and

(ii) the opposition division had failed to give due consideration to facts, evidence and arguments, which from the opponent's submissions were central to the alleged lack of an inventive step of the subject-matter of claims 1 and 8.

These fundamental deficiencies resulted in a substantial procedural violation and justified that the decision under appeal be set aside, a reimbursement of the appeal fee of the opponent be ordered and the case be remitted to the opposition division for further

examination on the basis of the second auxiliary request.

VII. The opponent and the patent proprietor replied to the Board's communication with letters of 6 June 2024 and 11 June 2024, respectively. With these letters,

- The opponent informed the Board that their request to hold oral proceedings was withdrawn on the condition that the patent proprietor did the same and a decision was issued in accordance with the preliminary opinion of the Board indicated in its communication.

- The patent proprietor withdrew their appeal and requested reimbursement of 50% of their appeal fee. They also withdrew their request for oral proceedings on the condition that the case be remitted to the opposition division for further consideration of the second auxiliary request. The proprietor also requested to accelerate opposition proceedings after remittal.

VIII. Oral proceedings were cancelled and the parties informed accordingly.

IX. The final requests of the parties were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the contested decision be set aside and the patent be maintained on the basis of any of the second to the twentieth auxiliary requests filed with letter dated 23 November 2021.

## **Reasons for the Decision**

### *Decision in written proceedings*

1. The present decision is taken in written proceedings without holding oral proceedings.

Both the appellant and the respondent withdrew their request for oral proceedings (see point VII. above). The appellant did so under the condition that a decision is issued in accordance with the Board's preliminary opinion expressed in the communication under Article 15(1) RPBA. The respondent did so under the condition that the case is remitted to the opposition division for further consideration of the second auxiliary request.

These requests are followed by the Board, so that the respective requests for oral proceedings do not become active.

In addition, the parties have been informed of the Board's preliminary assessment of the case, in which their whole submissions have been duly taken into consideration and have been given the opportunity to make further submissions. Thus, the principle of the right to be heard according to Article 113(1) EPC has been observed.

In view of the fact that the case is ready for decision on the basis of the parties' extensive written submissions, the Board issues this decision in written proceedings in accordance with Article 12(8) RPBA.

2. With the withdrawal of their appeal, the patent proprietor, now respondent, confirmed withdrawal of the former main request and first auxiliary request (letter of 11 June 2024, page 1, second paragraph). The second auxiliary request, which corresponds to the first auxiliary request underlying the contested decision, constitutes therefore the main request of the respondent. The opponent, now sole appellant, objects to novelty of claim 8 over each of D6, D7, D11, D31 and D32, to inventive step of claim 8 starting from D3 as the closest prior art and to inventive step of claim 1 taking any of D3, D8, D23 and D19 as the closest prior art.

*Novelty of claim 8*

3. Concerning the appellant's objection that each of D6, D7, D11, D31 and D32 is prejudicial to novelty of operative claim 8, the respondent submits that the appellant merely reiterated their submissions before the opposition division to which the respondent had already replied in detail to explain why these references neither anticipated nor enabled formation of a composition according to claim 8 (rejoinder, page 2, second paragraph). Reference is in particular made to section 6.3 of the respondent's letter of 11 June 2019 and Mr Duke's declaration D21, and section 2.5.4 of the respondent's letter of 11 May 2020 and Mr Duke's declaration D39.

Section 6.3 of the respondent's letter of 11 June 2019 concerns novelty of claim 8 over D6, D7 and D11. D21 concerns the suitability of the measuring methods used in D6, D7 and D11 to provide an accurate measurement of the ADS of the SBE- $\beta$ -CD.

Section 2.5.4 of the respondent's letter of 11 May 2020 concerns novelty of claim 8 over D31 and D32.

Declaration D39 comprises a section in which comments on D32 are given.

- 3.1 The submissions of the appellant before the opposition division in relation to novelty can be found in section 6.2 to 6.2.19 of their letter of 17 February 2020. Reference is made in particular to the teaching of D3 and D30, as well as declaration D29, which is in reply to declarations D21 and D22 of the respondent. It can be seen that D29 was submitted both in relation to the issue of novelty over D6, D7 and D11 (see above mentioned sections, in particular those relating to the production of a SEB- $\beta$ -CD with an ADS of 7.3 or more), as well as to that of inventive step starting from D3, which in accordance with the contested decision represented the closest prior art. Declaration D29 was also in response to declaration D21 which puts into question the accuracy of the analytical methods used in D6, D7 and D11 in order to determine the ADS of the SEB- $\beta$ -CD.
- 3.2 Concerning the issue of novelty of claim 8 over documents D6, D7, D11 and D31, the opposition division indicated that it followed the respondent's argumentation that the cited documents *"disclose analyses of SBE- $\beta$ -CD samples that were either purchased, donated to the authors, or prepared in their laboratories but the description of the preparation was described elsewhere"*. It was added that *"the documents themselves are silent about the preparation methods"*. Neither by reference to detailed submissions of the parties, nor by explanations in the Reasons for the contested decision, did the opposition division address

which SBE- $\beta$ -CD samples were concerned, which samples were purchased and why their sale would not make them available to the public and enabled, or if their preparation was described elsewhere, why that description did not enable the skilled person to obtain them.

- 3.3 The decision of the opposition division therefore failed to take into account all the arguments submitted by the opponent. A decision must show that all potentially refutative arguments adduced by a losing party are actually refutable (see e.g. T 246/08, Catchword and T 337/17, Reasons 1 to 4). However in the present case, the Board is left to study the parties' submissions before the opposition division and decide themselves which considerations were made by the opposition division in their decision. For the same reason, the appellant was in the Board's opinion not given an appropriate indication, i.e. which is based on objective considerations, of why their submissions were not held convincing.
- 3.4 Concerning novelty of claim 8 over D32, the opposition division decided that D32 described a method of preparation and disclosed an ADS of 8.6, but "*the analytical data are ambiguous and it is doubtful that SBE- $\beta$ -CD with a degree higher than 7.3. was obtained*". Similarly, only a conclusion without explanation as to why the analytical data were ambiguous and why it was doubtful that a SBE- $\beta$ -CD with a degree higher than 7.3 was provided.
- 3.5 According to settled case law, the obligation to give reasons under Rule 111(2) EPC, as an expression of the right to be heard enshrined in Article 113(1) EPC, also includes the principle that sufficient reasons are

provided, i.e. that the grounds upon which the decision was based and all decisive considerations in respect of the factual and legal aspects of the case must be discussed in detail in the decision (Case Law of the Boards of Appeal of the EPO, 10th edition 2022, III.K.3.4.3). The reasons for the decision must enable both the parties and the board of appeal to understand whether or not the decision is justified (Case Law, supra, V.A.9.4.4 b)).

On that basis, the part of the decision dealing with novelty of claim 8 is not reasoned within the meaning of Rule 111(2) EPC and thus is in violation of the appellant's right to be heard foreseen by Article 113(1) EPC.

4. Furthermore, the Board considers that multiple submissions forming the basis for objections of the opponent concerning inventive step of claims 8 and 1, which are addressed again on appeal by the appellant, were not given due consideration in the contested decision.

#### *Inventive step of claim 8 over D3*

- 4.1 The reasons given in the contested decision for acknowledging an inventive step of claim 8 over D3 taken as the closest prior art are essentially that the data provided by the appellant were not convincing and that no evidence was on file suggesting that an increase in butane sultone would increase the ADS of the resulting SBE- $\beta$ -CD over 7.3. The opposition division did not indicate which problem would be solved by the subject-matter of claim 8 over D3, but submitted in essence that the skilled person would not have been able to prepare the claimed composition.

4.1.1 The submissions of the appellant before the opposition division concerning inventive step over D3 can be found in particular in sections 7.2.4.11 and 7.2.4.12 of their letter of 17 February 2020 and sections 9.5 and 9.6 of their letter of 17 March 2021. They rely among others on declaration D29 mentioned above, as well as on additional declarations D47 and D48, which were submitted by the appellant with letter of 17 March 2021. These declarations were submitted in support of the argument that the skilled person would be able to obtain SBE- $\beta$ -CD with an ADS of 7.3 or more by increasing the amount of butane sultone added, as was taught in D3 (letter of 17 March 2021, sections 9.8 to 9.20).

They comprise extensive and detailed explanations in this respect, D29 and D47 comprising in addition numerous experimental data as attachments, whose results are analysed in the corresponding declarations.

4.1.2 The considerations of the opposition division in the Reasons for the contested decision do not go beyond the statement according to which "*The opposition division agrees with the Proprietor that the data provided by the Opponent are not convincing and that no evidence is on file suggesting that an increase in butane sultone would increase the ADS of the resulting SBE- $\beta$ -CD over 7.3. In the opposition division's view, none of the submitted data showed unequivocally an ADS higher than 7.3. Conclusions have to be drawn, assumptions to be made, or obscuring background be disregarded to interpret the data in such a way*". This general statement does not allow the Board to understand why the appellant's submissions were not convincing, let



alone whether those submissions were duly considered. In fact the opposition division did not deal with the submissions of the appellant to the extent that the Board would be in the position to understand which assumptions were made by that party, which background was obscure and which conclusions should be drawn. Having regard to the extensiveness of submissions made by the appellant with declaration D29, D47 and D48, this cannot be said to be implicit.

The opposition division noted in the reasons for the contested decision that one conclusive experiment by simply comparing (a) a batch process with increased amounts of butane sultone with (b) the process of the contested patent both analysed with the same chromatographic method had not been presented. This cannot amount to a sufficient reasoning when the submissions made by the appellant have not been shown to have been duly considered. In addition, product claim 8 does not refer to the process of the contested patent, meaning that this argument is not relevant to the submissions made by the appellant which concern the ability for the skilled person to prepare the compositions of claim 8 using the process taught in D3.

Furthermore, while acknowledging that D3 suggests to increase the amount of butane sultone in order to achieve a higher ADS, the opposition division merely opposed that the skilled person could not have had a reasonable expectation of success when following that teaching, since it was "*common general knowledge that chemical reactions are often limited as far as their efficiency is concerned*". This also cannot replace a proper consideration of the extensive submissions by the appellant as to why increasing the amount of butane sultone as explicitly taught in D3 in its paragraphs

[0114] and [0122] would result in SBE- $\beta$ -CD having an ADS above 7.3.

*Inventive step of claim 1 over D3*

4.2 Section 7.2 of the Reasons for the contested decision contains a short summary of the appellant's submissions as to why the problem solved over D3 should be formulated as the provision of an alternative method to prepare sulfoalkyl ether- $\beta$ -CD. Submissions in this respect can be found in sections 8.2.5 to 8.2.17 of the appellant's letter of 17 March 2021. They addressed in particular the meaning and relevance of the extent of the activation reaction (sections 8.2.9 to 8.2.13) and the fact that no experimental evidence relevant to the process of D3 had been submitted by the respondent, so that it would not have been demonstrated that the claimed process resulted in "greater synthetic efficiency" compared to the process of D3 (sections 8.2.16). These submissions of the appellant are not addressed in the contested decisions. The key point for acknowledging an inventive step is based on the experimental results shown in figures 6, 14 and 18-20 without explaining why they should be considered to be representative of the teaching of D3 taken as the closest prior art, although this is obviously not the case, those figures concerning a comparison with prior art D30.

*Inventive step of claim 1 over D8*

4.3 The objection according to which the subject-matter of claim 1 lacked an inventive step over D8 was maintained at the oral proceedings before the opposition division (section 4.3.1 of the minutes, first paragraph). The Reasons for the contested decision, however, do not

deal with that objection, as noted by the appellant on page 2 of their statement of ground of appeal (section 4.2, second paragraph) and page 9 thereof (third full paragraph).

- 4.4 In view of the above, the failure of the opposition division to give due consideration to facts, evidence, arguments and objections, which from the appellant's submissions are central to the alleged lack of an inventive step of the subject-matter of claims 1 and 8, constitutes a violation of the right to be heard in contravention of Article 113(1) EPC.
5. Finally, the Board finds that there is a causal link between the violations of the right to be heard (points 3.5 and 4.4, above) and the final decision reached by the opposition division, given that the patent was maintained on the basis of a finding which did not take into account all the pertinent arguments submitted by the appellant (see also Case Law, supra, III.B.2.2.1).
6. These above fundamental deficiencies justify that the decision under appeal be set aside, a reimbursement of the appeal fee of the opponent in accordance with Rule 103(1)(a) EPC be ordered and the case be remitted to the opposition division, in accordance with the provisions of Article 11 RPBA, for further examination on the basis of the second auxiliary request.

*Request for acceleration of the opposition proceedings after remittal*

7. With their letter of 11 June 2024, the respondent requested that this case be prioritised, and a hearing before the opposition division be scheduled to take place as soon as possible. It was submitted that the

ongoing opposition proceedings create uncertainty in relation to the validity of the patent, so that a delay in the further proceedings may adversely affect the respondent. In this respect the Board notes that any action after remittal lies in the competence of the opposition division. In any case, the attention of the opposition division is drawn to the instructions contained in section D-VII.1.2 (ii) of the Guidelines for Examination.

## 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.
3. The appeal fee of the appellant is to be reimbursed. The appeal fee of the respondent is to be reimbursed at 50% in accordance with Rule 103(3)(a) EPC.

The Registrar:

The Chairman:



A. Pinna

D. Semino

Decision electronically authenticated