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Datasheet for the decision of 20 October 2021

Case Number: T 1713/20 - 3.3.02

Application Number: 14758539.2

Publication Number: 3041845

IPC: C07D499/00, A61K9/20

Language of the proceedings: EN

Title of invention:
MICRONIZED AMOXICILLIN

Applicant:
Centrient Pharmaceuticals Netherlands B.V.

Headword:

Relevant legal provisions:
EPC Art. 113(1)
EPC R. 103(1)(a), 111(2)
RPBA 2020 Art. 11

Keyword:
Substantial procedural violation
Right to be heard
Remittal
Reimbursement of appeal fee

Decisions cited:
R 0019/10, R 0023/10, R 0017/11, T 0786/15

Catchword:

The requirement in Rule 111(2) EPC of a decision being reasoned is not met if the decision merely contains statements that at best give rise to speculation about what the deciding body might have intended to express (Reasons, 1.3.3).

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Case Number: T 1713/20 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 20 October 2021

Appellant: (Applicant)	Centrient Pharmaceuticals Netherlands B.V. Alexander Fleminglaan 1 2613 AX Delft (NL)
Representative:	de Pauw, Elmar Sebastian David DSM Sinochem Pharmaceuticals Netherlands B.V. Att: IP Department PP 9940850 Alexander Fleminglaan 1 2613 AX Delft (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 March 2020 refusing European patent application No. 14758539.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	M. Blasi

Summary of Facts and Submissions

I. The appeal by the applicant ("appellant") lies from the decision of the examining division to refuse European patent application No. 14 758 539.2.

II. The examining division in its decision considered the claims of a main request and of a first auxiliary request, both filed on 29 May 2019, and of a second auxiliary request filed on 13 January 2020. All three requests contain three independent claims: a product claim, a method claim and a use claim. The order of the independent claims in these claim requests varies. Independent claim 1 of the main request reads as follows:

"1. Composition comprising from 97.0% to 99.99% (w/w) of amoxicillin trihydrate, having a surface area of from 1.0 to 2.5 $m^2.g^{-1}$, characterized in that it further comprises less than 500 ppm of each of dichloromethane, isopropanol, pivalic acid and triethyl amine and from 2 to 500 ppm of protein."

III. The following documents are referred to in the present decision:

D1 Bittner et al, Journal of Pharmaceutical and Biomedical Analysis, vol. 54, 2011, 1059-64

D2 US 2006/0166958 A1

IV. The examining division came to the conclusion *inter alia* that none of the claim requests met the requirements of Article 56 EPC.

Lack of inventive step was the sole ground on which the examining division based the refusal of the application.

V. In its statement setting out the grounds of appeal, the appellant submitted that a substantial procedural violation had occurred since the decision to refuse the application had not been sufficiently reasoned. It requested as a main request that the matter be remitted to the examining division and that the appeal fee be refunded. Alternatively, it requested that a patent be granted on the basis of the claim set of the main request filed on 29 May 2019 or of either of auxiliary requests 1 and 2 filed on 29 May 2019 and 13 January 2020, repectively.

VI. In its communication of 23 April 2021, the board concurred with the appellant's point of view and expressed its preliminary opinion that the decision under appeal was not sufficiently reasoned within the meaning of Rule 111(2) EPC, amounting to a substantial procedural violation warranting a reimbursement of the appeal fee under Rule 103(1)(a) EPC. The board further considered that the lack of reasoning in the examining division's decision represented a fundamental deficiency within the meaning of Article 11 RPBA 2020 that justified remittal of the case without consideration as to its merits. The board lastly expressed its intention to take a decision in written proceedings without holding oral proceedings should the appellant submit no further comment or objection within two months of notification of the communication.

VII. No submission was filed by the appellant within that time.

VIII. The present decision was taken in written proceedings without holding oral proceedings.

IX. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

- The examining division failed to provide a detailed feature-by-feature analysis, such that it was impossible to understand how and why the subject-matter of claim 1 was rejected. Furthermore, the examining division did not provide any reasoning as to why the skilled person would have considered D1 and why they would have combined it with D2.

- The examining division failed to take into account the appellant's problem-solution approach for D2 in combination with D1 or to provide its own problem-solution approach.

- This represented a violation of the right to be heard.

- The appeal fee had to be reimbursed.

Reasons for the Decision

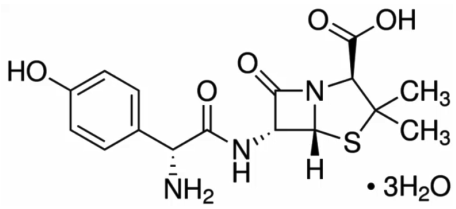
1. Substantial procedural violation

1.1 The appellant submitted that the examining division's decision had not been sufficiently reasoned, resulting in a substantial procedural violation.

1.2 Claim 1 of the main request (II, *supra*) relates to a composition comprising amoxicillin trihydrate. The latter is partially characterised in claim 1 by

reference to a surface area of from 1.0 to 2.5 $m^2.g^{-1}$ and a content of 2 to 500 ppm of protein.

Amoxicillin trihydrate is a broad-spectrum penicillin-type antibiotic of the following formula:



The compound of the claimed invention is produced by an enzymatic process.

The examining division refused the patent application on the ground that the claimed subject-matter did not involve an inventive step considering the disclosure of D1 and D2.

D1 is an article on the identification and particle-size determination of amoxicillin trihydrate.

D2 discloses an enzymatic process for producing amoxicillin trihydrate (Examples I-V).

1.3 According to Rule 111(2) EPC, decisions of the European Patent Office which are open to appeal must be reasoned. This ensures that the losing party is enabled to understand whether or not the decision was justified and to decide whether or not to lodge an appeal. It likewise ensures that the board of appeal, whose primary task it is to review the decision under appeal in a judicial manner, is enabled to understand the conclusions on which the decision is based and why they have been drawn. On the basis of the reasoning given in the decision under appeal, the board assesses whether

the conclusions drawn by the department which took the decision were correct.

Accordingly, the decision must address the facts, evidence and arguments which were relevant for reaching the decision, and must contain a logical chain of reasoning which led to the relevant conclusions (see also Case Law of the Boards of Appeal, 9th edition 2019, III.K.3.4.3).

Insufficient reasoning of a decision may also constitute a violation of the right to be heard under Article 113(1) EPC. The latter provision establishes a party's right not only to present comments but also to have the comments duly considered by the deciding body. By providing adequate reasoning the deciding body can demonstrate that it adhered to this.

In the present case, the decision under appeal contains reasons, but the board must conclude that the reasoning is insufficient under Rule 111(2) EPC and that this amounts to a violation of Article 113(1) EPC.

1.3.1 When examining inventive step, the examining divisions normally apply the problem-solution approach (see also Guidelines for Examination, edition November 2019, G-VII, 5, as the edition valid at the time of taking the decision under appeal), and there is no indication in the decision under appeal that the examining division, to which the Guidelines are primarily addressed and for which they represent general instructions (see also Guidelines, General Part, point 3), intended, for whatever reasons, not to follow the Guidelines or not to base the assessment of inventive step on the well-established problem-solution approach.

The problem-solution approach requires (i) identifying the closest prior art; (ii) identifying what the features distinguishing the claimed subject-matter with regard to the closest prior art are; (iii) identifying what effects (if any) are obtained by means of these distinguishing features, and defining what, based on these effects (if any), the objective technical problem is; and (iv) deciding whether the skilled person, starting from the closest prior art and confronted with the objective technical problem, would have arrived at the claimed subject-matter.

In the present case, the examining division's reasoning of a lack of inventive step which is provided on pages 5 and 6 of the decision under appeal is, however, incomplete. Only individual points of the problem-solution approach seem to have been addressed in isolation and it is not even clear in relation to which claims or claimed subject-matter the respective arguments or statements were made. There is no logical chain of argumentation concerning the assessment of inventive step of the claimed subject-matter. What has been presented is rather confusing. In particular, the following can be noted:

1.3.2 Re (i) Identification of the closest prior art

In the first paragraph of section 3) of the reasons (see page 5 of the contested decision), the examining division states that it "*concurs with the applicant that D2 represents the closest prior art which provides an enzymatic preparation procedure for amoxicillin trihydrate*". From this statement it might be derived that the disclosure of D2 was taken as the starting point for the assessment of inventive step.

Subsequently, however, in the first paragraph on page 6 of the decision, the examining division also addresses the question of whether a certain amount of protein, i.e. the distinguishing feature over D1 (see first full paragraph on page 5 of the contested decision) has any "impact" on the composition, and then states that "*[n]o data is on file which include a direct comparison of micronised amoxicillin produced enzymatically with the one prepared chemically as in D1*". From these statements, it seems that the examining division assessed whether any effect was obtained over D1, which would appear to imply that D1 – and not only D2 – was taken as the starting point for assessing inventive step.

Hence it is not at all clear from the decision as a whole from which document(s) the examining division in fact started when examining inventive step.

1.3.3 Re (ii) Identification of distinguishing features

In order to identify the distinguishing features, the features of the claim to be examined need to be compared with those disclosed in the closest prior art. This comparison can either be performed in the context of an examination of novelty over the closest prior art, or in the context of inventive step as part of the problem-solution approach. In the reasons of the contested decision, neither section 2 on novelty nor section 3 on inventive step contains any such comparison. In relation to document D2, these sections do not even clearly identify which feature is to be regarded as distinguishing. The only statement specifically made in the section on novelty mentions that D2 "does not reveal micronised amoxicillin

trihydrate". In the second paragraph of the section on inventive step, the solubility of micronised versus non-micronised amoxicillin is addressed. All that might possibly be deduced from the contested decision is thus that an unspecified claim, presumably of the main request, requires amoxicillin trihydrate to be micronised, while the closest prior art document D2 does not disclose this feature. However, looking at the independent claims of all the claim requests underlying the present decision, no reference at all to any amoxicillin being micronised is found. Hence the reader of the contested decision is at a loss as to which feature has been regarded by the examining division as the distinguishing feature with regard to D2. The board acknowledges that it may be speculated whether the reference to the feature "micronized" might imply any difference in particle size and whether this in turn might be viewed as implying any difference in surface area, a feature that is present in e.g. claim 1 of the main request. But the requirement in Rule 111(2) EPC of a decision being reasoned is not met if the decision merely contains statements that at best give rise to speculation about what the deciding body might have intended to express.

1.3.4 Re (iii) Identification of any effect and definition of the objective technical problem

In the impugned decision, the examining division first only referred to the problem as formulated by the appellant, i.e. the subjective technical problem (first paragraph of the reasons on inventive step). It only assessed whether the preparation of micronised amoxicillin trihydrate was obvious. There is however at no stage of the contested decision any definition of what the examining division considers to represent the

objective technical problem, let alone any identification of a technical effect associated with the distinguishing feature that forms the basis of the objective technical problem.

At best, the examining division in its reasoning on page 6, first paragraph referred to "a technical effect associated with the presence of protein as the distinguishing feature". However, the presence of protein appeared to be the distinguishing feature in view of the disclosure of D1 (see section on novelty in the reasons) rather than D2. Thus any technical effect associated with this distinguishing feature would be irrelevant as regards the objective technical problem solved over D2 taken as the closest prior art. The board acknowledges in this respect that the examining division might have considered D1 to be a secondary document (see point 1.5.5 below) that when combined with the closest prior art D2 leads in an obvious way to the claimed subject-matter. However, the step of assessing any technical effect is to be applied by considering the distinguishing feature(s) in view of the closest prior art (i.e. D2) and not in view of a secondary document (i.e. D1).

1.3.5 Re (iv) Obviousness

The examining division stated that "*the preparation of micronised amoxicillin trihydrate is per se obvious, in particular in view of the technical guidance provided by D1*" (first paragraph, page 6 of the decision). Hence D1 seems to have been used by the examining division to argue that the claimed solution was obvious. However, the examining division did not identify at all the passages in D1 which disclose the distinguishing feature(s) (whatever it/they may be) and why it would

have been obvious to combine this disclosure of D1 with D2 as the closest prior art.

1.3.6 In view of the above points 1.3.2 to 1.3.5, the board concludes that what was presented on the issue of inventive step in the reasons of the contested decision does not follow the well-established problem-solution approach in a logical way. On the basis of the explanations provided, the reader - in particular the board or the appellant - is left completely in the dark as to why the examining division concluded that subject-matter claimed in the main request lacked inventive step.

1.3.7 In the penultimate paragraph of section 3 of the reasons, the appealed decision contains the following statement:

"The above considerations apply in a similar manner to both the first and second auxiliary request."

The first auxiliary request 1 contains three independent claims 1, 7 and 10. Compared with claim 1 of the main request, claim 1 of the first auxiliary request is restricted in that the amoxicillin trihydrate of the claimed composition is produced enzymatically using a biocatalyst, and in that the protein contained in the claimed composition stems from the biocatalyst. By way of back-reference to claims 1 to 6, these limitations are also present in the further independent claims 7 and 10.

The second auxiliary request contains three independent claims 1, 4 and 10. Independent method claim 1 differs from independent method claim 7 of the main request in that the prepared composition is capable of forming a

clear solution after 3 g/l of said amoxicillin trihydrate is stirred in drinking water for 2 minutes at a certain speed and temperature, and in that the surface area is linked to the particle size. Independent composition claim 4 of the second auxiliary request is an entirely new claim wherein the claimed composition is exclusively defined by the process by which it is prepared.

From the above, it is clear that the claims of the auxiliary requests differ considerably from those of the main request. The above very general statement made by the examining division as regards inventive step of the auxiliary requests leaves it entirely open why these differences introduced into the claims of the auxiliary requests do not contribute to inventive step.

1.3.8 The decision is thus not reasoned within the meaning of Rule 111(2) EPC. As inventive step was the sole reason on which the decision to refuse the application was based, this lack of reasoning amounts to a violation of Article 113(1) EPC.

1.4 During the written proceedings, in particular in the letter of 29 May 2019, the appellant submitted an analysis of a problem-solution approach starting from D2 as the closest prior art for the subject-matter of claim 1 of the main request (paragraph "Inventive step"). In this letter it identified the distinguishing features in view of D2 ("micronized amoxicillin having a defined surface area and particle size distribution within a specific range", first paragraph of page 5), the technical effect achieved by the distinguishing feature was assessed (pages 5 and 6) and the objective technical problem was formulated ("the provision of enzymatically synthesized amoxicillin which forms clear

solutions under standard conditions", second paragraph of page 6). It concluded that the skilled person would not have been guided to the claimed subject-matter by D2 or D1 as neither of these documents addressed the technical problem, and that there was therefore no reason to combine D1 and D2. Even if they were combined, it would not lead the skilled person to the subject-matter of claim 1 as neither of the documents disclosed particles as defined in claim 1 (second paragraph of page 6).

In order to comply with Article 113(1) EPC, the party's arguments have to be considered. Although the examining division is not required in its written decision to address each and every argument presented by the party, the important question is whether the party concerned can objectively understand whether, in light of its submissions, the decision was justified (see also R 19/10, reasons 6.2, R 17/11, reasons 4 and T 786/15, reasons 1.14).

The line of argument based on the appellant's problem-solution approach should have been addressed in the reasons underlying the decision as it was potentially crucial for the outcome of the case. Also for this reason, the appellant's right to be heard has been violated.

1.5 As set out above, the decision does not meet the requirements of Rule 111(2) EPC, and infringes the appellant's right to be heard pursuant to Article 113(1) EPC.

1.6 As the lack of reasoning and infringement of the appellant's right to be heard concern the reason on which the refusal of the application had been based,

here the issue of inventive step, a substantial procedural violation has occurred and the impugned decision has to be set aside.

2. Remittal

2.1 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. As a rule, fundamental deficiencies which are apparent in the proceedings before that department constitute such special reasons.

2.2 The deficiency set out above in points 1.3 to 1.6 amounting to a violation of the appellant's right to be heard (Article 113(1) EPC) constitutes a fundamental deficiency within the meaning of Article 11 RPBA 2020, justifying remittal to the examining division.

3. Reimbursement of the appeal fee

3.1 According to Rule 103(1)(a) EPC the appeal fee is to be reimbursed in full where the board deems an appeal allowable, if such reimbursement is equitable by reason of a substantial procedural violation.

3.2 The remittal of the case to the examining division implies that the appellant's appeal is allowable. Since furthermore the board has come to the conclusion that a substantial procedural violation has occurred, due to which the decision under appeal is to be set aside, reimbursement of the appeal fee in full is equitable in accordance with Rule 103(1)(a) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division.

3. The appeal fee is refunded.

The Registrar: The Chairman:

M. Schalow M. O. Müller

Decision electronically authenticated