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**Datasheet for the decision
of the Enlarged Board of Appeal
of 16 March 2011**

Case Number: R 0019/10
Appeal Number: T 0945/09 - 3.3.02
Application Number: 97950310.9
Publication Number: 0946221
IPC: A61K 31/495
Language of the proceedings: EN

Title of invention:

Use of taurolidine or taurultam for the prevention and the treatment of infections in delivery systems

Patentee:

Ed Geistlich Söhne AG Für Chemische Industrie

Opponent:

TauroPharm GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 112a(2)(c)(d), 113
EPC R. 102, 104(b), 106, 107, 108
RPBA Art. 15(5)

Keyword:

"Petition for review - clearly unallowable"

Decisions cited:

R 0002/08, R 0009/08, T 0158/96, T 0763/04, T 1557/07

Catchword:

"It is not a procedural duty of the Boards of Appeal under Rule 104(b) EPC to analyse the submissions of the parties in order to identify potential requests which were not explicitly made by the parties" (point 5.2).



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Case Number: R 0019/10

D E C I S I O N
of the Enlarged Board of Appeal
of 16 March 2011

Petitioner: Ed Geistlich Söhne AG Für Chemische Industrie
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Representative: Barry, Robert Stewart Wilson
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Other party: TauroPharm GmbH
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Representative: Andrae, Steffen
Andrae Flach Haug
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Decision under review: **Decision of the Technical Board of Appeal**
3.3.02 of the European Patent Office of 23 June
2010.

Composition of the Board:

Chairman: P. Messerli
Members: B. Schachenmann
P. Alting van Geusau

Summary of Facts and Submissions

- I. The petition for review concerns decision T 945/09 of the Board of Appeal 3.3.02 revoking European patent No. 0 946 221 of the petitioner. The petition is based on the grounds of Article 112a(2)(c) and (d) in combination with Rule 104(b) EPC. The petitioner submitted that the Board of Appeal had failed to address or to decide on a relevant request of the patentee when revoking the patent.
- II. The patent refers to the use of taurolidine or taurultam in the manufacture of a catheter "lock" solution acting as an antimicrobial seal to prevent or reduce infection or sepsis caused by the catheter. An opposition to this patent was filed *inter alia* on the ground of Article 100(a) EPC - lack of novelty - due to an alleged public prior use as documented in a post-published document (3). The opponent submitted that document (3) was a case report of a Canadian medical team describing the treatment of a patient which took place before the priority date of the patent and corresponded to the claimed subject-matter.
- III. The opposition division rejected the opposition. With regard to the alleged public prior use it came to the conclusion that, during the medical treatment in question, the Canadian medical team was under an implicit obligation of confidentiality so that the prior use was not public. In addition, according to point 3.11 of the decision of the opposition division, it was only when the Canadian medical team decided that enough data was available to draw positive conclusions on the efficacy of the taurolidine lock, that the

notion of "therapeutic method" came into existence and could possibly be rendered available to the public. This point in time, however, could not be established with certainty.

- IV. The proceedings before the Board of Appeal 3.3.02, as far as relevant for the petition, can be summarized as follows:

The opponent filed an appeal against the decision of the opposition division contesting that any implicit obligation of confidentiality existed between the medical team, the patient and the later patentee. Such an obligation was excluded by the fact that the prior use, i.e. the treatment of the patient, had already started before the collaboration between the Canadian medical team and the later patentee. The objection of lack of novelty due to the alleged public prior use was therefore maintained.

The patentee, in its observations of 21 December 2009 on the grounds of appeal, endorsed the view of the opposition division referred to above (see above point III). With respect to the issue of point 3.11 of the decision of the opposition division the patentee emphasized that, whatever may have been disclosed by the authors of document (3) prior to the priority date of the patent, it could not have been enabling, but merely speculative because it would only have been based on insufficient data. According to the jurisprudence of the Boards of Appeal, a novelty attack against a medical use claim must be based on the disclosure of credible data, supporting the efficacy of

the cited medical use. Such a disclosure was lacking in the present case.

The appellant/opponent, in a further submission dated 22 May 2010, replied to the "insufficient data"-argument that the nature and effect of the measures taken by the Canadian medical team, as later claimed in the patent, were immediately clear to the skilled person. If there was any uncertainty, it could only have concerned the degree of success to be expected from the method, but not the essence of the method as such.

Oral proceedings before the Board of Appeal 3.3.02 were held on 23 June 2010. According to the minutes of these proceedings the appellant/opponent requested that the European patent be revoked and the respondent/patentee requested that the appeal be dismissed. At the end of the oral proceedings the Board of Appeal revoked the patent. The written decision of the Board of Appeal mainly concerns the alleged public prior use.

V. The patentee/respondent filed a petition for review on 29 November 2010. An additional written submission followed on 16 February 2011. Oral proceedings were held on 16 March 2011.

VI. In his written submissions and at the oral proceedings before the Enlarged Board of Appeal the petitioner argued essentially as follows:

(a) The petitioner/patentee had requested in the appeal proceedings that the Board of Appeal "uphold the novelty of the patent in suit, on the

basis, inter alia, that whatever was disclosed prior to the priority date of the patent in suit by the authors of E3, was not enabling but merely speculative and did not support the efficacy of the claimed medical use". This request was set out at pages 10 to 13 of the patentee's observations on the grounds of appeal and was based on the argument that if a skilled person were in possession of all of the data in document (3) prior to the priority date of the patent, he would not have had sufficient data to conclude that taurolidine could be used as an effective catheter-lock solution. The most that could potentially have been ascertained from the study reported in document (3) was that an investigation was being carried out on a single patient to find out whether taurolidine could be used as a catheter-lock solution for the effective and safe treatment for recurrent catheter-related blood stream infections. Thus, even if the patentee's arguments concerning the date of the prior use and its confidential nature were not found to be convincing, the argument of an non-enabling disclosure still remained valid and had to be decided on.

- (b) However, in its decision, the Board of Appeal completely failed to address or to decide on this issue. The Board of Appeal thereby breached Article 112a(2)(d) EPC, because it had decided on the appeal without deciding on a request relevant to that decision, contrary to Rule 104(b) EPC. This was also a breach of Article 112a(2)(c) EPC,

as it constituted a fundamental violation of the patentee's right to be heard under Article 113 EPC.

- (c) Even if the term "request" was not defined in the EPC and was used in different ways, it had to be concluded from Rule 102 in combination with Rule 104(b) EPC, that requests within the meaning of these provisions included evidence and arguments relevant to the decision. The purpose of Rule 104(b) EPC was to safeguard the right of a losing party to have its case decided on all relevant issues. If the term "request" were interpreted narrowly, this provision would become practically meaningless. Consequently, the request under Rule 104(b) EPC could not simply be identified with the final request stated by the Chairman according to Article 15(5) RPBA before closing the debate and reported in the minutes of the oral proceedings as this was only a shortened form of a party's request.
- (d) Concerning the right to be heard under Article 113(1) EPC, the petitioner submitted that point VII(c) of the summary of the patentee's arguments in the decision under review was confusing because it disregarded one of the two separate arguments which were presented. The first, scientific argument was that it was not possible to know whether the use of taurolidine as a catheter-lock was effective because of the possible use of concurrent therapy with systemic antibiotics and taurolidine. The second argument was that even if no concurrent therapy was being administered, the results reported in document (3)

did not establish an enabling prior use because, as a matter of law, according to the jurisprudence (see e.g. T 158/96, catchword), convincing data with regard to the actual existence of a therapeutic effect was needed for this purpose. In support of the second argument the patentee had filed a report from Mr Peter Wilkinson, a experienced pharmaceutical statistician, according to which document (3) did not provide any clinical evidence of efficacy. This report was neither mentioned in the summary of facts and arguments of the decision nor was it considered in the reasons.

- (e) In accordance with established jurisprudence of the Boards of Appeal, the right to be heard guaranteed the right to have the relevant grounds fully taken into account in the written decision (see e.g. T 763/04, point 4.3). However, the decision under review only dealt with the first argument but not with the second. Moreover, the statement in point 4.3 of the decision that *"document (3) even reports the authors as being convinced of the success of their use of antimicrobial taurolidine-lock with respect to infection being catheter related"* indicated a fundamental misconception on the part of the Board of Appeal: that document (3) accurately reflected the opinion of the authors at the priority date. By understanding document (3) in this manner the Board of Appeal took into account matter which was irrelevant as there was no evidence of what the authors of this paper thought at the priority date, before document (3) was written. This error meant

that the Board of Appeal did not properly consider the patentee's argument on novelty at all.

- VII. The petitioner requests that the decision T 945/09 be set aside and the proceedings before the Board of Appeal be re-opened. It is further requested that the members of the Board of Appeal who participated in taking this decision be replaced pursuant to Rule 108(3) EPC and that the fee for the petition be reimbursed in accordance with Rule 110 EPC.

Reasons for the Decision

Admissibility of the petition for review

1. The petitioner is adversely affected by the decision T 945/09 to revoke its patent. The petition for review was filed on the grounds of Article 112a(2)(c) and (d) in combination with Rule 104(b) EPC. It contains an indication of the decision to be reviewed and reasons for setting aside this decision. The petition therefore complies with the provisions of Article 112a(1) and (2) EPC and of Rule 107(1)(b) and (2) EPC.
2. The written decision T 945/09 was notified to the parties by registered letter posted on 21 September 2010. The two month period for filing a petition for review expired on 1 December 2010. The present petition for review was filed and the fee was paid on 29 November 2010. The petition therefore also complies with Article 112a(4) EPC.

3. Pursuant to Rule 106 EPC a petition under Article 112a(2)(a) to (d) EPC is only admissible where an objection in respect of the procedural defect was raised during the appeal proceedings and dismissed by the Board of Appeal, except where such objection could not be raised during the appeal proceedings. In the present case the petition is based on the submission that the Board of Appeal had not decided on a relevant request of the petitioner, in contravention of Rule 104(b) EPC, and had not properly considered the petitioner's argument on novelty, in contravention of Article 113 EPC. In particular the petitioner's objection under Rule 104(b) EPC could not logically have been raised before the Board of Appeal gave its decision. Therefore, the exception of Rule 106 EPC applies here.
4. Accordingly, the Enlarged Board of Appeal is satisfied that the petition is not clearly inadmissible.

Allowability of the petition for review

5. With regard to the objection under Article 112a(2)(d) in combination with Rule 104(b) EPC, the petitioner refers to its request to *"uphold the novelty of the patent in suit, on the basis, inter alia, that whatever was disclosed prior to the priority date of the patent in suit by the authors of E3, was not enabling but merely speculative and did not support the efficacy of the claimed medical use (see point VIII(a) above). On the other hand, according to the minutes of the oral proceedings, the petitioner had requested "that the appeal be dismissed" before the chairman of the Board of Appeal declared the debate closed (see point IV*

above). The question therefore arises which was the petitioner's request relevant to the decision within the meaning of Rule 104(b) EPC.

- 5.1 It is true that, as submitted by the petitioner, the EPC does not contain an explicit definition of the term "request". However, according to the common practice in the proceedings before the EPO, requests are in general directed to executable legal consequences sought by the parties. The arguments provided by the parties in support of these legal consequences do not normally belong to the legally binding requests as can be concluded from Article 114(1) EPC.
- 5.2 In the circumstances of the present case it is, however, not necessary to further consider this issue. As follows from the file the relevant request confirmed by the respondent/petitioner under Article 15(5) RPBA was that "*the appeal be dismissed*". In view of this fact and the common practice referred to above, the Board of Appeal had no reason to assume that the respondent/petitioner requested anything else. This is all the more so as the alleged request which included supporting arguments of the respondent/petitioner was never explicitly formulated during the appeal proceedings. As a basis for it, the petitioner refers to its observations in the letter of 21 December 2009 under the heading "Insufficient Data for Establishing Disclosure" on pages 10 to 13. However, this passage contains an argumentation without any recognizable request. It is not a procedural duty of the Boards of Appeal under Rule 104(b) EPC to analyse the submissions of the parties in order to identify potential requests which were not explicitly made by the parties.

5.3 For these reasons, the petitioner's objections based on Article 112a(2)(d) in combination with Rule 104(b) EPC (see point VIII(a) to (c) above) are clearly not justified.

6. As to the objection pursuant to Article 112a(2)(c) EPC it is to be contemplated whether the Board of Appeal fundamentally violated the right to be heard of the respondent/petitioner with regard to its argument that the results reported in document (3) did not establish an enabling prior use (see point VIII(d) and (e) above).

6.1 In point VII of the written decision, the Board of Appeal summarized the arguments of the respondent/petitioner. In particular, the argument of a non-enabling and therefore legally irrelevant prior use was summarized as follows:

"Not everything the authors of document (3) could have done and known before the priority date of the patent in suit had been established as a successful method. They only were beginning to try anything to help a patient in need of some therapy while suffering repeated catheter-related bloodstream infections with no explanation of their origin. Whether this action or any other accompanying administration of antibiotic or antiseptic substances led to success in treating this single - and therefore statistically irrelevant - patient was not known and at that time could not possibly be seen. Consequently, even if the information to be derived from document (3) was clearly disclosed, it was far from an established teaching capable of constituting prior use".

From this summary it follows that the Board of Appeal had, in fact, duly taken note of the argument of the respondent/petitioner that the patent could not be found to be invalid for lack of novelty, even if a non-confidential prior public disclosure of the teaching of document (3) was assumed, since this teaching was not based on sufficient data with regard to the existence of a therapeutic effect.

6.2 The petitioner further submits that Article 113(1) EPC not only enshrines a party's right to be heard before a decision is issued against it, but also guarantees its right to have the relevant grounds fully taken into account in the written decision (see point VIII(e) above). The Enlarged Board of Appeal in principle agrees. However, this principle is not without any limitation as explained in decision T 1557/07 referred to by the petitioner itself: provided that the reasons given enable the parties concerned to understand whether the decision was justified or not, the deciding organ is under no obligation to address each and every argument presented by the party concerned.

6.3 In the circumstances of the present case the Enlarged Board of Appeal is satisfied that the reasons given in the decision under review enabled the parties to understand, on an objective basis, the grounds for the decision of the Board of Appeal.

As stated in point 3.4 of the reasons, the Board of Appeal based "its conclusions on the knowledge of the patient being clear and concise enough that he could take notice of the technique used after replacement of

heparin-lock by taurolidine-lock, representing the teaching of claim 1. There was also no reason for him to treat this knowledge as a secret, because at that time the acting doctors simply tried to apply taurolidine of whatever provenance using a technique they derived freely and easily from the state of the art common to them at that time". Accordingly, the Board of Appeal concluded in point 3.5 of the reasons "that this teaching was performed beginning from July 1995 in the full knowledge of the patient without any obligation of confidentiality and thus was publicly available before the priority date of the patent in suit".

The decision of the Board of Appeal is therefore clearly based on the finding that what constituted the public prior use was the knowledge of the treated patient himself, as a member of the public. This argument had been introduced into the appeal proceedings by the appellant already with the statement of the grounds of appeal (see page 8, 2nd paragraph) and was therefore known to the respondent/petitioner.

Against this background it is apparent that it did not matter for the reasoning of the Board of Appeal whether or not the results reported in document (3) provided any clinical evidence of efficacy, as this had no bearing on the public prior use constituted by the direct knowledge of the applied technique by the treated patient, as a member of the public.

This was indicated by the Board of Appeal in point 4.4 of the reasons according to which "the action in the Canadian hospital of using the taurolidine-lock was not

typical of a clinical or even an experimental approach because it was dictated by the instant necessity to help a patient in a very desperate situation and thus had not been planned systematically as a scientific experiment".

- 6.4 In summary, the written decision makes it sufficiently clear that, in the opinion of the Board of Appeal, the public prior use was constituted by the knowledge of the treated patient himself, as a member of the public, so that the issue of whether the teaching of document (3) provided any clinical evidence of efficacy or satisfied the standards of a clinical study was not relevant for deciding on the novelty of the subject-matter of claim 1. Whether or not this finding is correct in substance cannot be the subject of the review proceedings (see R 2/08, point 5 of the reasons; R 9/08, point 6.3 of the reasons). In any case, the Enlarged Board of Appeal is satisfied that the alleged fundamental violation of Article 113 EPC did not occur in the proceedings under review.

Order

For these reasons it is unanimously decided that:

The petition for review is rejected as clearly unallowable.

The Registrar:

The Chairman:

P. Martorana

P. Messerli