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Datasheet for the decision of the Enlarged Board of Appeal of 22 October 2009

Case Number: R 0013/09

Appeal Number: T 0015/07 - 3.3.02

Application Number: 99956504.7

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IPC: A61K 31/435

Language of the proceedings: EN

Title of invention:
Antibiotic compositions for treatment of the eye

Patentee:
Alcon, Inc.

Opponent:
Teva Pharmaceutical Industries Ltd.

Headword:
Fundamental violation of Article 113 EPC/ALCON

Relevant legal provisions:
EPC Art. 112a, 113
EPC R. 106

Keyword:
"Petition for review - not clearly inadmissible - clearly unallowable"

Decisions cited:
R 0001/08

Catchword:
-

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Große Beschwerdekammer | Enlarged Board of Appeal | Grande Chambre de recours

Case Number: R 0013/09

D E C I S I O N
of the Enlarged Board of Appeal
of 22 October 2009

Petitioner: (Patent Proprietor)	Alcon, Inc. Bösch 69 P.O. Box 62 CH-6331 Hünenberg (CH)
Representative:	Best, Michael Lederer & Keller Patentanwälte Prinzregentenstrasse 16 D-50538 München (DE)
Other Party: (Opponent)	Teva Pharmaceutical Industries Ltd. 5 Basel Street P.O. Box 3190 Petah Tiqva 49131 (IL)
Representative:	Prins, Hendrik Willem Arnold & Siedsma Sweelinckplein 1 NL-2517 GK The Hague (NL)
Decision under review:	**Decision of the Technical Board of Appeal 3.3.02 of the European Patent Office of 30 April 2009.**

Composition of the Board:

Chairman: P. Messerli
Members: B. Schachenmann
M. Noël

Summary of Facts and Submissions

I. The petition for review concerns decision T 15/07 of the Board of Appeal 3.3.02 revoking European patent No. 1 117 401 with the title "Antibiotic compositions for treatment of the eye". The proceedings in this case can be summarized as follows:

II. Notice of opposition was filed against the grant of European patent No. 1 117 401 on the grounds that its content extended beyond the original application (Article 100(c) EPC) and that its subject-matter lacked inventive step (Article 100(a) EPC). The opposition division decided to reject the opposition. The appellant/opponent pursued its objections in appeal proceedings and requested revocation of the patent. After the written phase of the appeal proceedings the parties were summoned to oral proceedings at the end of which the Board announced the decision to revoke the patent. The decision was issued in writing on 5 June 2009. The reason for revocation was that the ground for opposition under Article 100(a) EPC - lack of inventive step of the subject-matter of independent claims 1 and 12 - prejudiced the maintenance of the patent.

III. On 14 August 2009 the proprietor/respondent (in the following referred to as the petitioner) filed a petition for review of this decision pursuant to Article 112a EPC and paid the prescribed fee. The petition is based on the ground referred to in Article 112a(2)(c) EPC. A fundamental violation of Article 113 EPC allegedly occurred when the Board of

Appeal 3.3.02 based its written decision on grounds on which the petitioner did not have the opportunity to comment. The petitioner therefore requests that the decision T 15/07 be set aside, that the proceedings before the Board of Appeal 3.3.02 be re-opened and that the fee for the petition for review be reimbursed.

IV. The contested decision, in a first part, deals with the opponent's objections under Article 100(c) EPC which were considered to be unfounded (see points 3.1 to 3.3 of the reasons). Then, starting with point 3.4, inventive step of the subject-matter of independent claims 1 and 12 is dealt with. This section is divided into a first subsection 3.4.1 containing an assessment of inventive step based on the problem-solution approach, followed by a subsection 3.4.2 entitled "Additional arguments of the respondent". It is only this latter part of the decision which is objected to by the petitioner under Article 113 EPC substantially for the following reasons:

(a) The invention (claim 1) refers to "A topical ophthalmic pharmaceutical composition comprising **moxifloxacin** [...] in a concentration of 0.1 wt.% to 1.0 wt% and a pharmaceutical acceptable vehicle therefor" (emphasis added). Prior art antibiotic ophthalmic compositions comprised **ciprofloxacin** as the active agent. A decisive question in connection with inventive step is whether a skilled person would have provided antibiotic ophthalmic compositions with **moxifloxacin** as the active agent despite the fact that this drug, when

compared to **ciprofloxacin**, was known to have little activity against the bacterium *Pseudomonas aeruginosa*, which is a key ophthalmic pathogen.

(b) In the course of the discussion of this question in the oral proceedings the petitioner *inter alia* submitted, as summarised under point 3.4.2 of the decision: *"Moxifloxacin was less potent than Ciprofloxacin against Pseudomonas aeruginosa, which was the most dangerous pathogen in eye infections where it played a role in about 20% of all cases. As ophthalmologists did not in general identify the pathogens but treated them empirically, a topical ophthalmological composition had to be effective against all the relevant ocular pathogens and certainly against Pseudomonas aeruginosa*". Consequently, the skilled person would not have considered to substitute **moxifloxacin** for **ciprofloxacin** as the active agent in antibiotic ophthalmic compositions.

(c) In the written decision the Board considered this submission under point 3.4.2 as follows: *"This argumentation is not in line with the problem as defined in the original application (see page 2, lines 3-6), which states that there is 'a need for improved compositions and methods for treatment ... that are more effective than existing antibiotics* ***against key ophthalmic pathogens*** *...' [emphasis by the board]. This passage does not specify that the improved compositions and methods of treatment need to be more effective against the key ophthalmic pathogens, let alone against all the relevant key ophthalmic pathogens. The*

ophthalmologist does in general treat empirically, but there are situations where he may want to specifically treat infections caused by MSSA or MRSA [= other ophthalmic pathogens] *rather than by Pseudomonas aeruginosa, and in these cases, which are encompassed by the subject matter of claim 1 and are included in the technical problem as defined in the original application, the enhanced efficacy of compositions comprising moxifloxacin was obvious in the light of the above reasoning. As a consequence, this argument cannot succeed.*"

(d) However, during the proceedings it was never discussed whether indeed an ophthalmologist would want to specifically treat infections caused by *MSSA* or *MRSA* rather than by *Pseudomonas aeruginosa*. It came to the petitioner as a surprise to read said ground in the written decision.

(e) Thus, under point 3.4.2 of the written decision one of petitioner's main arguments regarding inventive step of the subject-matter of the contested patent was rebutted using a ground which the petitioner could not comment on. It is likely that the decision would have been different if the Board had given the petitioner the chance to present his comments in this respect. Therefore, there is a causal link between the defect and the final decision of the Board.

(f) This fundamental violation of Article 113 EPC could not have been objected to before receiving the written decision of the Board 3.3.02. Thus,

the present review is admissible under Rule 106 EPC, second sentence.

Reasons for the Decision

1. *Admissibility of the petition for review*

1.1 The petitioner is adversely affected by the decision T 15/07 revoking its patent. The petition for review was filed on the ground referred to in Article 112a(2)(c) EPC. The petition therefore complies with the provisions of Article 112a(1) and (2) EPC.

1.2 The written decision was notified to the parties by registered letter posted on 5 June 2009. The two month period for filing the petition for review expired on 15 August 2009. As the petition was filed and the fee was paid on 14 August 2009, it also complies with Article 112a(4) EPC.

1.3 Finally, the exception mentioned in Rule 106 EPC applies in the present case as the objection concerns the written decision and could not be raised during the appeal proceedings.

1.4 The petition for review is therefore at least not clearly inadmissible.

2. *Allowability of the petition for review*

2.1 The petition for review is based on an alleged fundamental violation of Article 113 EPC. In its decision R 1/08, point 3 of the reasons, the Enlarged

Board of Appeal found that a petitioner, to succeed with this objection, had to establish (a) that the contested decision was based on an assessment or on reasoning relating to grounds or evidence which the petitioner was not aware of and had no opportunity to comment upon and (b) that a causal link existed between this procedural defect and the final decision, otherwise the alleged defect could not be considered decisive and hence not fundamental.

2.2 The petition for review is clearly not a means to review the application of substantive law. A review of the application of substantive law would mean adding a third instance to the procedure before the EPO (see CA/PL 17/00 of 27 March 2000, point 11). The petitioner's submissions are therefore to be considered strictly and exclusively under the aspect of the right to be heard. For this purpose, in the present case, it is nonetheless necessary to consider the discussion of inventive step during the proceedings in some detail.

2.3 As follows from points X and XI of the decision under review the main dispute between the parties concerned the assessment of inventive step using the problem-solution approach based on the prior art documents (3) and (18). It was common ground that document (3), proposing **ciprofloxacin** as active agent for antibacterial ophthalmic compositions, represented the closest prior art. The additional document (18) is a scientific paper comparing the *in vitro* activity of **ciprofloxacin** and **moxifloxacin** (designated as "BAY 12-8039") against a number of bacteria strains including *Pseudomonas aeruginosa*, *MSSA*(= *Methicillin sensitive staphylococcus aureus*), *MRSA*(= *Methicillin resistant*

staphylococcus aureus) and others. It was also common ground between the parties that, according to document (18), **ciprofloxacin** was much more active *in vitro* against *Pseudomonas aeruginosa*, which was an important ophthalmic pathogen, whereas **moxifloxacin** was more active against other bacteria such as e.g. *MSSA* and *MRSA* which, according to the patent (see table in paragraph [0010]), were also important ophthalmic pathogens.

2.4 In point 3.4.1 of the decision under review, the Board assessed the inventive step of the claimed subject-matter using the problem-solution approach based on the facts referred to above. In particular, it identified the technical problem with regard to document (3) as follows: "provision of a topical composition for treating or preventing ophthalmic infections which is more effective against key ophthalmic pathogens". It then came to the conclusion that for solving this problem the skilled person would select **moxifloxacin** to replace **ciprofloxacin** as the active agent since from document (18) it appeared to be more potent than **ciprofloxacin** against some of the key ophthalmic pathogens, as had been argued by the opponent/appellant.

2.5 As the petitioner has not objected to the statements and findings in point 3.4.1, the Enlarged Board of Appeal is satisfied that this part of the decision, in particular the definition of the problem to be solved, is based on grounds and evidence both parties were aware of and had opportunity to comment upon before the decision was taken. Thus, for this part of the decision, requirement (a) for a successful petition for review referred to in point 2.1, *supra*, is clearly not met.

2.6 Turning now to point 3.4.2 entitled "Additional arguments of the respondent", the question arises whether the findings objected to by the petitioner in this part of the decision fundamentally violated Article 113 EPC and, if so, had any influence on the Board's assessment of inventive step in point 3.4.1 (requirement (b) of point 2.1, *supra*).

2.6.1 Point 3.4.2 of the decision concerns the petitioner's additional argument that an ophthalmologist "did not in general identify the pathogens but treated them empirically" and that, therefore, "a topical ophthalmological composition had to be effective against all the relevant ocular pathogens and certainly against Pseudomonas aeruginosa". Consequently, the skilled person would not have considered to substitute **moxifloxacin** for **ciprofloxacin** as the active agent in antibiotic ophthalmic compositions (see point IV(b), *supra*).

2.6.2 The reason for which the Board rejected this argument was that "it is not in line with the problem as defined in the original application" since the formulation of the problem leaves it open against which "key ophthalmic pathogens" the improved composition should be more effective than existing antibiotics.

2.6.3 As stated at point 3.1 of decision R 1/08 of the Enlarged Board of Appeal, the EPC does not require that a Board of Appeal must provide a party with all foreseeable arguments in favour of or against a request in advance.

2.6.4 Even if the parties had not been informed in advance of the Board's view referred to above, it was nonetheless foreseeable that the additional argument of the petitioner could be used to support the presence of an inventive step only if it served to rebut some aspect of the specific chain of reasoning based on the problem-solution approach discussed at the oral proceedings. The petitioner could therefore not be surprised by the fact that the Board examined whether the additional argument was really relevant to the reasoning already presented. Nor could the petitioner be surprised by the conclusion of the Board that the additional argument was not in line with the stated problem and, as a consequence, could not succeed. As follows from uncontested point 3.4.1 of the decision under review and the patent itself the problem refers neither to improved efficacy against "all the relevant" ophthalmic pathogens nor to improved efficacy against specific ones, such as, in particular, *Pseudomonas aeruginosa:* the stated problem clearly remains unspecific in this respect. Thus, the conclusion reached by the Board in the objected part of the decision under review was based on a fact - the formulation of the problem - which the parties must have been aware of.

2.6.5 In this context the statement of the Board in point 3.4.2 that "there are situations where he [i.e. the ophthalmologist] may want to specifically treat infections caused by MSSA or MRSA rather than by Pseudomonas aeruginosa" did not add a new assessment or reasoning but illustrated the fact referred to above that the formulation of the relevant problem leaves open against which of the numerous possible key

ophthalmic pathogens the improved composition should be more effective, whether it be against *MSSA* and/or *MRSA* and/or *Pseudomonas aeruginosa* and/or any other bacteria.

2.6.6 Thus, the Enlarged Board of Appeal is satisfied that also the findings in point 3.4.2 of the decision clearly do not constitute a fundamental violation of Article 113 EPC. It is therefore not necessary to further examine whether, according to requirement (b) referred to in point 2.1, *supra*, a causal link existed between these findings and the final decision based on the findings in point 3.4.1 of the decision under review.

Order

For these reasons it is unanimously decided that:

The petition for review is rejected as clearly unallowable.

The Registrar: The Chairman:

W. Roepstorff P. Messerli