Internal distribution code:

(A) [-] Publication in OJ
(B) [X] To Chairmen and Members
(C) [-] To Chairmen
(D) [-] No distribution

Datasheet for the decision of 11 February 2019

Case Number: R 0009/18

Appeal Number: T 0239/16 - 3.3.01

Application Number: 05012711.7

Publication Number: 1591122

IPC: A61K31/663, A61P19/08, A61P19/10

Language of the proceedings: EN

Title of invention:
Method of administering bisphosphonates

Patent Proprietors:
Novartis AG
Novartis Pharma GmbH

Opponents:
Generics [UK] Limited
Sanovel Ilaç San. ve Tic. A.S.
Taylor Wessing LLP

Headword:
Petition for review

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Relevant legal provisions:
EPC Art. 112a(2)(c), 113(1)
EPC R. 106

Keyword:
Petition for review (clearly not allowable)
Violation of Article 112a(2)(c) EPC (no)

Decisions cited:

Catchword:

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Europäisches Patentamt
European Patent Office
Office européen des brevets

Große Beschwerdekammer

Enlarged Board of Appeal

Grande Chambre de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: R 0009/18

D E C I S I O N
of the Enlarged Board of Appeal
of 11 February 2019

Petitioners: (Patent Proprietors)	Novartis AG Lichtstrasse 35 4056 Basel (CH) Novartis Pharma GmbH Brunner Strasse 59 1230 Wien (AT)
Representative:	Warner, James Alexander Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Other party: (Opponent 1)	Generics [UK] Limited (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1AG (GB)
Representative:	Gillard, Richard Edward Elkington and Fife LLP Thavies Inn House 3-4 Holborn Circus London EC1N 2HA (GB)
Other party: (Opponent 3)	Sanovel IIaç San. ve Tic. A.S. Balabandere Cad. Ilaç Sanayi Yolu No: 14 Istinye-Sariyer 34460 Istanbul (TR)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)

Other party:
(Opponent 5)

Taylor Wessing LLP
5 New Street Square
London EC4A 3TW (GB)

Decision under review: **Decision of the Technical Board of Appeal 3.3.01 of the European Patent Office of 13 September 2017.**

Composition of the Board:

Chairman C. Josefsson
Members: W. Sekretaruk
G. Ashley

Summary of Facts and Submissions

I. The patent proprietor's petition for review of 21 June 2018 is directed against the decision of Board of Appeal 3.3.01 in case T 239/16 revoking European patent EP 1591122. The board's written decision was posted to the proprietor's representative on 12 April 2018. The petition for review is based on Article 112a(2)(c) EPC. The petitioner asserts that in the appeal proceedings two fundamental violations of its right to be heard had occurred. In two respects the board of appeal's reasoning was based on arguments on which the patent proprietors had not been given the opportunity to comment.

First violation: the selection of the prior art.

II. The petitioner's argument is that various parties considered the whole document 55, namely the prospective phase II clinical study consisting of a placebo arm and five zoledronic acid arms as the closest prior art for assessing the presence of an inventive step. However in its decision the Board held that the once-yearly arm in the phase II trial outlined in document 55 was the closest prior art. Neither the parties nor the Board had ever argued that any single arm should be the closest prior art. The patent proprietors were therefore taken by surprise by the Board's finding that the claimed subject-matter lacked an inventive step starting from the once-yearly arm as the closest prior art.

Second violation: the alleged impact of ethical considerations associated with phase II clinical trials on expectation of success.

III. At the heart of the Board's finding against the patent proprietors on the presence of an inventive step was its assumption that ethical considerations associated with clinical

trials imparted an expectation of success for all arms of a clinical trial. This had not been pleaded by any of the parties, nor had it been raised by the Board itself either in its communication or during oral proceedings. The absence of the opportunity to comment on this assumption violated the Petitioners' right to be heard.

IV. In a communication accompanying the summons to oral proceedings, the Enlarged Board informed the petitioner of its provisional view that the petition was clearly not allowable. With its letter of 11 January 2019 the petitioner took issue with that opinion. It stressed that it was evident from the decision of the Board of Appeal that the expectation of success of the once yearly arm treatment was only judged as being relevant for the last step of the problem-solution argument and in the determination of novelty. It further explained that the ethical considerations featured in the proceedings in two ways, firstly that ethical approval was required in order to conduct a human clinical trial and secondly that phase III clinical trials would need approval from an ethics committee. The Board's argument in the decision referred to ethical considerations in the phase II trials, which was different.

V. At oral proceedings held on 11 February 2019 the petitioner added that the violations of the Petitioners' right to be heard were of fundamental nature, because they were causal for the Board of Appeals' failure to come to a correct conclusion on the presence of an inventive step. In choosing an a different piece of prior art as the starting point for assessing inventive step, the Board had changed the whole factual framework. There was a change in the technical differences, which resulted in the formulation of a different technical problem. As a result the Board was locked into an artificial assessment of the presence of an inventive step. If there had been a corresponding argument in the proceedings, the Petitioner would have been in a position to address it. In fact

the result of a single arm of a trial is meaningless, as it reflects only one part, which has to be assessed in the context of the whole trial. This could have been clarified if the Board had pointed to its intent to consider the once-yearly arm of the trial as being the closest prior art. The Board was wrong in its view that for ethical reasons any of the arms in a phase-II-trial has to have an expectation of success. This may be different in phase III trials, given that in phase III a placebo arm is included. The Petitioners would only have been in a position to clarify this if they had known about this argument. They stressed that they did not have an opportunity to present their argument on the differences between phase II and phase III trials. The last paragraph of point X. of the Board of Appeal's decision could be interpreted in a misleading way, as opponent 3 only discussed the consequences of ethical considerations in phase III trials.

VI. The petitioner requests
1. That the decision of the Technical Board of Appeal in T0239/16 be set aside and that the proceedings before the Technical Board of Appeal be reopened.
2. Reimbursement of the petition fee.

Reasons for the Decision

1. The petition meets the requirements with respect to the time limit and payment of the petition fee.

2. The petition complies with Rule 106 EPC. An objection in respect of the alleged procedural defects had not been possible before the Board, as the alleged deficiencies only became apparent with the reasons of the decision.

First alleged violation (see point II above)

3. With this part of the petition the petitioner complains that taken by surprise by the Board's finding that the claimed subject-matter lacked an inventive step starting from the once-yearly arm as the closest prior art.

The law and general principles

3.1 Article 113(1) EPC reads:

The decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments.

This implies that a party may not be taken by surprise by the reasons of the decision, referring to unknown grounds or evidence. On the other hand, the right to be heard does not go so far as to impose a legal obligation on a board to disclose in advance to the parties, how and why, on the basis of the decisive issues under discussion – or at least those foreseeable as the core of the discussion – it will come to its conclusion.

3.2 The facts and arguments in the decision

The Enlarged Board of Appeal refers to point IX. Inventive step of the impugned decision part "Summary of Facts and Arguments" (pages 8 and 9) referring to the appellant-proprietor's arguments:

The study arm of document 55 relating to a once-yearly dosage regimen would not have been considered by the skilled person for the following reasons… In addition to the line taken in these cited decisions it was also important to consider the set-up of the study disclosed in document (55). Out of the five study arms three involved three-monthly dosing. The skilled person would thus consider that the three-monthly dosing interval was the most likely to succeed. There was no indication in document (55) that would lead the skilled person to the expectation that effective treatment would be provided in the once-yearly study arm. The once-yearly arm might have been a further control to check when the biomarkers would start to drop.

The appellant-proprietors stressed that the skilled person was not led to an expectation of success of the once-yearly study arm by the disclosure of the other documents on file.

The Enlarged Board of Appeal further refers to point X. Novelty of the impugned decision part "Summary of Facts and Arguments" (page 13) referring to the arguments of appellant-opponents 1,3 and 5:

Based on the general knowledge, the skilled person knew that osteoporosis would be treated to some extent in each of the study arms.

Seen objectively, the petitioner could not have been taken by surprise when the Board of Appeal in its decision assessed inventive step with respect to the once-yearly arm in the Phase II trial of document 55, as the trial including the various arms had indeed been discussed and the disputed claim was itself directed to a once-yearly administration.

In summary, the ground (inventive step) and the facts (the disclosure of document 55) had been discussed. That the Board assessed the facts differently to the petitioner does not mean that there was a loss of the right to be heard, as the petitioner had had opportunity to put forward his argument as to why the claimed subject-matter was inventive over the disclosure of document 55.

4. Second alleged violation(see point II above)

In its assessment on the presence of an inventive step the Board assumed that ethical considerations associated with clinical trials imparted an expectation of success for all arms of a clinical trial. The Petitioner submitted that the absence of the opportunity to comment on this assumption was contrary to its right to be heard.

In this respect the Enlarged Board of Appeal refers to point X. Inventive step of the impugned decision part "Summary of Facts and Arguments" (page 14), referring to the arguments of appellant-opponents 1,3 and 5:

Each treatment arm of the clinical study was technically credible. It was credible that in each arm some treatment of osteoporosis would be provided. The very inclusion of a study arm in a study led to a reasonable expectation (not certainty) of success, because clinical studies were only carried out on technically sound premises due to their being costly and time-consuming, involving patients and the associated ethical considerations.

The Enlarged Board of Appeal comes to the conclusion that the Board of Appeal relied on information that was on file and that the petitioner could have commented on the assumption that ethical considerations associated with clinical trials imparted an expectation of success for all arms of a clinical trial.
In the light of the foregoing, the Enlarged Board of Appeal cannot see a fundamental violation of the petitioner's right to be heard.

Order

For these reasons it is decided that:

The petition is unanimously rejected as clearly unallowable.

The Registrar: The Chairman:

N. Michaleczek C. Josefsson

Decision electronically authenticated