Internal distribution code:

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

Datasheet for the decision of 24 May 2018

Case Number: T 2187/17 - 3.2.02

Application Number: 04794783.3

Publication Number: 1682014

IPC: A61B17/22, A61B17/225

Language of the proceedings: EN

Title of invention:
CONFINEMENT OF KIDNEY-STONE FRAGMENTS DURING LITHOTRIPSY

Applicant:
Pluromed, Inc.

Headword:

Relevant legal provisions:
EPC Art. 106(1), 109(1), 111, 113(1)
EPC R. 103, 111(2), 116
RPBA Art. 11

Keyword:

Appealed decision reasoned (no)
Right to be heard respected (no)
Substantial procedural violation - (yes)
Remittal to the department of first instance - (yes)
Reimbursement of appeal fee - (yes)

Decisions cited:

T 0094/84, T 0775/97, T 0278/00, T 1997/08, T 2003/08, T 1069/11

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres 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: T 2187/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 May 2018

Appellant: (Applicant)	Pluromed, Inc. Five Oak Meadow Road Lincoln, MA 01773 (US)
Representative:	Lee, Nicholas John Kilburn & Strode LLP Lacon London 84 Theobalds Road London WC1X 8NL (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 21 April 2017 refusing European patent application No. 04794783.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	D. Ceccarelli

Summary of Facts and Submissions

I. The appeal is directed against the decision of the Examining Division posted on 21 April 2017 to refuse the application. The decision was a so-called decision according to the state of the file.

The decision reads as follows:

"In the communication(s) dated 05.03.2012, 19.03.2015, 08.08.2016 the applicant was informed that the application does not meet the requirements of the European Patent Convention. The applicant was also informed of the reasons therein.

The applicant filed no comments or amendments in reply to the latest communication but requested a decision according to the state of the file by a letter received in due time on 27.03.2017.

The European patent application is therefore refused on the basis of Article 97(2) EPC."

II. Notice of appeal was filed on 21 June 2017, and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 17 August 2017.

III. The appellant requested in its notice of appeal and in the statement setting out the grounds of appeal that the decision be rectified by means of interlocutory revision because of the failure to take the submission of 27 February 2017 into account, and that the appeal fee be refunded because of that substantial procedural violation.

IV. After the communications of the Examining Division dated 5 March 2012 and 19 March 2015, the appellant filed the version of claim 1 on file with a letter dated 25 September 2015.

V. On 8 August 2016 the Examining Division issued summons to attend oral proceedings on 28 March 2017. The final date for making written submissions and/or amendments pursuant to Rule 116 EPC was indicated on the summons as being 28 February 2017.

In the annex to the summons the Examining Division presented its view that the claimed composition was not patentable pursuant to Article 54(5) EPC. It explained the following in point 1.3.4:

"*Accordingly the present composition is not considered as falling under the requirements of Article 54(5) EPC because*

a) the composition comprising an inverse thermosensitive polymer is not already known as a medicine or a medicament;

b) it is not a finished product ready to use without surgical insertion into the body; instead the finished product is obtained by the gelation of the polymer after this is injected in the lumen and is solidified by the change in temperature, nor

c) it comprisesan active ingredient, but instead derives its functionality from the mechanical properties of the plug it forms after gelation."

and it concluded in point 1.4:

"*As a consequence claim 1 is still not considered new in view of the disclosure of document D1 for the same reasons as provided in the previous communication dated 19.03.2015 (see point 2).*"

To support its view the Examining Division referred to T 775/97, and for the first time to T 2003/08 and T 1069/11 and to the *travaux préparatoires* for Article 54(5) EPC.

VI. On 27 February 2017 the appellant filed a nine-page submission in preparation for the oral proceedings in which it analysed the legal texts, the guidelines, the alleged requirement for the presence of a therapeutic effect and the cited decisions and concluded that the claim directed to the composition was allowable pursuant to Article 54(5) EPC.

VII. On 27 March 2017 the appellant informed the Examining Division that it would not attend the oral proceedings, and it requested a decision according to the state of the file.

VIII. Claim 1 reads as follows:

"A first composition comprising an inverse thermosensitive polymer for use in a method of lithotripsy to mitigate the risk of damage to surrounding body tissue, the method comprising: injecting the first composition into a lumen of a mammal at a first distance from a concretion, wherein said first composition does not contact said concretion; and directing energy to said concretion causing the fragmentation of said concretion into a plurality of fragments."

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention concerns a composition for use in relation to lithotripsy to mitigate the risk of damage to surrounding body tissue when energy is applied to the concretion for fragmentation. The composition is liquid below body temperature but becomes a gel at about body temperature, and is used as a barrier in the body lumen close to the concretion.

3. Under Article 106(1) EPC, the decisions of the examining divisions are open to appeal. According to Rule 111(2) EPC, decisions of the European Patent Office which are open to appeal must be reasoned.

It is established jurisprudence of the boards of appeal that for this requirement to be fulfilled the decision must include, in logical sequence, the arguments justifying the order. The grounds upon which a decision is based and all decisive considerations in respect of the factual and legal aspects of the case must be discussed in detail in the decision (e.g. T 278/00, OJ 2003, 546).

These requirements obviously aim at allowing the losing party to understand the reasons for the negative decision taken against it so that it can envisage the filing of an appeal. The same is true for the board of appeal which may have to deal with the appeal and has to understand why the department of first instance took the impugned decision.

It should be noted that a request for a decision based on the current state of the file is not to be understood as a waiver by the party of its right to a fully reasoned decision. The departments of the European Patent Office cannot omit to give reasons for their decisions when the EPC requires them to do so.

4. In the present case the impugned decision solely refers to two communications, and an annex to the summons to attend oral proceedings.

As can be seen from points III and IV above, the annex to the summons posted on 8 August 2016 for the first time addressed the version of the claim filed with the letter of 25 September 2015 to be discussed in the oral proceedings of 28 March 2017 and contained a number of new arguments/reasons why the claim was not allowable.

5. The appellant filed counter-arguments to all of these in its nine-page submission of 27 February 2017. It addressed in particular the reasons why the Examining Division considered the composition not to fall under the requirements of Article 54(5) EPC. This submission was thus a direct answer to the annex to the summons, and it was also filed in due time before the deadline of 28 February 2017, fixed by the Examining Division pursuant to Rule 116 EPC, for it to be taken into account by the latter.

6. The impugned decision does not contain any reasons as to why these arguments presented by the appellant in support of the allowability of claim 1 were not relevant and were unable to convince the Examining Division.

Therefore, it is left to the appellant and to the present Board to speculate on the very reasons for the refusal.

7. By failing to give the reasons for the decision and explain why the applicant's last arguments were not considered convincing, the Examining Division did not issue a reasoned decision within the meaning of Rule 111(2) EPC, thereby depriving the appellant of its right to obtain such a fully reasoned decision, which constitutes a substantial procedural violation.

8. In addition, by stating in the short reasons for the decision that no comments had been filed in response to its last communication, the Examining Division clearly indicated that it had not considered the appellant's last arguments, in particular in relation to the objections/arguments first raised in the preceding communication.

Moreover, the Examining Division had the opportunity - at the latest when the appellant filed its appeal and drew the attention of the Examining Division to the existence of the submission of 27 February 2017 - to correct its mistake by allowing interlocutory revision of the decision pursuant to Article 109(1) EPC, which it did not do.

Article 113(1) EPC 1973 requires a decision to be based on grounds on which a party has had an opportunity to present its comments. The right to be heard also guarantees that grounds put forward are taken into consideration (T 94/84, OJ EPO 1986, 337; T 1997/08). In the present case the Examining Division neglected arguments which had been set out in a clear fashion. This has the same effect as if the applicant had not

been allowed to put them forward at all. The impugned decision does not deal with the appellant's last arguments.

This absence of due consideration of the appellant’s arguments hence also constitutes a violation of Article 113(1) EPC, as it amounts to refusing to take into consideration the comments made by the appellant in the exercise of its right to be heard, which constitutes a further substantial procedural violation.

9. In view of these substantial procedural violations it appears necessary to set the impugned decision aside.

10. For the reasons mentioned above the appellant had to appeal in order to seek redress and obtain a fully reasoned decision. It therefore appears equitable to order reimbursement of the appeal fee pursuant to Rule 103 EPC.

11. Since a fundamental deficiency is apparent in the first-instance proceedings and no special reasons present themselves for doing otherwise, the case is remitted to the department of first instance for further prosecution pursuant to Article 111 EPC and Article 11 RPBA (OJ EPO 2007, 536).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

3. Reimbursement of the appeal fee is ordered.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated