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**Datasheet for the decision
of 5 October 2016**

Case Number: T 0327/15 - 3.2.02

Application Number: 05768322.9

Publication Number: 1790364

IPC: A61M1/18, A61M1/16, B01D61/24,
B01D63/02

Language of the proceedings: EN

Title of invention:
POLYSULFONE HEMODIALYZER

Patent Proprietor:
Asahi Kasei Medical Co., Ltd.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(b), 113(1)
EPC R. 103(1)(a), 111(2)
RPBA Art. 11

Keyword:

Substantial procedural violation - appealed decision reasoned
(no) - reimbursement of appeal fee (yes)
Remittal to the department of first instance - fundamental
deficiency in first instance proceedings (yes)

Decisions cited:

Catchword:



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Case Number: T 0327/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 October 2016

Appellant: Fresenius Medical Care Deutschland GmbH
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Respondent: Asahi Kasei Medical Co., Ltd.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on
23 December 2014 rejecting the opposition filed
against European patent No. 1790364 pursuant to
Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	M. Stern

Summary of Facts and Submissions

- I. The opponent has appealed the Opposition Division's decision, dispatched on 23 December 2014, to reject the opposition against European patent No. 1 790 364.
- II. The patent was opposed on the grounds of lack of novelty, lack of inventive step (Article 100(a) EPC), and insufficiency of disclosure (Article 100(b) EPC).
- III. The notice of appeal was received on 13 February 2015. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 30 April 2015.
- IV. The respondent replied to the statement of grounds by letter dated 18 September 2015.
- V. The Board set out its provisional opinion in a communication dated 17 February 2016. It expressed its intention to set aside the impugned decision and remit the case to the department of first instance for further prosecution.
- VI. Following the Board's communication the parties withdrew their requests for oral proceedings, submitted in the preceding written proceedings, provided that the Board decided to set aside the impugned decision and remit the case.
- VII. The appellant's final requests were that the decision under appeal be set aside and that the patent be revoked.
- VIII. The respondent's final requests were that the appeal be dismissed or, in the alternative, that the decision

under appeal be set aside and the patent be maintained on the basis of one of auxiliary requests 1 to 3 filed with letter dated 18 September 2015.

IX. Claim 1 of the patent as granted reads as follows:

"A polysulfone hemodialyzer comprising a tubular housing (1) having a body portion (2) and head portions (3) and providing a dialysate inlet port (4a) in one of the head portions (3) and a dialysate outlet port (4b) in the other head portion (3), a hollow fiber membrane bundle (5) which is formed from a polysulfone polymer and polyvinylpyrrolidone and filled in the tubular housing (1), a resin layer portion (7) provided on an end of the head portion (3) of the housing (1), securing the bundle (5) in the housing (1) and forming an open end (6) for the hollow fiber membranes, and a header portion (9) which has a blood circulation port (8) and with which the resin layer portion (7) is capped,
the hemodialyzer having a membrane area of from more than 2.4 m² to 3.2 m², and the bundle (5) including straight portion (10) **characterized in that** the bundle includes a dialysate rectifying portion (11), a ratio of a dialysate channel area in a diameter-expansion-start surface (12) to a dialysate channel area inside the resin layer portion (7) is 0.2 to 0.5, and the dialysate rectifying portion (11) having a distance from the diameter-expansion-start surface (12) to the inside of the resin layer portion (7) of 10 to 46 mm is provided in a dialysate inlet port (4a) side end portion of the bundle (5)."

Claim 13 of the patent as granted reads as follows:

"The polysulfone hermodialyzer according to any of claims 1 to 12, having a urea overall mass transfer coefficient of 9.50×10^{-4} cm/sec or more at a blood flow rate of 400 ml/min and a dialysate flow rate of 800 ml/min, and a difference ($Ko_{(C)} - Ko_{(AVE)}$) between a urea center portion overall mass transfer coefficient ($Ko_{(C)}$) and an average urea peripheral portion overall mass transfer coefficient ($Ko_{(AVE)}$) at a blood flow rate of 400 ml/min and a dialysate flow rate of 800 ml/min of -2.7×10^{-4} to 2.5×10^{-4} cm/sec."

- X. As far as they are relevant for the present decision, the appellant's arguments may be summarised as follows:

The opposition was based on the grounds according to Article 100(a) as well as Article 100(b) EPC. However, the impugned decision contained no reasoning as to why the Opposition Division considered that the ground for opposition according to Article 100(b) EPC did not prejudice the maintenance of the patent.

The absence of any such reasoning made it difficult for the appellant to provide arguments as to why on this ground the impugned decision should be set aside.

- XI. On the specific issue of the missing reasoning in the impugned decision concerning the ground for opposition according to Article 100(b) EPC, the respondent provided no arguments.

Reasons for the Decision

1. The appeal is admissible.
2. The invention relates to a haemodialyser used in a haemodialysis system for performing a haemodialysis treatment on a patient who has lost his kidney function.

A haemodialyser is the component in which the extraction of waste products from the blood of the patient undergoing the treatment takes place. Typically, it comprises two compartments separated by a dialysis membrane: a blood-side compartment to be filled by the blood of the patient circulating in the system and a dialysate-side compartment. During treatment waste products will diffuse through the dialysis membrane from the blood-side compartment into the dialysate-side compartment, and some dialysate will diffuse in the opposite direction, to achieve an electrolyte balance in the treated blood. The treated blood is then re-infused into the patient.

The invention focuses on the provision of a particular hollow fibre membrane bundle as the dialysis membrane.

3. The patent was opposed, *inter alia*, on the ground according to Article 100(b) EPC. More particularly, under item VIII of the notice of opposition, the appellant objected to claim 13 of the patent as granted and submitted that the patent specification did not contain any information on how the defined urea mass transfer coefficient of the haemodialyser could be obtained. It followed that the subject-matter of claim 13 was not disclosed in a manner sufficiently

clear for it to be carried out by a person skilled in the art.

The ground for opposition according to Article 100(b) EPC was never withdrawn by the appellant. As can be seen from the impugned decision (point 7) and the minutes of the oral proceedings before the department of first instance (forth and third sentences from the end), this ground was even addressed during the oral proceedings, with the parties referring to their preceding written submissions without presenting any further arguments.

The Opposition Division, however, did not deal with that ground in the reasons for the decision. As also pointed out by the appellant, it is only in the communication accompanying the summons to oral proceedings that the Opposition Division briefly addressed it (point 9.1), and even in that communication merely a "preliminary and non-binding opinion" without any detailed reasoning was provided:

"Concerning lack of insufficient disclosure of claim 13 which is based on the allegation that a skilled person is not enabled to provide the hemodialyzer of claims 1 to 12 having an overall mass transfer coefficient as defined in claim 13 the Opposition Division at present shares the view of the Patentee that the Opponent did not submit any evidence for its allegation."

4. Under Rule 111(2) EPC, "decisions of the European Patent Office which are open to appeal shall be reasoned".

The reasons should make it possible for the adversely

affected party to consider whether it may be worth filing an appeal with a reasonable expectation of success, and for the Board to establish whether the decision was justified or should be set aside. The reasons also serve the purpose of showing that arguments of the adversely affected party have been duly considered by the deciding body, having regard to the right to be heard enshrined in Article 113(1) EPC.

It follows that the lack of reasoning concerning the ground for opposition according to Article 100(b) EPC in the impugned decision is in breach of Rule 111(2) EPC and Article 113(1) EPC. This constitutes a substantial procedural violation.

5. Under Article 11 RPBA the Board should remit the case to the Opposition Division "if fundamental deficiencies are apparent in the first instance proceedings, unless special reasons present themselves for doing otherwise".

Given the substantial procedural violation established above and the fact that no special reasons against a remittal arise, the Board concludes that the case should be remitted to the Opposition Division for further prosecution.

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

As concluded above, the case should be remitted to the Opposition Division. It follows that the impugned decision is to be set aside. Hence, the appeal is allowable.

As explained above, the lack of reasoning concerning the ground for opposition under Article 100(b) EPC constitutes a substantial procedural violation.

Furthermore, the Board notes that if the ground for opposition under Article 100(b) EPC was found to prejudice the maintenance of the European patent, the opposition would be successful irrespective of the conclusions reached for other grounds.

Therefore, the Board considers it equitable to order the reimbursement of the appeal fee under Rule 103(1)(a) EPC.

7. Under these circumstances, all other requests submitted by the parties in the appeal proceedings, in particular in relation to the admissibility of new evidence, are left for the Opposition Division to decide upon.

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. The appeal fee is to be reimbursed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated