

**Internal distribution code:**

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

**Datasheet for the decision  
of 23 October 2008**

**Case Number:** T 0588/07 - 3.3.10

**Application Number:** 89907896.8

**Publication Number:** 0427741

**IPC:** A61L 15/16

**Language of the proceedings:** EN

**Title of invention:**

Subsaturated transdermal delivery device

**Patentee:**

ALZA Corporation

**Opponent:**

LTS Lohmann Therapie-Systeme AG

**Headword:**

Transdermal delivery device/ALZA

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

"Both requests: Amendments (not allowable) - added subject-matter"

**Decisions cited:**

G 0009/91

**Catchword:**

-



Case Number: T 0588/07 - 3.3.10

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.10  
of 23 October 2008

**Appellant:** LTS Lohmann Therapie-Systeme AG  
(Opponent) Postfach 1525  
D-56605 Andernach (DE)

**Representative:** -

**Respondent:** ALZA Corporation  
(Patent Proprietor) 950 Page Mill Road  
P.O. Box 10950  
Palo Alto  
California 94303-0802 (US)

**Representative:** Brown, Fraser Gregory James  
fJ Cleveland  
40-43 Chancery Lane  
London WC2A 1JQ (GB)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
30 January 2007 concerning maintenance of  
European patent No. 0427741 in amended form.

**Composition of the Board:**

**Chairman:** R. Freimuth  
**Members:** J. Mercey  
D. S. Rogers

## Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal on 3 April 2007 against the interlocutory decision of the Opposition Division posted 30 January 2007 which found that European patent No. 427 741 in amended form met the requirements of the EPC.

II. Notice of Opposition had been filed by the Appellant requesting revocation of the patent as granted in its entirety on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC) and insufficient disclosure (Article 100(b) EPC).

III. The decision under appeal was based on an amended set of twelve claims, independent claim 1 of which read as follows:

"A transdermal delivery device (1) for delivering an agent consisting of nicotine over a predetermined administration period between 8 hours and 3 days comprising:

(i) a reservoir (3) comprising said agent dissolved in anhydrous natural or synthetic rubber or polymer,

(ii) an agent release rate controlling membrane through which said agent, but not said rubber or polymer, permeates in use from the device to the skin of the patient, and

(iii) in-line adhesive means through which said agent must pass to reach the skin (5),

wherein said agent is a solvent for the adhesive, the initial equilibrated activity of said agent in said reservoir is below saturation and at a level at which

the adhesive layer (5) retains adhesive properties, the initial loading of agent in the reservoir and the agent release rate control conferred by said membrane are sufficient to prevent the activity of the agent in the reservoir from decreasing by more than 75% during the predetermined administration period, and wherein at least 50% of the initial equilibrated loading of the agent in the device is in the reservoir (3)."

- IV. The Opposition Division held that the amendments made to the then pending main request fulfilled the requirements of Article 123(2) and (3) EPC, that the invention was sufficiently disclosed and that the subject-matter thereof was novel and involved an inventive step.
- V. At the oral proceedings before the Board, held on 23 October 2008, the Respondent (Proprietor of the patent) defended the patent in suit in the form as maintained by the Opposition Division as the main request, or subsidiarily, on the basis of the auxiliary request submitted during these oral proceedings before the Board. Claim 1 of the auxiliary request differed from claim 1 of the main request exclusively in that feature (i) read: "an anhydrous reservoir (3) comprising said agent dissolved in natural or synthetic rubber or polymer".
- VI. The Appellant argued that at least the feature of claim 1 of both requests that the agent was dissolved in natural or synthetic rubber or polymer had no basis in the application as filed and thus did not fulfil the requirements of Article 123(2) EPC.

VII. The Respondent submitted that claim 1 of both requests did not offend against the requirements of Article 123(2) EPC, since it was clear from page 11, lines 7 to 8 and claim 1 as originally filed that the agent, namely nicotine, was dissolved in the diluent. That the reservoir material described on page 10, lines 1 to 2 was the reservoir diluent was apparent from Example 1 on page 11, line 29 of the application as filed, wherein ethylene/vinyl acetate copolymer (EVA) was used as reservoir diluent.

VIII. The Appellant requested that the decision under appeal be set aside and the patent be revoked.

The Respondent requested that the appeal be dismissed or, subsidiarily, that the decision under appeal be set aside and the patent be maintained on the basis of the auxiliary request submitted at the oral proceedings on 23 October 2008.

IX. At the end of the oral proceedings, during which all objections and requests of the Appellant regarding alleged procedural defects and of the Respondent regarding apportionment of costs were withdrawn, the decision of the Board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.

2. *Admissibility of auxiliary request*

In response to an objection raised during the oral proceedings before the Board with regard to support in the application as filed (Article 123(2) EPC) for subject-matter in the main request, the Respondent submitted an auxiliary request containing an amendment prompted by the objection raised. Therefore this amendment is considered to be appropriate and necessary. Furthermore, the Appellant did not object to the late-filing of this request and had no additional formal objections thereto. For these reasons the Board exercises its discretion to admit the auxiliary request into the proceedings.

*Main and auxiliary request*

3. *Article 123(2) EPC*

3.1 Since Article 100(c) EPC was not raised by the Appellant as a ground of opposition, nor was it dealt with in the appealed decision, only those amendments to the claims made in the opposition (appeal) proceedings may be examined for subject-matter extending beyond the application as filed (cf. G 9/91, OJ EPO 1993, 408, points 18 and 19 of the reasons).

3.2 In the present case, claim 1 as granted defined the reservoir (3) as containing an agent and a diluent. Claim 1 of both requests has been amended *vis-à-vis* claim 1 as granted *inter alia* in that the reservoir (3) is now defined as comprising the agent, namely nicotine, "dissolved in [...] natural or synthetic rubber or polymer".

3.3 It is established jurisprudence of the Boards of Appeal that an amendment offends against Article 123(2) EPC, if the amended subject-matter is not directly and unambiguously derivable from the application as filed.

3.4 According to the Respondent, the basis for this amendment was to be found on page 10, lines 1 to 2 of the application as filed. The Board, however, holds that said sentence cannot provide a basis for the amendment, since it states that the reservoir is formed of natural or synthetic rubbers or polymers, which is not tantamount to the agent being dissolved in said rubber or polymer.

The Respondent further argued that the basis for the agent, namely nicotine, being dissolved in the diluent was to be found at page 11, lines 7 to 8 and claim 1 as originally filed. However, neither these passages, nor page 10, lines 1 to 2, nor any other part of the application as filed, discloses natural or synthetic rubbers or polymers in general as being a diluent, let alone the reservoir diluent in which the agent is dissolved.

Finally, the Respondent argued that the reservoir material described on page 10, lines 1 to 2 was the reservoir diluent was apparent from Example 1 on page 11, line 29 of the application as filed, wherein ethylene/vinyl acetate copolymer (EVA) was described as being used as reservoir diluent. However, this example discloses merely a very particular polymer as diluent, and thus cannot provide a basis for natural or

synthetic rubbers, nor for polymers in general, as diluent.

- 3.5 Since, thus, the feature "reservoir (3) comprising said agent dissolved in [...] natural or synthetic rubber or polymer" has no adequate support in the application as filed, claim 1 of both requests is amended in such a way that subject-matter extending beyond the application as filed is added, contrary to the requirements of Article 123(2) EPC, with the consequence that the main request and the auxiliary request are not allowable.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

R. Freimuth