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D E C I S I O N
of 13 October 2004

Case Number: T 0427/03 - 3.3.2

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:

Delivery device/ALZA CORPORATION

Relevant legal provisions:

EPC Art. 102(1), 100, 111

EPC R. 67, 68(2)

Keyword:

"Remittal to the first instance - yes: insufficiently reasoned
decision and no legal basis for the decision"

"Reimbursement of the appeal fee - no: not equitable"

Decisions cited:

-

Catchword:

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Case Number: T 0427/03 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 13 October 2004

Appellant: ALZA CORPORATION
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Respondent: LTS Lohmann Therapie-Systeme 19
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Representative: Dr. Siemund
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 30 January 2003
revoking European patent No. 0427741 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

- I. European patent No. 0 427 741 based on application No. 89 907 896.8 was granted on the basis of 25 claims.

Independent claim 1 as granted read as follows:

"1. A transdermal delivery device (1) for delivering an agent over a predetermined administration period comprising a reservoir (3) containing an agent and a diluent, release rate controlling means through which said agent, but not said diluent, permeates in use from the device to the skin of a patient, and in-line adhesive means through which said agent must pass to reach the skin (5), wherein said agent is a solvent for the adhesive, characterised in that the initial equilibrated activity of said agent in said reservoir is below saturation and at a level at which the adhesive means (5) retains adhesive properties, and the initial loading of the agent in the reservoir is sufficient to prevent the activity of the agent in the reservoir from decreasing by more than 75% during the predetermined administration period."

- II. Notice of opposition was filed against the granted patent by the opponent.

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and under Article 100(b) for insufficiency of disclosure.

- III. The decision of the Opposition Division posted on 30 January 2003 established that the set of claims filed by the patentee with its letter dated 28 February

2002 differed from the set of claims considered allowable under the EPC at the end of the oral proceedings held on 12 October 2000, because it contained amendments in claim 1 and a new claim (ie claim 2) sidestepping the limitation to nicotine as agent of the latter set of claims.

The Opposition Division revoked the patent.

Claim 1 of the set of claims which allowable under the EPC at the end of the oral proceedings held on 12 October 2000, as attached to the minutes, reads:

"1. 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 a patient, and
- (iii) in-line adhesive means through which said agent must pass to reach the skin comprising an adhesive layer (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)."

Claim 1 and new claim 2 of the set of claims filed by the patentee with its letter dated 28 February 2002 reads:

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

- (i) a reservoir (3) comprising nicotine dissolved in anhydrous natural or synthetic rubber or polymer
- (ii) a nicotine release rate controlling membrane through which said agent, but not said rubber or polymer, permeates in use from the device to the skin of a patient, and
- (iii) in-line adhesive means through which the nicotine must pass to reach the skin comprising an adhesive layer (5),

wherein the nicotine is a solvent for the adhesive, the initial equilibrated activity of the nicotine in said reservoir is below saturation and at a level at which the adhesive layer (5) retains adhesive properties, the initial loading of the nicotine in the reservoir and the nicotine release rate control conferred by said membrane are sufficient to prevent the activity of the nicotine 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 nicotine in the device is in the reservoir (3)."

"2. The device of claim 1 wherein in addition to nicotine, the reservoir contains one or more further agents such as a permeation enhancer or a drug."

IV. The appellant (patentee) lodged an appeal against the said decision.

V. Oral proceedings were held before the Board on 13 October 2004.

VI. The appellant maintained that the new set of claims did not in fact differ in substance from the set of claims deemed to fulfil the requirements of the EPC.

It moreover requested reimbursement of the appeal fee because of the particular unhelpful conduct of the Opposition Division after the conclusion of the oral proceedings.

VII. The respondent (opponent) shared the Opposition Division's findings.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request (set of claims on which the revocation was based), or, alternatively, on the basis of the first (set of claims filed with letter of 8 June 2003) or second auxiliary request (set of claims as approved by the Opposition Division at the end of the oral proceedings), and that the appeal fee be reimbursed.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. *Remittal to the department of first instance
(Article 111 EPC)*

According to Article 102(1) EPC, "If the Opposition Division is of the opinion that the grounds for opposition mentioned in Article 100 prejudice the maintenance of the European Patent, it shall revoke the patent".

Moreover, Rule 68(2) stipulates that the "Decisions of the European Patent Office which are open to appeal shall be reasoned".

In these respects, the Board observes, on the one hand, that the decision under appeal does not refer, either explicitly or implicitly, to any Article or Rule of the EPC as the legal basis for the revocation, and, on the other hand, that no reasoning is provided to justify the revocation.

The mere statement that the latter set of claims differs from the set of claims considered allowable under the EPC at the end of the oral proceedings held on 12 October 2000 is not sufficient for that purpose. The statement does not release the Opposition Division

from its obligation to explain and demonstrate which Article and/or Rule of the EPC would be contravened.

The Board also notes that the decision under appeal is totally silent about the admissibility of this latter set of claims filed by the appellant.

In fact, it is, *a priori*, very questionable whether a further set of claims, filed 16 months after the announcement of the Opposition Division at the end of the oral proceedings that the patent could be maintained in amended form on the basis of the last set of claims put forward at the end of the oral proceedings (provided an appropriately adapted description is provided), can be introduced and accepted in the procedure without taking into account the lateness of the filing.

Under these circumstances, the Board considers that the decision under appeal has to be set aside by reason of a substantial procedural violation.

3. *Reimbursement of the appeal fee under Rule 67 EPC*

In accordance with Rule 67 EPC, reimbursement of an appeal fee is to be ordered when a Board deems an appeal to be allowable "if such reimbursement is **equitable** by reason of a substantial procedural violation".

In that respect, the Board observes that the appellant contributed to the present situation by filing a new set of claims 16 months after the announcement of the Opposition Division at the end of the oral proceedings

that the patent could be maintained in amended form on the basis of the last set of claims put forward at the end of the oral proceedings instead of providing an adapted description as requested.

Under these circumstances it does not therefore appear to be equitable to reimburse the appeal fee (Rule 67 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:

A. Townend

U. Oswald