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**D E C I S I O N**  
**of 21 April 2005**

**Case Number:** T 0584/01 - 3.3.2

**Application Number:** 92309727.3

**Publication Number:** 0539215

**IPC:** A61K 47/22

**Language of the proceedings:** EN

**Title of invention:**

Penetration enhancement of topically applied formulations

**Patentee:**

Stafford-Miller Ltd., et al

**Opponent:**

Hexal Aktiengesellschaft

**Headword:**

Topically applied formulations/STAFFORD-MILLER LTD

**Relevant legal provisions:**

EPC Art. 108, 123(2)

EPC R. 65(1)

**Keyword:**

"Appeal by the patentee: admissible - no: missing statement of grounds"

"Added matter - yes: disclaimer not allowable since anticipation was not accidental"

**Decisions cited:**

G 0001/03

**Catchword:**

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Case Number: T 0584/01 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 21 April 2005

**Appellant:** Hexal Aktiengesellschaft  
(Opponent) Industriestr. 25  
D-83607 Holzkirchen (DE)

**Representative:** -

**Respondent:** Stafford-Miller Ltd.  
(Proprietor of the patent) Broadwater Road  
Welwyn Garden City  
Hertfordshire AL7 3SP (GB)

**Representative:** Morris, Miriam Elizabeth  
GlaxoSmithKline  
Corporate Intellectual Property  
980 Great West Road  
Brentford  
Middlesex TW8 9GS (GB)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
22 March 2001 concerning maintenance of  
European patent No. 0539215 in amended form.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** J. Riolo  
J. H. P. Willems

## Summary of Facts and Submissions

- I. European patent No. 0 539 215, based on application No. 92309727.3, was granted on the basis of 10 claims.

Independent claim 1 as granted reads: "Use of vitamin E in the manufacture of a topically applied composition comprising a therapeutically-active agent, the ability of the composition to penetrate thereby being enhanced".

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

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

The following document, inter alia, was cited during the proceedings before the Opposition Division and the Board of Appeal:

- (9) Abstract 98:221871 of JP-A-58055417 from the online database of chemical abstract)

- III. The appeal lies against an interlocutory decision of the Opposition Division maintaining European patent No. 539 215 in amended form as provided for in Article 102(3) and Article 106(3) EPC, pronounced on 7 February 2001, posted on 22 March 2001.

The Opposition Division found that the patent in suit could be maintained on the basis of auxiliary request 6a.

The Opposition Division took the view that the claims of the patent in suit as granted and according to auxiliary requests 1 to 6 lacked novelty over the prior art documents.

It was of the opinion that the disclaimer in auxiliary request 6a related to an accidental novelty-destroying disclosure in document (9) since the disclosure in this document did not address the problem of improved drug penetration and could not be considered relevant for inventive step. It therefore accepted this amendment with respect to Article 123(2) EPC.

The Opposition Division considered that the subject-matter of claim 1 according to auxiliary request 6a was rendered novel by the restriction of the active agent to a non-steroidal anti-inflammatory agent present in a particular form in the composition and on account of the disclaimer with respect to document (9).

As regards inventive step, the Opposition Division considered that none of the available prior art documents addressed the problem of enhancing the penetration of active agents and that they therefore could not be seen as relevant in the assessment of inventive step.

It concluded that it was not obvious from these documents, or any other cited document, that vitamin E present in the known composition was the ingredient responsible for the demonstrated enhanced penetration.

It therefore arrived at the conclusion that a patent could be maintained on the basis of auxiliary request 6a.

- IV. On 22 May 2001, the patent proprietor filed a notice of appeal against the interlocutory decision of the Opposition Division and paid the appeal fee.
- V. In a communication dated 10 August 2001, sent by registered letter with advice of delivery, the Registry of the Board informed the patentee that no statement of grounds had been filed and that the appeal could be expected to be rejected as inadmissible pursuant to Article 108 and Rule 65(1) EPC.

The patentee was invited to file observations within two months.

- VI. The appellant (opponent) also lodged an appeal against the decision of the Opposition Division and filed arguments in support of its appeal.
- VII. In the communication of 15 November 2004 accompanying the summons to the oral proceedings, the Board expressed its doubts about the allowability of the disclaimer in claim 1 in auxiliary request 6a with respect to Article 123(2) EPC having regard to decision G 1/03 of the Enlarged Board of Appeal, OJ EPO 2004, p.413.

It furthermore expressed its preliminary negative view as to novelty and inventive step of the subject-matter of claim 1 of auxiliary request 6a in the light of the available prior art.

VIII. The submissions of the appellant (opponent) can be summarised as follows:

As regards added matter, the appellant was of the opinion that document (9) did not relate to an accidental disclosure. It was moreover of the opinion that this disclaimer did not restore novelty over document (9).

IX. As regards added matter, the respondent (patentee) made no submissions and did not take any position on the doubts expressed by the Board in its communication dated 15 November 2004 with respect to the allowability of the disclaimer in claim 1 under Article 123(2) EPC.

X. In its letter dated 1 April 2005, the respondent (patentee) indicated that it would not attend the oral proceedings.

XI. Oral proceedings were held before the Board on 21 April 2005.

XII. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent (patentee) requested in writing that the appeal be dismissed and that the patent be maintained in amended form as maintained by the Opposition Division.

## Reasons for the decision

1. Appeal by the patent proprietor

As no written statement setting out the grounds of appeal has been filed and in the absence of any reply to the invitation to file observations in that respect (see point V. above), the appeal has to be rejected as inadmissible (Article 108 EPC in conjunction with Rule 65(1) EPC).

2. *Appeal by the opponent*

The appeal is admissible.

3. Main request: admissibility of claim 1 in view of Article 123(2) EPC

3.1 The patent is concerned with improved compositions for the topical delivery of pharmaceutically-active agents to human and animal tissue and systems (see patent in suit on page 3, lines 5 to 6).

Claim 1 relates more specifically to the use of vitamin E in the manufacture of a gel, paste, ointment, cream, lotion, liquid suspension or suppository comprising a non-steroidal anti-inflammatory agent.

Claim 1 further contains the following proviso "provided that the composition is not in a poultice comprising ethylene glycol monosalicylate and alpha-dl-tocopherol".

3.2 Article 123(2) EPC prohibits amendments of a European patent that result in the extension of its subject-matter beyond that of the application as filed. However, an amendment to a claim by the introduction of a disclaimer may not be refused under Article 123(2) EPC for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim have a basis in the European patent application as filed (according to Headnote I of decision G 1/03 of the Enlarged Board of Appeal).

In decision G 1/03, the Enlarged Board of Appeal established, moreover, that the introduction of a disclaimer excluding the subject-matter of an **accidental** anticipation of the invention is assumed not to change the technical information of a patent application (or of an opposed patent) within the meaning of Article 123(2) EPC (see G 1/03, item 2.2.2 of the reasons).

In this decision, the criterion for an anticipation to be regarded as accidental was defined as if it were so unrelated and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when working on the invention (see G 1/03, Headnote II.1).

In other words, when an anticipation is taken as accidental, this means that it appears from the outset that the anticipation has nothing to do with the invention. Only if this is established can the non-disclosed disclaimer be allowable (see G 1/03, item 2.3.4 of the reasons).



3.3 The Board observes that the proviso introduced in claim 1 lacks any basis in the European patent application as filed.

The Board also notes that document (9) deals with pharmaceutical compositions for external application containing, inter alia, an anti-inflammatory agent and vitamin E. The working examples relate to the manufacture of poultice comprising these compositions.

It is therefore evident that this prior art is closely related to the invention defined in present claim 1 (see item 3.1 above). The skilled person would have taken this prior art into consideration when working on topically-applied compositions comprising an anti-inflammatory agent.

Thus, document (9) cannot be considered an accidental anticipation within the meaning of G 1/03 of the present invention.

3.4 Since the proviso introduced in claim 1 does not amount to disclaiming an allowable accidental anticipation, this claim violates Article 123(2) EPC.

Therefore, the respondent's sole request is not allowable.

**Order**

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

1. The appeal filed by the patentee is dismissed as inadmissible.
2. The decision under appeal is set aside.
3. The patent is revoked.

The Registrar:

The Chairman:

A. Townend

U. Oswald