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D E C I S I O N
of 29 March 2006

Case Number: T 0036/02 - 3.3.10

Application Number: 90309608.9

Publication Number: 0416842

IPC: A61L 15/44

Language of the proceedings: EN

Title of invention:

Solid matrix system for transdermal drug delivery

Patentee:

Ortho-McNeil Pharmaceutical, Inc.

Opponents:

Berghof Labor- und Automationstechnik GmbH
Schwarz Pharma AG
LTS Lohmann Therapie System GmbH
Rotta Research Laboratorium S.p.A.
Schering AG

Headword:

Solid matrix system for transdermal drug delivery/ORTHO-MCNEIL

Relevant legal provisions:

EPC Art. 100(c), 111(1), 113(1), 123(2)

Keyword:

"Jurisdiction of the Boards on issues decided by the first instance - power on the Board to review each issue"
"Party to the proceedings - right to comment on any relevant issue"
"Amendments (not allowable) - undue generalisation of a commercial product"

Decisions cited:

G 0009/91, G 0010/91

Catchword:

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Case Number: T 0036/02 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 29 March 2006

Party as of right:
(Opponent 01) Berghof Labor- und
Automationstechnik GmbH
Harretstr. 1
D-7412 Eningen (DE)

Representative: Boeters, Hans Dietrich
BOETERS & LIECK
Oberanger 32
D-80331 München (DE)

Appellant I:
(Opponent 02) Schwarz Pharma AG
Alfred-Nobel-Strasse 10
D-40789 Monheim (DE)

Representative: Werner, Hans-Karsten
Patentanwälte
Von Kreisler-Selting-Werner
Postfach 10 22 41
D-50462 Köln (DE)

Appellant II:
(Opponent 03) LTS Lohmann Therapie System GmbH
Lohmannstr. 2
D-56626 Andernach (DE)

Representative: Flaccus, Rolf-Dieter
Patentanwalt
Bussardweg 10
D-50389 Wesseling (DE)

Party as of right:
(Opponent 04) Rotta Research Laboratorium S.p.A.
Via Valosa di Sopra, 7
I-20052 Monza (IT)

Representative: Boeters, Hans Dietrich
BOETERS & LIECK
Oberanger 32
D-80331 München (DE)

(former Opponent 05)

Schering AG
Gewerblicher Rechtsschutz
D-13342 Berlin (DE)

Representative:

Lederer, Franz
Lederer & Keller
Patentanwälte
Prinzregentenstrasse 16
D-80538 München (DE)

Respondent:

(Proprietor of the patent)

Ortho-McNeil Pharmaceutical, Inc.
U.S. Route No. 202
Raritan
NJ 08869-0606 (US)

Representative:

Hallybone, Huw George
Carpmaels and Ransford
43 Bloomsbury Square
London WC1A 2RA (GB)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted
13 November 2001 concerning maintenance of
European patent No. 0416842 in amended form.**

Composition of the Board:

Chairman: R. Freimuth
Members: J. Schmid
J. P. Seitz

Summary of Facts and Submissions

I. Appellant I (Opponent 02) and Appellant II (Opponent 03) lodged an appeal on 4 and 11 January 2002, respectively, against the interlocutory decision of the Opposition Division, posted on 13 November 2001, which found that the European patent No. 416 842 in the form as amended during opposition proceedings according to the then pending second auxiliary request met the requirements of the EPC.

II. Notices of opposition were filed against the granted patent by five parties requesting revocation of the patent in suit in its entirety. The Opponents 01 and 04 are Parties as of right pursuant to Article 107 EPC in the appeal proceedings. The opposition of Opponent 05 has been withdrawn already during the opposition proceedings.

The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC on the ground of extending the subject-matter beyond the content of the application as filed.

Inter alia the following document was submitted in opposition proceedings:

(9) Online database of Chemical Abstract, file Registry, 1996, entry RN 30900-72-2,

III. The Opposition Division held that the subject-matter of the patent in suit as amended was clear and did not

extend beyond the content of the application as filed and that the documents cited neither anticipated nor rendered obvious the claimed subject-matter. With respect to the amendments made to claim 1 the Opposition Division found that the basis for the feature vinyl acetate-acrylate copolymer "comprising/being a copolymer of at least 2-ethylhexyl acrylate" was supported by the passage bridging pages 6 and 7 of the original application disclosing the use of commercially available vinyl acetate-acrylate copolymers, sold under the trademarks GELVA 737, GELVA 788, Morstik 207 and Morstik 607, which were believed to be based on 2-ethylhexyl acrylate.

- IV. The Respondent (Proprietor of the patent) defended the maintenance of the patent in suit on the basis of the amended sets of claims held to be patentable by the Opposition Division, and submitted in retyped form dated 17 October 2002 which was annexed to a letter dated 12 November 2002, for the designated Contracting States AT BE CH DE DK FR GB IT LI LU NL SE, and for ES and GR.

Claims 1 and 3 of the main request for the Contracting States AT BE CH DE DK FR GB IT LI LU NL SE read as follows:

"1. A drug-containing matrix for use in a transdermal or transmucosal drug delivery device for administering at least one steroid estrogen drug to an area of skin or mucosa wherein the drug is dispersed in an amount below or at saturation in a body comprising a pressure sensitive adhesive vinyl acetate-acrylate copolymer, said copolymer being a copolymer of at least

2-ethylhexyl acrylate and vinyl acetate, said matrix being free of a skin permeation enhancer.

3. The matrix of claim 1 wherein the copolymer comprises approximately 72 wt% 2-ethylhexyl acrylate and approximately 28 wt% vinyl acetate (Monsanto GELVA® 737)."

Subsidiarily the Respondent defended the maintenance of the patent in suit on the basis of the sets of claims submitted at the oral proceedings before the Board as auxiliary requests 1 and 2. Independent claim 1 of auxiliary request 1 was the combination of claims 1 and 3 of the main request. Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 only in replacing the term "comprises" by the term "consists of" in the definition of the copolymer.

V. With respect to the issue of added subject-matter, the submissions of the Appellants can be summarized as follows:

The amendment of vinyl acetate-acrylate copolymers into copolymers of at least 2-ethylhexyl acrylate and vinyl acetate was not supported by the original disclosure. The basis for this amendment could not be the specific commercial products Morstik® and GELVA® disclosed in the original application. Those materials were vinyl acetate 2-ethylhexyl acrylate copolymers having particular ratios of 2-ethylhexyl acrylate and vinyl acetate. The omission of those ratios in claim 1 represented an undue generalisation. Moreover, the wording of claim 1 did not exclude the presence of further monomers in the copolymer which had no proper

basis in the application as filed and it covered also copolymers going beyond the commercial products specifically disclosed in the original application. In support of its argumentation Appellant I submitted in its statement of the grounds of appeal *inter alia* safety data sheets for the commercial products GELVA® 788 and 2484 and for GELVA® 737:

(35) GELVA® MULTIPOLYMER SOLUTION 737 Solutia Inc.

Material Safety data Sheet dated 19 December 2001.

Furthermore, the composition of a commercial product possibly could change over time. The analysis of the product GELVA® 737 was made by the Respondent after the filing and priority dates of the patent in suit. There was no certainty that the commercial product which was analysed at that time was the one of the examples in the patent in suit. They furthermore put forward that the subject-matter of claim 1 of the first and second auxiliary request was the combination of a particular matrix with a particular drug for which no basis could be found in the original application.

VI. The Respondent challenged that Appellant II was entitled to comment at the oral proceedings on the issue of added subject-matter, since it has not invoked this ground in its statement setting out the grounds of appeal. Furthermore the Respondent submitted that the examination of the ground for opposition pursuant to Article 100(c) EPC should be restricted during the oral proceedings to those aspects already raised in the written appeal proceedings by Appellant I.

As regards added subject-matter, the Respondent submitted that from the passage on page 7, lines 2 to 5 of the application as filed it was clear that, among the vinyl acetate-acrylate copolymers, it was the vinyl acetate 2-ethylhexyl acrylate copolymer which had superior properties, and thus this passage provided a direct and unambiguous basis for the restriction to the subgroup of copolymers of at least 2-ethylhexyl acrylate and vinyl acetate. Furthermore the basis for the fresh feature in claim 1 of the first and second auxiliary requests was the passage bridging pages 6 and 7 of the application as filed which indicated the monomers comprised in the copolymer GELVA® 737. Only the proportion of the monomers was not disclosed in the original application. However, the disclosure of the commercial product GELVA® 737 inherently disclosed its composition. The affidavit dated 9 November 1990 and submitted during the examination proceedings showed that the chemical composition of GELVA® 737, as determined by Fourier Transform Infrared spectroscopy, was approximately 72 wt% 2-ethylhexyl acrylate and 28 wt% vinyl acetate. There were no reasons to doubt about the accuracy of this analysis. The Respondent furthermore pointed out that this affidavit was signed shortly after the filing date of the patent in suit.

VII. The Parties as of right did not file any submission or request in the appeal proceedings.

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

The Respondent requested that the appeal be dismissed, and subsidiarily that the patent be maintained on the

basis of either auxiliary requests 1 or 2, filed during the oral proceedings.

- IX. The oral proceedings were held on 29 March 2006 in the absence of the Parties as of right, which after having been duly summoned, informed the Board by telephone on 23 March 2006, that they will not attend. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. *Jurisdiction of the Board*

Having regard to the issue of added subject-matter with respect to some features of claim 1 of the main request, the Respondent disputed the power of the Board to review and to decide on that issue since this ground for opposition, though formally raised in the statement of opposition, was confined to particular objections and since it was decided by the first instance in the Respondent's favour.

An opposition division has the power to challenge the patent in suit on any ground for opposition, in application of Article 114(1) EPC, of its own motion even if that ground for opposition was not covered by the statement of opposition pursuant to Rule 55(c) EPC (decision G 9/91, OJ 1993, 408, point 16 of the reasons; opinion G 10/91, OJ 1993, 420, point 2 of the opinion). In the present case, the issue of added subject-matter

was raised as a ground for opposition in a notice of opposition and was decided by the Opposition Division in the decision under appeal. Regardless of whether or not this ground for opposition under Article 100(c) EPC was substantiated with respect to particular objections in an Opponent's notice, the Opposition Division had the power to consider the issue of added subject-matter and to decide on it, which the Opposition Division did in the decision under appeal arriving to the conclusion that the then pending second auxiliary request met the requirements of Article 123(2) EPC. Therefore, once an appeal is lodged by an Appellant-Opponent against that decision, the decision under appeal as a whole is subject to review by the Board of Appeal and is within its jurisdiction. The appeal lying from the decision as a whole, it is the Board's power and duty pursuant to Article 111(1) and 102 EPC to decide for itself upon each matter and each issue addressed and decided in the decision under appeal and the Board is not bound by any finding of that decision. Thus, the Board is empowered to review and to decide upon all issues covered by the decision of the Opposition Division, i.e. in the present case the issue of subject-matter extending beyond the content of the application as filed with respect to any feature under consideration.

For these reasons, the Respondent's objections to the jurisdiction of the Board have no legal basis and are to be rejected.

3. *Procedural matters*

- 3.1 The Respondent put forward that the examination of the ground for opposition pursuant to Article 100(c) EPC should be restricted during the oral proceedings to those aspects raised in the written appeal proceedings by Appellant I.

Irrespective of the above findings that the Board is empowered to decide the issue of added subject-matter with respect to any feature under consideration (see point 2 supra), the Respondent's objection is not supported by the facts.

Appellant I, in its statement of the grounds of appeal (see section III thereof), objected to the mandatory presence of the monomer 2-ethylhexyl acrylate in the copolymer according to claim 1 as being an undue generalisation of originally disclosed subject-matter, thereby extending beyond the content of the application as filed. This particular objection pursuant to Article 100(c) EPC was discussed at the oral proceedings and is the basis for the Board's decision (see point 4 below), thus rendering the Respondent's arguments void.

- 3.2 The Respondent challenged that Appellant II was entitled to comment at the oral proceedings on the issue of added subject-matter, since it has not invoked this ground in its statement setting out the grounds of appeal.

According to Article 107 EPC, any party to the proceedings adversely affected by a decision may appeal

and any other parties to the proceedings shall be parties to the appeal proceedings as of right, so that it is clear from this provision that several admissible appeals do not initiate a corresponding number of parallel appeal proceedings.

The patent in suit was opposed on the ground of added subject-matter pursuant to Article 100(c) EPC (see point II above) and this issue was decided by the Opposition Division thereby forming part of the factual and legal framework of opposition(appeal) proceedings.

Therefore, in the Board's judgment, the attempt of the Respondent to prevent another Party to the proceedings, here the Appellant II, from commenting on an opposition ground, on which the decision under appeal was based and which is therefore subject to review by the Board of Appeal, is contrary to the requirement of Article 113(1) EPC in that the decisions of the EPO may only be based on grounds on which the parties concerned, including the Appellant II, have had an opportunity to present their comments. The request of the Respondent, hence, amounts to denying one of the parties to the proceedings its right to be heard with the consequence that this request must be rejected.

Consequently, the Board gave each of the parties ample opportunity to present its comments on the issues, including that of added subject-matter, which were discussed during the oral proceedings and on which the Board's decision is based, thereby safeguarding their right to be heard.

Main request

4. *Amendments (Article 100(c) EPC)*

4.1 The patent in suit has been opposed *inter alia* on the ground that the subject-matter of the patent extended beyond the content of the application as filed (Article 100(c) EPC). Therefore the amendments comprised in present claim 1 which were already comprised in claim 1 as granted must be fully examined by the Board as to whether or not that objection is well founded.

4.2 Claim 1 comprises the amended feature defining the vinyl acetate acrylate copolymer as being a copolymer of at least 2-ethylhexyl acrylate and vinyl acetate. The Appellants and the Respondent had divergent views on the matter whether or not the application as filed provided a proper basis for that amendment.

4.3 In order to determine whether or not the subject-matter of a claim in a patent extends beyond the content of the application as filed it has to be examined whether that claim comprises technical information which a skilled person would not have objectively and unambiguously derived from the application as filed.

4.4 Notwithstanding their divergent views, the Respondent and the Appellants, in support thereof, referred exclusively to the same first paragraph of page 7 of the application as filed as providing or not a proper basis for that amended feature.

It is true that this paragraph of the application as filed is actually the sole specification of the monomer 2-ethylhexyl acrylate, however, only in order to define the Morstik® 607 and the GELVA® materials "which are believed to be based on 2-ethylhexyl acrylate". Thus, it has to be established whether or not those specific commercial products form a proper basis for generalising that monomer to become a mandatory feature of any copolymer covered by claim 1, i.e. copolymers of at least 2-ethylhexyl acrylate and vinyl acetate.

The commercial products referred to in this paragraph describe particular vinyl acetate 2-ethylhexyl acrylate copolymers. Therefore, in the Board's judgement, the skilled person derives from the disclosure of those commercial products in the application as filed nothing more than the bare disclosure of their specific structural elements and (co)monomers ratios, and their specific product characteristics in their particular combination.

Therefore, the original disclosure of those particular combinations of specific structural elements and (co)monomers ratios, and specific product characteristics cannot support the generalisation indicated in claim 1 which results in covering copolymers having any ratio of 2-ethylhexyl acrylate and vinyl acetate, and including any further comonomer. To dismantle the particular monomer "2-ethylhexyl acrylate" from further specific product characteristics of those commercial products and to generalise the presence of that particular monomer over the whole scope of copolymers according to claim 1 provides the skilled person with technical information which is not

directly and unambiguously derivable from the application as filed.

Thus, the commercial products Morstik®607 and GELVA® do not provide a proper basis for defining the specific sub-group of copolymers as now defined in claim 1. As a consequence, claim 1 is an undue generalisation of what was originally disclosed generating fresh subject-matter.

- 4.5 Therefore the Board concludes that claim 1 extends the subject-matter claimed beyond the content of the application as filed justifying the ground for opposition pursuant to Article 100(c) EPC, so that the main request must be rejected.

First and second auxiliary request

5. *Amendments (Articles 100(c) and 123 (2) EPC)*

- 5.1 The Respondent has presented two fresh auxiliary requests comprising an amended claim 1 in the course of the oral proceedings before the Board (see point IV above). In case of such amendments, they must be fully examined by the Board as to their compatibility with the requirements of the EPC, such as with the provisions of Article 123 EPC; furthermore Article 100(c) EPC was raised as a ground for opposition in the present case.

- 5.2 Claim 1 of both auxiliary requests includes the features derived from claim 3 of the main request and claim 2 as granted, namely that the copolymer comprises or consists of, respectively, "approximately 72 wt%

2-ethylhexyl acrylate and approximately 28 wt% vinyl acetate (Monsanto GELVA® 737)" (cf. point IV above).

- 5.3 That feature has been extracted from an affidavit submitted during the examination proceedings on 20 September 1993 which was purported to indicate the chemical composition of GELVA® 737.

It is established case law of the Boards of Appeal that the content of the application as filed only encompasses what is directly and unambiguously disclosed in the original application either explicitly or implicitly. In this context implicit disclosure means disclosure which any person skilled in the art would objectively consider as necessarily implied in the explicit content.

- 5.4 The Respondent's affidavit describes GELVA® 737 as being a copolymer of exclusively "approximately 72 wt% 2-ethylhexyl acrylate and approximately 28 wt% vinyl acetate" without giving any further details on that chemical product. However, the mere indication of two comonomers in an approximate amount is not a complete description of that particular commercial product. It is necessarily characterised by additional features such as its state of matter (e.g. liquid, solid, in solution) and, since it is a copolymer, by further polymeric features such as molecular weight and polymeric structure (linear, branched, etc.). Therefore, the specifications in the claims of GELVA® 737 are an incomplete definition of that specific commercial product and indicate merely a part of the particular characteristics implicitly disclosed in combination by means of that specific product. A generalisation of the

originally disclosed product GELVA® 737 has thus been made since features mandatory for its characterisation have been omitted. Therefore the features indicated in the claim define a copolymer which is broader in scope than the originally disclosed particular commercial product and, thus, embraces copolymers and products different to GELVA® 737.

As a consequence the features given in claim 1 are not based on the implicit disclosure of that commercial product but are an undue generalisation thereof which extends beyond the content of the application as filed.

5.5 The definition given in the claims for GELVA® 737 specifies the presence of only two comonomers in that copolymer. However, documents (9) and (35) reveal that further comonomer(s) appear to be incorporated in the copolymer which is in solution. The omission of those comonomers in the definition given in claim 1 of auxiliary requests 1 and 2 would represent a further undue generalisation of the originally disclosed product GELVA® 737.

However, in view of the deficiencies indicated in point 5.4 above, there is no need for the Board indeed to establish whether or not the definition given in these claims is also defective as regards the comonomers indicated.

5.6 Accordingly, claim 1 of the first and second auxiliary request contravenes the requirement of Article 123(2) EPC. In these circumstances, these requests of the Respondent are not allowable and must be rejected pursuant to Article 100(c) EPC.

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. Moser

R. Freimuth