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D E C I S I O N
of 8 October 1998

Case Number: T 0871/96 - 3.3.2

Application Number: 86112848.6

Publication Number: 0216303

IPC: A61K 47/00

Language of the proceedings: EN

Title of invention:
External medication

Patentee:
Kao Corporation

Opponent:
Henkel Kommanditgesellschaft auf Aktien

Headword:
External medication/KAO

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty (yes) - no individualisation of the claimed medication"
"Inventive step (no): disclaimer neutral in assessing of the inventive step"
"Experimental confirmation of an effect clearly suggested by the closest prior art"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0871/96 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 8 October 1998

Appellant: (Proprietor of the patent)
Kao Corporation
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Representative:
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Respondent: (Opponent)
Henkel
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Representative:
-

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 26 July 1996 revoking European patent No. 0216303 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: C. Germinario
R. E. Teschemacher

Summary of Facts and Submissions

I. European Patent No. 0 216 303 was granted in response to European patent application No. 86 112 848.6 on the basis of one single claim for all the designated Contracting States.

II. Notice of opposition was filed by the respondent, requesting revocation of the patent in its entirety on the grounds of lack of novelty and lack of inventive step. The opponent relied on the following documents:

(1) EP-A-0 025 302
(2) JP-A-82-123108 (German translation)
(3) EP-B-0 144 069
(4) EP-A-0 162 239

III. In its interlocutory decision, which was based on a new set of three amended claims, the opposition division held that none of documents (1) to (3) could be considered as prejudicial to the novelty and to the inventive activity of the subject-matter of the amended claims.

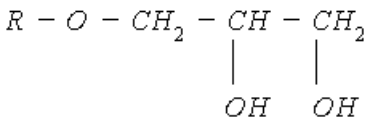
As regards document (4), which was comprised in the state of the art pursuant to Article 54(3) and (4) EPC, the opposition division held that all the elements and features defining the subject-matter of claim 1 of the patent in suit, namely the α-monoglyceryl ether, the oily material, the physiologically active material, the emulsion type preparation, and the enhanced percutaneous absorption of the physiologically active material were all disclosed in this document. As to the skin-occlusive properties of the external medication of

claim 1, which were not explicitly mentioned in (4), the opposition division expressed the opinion that, as this feature resulted from the association of the α-monoglyceryl ether with the oily material, both disclosed in (4), there was no reason or indication to conclude that the skilled person in carrying out the teaching of (4) would arrive at a preparation having different properties compared with the external medication of the present patent. Therefore, the opposition division was of the view that the teaching of (4) made available all the aspects of the claimed subject-matter. The patent was accordingly revoked on the ground of lack of novelty.

IV. The appellant (patentee) lodged an appeal against this decision. Oral proceedings were held on 8 October 1998.

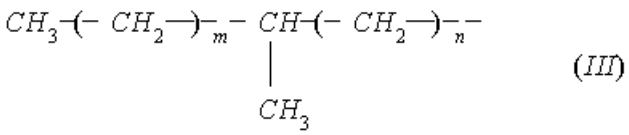
During the written proceedings the appellant filed a new amended single claim reading as follows:

"Use of α-monoglyceryl ether represented by the following formula (I)



(I)

wherein R means a monomethyl-branched alkyl group represented by the following formula (III)



(III)

wherein m stands for an integer of 2 to 14, n is an integer of 3 to 11 and the sum of m and n is 9 to 21 in combination with an oily material and a physiologically active material for preparing an external medication of the emulsion type with skin occlusive properties which does not contain a cholesteryl ester of fatty acids, wherein the α-monoglyceryl ether together with the oily material improve the percutaneous absorption of said physiologically active material".

V. In the statement setting out the grounds of appeal and during the oral proceedings, the appellant expressed the opinion that the novelty of the claimed subject-matter over (4) had to be recognised, firstly, because the external medication to be prepared according to the claim was novel in itself, and secondly, because the claimed intended use of said medication for skin occlusion was also novel.

As to the first point, he stressed that the composition of (4) was not in the form of an emulsion, as was evident from the examples. Although, as underlined by the respondent, document (4) also envisaged as a possible formulation a "cream" (see page 11, line 9), this did not necessarily imply that said cream was in the form of an emulsion.

Additionally, the appellant argued that the presence in the composition of (4) of an oily material was merely optional.

As to the second point, the appellant stressed the double aspect of the present invention, which consisted

in the preparation of an external medication exhibiting, at the same time, skin-occlusive properties and an enhanced percutaneous absorption of the active agent. Document (4) simply related to the latter aspect, without giving any instruction to the skilled person as to the former aspect. Thus, the skin-occlusive property for the compositions of (4) remained an undisclosed feature hidden in the teaching of that document. The recognition of this hitherto unknown effect opened a novel way of technical applications, namely the preparation and use of medicaments for the treatment of diseases which previously required a special occlusive dressing technique. For these reasons, document (4) could not prejudice the novelty of the subject-matter claimed in the patent at issue.

VI. The respondent shared the view of the opposition division that the compositions disclosed in (4), having all the structural features of the external medication of the present invention, necessarily also exhibited all the same properties, including the occlusive properties, which therefore were neutral for the assessment of the novelty of the claim.

VII. At the oral proceedings, the inventive step involved in the claimed subject-matter over the teaching in documents (1) to (3) was also discussed by the parties. Document (2) was indicated as the closest prior art.

The appellant, having highlighted the essential feature of the medication of the patent claim represented by the enhanced percutaneous adsorption of the physiologically active material, maintained that document (2) was not concerned with this aspect since

all the medicaments cited in this document (see page 8, first paragraph) were intended for external topical application.

VIII. The appellant (patentee) requested that the decision under appeal be set aside and the patent be maintained on the basis of the single claim submitted on 12 August 1997.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. The new amendments in the single claim do not introduce subject-matter questionable under Article 123(2) EPC as they are disclosed in the original application, more precisely in the single claim and in the description, on page 6, formula III, on page 11, lines 4 to 7 and 19 to 24, and on page 12, lines 1 to 5. As compared with the granted claim, the amended claim gives a more precise definition of the invention. Therefore the protection conferred by the granted claim is not extended (Article 123(3) EPC).

Allowability under Article 123 EPC was not disputed by the respondent.

3. *Novelty*

3.1 The patent was revoked by the opposition division for lack of novelty over document (4), which is comprised in the state of the art pursuant to Article 54(3) and (4) EPC.

The subject-matter of the single claim under consideration is the use of an α-monoglyceryl ether of formula (I) as further defined by formula (III), in combination with an oily material and a physiologically active material for preparing an external medication in the form of an emulsion. The specific monoglyceryl ether, the oily material, the physiologically active material and the emulsion form represent a fixed combination of essential structural features which define the medication according to the claim. Only the same fixed combination of features, described in individualised form in a document of the prior art could be prejudicial to the novelty of the claimed subject-matter.

3.2 Document (4) describes percutaneous adsorption accelerator preparations, which may exhibit all the four aforementioned structural features, though not necessarily in concomitant combination.

It is undisputed that none of the examples cited in (4) discloses preparations exhibiting the abovementioned fixed combination of structural features. Therefore none of them is prejudicial to the novelty of the patent claim. This was inherently admitted by the respondent who did not base his arguments of lack of

novelty on any specific examples, but simply on the general part of this document.

On the other hand, said general part of (4) gives the skilled reader the following teaching.

As to the monoglyceryl ether, the document discloses on pages 8 to 10 about thirteen families of compounds exemplified by means of as many as 40 specific compounds. Among those cited, there is the monomethyl-branched alkyl α-monoglyceryl ether of formula (I) and (III) according to the patent claim see (4), page 8, line 13 "*1-O-methyl-branched isostearylglycerols*" as further defined by the formula on page 6. However, the use of this specific compound is one choice of the many possibilities envisaged in (4).

An oily material is also envisaged in the formulation of (4) as a compound having a percutaneously adsorbing property (see page 10, lines 12 to 21). It must however be noted that not only this compound is an optional component of the formulation of (4), as is evident from preparations 5 to 8 of example 1 (pages 21 and 22), but it is furthermore not necessarily an oily material. In fact, among the twelve examples of punctual compounds or families of compounds cited in the last paragraph of page 10, some of them, such as dimethylsulfoxide, dimethylacetamide or dimethylformamide, are water-soluble liquids. Therefore, the presence in the composition of an oily material is, in the board's view, the result of a further choice to be made by the skilled person.

The further essential feature of the medication according to the patent is the form of the medication, namely an emulsion. Document (4) does not cite *expressis verbis* emulsion-type preparations, but indicates many topical preparations, such as a liquid spraying agent, a lotion, an ointment, a cream, a gel, a sol, an aerosol, a cataplasm or a plaster (see page 11, first paragraph). As agreed by the parties at the oral proceedings, and in accordance with the general common knowledge, under the term "cream" the skilled person understands, though not exclusively, an emulsion. However, regardless of its meaning, the option "cream" represents in any case a still further choice among all the envisaged possible formulations.

From the foregoing, it becomes clear that, by relying on document (4), the skilled person would be obliged to choose from different groups of many independent options the specific α-monoglyceryl ether, an oily material and the specific emulsion type formulation and to combine the result with a physiologically active agent in order to obtain a composition falling within the scope of the single patent claim. The result of this process of various choices and combinations would be a specific composition, which is not actually individualised in document (4). At least for this reason, the teaching in document (4) is not prejudicial to the novelty of the amended single claim of the patent at issue.

3.3 Among the other cited documents, only document (2) was considered during the opposition proceedings for the purpose of novelty. However, the opposition division was satisfied that the novelty of the patent claim over

the content in (2) was formally guaranteed by disclaiming the "cholesteryl ester of fatty acids" from the scope of the patent claim.

3.4 As no other document can be regarded as relevant for the purpose of novelty, the board's judgment is that the subject-matter of the amended single claim is novel.

4. *Inventive step*

4.1 Although the patent was revoked for lack of novelty, inventive step has also been discussed before the first instance and the opposition division has also commented, in the decision under appeal, on this question with reference to documents (1) to (3). For this reason, the appellant had the opportunity to argue the question of inventive step before this instance. Hence, there is no reason for the Board to refer the case back to the opposition division to deal with inventive step again.

4.2 As seen above, the novelty of the subject-matter of the patent claim versus document (2) is formally provided by the disclaimer which excises from the scope of the protection the oily material "cholesteryl ester of fatty acids".

According to established Board of Appeal case law, in cases where what is claimed in general overlaps with an incidental anticipation in the prior art, it is permissible to exclude the content of such an anticipation from the scope of the claim by means of a disclaimer, even if it is not disclosed in the original application. However, as clarified by decision T 170/87 (OJ EPO 1989, 41), a disclaimer can be used to make an

inventive teaching which accidentally overlaps with the state of the art, novel, but it cannot make an obvious teaching inventive. Therefore, the limiting clause represented by the disclaimer is meaningless in assessing the inventive step, if any, involved in the claimed subject-matter. For this reason, and as already laid down in decision T 434/92 (28 November 1995, not published in the OJ), the invention in its entirety and without discontinuities between the claimed subject-matter and that part of the original subject-matter excised by way of a disclaimer has to solve uniformly what is regarded as the underlying technical problem.

4.3 Due to its accidental character, an accidental anticipation normally looses most of its relevance after introduction into the claim of a correct and admissible disclaimer. It is not the case here, and the board shares the opinion of the parties that document (2) represents the closest prior art.

This document discloses a W/O emulsion comprising the same α-monoglyceryl ether of the present invention (see (2) claim 3), an oily material and a physiologically active material. The oily material comprises, as an essential component, a cholesteryl ester of fatty acids, optionally in addition to other oily materials such as those cited in the patent under opposition (see (2), claim 1 and page 7, first and second paragraphs from the bottom). The physiologically active material is an antiphlogistic, a bactericide, an antiallergic, a vitamin or an agent for preserving skin humidity, as described in the first paragraph of page 8 and in examples 2 to 5. The intended purpose of the emulsion is that of causing skin occlusion, thereby preventing

transpiration and loss of water from the epidermis (page 4, last paragraph).

4.4 In the circumstances of the present case, it becomes clear that the exclusion from the scope of the claim of "Cholesteryl ester of fatty acids" cannot contribute in any way to the definition of the technical problem underlying the present invention. Thus the technical problem may be defined as the enlargement of the field of applicability of the emulsion disclosed in document (2).

4.5 The solution proposed by the patent at issue is the use of the external medication according to the single patent claim [and equally according to document (2)] to achieve, in addition to the skin-occlusive effect already recognised in (2), the effect of **allowing** the percutaneous absorption of the physiologically active material administered topically.

4.6 During the oral proceedings, the appellant repeatedly highlighted the effect brought about by the external medication of the invention of an "enhanced" percutaneous absorption. In the appellant's opinion, this effect, which is specifically emphasised by the wording of the claim: "wherein the α-monoglyceryl ether together with the oily material... improve the percutaneous absorption..." (emphasis added), is substantiated by the comparative examples reported in the patent disclosure.

The Board cannot share this opinion because any consideration focussing on an alleged "improved" or "enhanced" effect could only derive from the comparison

with another composition different from that claimed. However, any such a different composition would represent a state of the art far more distant from the claimed medication than the compositions disclosed in document (2), which are simply formally different but substantially identical to those of the patent in suit.

Neither could an alleged "therapeutically effective systemic absorption" from the claimed medication be considered by the board, since this aspect is simply not part of the invention. Such an effect is indeed neither disclosed in general nor proved experimentally by results. Concerning this point, the appellant pointed out, during the oral proceedings, the results reported in table 1 illustrating the blood level of indomethacin upon administration of the composition of the invention or comparative compositions. In the board's view, however, table 1 merely proves that there is indeed a percutaneous absorption of the medicament into the blood stream. Whether or not the blood levels reported in the table are sufficient to prove a therapeutically effective systemic absorption is a question which is nowhere answered in the patent disclosure.

For all these reasons, the board cannot take into account for the formulation of the technical problem any alleged improvement in percutaneous absorption, but simply the "existence" of a percutaneous adsorption in itself.

4.7 As seen above, the experimental tests reported in the patent disclosure prove indisputably that the physiologically active material is actually absorbed

through the skin upon topical administration. Therefore the board is satisfied that the problem has been solved.

4.8 The decisive question is whether or not the proposed solution is derivable in an obvious way from the teaching in the closest prior art or any other document.

Document (2) underlines, on page 8, first paragraph, that the emulsion described is specifically suitable as a base excipient for compositions and cosmetic products intended for topical application. When this emulsion is used as an excipient for topical application, it may comprise active agents such as antiphlogistic, bactericide, antiallergic agents, vitamins or occlusive substances. Examples 2, 3 and 4 report respectively an antiphlogistic cream, a disinfectant cream and a cream comprising vitamins.

In the appellant's contention all the active agents cited in (2) are intended for external use only. Therefore they are not expected to be absorbed, but to perform their therapeutic effect simply at the surface of the skin. For this reason, document (2), beyond the skin occlusive effect, could not suggest to the skilled person the novel application envisaged by the patent at issue.

The board does not question that a topical composition is normally intended for local treatment and that it should normally prevent the systemic absorption of the active agent. However, this is not in contradiction with the fact that the active agent, such as an antiphlogistic as envisaged in (2), must, upon topical administration, be able to be absorbed, though only at

local level, in the depth of the tissues in order to perform its therapeutic activity. As a matter of common general knowledge and as pointed out by the respondent at the oral proceedings, many commercial topical antiphlogistic compositions are used in the treatment of inflammatory states within the tissues, eg the muscle system. This medical use necessarily and indisputably implies that the anti-inflammatory agent is percutaneously absorbed.

Therefore, in the board's view, not only would the skilled reader of (2) not associate the therapeutic compositions of (2) with a strictly external therapeutic effect, but he would also understand that the emulsions disclosed in (2) actually allow at least a local percutaneous absorption of the physiologically active material, that could specifically be expected when this material is an antiphlogistic medicament.

Under these circumstances, the board is of the opinion that the contribution made by the patent at issue was simply to confirm by way of experimental results an effect already clearly suggested by the closest prior art document. Thus, the subject-matter of the single patent claim does not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Martorana P. Lançon