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**Datasheet for the decision  
of 16 July 2009**

**Case Number:** T 2041/08 - 3.3.07

**Application Number:** 01944453.8

**Publication Number:** 1299068

**IPC:** A61K 7/00

**Language of the proceedings:** EN

**Title of invention:**

Sulfur containing dermatological compositions and methods for reducing malodors in dermatological compositions

**Applicant:**

Medicis Pharmaceutical Corporation

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 84, 111(1), 123(2)

**Keyword:**

"Amendments - added subject-matter (yes) - main request, 1<sup>st</sup>, 2<sup>nd</sup> auxiliary requests"

"Clarity and conciseness (no) - 1st auxiliary request"

"Amendments - added subject-matter (no) - 3<sup>rd</sup> auxiliary request"

"Remittal (yes) - 3rd auxiliary request"

**Decisions cited:**

T 0157/90, T 0187/91

**Catchword:**

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Case Number: T 2041/08 - 3.3.07

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.07  
of 16 July 2009

**Appellant:** Medicis Pharmaceutical Corporation  
7720 North Dobson Road  
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**Representative:** Vossius & Partner  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 15 April 2008  
refusing European application No. 01944453.8  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** S. Perryman  
**Members:** D. Semino  
B. ter Laan

## Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application No. 01 944 453.8 originating from international application PCT/US01/18907 having an international filing date of 12 June 2001, claiming a priority of 30 June 2000 (US 09/607,881) and published as WO-A-02/02059. The application as filed contained 36 claims. Claim 1 read as follows:

"1. A composition suitable for topical application to human skin or hair, comprising:  
at least one sulfur ingredient; and  
a pharmaceutically acceptable carrier; wherein  
the composition has a pH of from about 6.5 to about 8.1."

II. In its decision posted on 15 April 2008, the examining division refused the application on the ground that the sole request of 13 claims filed with letter dated 12 February 2008 did not comply with the requirements of Article 123(2) EPC.

Claim 1 of that request read as follows:

"1. A composition suitable for topical application to human skin or hair, comprising:  
a pharmaceutically acceptable carrier;  
wherein the composition has a pH of 6.5 to 8.1, wherein  
the composition comprises precipitated sulfur and  
wherein the composition comprises sodium sulfacetamide,  
and wherein the carrier is a cleanser."

III. The examining division found that there was no disclosure in the application as originally filed of a composition comprising precipitated sulfur and sodium sulfacetamide with a cleanser carrier, particularly in combination with the pH values provided (6.5 to 8.1). The application as originally filed referred to lotions, face masks and cleanser as possible formulations for the treatment of acne. As such, limiting the claims solely to a cleanser did not appear to be representative of the original intended scope of the application. Moreover, there was no direct and unambiguous disclosure of the combination of precipitated sulfur and sodium sulfacetamide, so that the amended set of claims did not meet the requirements of Article 123(2) EPC.

IV. On 24 June 2008, the applicants (appellants) filed a notice of appeal against the above decision, the prescribed fee being paid on the same day. With the statement setting out the grounds of appeal filed on 25 August 2008, the appellants maintained as main request the amended set of claims upon which the decision under appeal was based. Two further sets of 9 and 8 claims respectively were filed as first and second auxiliary requests.

Claim 1 of the first auxiliary request read as follows:

"1. A composition suitable for topical application to human skin or hair, comprising:  
a pharmaceutically acceptable carrier;  
wherein the composition has a pH of 7.0 to 7.1, wherein the composition comprises precipitated sulfur and wherein the composition comprises sodium sulfacetamide,

and wherein the carrier is a cleanser and the composition exhibits substantially reduced sulfur odor."

Claim 1 of the second auxiliary request read as follows:

"1. A composition suitable for topical application to human skin or hair, comprising:  
disodium oleamide MEA sulfosuccinate, sodium methyl oleyltaurate, PEG-55 propylene glycol oleate, sodium cocoyl isethionate, methylparaben, propylparaben, Na<sub>2</sub>EDTA, BHT, water, cetyl alcohol, stearyl alcohol, sorbitan stearate, glyceryl stearate and PEG-100 stearate, sulfacetamide sodium, sodium thiosulfate, precipitated sulfur, magnesium aluminium silicate, and xanthan gum;  
wherein the composition is a cleanser composition and has a pH of from 7.0 to 7.1, or from 7.3 to 7.7."

- V. Oral proceedings were held on 16 July 2009. During the oral proceedings the appellants submitted a further set of 5 claims as third auxiliary request.

Claim 1 of the third auxiliary request read as follows:

"1. A cleanser composition suitable for topical application to human skin or hair, comprising:  
disodium oleamide MEA sulfosuccinate, sodium methyl oleyltaurate, PEG-55 propylene glycol oleate, sodium cocoyl isethionate, methylparaben, propylparaben, Na<sub>2</sub>EDTA, BHT, water, cetyl alcohol, stearyl alcohol, sorbitan stearate, glyceryl stearate and PEG-100 stearate, sulfacetamide sodium, sodium thiosulfate,

precipitated sulfur, magnesium aluminium silicate, and xanthan gum;  
wherein the composition has a pH of from 7.0 to 7.1."

VI. The arguments of the appellants can be summarized as follows:

- (a) Cleansers were mentioned in the original description and in several original claims (for instance in original claim 36). Furthermore, all samples of example 3 were cleanser compositions with several different pH values. Article 123(2) did not require that for the limitation to a "cleanser composition" cleansers were explicitly defined as preferred compositions in the original text, but only that cleanser compositions were disclosed.
  
- (b) Original claim 1 concerned a composition comprising "at least one sulfur ingredient". On page 4, line 14 to page 6, line 8, of the description suitable sulfur ingredients were disclosed, including elemental sulfur and sulfur compounds. As preferred sulfur compounds, sulfur sulfacetamide (page 4, lines 16-17) and precipitated sulfur (page 5, lines 5-6) were mentioned. In addition, in all examples (including example 3 directed to cleanser compositions) a combination of sodium sulfacetamide and precipitated sulfur was used, which clearly indicated that this combination was preferred.

Further, original claims 18 and 19 and also 10-12, 20-22 and 32-34 gave a clear indication that a

combination of precipitated sulfur and sodium sulfacetamide was a preferred combination; since all those claims referred to a pH of 6.5 to 8.1, said combination was also disclosed together with that pH range.

(c) Reference was made to T 187/91 (OJ EPO, 1994, 572) and T 157/90 of 12 September 1991 to support the argument that the purpose of Article 123(2) EPC was mainly to inform the skilled reader of the published European patent application of the maximum extent of its subject-matter, and therefore its maximum content, some time before the text of the application was finalised. In the present case, amended claim 1 was narrower in scope than original claim 1 and included a limitation to features all individually disclosed in the original application and corresponding to the preferred idea of the invention. Even though those features were not explicitly mentioned in combination, the skilled person would know from the whole disclosure that that specific combination of features was preferred. Therefore Article 123(2) EPC was complied with.

(d) As to the auxiliary requests, the first auxiliary request eliminated the possible concerns related to the disclosure of the specific features of claim 1 of the main request in combination with the broad pH range, claim 1 according to the second auxiliary request was based on example 3 and original claim 8, while claim 1 of the third auxiliary request was limited only to the embodiment of example 3, so that they should

overcome all possible objections regarding fulfilment of the requirements of Article 123(2) EPC.

VII. The appellants requested that the decision under appeal be set aside and that the case be remitted for further prosecution on the basis of the set of claims 1 to 13 filed on 28 February 2008 as main request, or on the basis of claims 1 to 9 of the first auxiliary request or claims 1 to 8 of the second auxiliary request both filed 25 August 2008, or claims 1 to 5 of the third auxiliary request filed at the oral proceedings on 16 July 2009.

## **Reasons for the Decision**

1. The appeal is admissible.

### *Main request*

2. *Amendments*

2.1 Claim 1 of the main request has been amended compared to claim 1 as originally filed in the following features:

(a) the presence in the composition of "at least one sulfur ingredient" has been replaced by the feature "wherein the composition comprises precipitated sulfur and wherein the composition comprises sodium sulfacetamide";

(b) the carrier should now be a cleanser;



(c) the definition of the pH as "of from about 6.5 to about 8.1" has been replaced by "a pH of 6.5 to 8.1".

2.2 Amendment (c) has not been objected to by the examining division and the Board sees no reason to take a different view.

2.3 With regard to amendment (b), the original claims mention three possible carriers, namely a lotion (claims 6 and 29), a mask (claims 7 and 30) and a cleanser (claims 8, 31, 35 and 36), which disclosure is confirmed also by the examples, example 1 concerning a lotion, example 2 a mask and example 3 a cleanser. In view of this, the requirement that the carrier should be a cleanser amounts to a selection out of a list of three explicitly mentioned alternatives. While claims 8 and 31 mention specific narrow ranges of pH (7.3 to 7.7 and 7.0 to 7.1 respectively), in example 3 several pH values falling under the range of original claim 1 are disclosed in combination with a cleanser (Table on page 22). Cleansers are further mentioned in the description (e.g. page 4, line 6; page 6, line 10) without any reference to a limited pH range. Therefore, the disclosure in the original application indicates a cleanser as one explicitly disclosed alternative for the carrier of claim 1 for the whole pH range disclosed therein, so that the addition of feature (b) by itself would meet the requirements of Article 123(2) EPC.

2.4 However, as to amendment (a), original claims 4-5, 18-19 and 27-28, to which the appellants referred, only mention either one or the other compound as the sulfur

ingredient. None of these claims provides a basis for the specific combination of precipitated sulfur and sodium sulfacetamide.

2.4.1 Also the general part of the original description where information is provided about suitable sulfur ingredients (page 4, line 14 to page 5, line 6) does not provide a basis for the combination of precipitated sulfur and sodium sulfacetamide. The first sentence of that cited part of the description mentions a number of classes of sulfur compounds (elemental sulfur, sulfides, sulfites and mercaptans and combinations thereof). Sodium sulfacetamide is mentioned as a preferred sulfur compound (page 4, lines 16-17) and precipitated sulfur is mentioned as a preferred form of sulfur (page 5, lines 5-6). The combination of precipitated sulfur and sodium sulfacetamide within the sulfur ingredients therefore results from a first selection of the classes of sulfur compounds and a second selection of choosing the preferred element within each of the classes. That amounts to a multiple selection out of lists of a certain length which results in new information which cannot be considered as directly and unambiguously disclosed in the cited passages of the original description.

2.4.2 As to the original examples, although precipitated sulfur and sodium sulfacetamide are present in the three compositions disclosed therein, they are disclosed in specific mixtures with other specific compounds and they are not the only sulfur compounds present therein. In particular, the only composition referring to a cleanser (example 3) also contains sodium methyl oleyltaurate, disodium oleamide MEA

sulfosuccinate, sodium cocoyl isethionate and sodium thiosulfate as further sulfur compounds. Hence, the examples cannot provide a basis for the disclosure of precipitated sulfur and sodium sulfacetamide without the combination with the other compounds. The same applies to the disclosure in claims 10-12, 20-22 and 32-34, where the same lists of components as in examples 1-3 are disclosed.

2.5 While amendment (a) by itself has no direct and unambiguous disclosure in the original application, also its combination with amendment (b) results from multiple selections out of different individual pieces of information contained in the original application. In other words, while the individual features "the carrier is a cleanser", "the composition comprises precipitated sulfur" and "the composition comprises sodium sulfacetamide" are disclosed in the original application and one specific example is present in which all three features are present, however in a specific composition containing other ingredients, no basis can be found for the intermediate generalisation of claim 1 of the main request in which the three features are present in combination without being limited to the specific composition of example 3.

2.6 No different conclusion can be reached in view of the case law cited by the appellants, in particular with reference to T 187/91 (*supra*). Article 123(2) EPC is meant to guarantee that no extension of subject-matter takes place after filing. However, this cannot be interpreted as meaning that any limitation with respect to the original disclosure should be allowable under Article 123(2) EPC as long as some basis for the

limiting features is present in the original application. It is established case law (see Case Law of the Board of appeal of the EPO, 5th edition 2006, III.A.2) that the relevant question to be decided in assessing whether the requirements of Article 123(2) EPC have been met is whether the proposed amendments, each by itself as well as in combination, were directly and unambiguously derivable from the application as filed. Therefore, in a case as the present one, in which no disclosure can be found in the original application for the specific combination of features resulting from the amendments, the requirements of Article 123(2) EPC cannot be considered as being met.

*First auxiliary request*

3. *Amendments*

3.1 Claim 1 of the first auxiliary request contains the same combination of features (cleanser, sodium sulfacetamide, precipitated sulfur) as the main request, for which no basis was found to be present in the original application. For the same reasons as above, claim 1 of the first auxiliary request does not meet the requirements of Article 123(2) EPC either.

4. *Clarity*

4.1 Claim 1 of the first auxiliary request specifies that "the composition exhibits substantially reduced sulfur odor" without giving any information about the conditions with respect to which a reduction of the desired property should take place, nor any indication of how the claimed result should be determined.

Moreover, such information is neither present in the description, nor have the appellants been able to provide any proof that a standard method exists by means of which the skilled person could determine whether a composition possesses the claimed property.

4.2 It is not clear from the disclosure in the application whether the exhibition of substantially reduced sulfur odor should be considered as a limiting feature or is a direct result from the remaining features of the claim. However, in both cases the requirements of Article 84 EPC cannot be considered as satisfied. If the feature is not limiting and any composition with the proper pH range possesses the disputed property, then the amended feature is superfluous and results in lack of conciseness. If instead it is meant to further limit the scope of the claim, then in the absence of a clear reference to the conditions with respect to which a reduction should take place and of a method of measurement, it results in lack of clarity.

4.3 For these reasons, claim 1 according to the first auxiliary request does not meet the requirements of Article 84 EPC.

#### *Second auxiliary request*

#### 5. *Amendments*

5.1 Claim 1 of the second auxiliary request contains, with respect of claim 1 of the main request, the following amendments:

- (a) a full list of components is given; in addition to precipitated sulfur and sodium sulfacetamide, disodium oleamide MEA sulfosuccinate, sodium methyl oleyltaurate, PEG-55 propylene glycol oleate, sodium cocoyl isethionate, methylparaben, propylparaben, Na<sub>2</sub>EDTA, BHT, water, cetyl alcohol, stearyl alcohol, sorbitan stearate, glyceryl stearate and PEG-100 stearate, sodium thiosulfate, magnesium aluminium silicate, and xanthan gum are specified;
- (b) the formulation of the composition as a cleanser is expressed by the direct specification that "the composition is a cleanser composition" instead of mentioning a pharmaceutically acceptable carrier which is a cleanser;
- (c) the pH range is limited to "from 7.0 to 7.1, or from 7.3 to 7.7".

5.2 Amendment (b) only amounts to a reformulation of the claim which does not change its scope and does not need to be discussed in any further detail.

5.3 The list of components under amendment (a) corresponds to the components of the cleanser compositions of example 3, which further specifies a number of pH values at which samples were prepared (page 21, lines 17-19 and Table on page 22). However, example 3 cannot provide a proper basis for a composition including the components as in that example, but with a pH "from 7.3 to 7.7", since only one pH value falling within the range is disclosed in the Table on page 22 (pH of 7.5) and there is no disclosure of the two

limits of the range. Also original claims 8 and 12 cannot provide a basis for a cleanser composition comprising the specific list of components and with a pH in the range from 7.3 to 7.7. Although the former refers to a cleanser with the specific pH and the latter to a composition with the specific components, those claims, only depending on original claim 1, have no relationship to each other. As to the original description, the pH range 7.3 to 7.7 is disclosed only as the preferred one in example 2, which, however, concerns a mask and not a cleanser with a composition that contains a different list of components and results in a quite different product, so that it cannot provide a basis for a cleanser with the components of example 3 and a pH of 7.3 to 7.7.

- 5.4 Therefore, since the pH range of 7.3 to 7.7 is not disclosed in the original application in combination with the other features of claim 1 of the second auxiliary request, also the second auxiliary request does not meet the requirements of Article 123(2) EPC.

*Third auxiliary request*

6. *Amendments*

6.1 Claim 1 of the third auxiliary request concerns a cleanser composition comprising the components listed in example 3 in combination with a pH of "from 7.0 to 7.1".

6.2 In example 3 it is specified that a reference sample of the cleanser composition was prepared with the listed components and a pH of 7.0 to 7.1 (page 21, lines 17-18)

and was considered as obtaining the best performance in terms of smell reduction (results in the Table on page 22). Example 3 therefore provides a direct basis for the combination of features of claim 1 of the third auxiliary request. In this respect the Board is of the opinion that the person skilled in the field of cosmetics would have recognised that the claimed features were not so closely associated with the other features of the examples (in particular the specific composition) as to determine the effect of that embodiment of the invention to a significant degree, so that claim 1 of the third auxiliary request meets the requirements of Article 123(2) EPC.

6.3 Claim 2 of the third auxiliary request is based on the disclosure on page 6, lines 12-15, where a list of additional ingredients which may be included in the compositions of the invention are listed, while claims 3 to 5 of the request are also based on example 3 (see the quantities of the components in the list starting on the bottom of page 18 and the use of the composition for treating acne rosacea on page 21, lines 23-16). For these reasons, it is concluded that the whole set of claims of the third auxiliary request meets the requirements of Article 123(2) EPC.

7. The decision under appeal did not consider claim 1 as in the third auxiliary request, since such request was submitted only in appeal in consideration of the objections under Article 123(2) EPC raised by the Board. In addition, no decision has been taken by the first instance on novelty and inventive step of the single request before it. Under these circumstances and in view of the explicit request of the appellants in this



respect, the Board considers it appropriate to exercise the power conferred by Article 111(1), second sentence EPC to remit the case to the examining division for further prosecution.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted for further prosecution on the basis of the claims 1 to 5 of the third auxiliary request filed at the oral proceedings on 16 July 2009.

The Registrar

The Chairman

S. Fabiani

S. Perryman