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Datasheet for the decision of 21 September 2020

Case Number: T 0833/17 - 3.3.07

Application Number: 03772600.7

Publication Number: 1556009

IPC: A61K9/12

Language of the proceedings: EN

Title of invention:
COSMETIC AND PHARMACEUTICAL FOAM

Patent Proprietor:
Foamix Pharmaceuticals Ltd.

Opponents:
Guderma GmbH
Henkel AG & Co. KGaA

Headword:
Cosmetic and pharmaceutical foam /FOAMIX

Relevant legal provisions:
EPC Art. 123(2), 123(3), 83, 84, 54(2), 56
EPC R. 103

Keyword:

Amendments - added subject-matter (no) - broadening of claim (no)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)
Reimbursement of appeal fee - (yes)

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Case Number: T 0833/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 September 2020

Appellant: (Opponent 1)	Guderma GmbH Am Hohen Kamp 12 59192 Bergkamen (DE)
Representative:	Glawe, Delfs, Moll Partnerschaft mbB von Patent- und Rechtsanwälten Postfach 13 03 91 20103 Hamburg (DE)
Appellant: (Opponent 2)	Henkel AG & Co. KGaA Henkelstrasse 67 40589 Düsseldorf (DE)
Representative:	Henkel AG & Co. KGaA CLI Patents Z01 40191 Düsseldorf (DE)
Respondent: (Patent Proprietor)	Foamix Pharmaceuticals Ltd. 2 Holzman Street Weizmann Science Park Rehovot 7670402 (IL)
Representative:	Nack, Ralph Noerr Partnerschaftsgesellschaft mbB Rechtsanwälte BriennerStr.28 80333 Munich GERMANY
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 February 2017 concerning maintenance of the European Patent No. 1556009 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	C. Schmidt

Summary of Facts and Submissions

I. European Patent 1 556 009 (hereinafter "the patent") was granted on the basis of 19 claims.

Claim 1 of the patent pertained essentially to an alcohol-free foamable pharmaceutical or cosmetic carrier, comprising defined amounts of:

- a foamable composition comprising a liquid, non-volatile hydrophobic solvent, water, selected foam adjuvant agents, selected surfactants, and a water gelling agent; and

- a liquefied or compressed gas propellant.

II. Two oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

III. The opposition division took the interlocutory decision that, on the basis of the main request filed on 19 January 2017, the patent met the requirements of the EPC.

Claim 1 of this main request read as follows:

"An alcohol-free foamable pharmaceutical or cosmetic carrier, comprising:
a foamable composition comprising:
about 2-5% by weight of composition of a liquid, non-volatile hydrophobic solvent and about 80-98% by weight of composition of water; or about 5-10%

by weight of composition of a liquid, non-volatile hydrophobic solvent and about 75-95% by weight of composition of water; or about 10-20% by weight of composition of a liquid, non-volatile hydrophobic solvent and about 60-90% by weight of composition of water; or about 20-75% by weight of composition of a liquid, non-volatile hydrophobic solvent and about 25-75% by weight of composition of water;

about 0.1% to 5% by weight of composition of a foam adjuvant agent selected from the group consisting of fatty alcohols, fatty acids, hydroxyl-substituted fatty alcohols, hydroxyl-substituted fatty acids, and fatty acids and fatty alcohols including at least one double bond in its carbon atom chain;

about 0.1% to 5% by weight of composition of a surfactant, wherein the surfactant is solely non-ionic, comprising one or more non-ionic surfactants, or wherein the surfactant is a mixture of one or more non-ionic surfactants and one or more ionic surfactants in a ratio greater than 6:1, and

about 0.1% to 5% by weight of composition of a water gelling agent,

and

a liquefied propellant, at a concentration of about 5% to about 25% by weight of the foamable carrier, wherein the liquefied propellant comprises a volatile hydrocarbon or fluorocarbon gas;

wherein, the combined amount of foam adjuvant agent, surface-active agent and water gelling agent is less than about 5% by weight of the foamable composition;

wherein when the composition is released from a container, it provides a shear-force breakable foam suitable for topical or mucosal administration that does not break down easily on discharge but which upon rubbing onto the skin collapses easily."

IV. The appealed decision made reference, among others, to the following documents:

D1: B. Ziolkowsky "Modem aerosol foams in cosmetics", Seifen-Ole-Fette-Wachse, 112(13), 1986, pages 429-429

D7: EP 0213827

D30: US 5378451

V. In particular, the opposition division found that:

(a) The combination of the feature pertaining to the presence of a propellant with the amounts for each component did not infringe Article 123(2) EPC.

(b) The term "volatile" introduced into the claim did not lack clarity in the context of propellants.

(c) The requirements of sufficiency of disclosure were met. Despite the fact that the feature pertaining to the ability of the composition to provides a shear-force breakable foam was unclear, the skilled person had enough instruction to know what was encompassed by the claim.

(d) The claimed subject-matter was novel over the insect repellent foam of D1, because in the composition of D1 the ratio of non-ionic surfactants to ionic surfactants was not greater than 6:1.

(e) D7 was selected as the most promising starting point for the assessment of inventive step. The subject-matter of claim 1 differed from the emulsion concentrate of D7 in that a liquefied propellant comprising a volatile hydrocarbon or fluorocarbon gas was used, and in that the amount of foam adjuvant, surfactant and water gelling agent were limited to less than 5%. The problem to be solved was the provision of an easily collapsible foam able to provide high levels of hydrophobic agent. The prior art did not motivate the skilled person to modify the disclosure of D7 in these two aspect. Thus an inventive step was acknowledged.

VI. Both opponent 1 (appellant 1) and opponent 2 (appellant 2) filed an appeal against the above interlocutory decision.

VII. In its reply to the appellants' statements of grounds of appeal, the patent proprietor (respondent) defended its patent on the basis of the main request upheld by the opposition division and on the basis of auxiliary requests 1-8, all filed on 19 January 2017 before the opposition division.

VIII. On 2 April 2020, the Board notified to the parties its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

IX. By letter dated 20 July 2020, appellant 2 withdrew its request for oral proceedings. By letter dated 21 August 2020, appellant 1 withdrew its appeal and requested a reimbursement of its appeal fee. The oral proceedings were cancelled.

X. Appellant 2's arguments, as far as relevant for the present decision, can be summarised as follows:

(a) The main request did not meet the requirements of Article 123(2) EPC, because the combination of features of claim 1 of the main request was not derivable from the application as filed. In particular, neither the upper limit of 5% for the combined amounts of foam adjuvant agent, surface-active agent and water gelling agent nor the feature pertaining to the volatile hydrocarbon or fluorocarbon gas were originally presented as preferred, such that their combination represented added subject-matter.

(b) In comparison with claim 1 as granted, in claim 1 of the main request, the propellant represented about 5-25% by weight of the "foamable carrier" and not anymore of the "total composition". However, in several passages of the patent as granted, the amount of 5-25% was either based on the total composition with propellant or on the composition without propellant. As a result, the amendment of "total composition" into "foamable carrier" led to a shift in the protection conferred, and thus infringed Article 123(3) EPC.

(c) In claim 1 of the main request, in comparison with claim 1 as granted, the liquefied propellant had been limited by the feature that it comprised a

volatile hydrocarbon or fluorocarbon gas. The term "volatile" was a relative term and was unclear in the absence of indication of the pressure at which these propellants should be liquefied, as confirmed by D30.

Furthermore it was unclear whether the foamable carrier used as basis for the calculation of the 5-25% propellant referred to the total composition with or without propellant.

(d) As acknowledged in the appealed decision, the feature "when the composition is released from a container, it provides a shear-force breakable foam suitable for topical or mucosal administration that does not break down easily on discharge but which upon rubbing onto the skin collapses easily" was unclear. The patent neither provided a definition nor a method of measurement, such that it could not be verified if this feature was fulfilled. It was furthermore not credible that this result was achieved over the whole range of propellant concentrations. The patent did not teach how to select the components and their concentrations so as to obtain an acceptable foam. Consequently, the main request did not fulfill the requirements of sufficiency of disclosure.

(e) The subject-matter of claim 1 of the main request lacked novelty over the insect repellent foam of D1 (see page 429, "Insektenabwehrschaum"). In particular, the composition of D1 comprised a propellant gas which was a mixture of chlorofluorocarbons (CFC). In light of paragraph [0168] of the description, such CFCs fell within the scope of claim 1.

(f) Regarding inventive step, D7 represented the closest prior art. D7 described a composition comprising an emulsion concentrate and up to 5wt% propellant gas. The subject matter of claim 1 of the main request differed from the composition of of D7 by the nature of the propellant, and in that the combined amount of foam adjuvant agent, surface-active agent and water gelling agent was less than about 5% by weight of the foamable composition.

Regarding the nature of the propellant, D7 disclosed that it was preferable to dispense with hydrocarbons and halogenated hydrocarbon gases. The aim of the D7 was to provide a stable mousse that did not foam. If, however, based on D7, the task was to produce a less stable foam that broke more easily due to shear forces, a person skilled in the art would have learned from D1 that better foaming could be achieved with propane or butane. The subject-matter of claim 1 was therefore not inventive over D7 in combination with D1.

Alternatively, D1 could represent the closest prior art in view of its similar purpose and number of matching features. Starting from the insect repellent foam disclosed in D1, if the amount of nonionic surfactant was regarded as a distinguishing feature, the corresponding effect was according to paragraph [0062] of the patent less irritation to the skin for the foam quality. This effect of nonionic surfactants was however known from D1, D7 and D30. As to the type of propellant, if it was regarded as a distinguishing

feature over D1, the use of hydrocarbons was also disclosed in D1.

Accordingly, the main request did not satisfy the requirements of inventive step.

XI. The respondent's arguments, as far as relevant for the present decision, can be summarised as follows:

(a) The main request complied with Article 123(2) EPC. Claim 1 of the main request was based essentially on the disclosure in the application as filed of four general classes of formulation (i.e. compositions of Class A, Class B, Class C and Class D), each of which further contained the same amounts ("about 0.1 to 5%") of foam adjuvant agent, surface-active agent and water gelling agent. Additionally, the range of propellant content and its nature were limited as disclosed on page 22, lines 20-21 of the application as filed.

(b) The amendments complied with Article 123(3) EPC and did not broaden the protection conferred.

(c) The objections raised by the appellants under Article 83 EPC appeared to be in reality arguments of lack of clarity under Article 84 EPC, which was not a ground for opposition.

(d) The subject-matter of claim 1 was novel over the insect repellent of D1 because the latter contained ionic surfactant such that the ratio of non-ionic surfactant to ionic surfactant was not greater than 6:1, and because the propellants used in D1 were chlorofluorocarbon (CFC) propellants, and not hydrocarbons or fluorocarbons.

(e) Regarding inventive step, D7 was the closest prior art, because it disclosed a non-lathering, foamable composition comprising a high level of hydrophobic solvent, non-ionic surfactants, a foam adjuvant and a water-gelling agent. Additionally, like the compositions of the present invention, the composition of D7 was a non-rinse formulation designed to deliver skin conditioning agents to the skin. In contrast, the formulations of D1 typically had high levels of ionic surfactant and/or contained no gelling agent.

The subject-matter of claim 1 of the main request differed from D7 in that the combined amount of foam adjuvant agent, surface-active agent and water gelling agent was less than 5% by weight, and in that it required the use of a liquefied hydrocarbon or fluorocarbon propellant, at a concentration of about 5% to about 25% by weight of the total composition.

The objective problem was the provision of a non-irritant, low specific gravity, more voluminous foam with a high content of hydrophobic material that collapsed easily when rubbed onto the skin. D7 did not provide the skilled person with any motivation to replace its nitrous oxide propellant with a higher amount of the claimed liquefied propellants. On the contrary, D7 advised against the use of hydrophobic propellants such as hydrocarbons. D1 did not provide any motivation either to replace the nitrous oxide propellant with a liquefied hydrocarbon or fluorocarbon propellant in the emulsion concentrate of D7.

XII. Appellant 2 requests that the decision under appeal be set aside and that the patent be revoked.

XIII. The respondent requests that the appeals be dismissed and the patent be maintained on the basis of the main request, or alternatively, on the basis of one of the auxiliary requests 1-8, all filed on 19 January 2017.

Reasons for the Decision

Main request

1. Article 123(2) EPC

According to appellant 2, the combination, in claim 1 of the main request, of the upper limit of 5% for the combined amounts of foam adjuvant agent, surface-active agent and water gelling agent with the feature pertaining to the volatile hydrocarbon or fluorocarbon gas represents added subject-matter. The Board does not share this view. The upper limit of 5% for the combined amounts of components is the lowest of the two values given on page 23 (lines 10-12) of the description as filed, namely 8% and 5%. The volatile hydrocarbon or fluorocarbon gases are the only suitable propellants disclosed on page 22 (lines 21-23), and can accordingly be considered as preferred. This conclusion is not modified by the passage cited by appellant 2 (page 47), which generally mentions examples of liquefied and compressed gas propellants but does not present them as suitable in the claimed invention. Under these circumstances, the Board does not regard the combination of these features as extending beyond the content of the application as filed.

Accordingly, the main request meets the criteria of Article 123(2) EPC.

2. Article 123(3) EPC

2.1 The following feature of claim 1 of the patent as granted has been amended as follows in the main request:

"a liquefied ~~or compressed gas~~ propellant, at a concentration of about 5% to about 25% by weight of the ~~total composition~~ foamable carrier, wherein the liquefied propellant comprises a volatile hydrocarbon or fluorocarbon gas" (amendments emphasized by the Board)

2.2 Appellant 2 considers that the amendment of "total composition" into "foamable carrier" infringes Article 123(3) EPC.

2.3 In the Board's view, claim 1 as granted relates to an "alcohol-free foamable pharmaceutical or cosmetic carrier" comprising "a foamable composition" and a propellant. The amount of propellant is 5-25% by weight "of the total composition". The expression "total composition" is ambiguous as it could refer either to the foamable composition (i.e. the claimed composition without the propellant) or to the foamable carrier (i.e. the claimed composition with the propellant). This ambiguity can be resolved, and the extent of the protection conferred by the granted patent can be determined, by interpreting the claim in light of the description. Paragraph [0084] of the patent specification clarifies that the 5-25wt% of propellent are based on the foamable carrier, i.e. the "total

composition including propellant, foamable compositions and optional ingredients". This is not contradicted by the passages cited by appellant 2: paragraph [0175] mentions 5-25w% of a composition mass without defining what this composition mass refers to, and page 4 (lines 49-51) does not mention any amount for the propellant.

Accordingly, the scope of protection is not extended by the amendments of "total composition" into "foamable carrier", because these expressions as synonymous in the context of the patent as granted. The main request complies with the requirements of Article 123(3) EPC.

3. Clarity

3.1 In claim 1 of the main request, in comparison with claim 1 as granted, the liquefied propellant has been limited by the feature that it comprises a volatile hydrocarbon or fluorocarbon gas. This feature was not present in the claims as granted and is therefore open to examination for compliance with Article 84 EPC. The Board nonetheless shares the opinion of the opposition division in this respect. Although the term "volatile" is *per se* a relative term, it does not lead to a lack of clarity because the skilled person would know how to choose such volatile hydrocarbon or fluorocarbon gas in the context of the liquefied propellant component. The arguments of appellant 2 regarding the absence of indication of the pressure at which the propellant is liquid are not related to the clarity of the term "volatile". In this regards, the reference to claim 1 of D30 is unconvincing since this passage of D30 does not mention the term "volatile".

3.2 Appellant 2 furthermore expressed the view that the foamable carrier used as basis for the calculation of

the 5-25% propellant is not clearly defined. The Board does not concur. The antecedent for the expression "foamable carrier" in claim 1 is clearly the "alcohol-free foamable pharmaceutical or cosmetic carrier", i.e. the whole claimed composition or "total composition including propellant, foamable compositions and optional ingredients". This interpretation is in accordance with the description (see 2.3 above).

3.3 In summary, the amendments do not introduce any non-compliance with the criteria of Article 84 EPC.

4. Sufficiency of disclosure

4.1 Appellant 2 objected to insufficiency of disclosure in respect of the feature "when the composition is released from a container, it provides a shear-force breakable foam suitable for topical or mucosal administration that does not break down easily on discharge but which upon rubbing onto the skin collapses easily". In the Board's view, the arguments put forward by the appellants and relating to the absence of measurement method or objective criteria for assessing this feature pertain to the possibility to ascertain the boundaries of the claim, which is an issue of clarity rather than sufficiency of disclosure. No evidence was filed regarding compositions comprising the claimed components in the claimed amounts and failing to meet this criteria. There is thus no serious reason to doubts that the skilled person would be able to prepare compositions meeting the features of claim 1.

Accordingly, the main request meets the requirements of sufficiency of disclosure.

5. Novelty

D1 discloses an insect repellent foam, i.e. a foamable pharmaceutical or cosmetic carrier, comprising a foamable composition and 10% of propellant gas 12/114 (see page 429, "Insektenabwehrschaum"). The propellant gas 12/114 is a mixture of chlorofluorocarbons (CCl_2F_2 and $ClF_2C-CClF_2$).

The Board shares the respondent's opinion that the propellant 12/114 does not qualify as a hydrocarbon or fluorocarbon gas. The CFC propellants of D1 neither fall within the commonly accepted definition of hydrocarbons (compounds consisting of carbon and hydrogen only) nor that of fluorocarbons (compounds consisting wholly of fluorine and carbon). The passage of the description cited by appellant 2 ([0168]) cites CFC among liquid propellants, but it does not redefine hydrocarbons or fluorocarbons. Thus, in the insect repellent foam of D1, the propellant does not comprise a volatile hydrocarbon or fluorocarbon gas.

It is accordingly not necessary to determine whether D1 discloses that the ratio between the non-ionic surfactants (chremophor A11 and and glycerine stearate) and the ionic surfactants (according to the respondent, the soap formed by triethanolamine and stearic acid) is greater than 6:1.

Accordingly, the main request meets the criteria of novelty.

6. Inventive step

6.1 The problem underlying the present invention is to provide foam compositions suitable for topical

treatment that do not comprises alcohol, that are robust and suitable for inclusion of a wide range of active ingredients. Upon discharge from an aerosol container, the composition should form a breakable foam which does not break down immediately upon discharge, but collapses to spread easily onto a skin area upon slight rubbing (see paragraphs [0030]-[0031]).

6.2 D7 (see columns 1 and 2) addresses a similar problem of achieving the right foam stability: D7 aims at providing a skin cleansing mousse-forming composition which is non-foaming, i.e. does not lather and does not require rinsing from the skin. The Board therefore concurs with the opposition division in that D7 represents a suitable starting point for the assessment of inventive step.

6.2.1 D7 describes (see claim 1) a composition comprising an emulsion concentrate and 0.5-5wt% of a water-soluble propellant gas. The emulsion concentrate generally comprises:

- 1.5-15wt% of a nonionic surfactant,
- 10-40wt% of an emollient,
- 5-20wt% of a skin moisturizer, and
- the balance water.

In example 1 of D7, the composition contains 2wt% pressurized nitrous oxide as propellant, and an emulsion concentrate comprising:

- 19wt% hydrophobic components (mineral oils in Semtol 70 M.O. and Amerchol L-101; emolients, namely ethylhexyloxystearate and myristylethoxy(3)palmitate),
- about 65% water,

- 2.9wt% fatty alcohols (cetyl alcohol and lanolin alcohol in the Amerchol L-101) which can be regarded as foam adjuvant agents,
- 4.1wt% non-ionic surfactants (Glucamate SSE-20 and Glucate SS) and 0.1wt% ionic surfactant (Na_4EDTA) as surface-active agents, and
- 0.1wt% of a water gelling agent (carbopol 1342),

6.2.2 In the Board's view, the subject matter of claim 1 of the main request differs from the composition of example 1 of D7 by the following features:

- the liquefied propellant is present at a concentration of about 5% to about 25% by weight of the foamable carrier,
- the liquefied propellant comprises a volatile hydrocarbon or fluorocarbon gas, and
- the combined amount of foam adjuvant agent, surface-active agent and water gelling agent is less than about 5% by weight of the foamable composition.

6.2.3 The claimed foamable carriers are not shown to achieve any particular effect, as a result of these differences, in comparison with the composition of D7.

6.2.4 Starting from D7, the technical problem to be solved is therefore to provide a further alcohol-free foamable carrier which upon release forms a shear-force breakable foam suitable for topical or mucosal administration that does not break down easily on discharge but which upon rubbing onto the skin collapses easily.

6.2.5 The opposition division pointed to the passage of D7 (column 7, lines 36-39) according to which the composition is preferably free of hydrocarbon and

halohydrocarbon propellants. The opposition division also questioned that the skilled person would have an incentive to decrease the amount of adjuvants (i.e. foam adjuvant agent, surface-active agent and water gelling agent). The Board concurs. Considering the statement regarding hydrocarbon and halohydrocarbon propellants in D7, the skilled person would not consider a combination with the teaching of D1 (see page 428, top of the left column) and at the same time lower the amount of said adjuvants. It is additionally noted that the above passage of D1 relates to the choice between hydrocarbon or fluorohydrocarbon propellents, but it does not mention any effect of using such propellants in comparison with e.g. water-soluble propellants as in D7 or the chlorofluorocarbons of the insect repellent composition of D1.

6.3 An objection of lack of inventive step starting from D1 as closest prior art was also raised by appellant 2. The Board however notes that in the insect repellent composition of D1, the components identified by the appellants as non-volatile hydrophobic solvents (6% dimethyl phthalate and / or 6% diethyl toluamide) are in fact the insect repellent active compounds. The insect repellent foam of D1 is thus a fully formulated composition including active ingredients, and not a carrier comprising hydrophobic solvents to be used for inclusion of water or oil soluble pharmaceutical and cosmetic agents.

6.3.1 It is therefore doubtful whether D1 is equally suitable as D7 as a starting point for the assessment of inventive step. However, even if starting from D1, the Board concludes that the subject-matter of the main request involves an inventive step for the following reasons.

6.3.2 The subject-matter of claim 1 of the main request differs from the CFC-containing insect repellent foam of D1 as explained above with respect to novelty (see 5.), i.e. at least in that the propellant comprises a volatile hydrocarbon or fluorocarbon gas.

6.3.3 No effect is demonstrated to arise from this differentiating feature. The problem to be solved is therefore the same as above (see 6.2.4), namely to provide a further alcohol-free foamable carrier which upon release forms a shear-force breakable foam suitable for topical or mucosal administration that does not break down easily on discharge but which upon rubbing onto the skin collapses easily.

6.3.4 In order to arrive at the claimed subject-matter, the skilled person would firstly have to consider modifying the particular insect repellent composition of D1 in respect of the propellant component, possibly in addition to the surfactant components. But additionally, the skilled person would have to anticipate that modified composition would solve the problem, i.e. be suitable as a foamable carrier. Appellant 2 did not substantiate why the prior art would make the use of such a modified fully formulated composition as a carrier for inclusion of water or oil soluble pharmaceutical and cosmetic agents obvious.

Accordingly, the subject-matter of the main request complies with the requirements of Article 56 EPC.

7. Refund of the appeal fee

By letter dated 21 August 2020, appellant 1 withdrew its appeal and requested a reimbursement of its appeal fee in accordance with Rule 103(4)(a) EPC.

Rule 103(4)(a) EPC, in its version as in force since 1 April 2020, provides for a reimbursement of the appeal fee at 25% if the appeal is withdrawn after expiry of the period under paragraph 3(a) - which was the case here - and before a decision was announced at the oral proceedings.

Since, in the current case, no oral proceedings took place, the withdrawal also occurred before a decision could be announced at oral proceedings. Thus the requirements of Rule 103(4)(a) EPC are met and the appeal fee is to be reimbursed at 25%.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. 25% of appellant 1's appeal fee is to be reimbursed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated