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Case Number: T 1689/10 - 3.3.10

Application Number: 04292331.8

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Language of the proceedings: EN

Title of invention:
Retinoid-containing compositions having reduced irritation effect

Applicant:
Johnson & Johnson Consumer France SAS

Headword:
Retinoid-containing compositions/JOHNSON & JOHNSON

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
T 0197/86, T 0939/92

Catchword:
-

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Case Number: T 1689/10 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 11 July 2013

Appellant: (Applicant)
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 5 February 2010 refusing European patent application No. 04292331.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
F. Blumer

Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division refusing European patent application No. 04 292 331.8.

II. The Examining Division held that the subject-matter of the then pending main request and auxiliary request I extended beyond the content of the application as filed and did not admit auxiliary requests II and III into the proceedings for being late-filed and *prima facie* unallowable. It held that the subject-matter of auxiliary requests IV and V lacked inventive step over documents (3) and (7):

(3) US-A-2003/095959 and
(7) WO-A-00/67626.

document (3) describing that the skin irritation caused by topical compositions containing retinoids could be alleviated by the incorporation into the composition of irritancy mitigants such as oat extract. The skilled person, when seeking alternative irritancy mitigants would look to document (7), which taught the use of an oat extract containing aventhranamide for the preparation of a dermatological composition for the treatment of inflammations and/or irritations of the skin.

III. With a letter dated 14 June 2010, the Appellant (Applicant) submitted a main request and auxiliary requests I to V.

Claim 1 of the main request read as follows:

"A composition comprising:
(a) retinol, and
(b) avenanthramide or an avenanthramide derivative as the interleukin-8 inhibitor,
(c) wherein said composition provides at least about a 40 percent reduction in interleukin-8 produced by human epidermis after contact with said composition compared with a control composition comprising the same ingredients in the same amounts except for the said interleukin-8 inhibitor measured by the ELISA method."

Claim 1 of auxiliary request I differed from claim 1 of the main request exclusively in that the avenanthramide or avenanthramide derivative was specified as being present in an amount of 0.0001 to 0.00035 weight-%.

Claim 1 of auxiliary request II differed from claim 1 of auxiliary request I exclusively in that the retinol was specified as being present in an amount of 0,001 to 1 wt.-%.

Claim 1 of auxiliary request III differed from claim 1 of the main request exclusively in that the avenanthramide or avenanthramide derivative was specified as being present in an amount of 0.0005 weight-% or less.

Claim 1 of auxiliary request IV differed from claim 1 of auxiliary request I exclusively in that the retinol was specified as being present in an amount of 0,075 wt.-%.

Claim 1 of auxiliary request V differed from claim 1 of auxiliary request I exclusively in that component (a) was specified as being at least one retinoid.

IV. The Appellant argued that with regard to inventive step, document (3), which disclosed topical skin compositions for the cosmetic treatment of aging, represented the closest prior art. The claimed compositions were inventive thereover, since the focus of said document was on the mandatory ingredients of the compositions described therein, namely an anti-superoxide component, an anti-hydrogen peroxide and/or an anti-peroxyl radical component, and an anti-hydroxyl radical component. Retinoids such as retinol were merely one of many optional ingredients, oat extract being a further optional ingredient, when retinoids were present. Although document (3) taught that retinoids caused skin irritation, it solved that problem by either reducing the concentration of retinoids in the compositions or by incorporating an irritancy mitigant therein. Thus, to arrive at the present invention, the skilled person had to first choose the latter option and then the oat extract from a list of thirteen irritancy mitigants. There was, however, no motivation to purposively opt for oat extract, let alone to actively select avenanthramide among the active compounds of oat extracts, such that the argumentation of the Examining Division denying inventive step was based on hindsight. Document (7) taught that apart from avenanthramide, the carbohydrates and protein in oat derivatives also had beneficial effects on the skin, such that to arrive at the claimed compositions, avenanthramide also had to be chosen from within this document. Furthermore, although said document taught the use of avenanthramide for

treating erythema, pruritus, otitis, inflammations, irritations, and/or allergies affecting the skin, as well as in the treatment of sensitive skin and/or redness, it did not teach that avenanthramide could treat the skin irritation caused by retinoids. In addition, from Table 2 of the present application, it could be seen that a composition comprising avenanthramide was more effective in reducing interleukin-8 release than a composition comprising oat straw. The amounts of active ingredients specified in the auxiliary requests were those specific amounts which led to a high reduction in interleukin-8 production, and were much narrower ranges and much smaller amounts than those disclosed in the cited prior art. An inventive step could therefore also be based on these specific amounts.

V. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or, subsidiarily, on the basis of one of auxiliary requests I to V, all requests filed with letter dated 14 June 2010.

VI. At the end of the oral proceedings, held on 11 July 2013, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Inventive Step*

Main request

2.1 The Board considers, in agreement with the Examining Division and the Appellant, that the closest prior art is the disclosure of document (3).

Document (3) discloses topical skin compositions (see claim 1) which may contain retinoids such as retinol (see paragraph [0055]). It teaches that retinoids tend to irritate the skin such that irritancy mitigants such as oat extract may be incorporated into the composition to assist in preventing undue discomfort to the user (see paragraph [0056]).

2.2 In view of this state of the art, the Appellant defined the problem underlying the present application as the provision of alternative compositions comprising retinol which counteract the skin irritation caused by said retinol.

2.3 As the solution to this problem, the main request proposes a composition as defined in claim 1, characterised in that it contains avenanthramide or an avenanthramide derivative.

2.4 Having regard to the test results given in Examples 1 to 4 of the present application, the Board is satisfied that the technical problem as defined in point 2.2

above has been successfully solved by the claimed compositions.

2.5 Finally, it remains to decide whether or not the proposed solution to the problem underlying the application is obvious in view of the state of the art.

2.5.1 When starting from a composition comprising retinol known from document (3), it is a matter of course that the person skilled in the art seeking to provide an alternative composition wherein the skin irritation known to be caused by the retinol is reduced, would turn his attention to that prior art addressing compounds for use in compositions which treat skin irritation, for example, document (7). Said document (see claims 10 to 14) teaches that an oat extract containing avenanthramide may be used for the preparation of a topical dermatological composition for treating *inter alia* inflammations and irritations affecting the skin. Document (7) thus gives a clear incentive on how to solve the problem underlying the application in suit of providing merely alternative compositions comprising retinol which counteract the skin irritation caused by the retinol, namely by incorporating avenanthramide into the retinol-containing compositions of document (3). Thus by combining the teachings of documents (3) and (7), the person skilled in the art would arrive at the subject-matter of claim 1 of the main request without exercising an inventive step.

2.6 For the following reasons, the Board is not convinced by the Appellant's submissions in support of the presence of an inventive step.

2.6.1 The Appellant argued that the compositions were inventive over document (3), since the focus of said document was on the mandatory ingredients of the compositions described therein, namely an anti-superoxide component, an anti-hydrogen peroxide and/or an anti-peroxyl radical component, and an anti-hydroxyl radical component. Retinoids such as retinol were merely one of many optional ingredients.

However, present claim 1 is not directed to compositions containing **only** retinol and avenanthramide or a derivative thereof, but rather to compositions **comprising** these ingredients, such they may contain any other additional components including, for example, the mandatory ingredients of document (3). Thus, the compositions of present claim 1 do not differ from those of document (3) in this respect and the Appellant's argument is thus not pertinent.

2.6.2 The Appellant further argued that document (7) taught that apart from avenanthramide, the carbohydrates and protein in oat derivatives also had beneficial effects on the skin, such that avenanthramide had to be chosen from other active ingredients disclosed in this document. Indeed, the combination of avenanthramide together with the treatment of skin irritation from the list of other skin ailments disclosed in document (7) and retinol from document (3) was only obvious with the benefit of hindsight.

However, the starting point for assessing inventive step is the composition containing retinol according to document (3) (see point 2.1 above). The fact that the

skilled person had several alternatives at his disposition when looking for an alternative irritancy mitigant for incorporation into the retinol-containing compositions of document (3) has no impact on the assessment of inventive step, since a mere choice from a host of possible solutions does not in itself involve inventive ingenuity (see decision T 939/92, OJ EPO 1996, 309, points 2.5.2 and 2.5.3 of the reasons). Indeed there is in fact a specific motivation to choose avenanthramide from within document (7), since the claims of said document are directed specifically to compositions containing this active ingredient, carbohydrates and protein for soothing the skin being mentioned merely in the description of the background art (see page 2, lines 1 to 3).

2.6.3 Finally, the Appellant argued that it could be seen from Table 2 of the present application that a composition comprising avenanthramide was more effective in reducing interleukin-8 release than a composition comprising oat straw, such that the selection of this specific active ingredient from an oat extract provided an unexpected effect *vis-à-vis* the teaching of document (3).

However, according to established jurisprudence, in the case where comparative tests are chosen to demonstrate an inventive step with an improved effect, the nature of the comparison with the closest state of the art must be such that the effect is convincingly shown to have its origin in the feature differentiating the invention from this prior art (see T 197/86, OJ EPO 1989, 371, points 6.1.2 and 6.1.3 of the reasons).

In the present case, and as acknowledged by the Appellant at the oral proceedings before the Board, the amounts of the various active ingredients given in Table 2 for purposes of comparison are not the same. More particularly, the two test products according to the invention contain Dragocalm® "at concentrations of 1.5 wt.% and 3.5 wt.% (0.0001 to 0.00035 wt.% of active matter)" (see page 8, penultimate two lines), said active ingredient being avenanthramide (see page 4, lines 1 to 2), whereas the test product referred to by the Appellant for comparison contains oat straw at a concentration of 0.1 wt.% as well as willow herb at the same concentration. Thus, any effect shown may in fact be merely due to these differing amounts and not necessarily to the nature of the active ingredient. In addition, it has not been shown that oat straw does not itself contain avenanthramide. Thus no unexpected effect has been shown by the Appellant which might support the presence of an inventive step.

2.7 As a result, the Appellant's main request is not allowable as the subject-matter of claim 1 thereof lacks inventive step pursuant to Article 56 EPC.

Auxiliary requests I to V

3. Claim 1 according to the auxiliary requests I to V has been amended *vis-à-vis* claim 1 of the main request in that component (a), namely retinol, is specified as being present in an amount of 0.001 to 1 wt.-% (auxiliary request II) or 0.075 wt.-% (auxiliary request IV) and component (b), namely avenanthramide or a derivative thereof, is specified as being present in an amount of 0.0001 to 0.00035 weight-% (auxiliary

request I, II, IV and V) or 0.0005 weight-% or less (auxiliary request III). The wording of claim 1 of auxiliary request V differs additionally from claim 1 of auxiliary request I in that component (a) is defined as being at least one retinoid.

3.1 No unexpected effect has been shown to be associated with the particular weight amounts of avenanthramide or a derivative thereof and of retinol specified in claim 1 of these auxiliary requests. The act of picking out at random a range or particular value for the amounts of avenanthramide or a derivative thereof and of retinol is within the routine activity of the skilled person faced with the mere problem of providing alternative compositions comprising retinol which counteract the skin irritation caused by the retinol. In the present case, the skilled person is all the more guided to pick out the amounts claimed, since topical skin compositions comprising retinoids in an amount of 0.01 to 5% by weight are preferred in document (3) (see paragraph [0057]) and compositions for treatment of skin comprising avenanthramide in a concentration of 0.01 to 150 ppm, which corresponds to 0.000001 to 0.0150 wt.-%, are described in document (7) (see claim 1). Therefore, the arbitrary choice of amounts falling under those already taught in the state of the art cannot provide the claimed composition with any inventive ingenuity. In addition, the replacement of the feature "retinol" by "at least one retinoid" in claim 1 of auxiliary request V cannot contribute to inventive step, since the generic term "retinoid" embraces the specific compound "retinol", such that all argumentation and conclusions of the Board herein regarding the inventiveness of compositions containing

retinol apply equally to compositions containing retinoids.

3.2 The Appellant argued that the amounts of active ingredients specified in the auxiliary requests were those specific amounts which led to a high reduction in interleukin-8 production, as shown in the Examples of the application in suit, and were much narrower ranges and much smaller amounts than those disclosed in documents (3) and (7).

However, so long as no unexpected effect has been shown to be associated with the particular weight amounts claimed, they may only be regarded as arbitrary, the "high" reduction in interleukin-8 production shown in the Examples of the application in suit not having been compared with that obtained with amounts outside the claimed ranges.

3.3 Thus, the auxiliary requests I to V are also not allowable, since the subject-matter of claim 1 of each request lacks an inventive step pursuant to Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka