

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [x] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 12 June 2008**

Case Number: T 1239/05 - 3.3.10

Application Number: 97948203.1

Publication Number: 0941051

IPC: A61K 7/42

Language of the proceedings: EN

Title of invention:

Sunscreen with disappearing color indicator

Patentee:

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.

Opponents:

The Boots Company PLC
BEIERSDORF AG
HENKEL KGaA

Headword:

Sunscreen/SCHERING-PLOUGH

Relevant legal provisions:

EPC Art. 100(c), 123(3)

Keyword:

"Main and auxiliary requests 1, 2, 9 to 11: extension of protection conferred (yes) - deletion of a proviso"
"Auxiliary requests 3 to 8: added subject-matter (yes) proviso not unambiguously derivable from the application as filed"

Decisions cited:

T 0288/92, T 0680/93

Catchword:

-



Case Number: T 1239/05 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 12 June 2008

Appellant: SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.
(Patent Proprietor) 3030 Jackson Avenue
Memphis
TN 38151 (US)

Representative: Adams, Harvey Vaughan John
Mathys & Squire LLP
120 Holborn
London EC1N 2SQ (GB)

Respondent I: The Boots Company PLC
(Opponent 1) 1 Thane Road West
Nottingham NG2 3AA (GB)

Representative: Jones, Stephen Anthony
AdamsonJones
BioCity Nottingham
Pennyfoot Street
Nottingham NG1 1GF (GB)

Respondent II: BEIERSDORF AG
(Opponent 2) Unnastrasse 48
D-20245 Hamburg (DE)

Representative: Dinné, Erlend
Hardenbergstrasse 11
D-22587 Hamburg (DE)

Respondent III: HENKEL KGaA
(Opponent 3) VTP (Patente)
D-40191 Düsseldorf (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 28 July 2005
revoking European patent No. 0941051 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:
Chairman: R. Freimuth
Members: J.-C. Schmid
F. Blumer

Summary of Facts and Submissions

I. The Appellant (Proprietor of the patent) lodged an appeal on 26 September 2005 against the decision of the Opposition Division posted on 28 July 2005 revoking European patent No. 941 051, independent claim 1 thereof reading as follows:

"1. A colored sunscreen emulsion comprising:

- a) 0.0005 to 0.5 percent by weight of at least one water-soluble dye that imparts a color other than white to the sunscreen emulsion, such that when the sunscreen emulsion dries after it is spread on skin and/or is rubbed into skin, the color substantially disappears;
- b) at least one sunscreen active ingredient in an amount effective to protect against the actinic radiation of the sun;
- c) at least one emulsifier; and
- d) sufficient water to form the colored emulsion,

the water-soluble dye being such that the disappearance of color of the sunscreen emulsion is not a result of a change in its pH."

II. Notices of Opposition had been filed by the Respondents I, II and III (Opponents (1), (2) and (3) respectively) requesting revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficient disclosure (Article 100(b) EPC), and of extending the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).

III. The Opposition Division held that the feature found in the granted claim 1 that "the water-soluble dye being such that the disappearance of the colour of the sunscreen emulsion is not a result of a change in its pH" was not directly and unambiguously derivable from the application as filed, but was a proviso based on an undue generalisation.

The amendments carried out in independent claims 1 of the then pending auxiliary request 1 did not fulfil the requirements of clarity while claim 1 of the then pending auxiliary request 2 met the requirement of Article 123(2) and (3) EPC but its subject-matter lacked novelty (Article 54 EPC).

IV. At the oral proceedings before the Board held on 12 June 2008 the Appellant defended the maintenance of the patent in suit on the basis of the claims of a main request or subsidiarily on the basis of the claims of auxiliary requests 1 to 11, the claims of the main and auxiliary requests 1 and 2 being identical to the claims filed on 9 June 2008 as former auxiliary requests 8, 9 and 10 respectively, the claims of auxiliary requests 3 to 9 being identical to the claims filed in opposition proceedings with letter dated 12 May 2005 as former auxiliary requests 1 to 7 respectively, while the claims of auxiliary requests 10 and 11 were filed at the oral proceedings before the Board.

Claim 1 of the main request reads as follows:

- "1. A colored sunscreen emulsion comprising:
- a) 0.0005 to 0.5 percent by weight of at least one water-soluble dye that imparts a color other than white to the sunscreen emulsion, such that when the sunscreen emulsion dries after it is spread on skin and/or is rubbed into skin, the color substantially disappears;
 - b) at least one sunscreen active ingredient in an amount effective to protect against the actinic radiation of the sun;
 - c) at least one emulsifier; and
 - d) sufficient water to form the colored emulsion

wherein the at least one water-soluble dye is selected from the group consisting of FDC Blue#1, FDC Blue#2, FDC Green#3, DC Green#5, Ext DC Violet #2, DC Green#8, and mixtures thereof".

Claim 1 of auxiliary request 1 differed from claim 1 of the main request only in that the at least one sunscreen active ingredient was further defined to be "a mixture of one or more sunscreensing UV-B actives and one or more sunscreensing UV-A actives".

Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 only in that the amount of the dye present in the composition was restricted to "0.01 to 0.05" percent by weight.

Claim 1 of the auxiliary requests 3 to 5 was based on claim 1 as granted and still comprised the proviso that

"the water-soluble dye being such that the disappearance of color of the sunscreen emulsion is not a result of a change in its pH", without giving a list of individual dyes as done in the preceding requests.

Claim 1 of auxiliary request 6 was directed to the

"use of:

- a) 0.0005 to 0.5 percent by weight of at least one water-soluble dye that imparts a color other than white to the sunscreen emulsion,
- b) at least one sunscreen active ingredient in an amount effective to protect against the actinic radiation of the sun, wherein the at least one sunscreen active ingredient is one or more suncreening UV-B actives or a mixture of one or more sunscreening UV-B actives and one or more sunscreening UV-A actives;
- c) at least one emulsifier; and
- d) sufficient water to form the colored emulsion,

in the manufacture of a colored sunscreen emulsion for topically applying to the skin to protect the skin against sunburn by providing an SPF of at least 2 to 15 in the case where the at least sunscreen active ingredient is one or more suncreening UV-B actives and from 2 to 50 in the case where the at least one sunscreen active ingredient is a mixture of one or more sunscreening UV-B actives and one or more sunscreening UV-A actives, wherein after the emulsion is spread on the skin the color is visible, but when the emulsion subsequently dries and/or is rubbed into the skin, the color substantially disappears, the water-soluble dye being such that the disappearance of color of the

sunscreen emulsion is not a result of a change in its pH".

Claim 1 of auxiliary request 7 was directed to the use of the components (a), (b), (c) and (d) as set forth for the definition of the emulsion of granted claim 1 in the manufacture of a colored sunscreen emulsion for topically applying to the skin to protect the skin against sunburn still comprising the proviso that "the water-soluble dye being such that the disappearance of color of the sunscreen emulsion is not a result of a change in its pH".

Claim 1 of auxiliary request 8 differed from granted claim 1 only in that the amount of the dye present in the composition was restricted to "0.002 to 0.2" percent by weight.

Claim 1 of auxiliary request 9 differed from claim 1 of the main request only in that the group of dyes, besides those already listed in the main request, further comprised FDC Red#3, FDC Red#4, FDC Yellow#5, FDC Yellow#6, DC Red#22, DC Red#28, DC Red#33, DC Yellow#10, Ext DC Yellow#7, DC Orange#4 and DC Yellow#8.

Claim 1 of auxiliary requests 10 and 11 differed from claim 1 of the main and auxiliary request 1 respectively only in that the group of dye was restricted to FDC Blue#1, FDC Blue#2, DC Green#5 and DC Green#8.

V. According to the Appellant, the claims as granted did not contain subject-matter extending beyond the content of the application as filed. The contested amendment

simply improved the clarity of the original language in the light of the teaching contained within the original application, in particular on page 1, sections with the heading "background" and "summary of invention", page 8, lines 11 to 18 and page 3, line 30 to page 4, line 7.

The section "background" was concerned with sunscreens containing a pH colour indicator at a pH greater than 9 and their drawbacks. It was directly followed by the section "summary of invention" which disclosed a sunscreen composition containing a water-soluble dye. From that sequence, the skilled man would necessarily have considered that the claimed compositions contained water-soluble dyes involving a mechanism of colour disappearance different to that of pH colour indicators, which had nothing to do with a change of pH.

The fact that the application as filed failed to specify pH indicators and their use in the sunscreen emulsions according to the invention, but instead listed a wide range of water-soluble dyes as being suitable, not undergoing any colour change at around the pH of the skin, was clearly a support for the contested amendment, all the more because numerous pH indicators were known in the art.

As regards the objection according to Article 123(3) EPC against the requests no longer comprising the proviso of claim 1 as granted, the Appellant submitted that the granted claims did include the presence of pH indicators because of the definition of the claimed emulsions which were characterised by the term "comprising" opening the claimed compositions to the presence of any further components. The claimed

emulsions were defined by the minimum requirement that the emulsions comprise the components as defined in the claims, but besides these compulsory components could comprise any further components, including pH indicators. There was therefore no extension of the scope of protection for claim 1 of those requests.

- VI. The respondents submitted *inter alia* that the claims of the main request were amended in such a way as to extend the protection conferred by the claims of the granted patent. An emulsion comprising a water-soluble dye consisting of a pH indicator and a dye from the group of dyes according to the main request did not fall within the scope of the granted claims, but was within the scope of claim 1 of the main request.

As regards the objection under Article 100(c) EPC, there was absolutely nothing in the application as filed to suggest that dyes that changed colour as a result of pH change were to be excluded from the compositions of the invention. The emulsions were not limited to formulations containing the specific dyes listed in table 1, which were explicitly stated to be some of the suitable dyes. The proviso in granted claim 1 did not present the skilled reader with information directly and unambiguously derivable from the content of the application as filed.

- VII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed as auxiliary request 8 on 9 June 2008, or on the basis of auxiliary requests 1 to 2, filed as auxiliary requests 9 and 10 on 9 June 2008, or on the basis of auxiliary requests 3 to 9,

filed as auxiliary requests 1 to 7 with letter dated 12 May 2005 or on the basis of auxiliary requests 10 and 11 filed at the oral proceedings before the Board.

The respondents requested that the appeal be dismissed.

VIII. At the end of the oral proceedings the decision of the Board was given orally.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Article 123(3) EPC*

Article 123(3) EPC requires that the claims of a patent may not be amended during opposition proceedings in such a way as to extend the protection conferred. In order to decide whether or not an amendment of the patent in suit satisfies that requirement, it is necessary to compare the protection conferred by the claims before amendment, i.e. as granted, with that of the claims after amendment.

2.1 *Scope of granted claim 1*

2.1.1 Claim 1 as granted is directed to sunscreen emulsions comprising a water-soluble dye.

The claimed sunscreen emulsion is subject to a proviso which imposes that the water-soluble dye is such that

the disappearance of colour of the sunscreen emulsion is not a result of a change in its pH, in other words a pH indicator being excluded. The proviso is directed to defining the claimed emulsion *per se* and does not merely supplement the definition of a component therein, i.e. component (a)

This proviso is self-contained standing apart from the other sections of claim 1; thus it is separated from, and without any link to, those sections of the claim defining components (a) to (d) comprised in the claimed emulsions. Accordingly, the proviso does not contribute to the definition of any of those components, including component (a), comprised in the emulsion, but applies to any water-soluble dye present therein. Hence the proviso in granted claim 1 prohibits water-soluble pH indicators from being incorporated into the claimed emulsion.

Thus, the proviso in claim 1 as granted restricts the dyes to be allowed into the claimed invention thereby excluding pH indicators, such as phenolphthalein, from being present in the claimed emulsions.

2.1.2 The Appellant submitted that granted claim 1 included the presence of pH indicators because of the definition of the claimed emulsions using the term "comprising", thus opening the claimed compositions to the presence of any further components.

The Board concurs with the Appellant that the claimed emulsions are open to including any further component. However, those components, which are explicitly excluded by the proviso present in granted claim 1, may

not be comprised in the claimed emulsions, otherwise said proviso would be devoid of sense.

This interpretation of the claim is in line with the fact that the proviso has been introduced into claim 1 during the examination proceedings just in order to delimit the claimed subject-matter from a sunscreen composition of the art comprising phenolphthalein, which is a pH indicator, whose colour changes according to the pH applied.

Hence, the Board comes to the conclusion that a water-soluble dye which is such that the disappearance of colour is the result of a pH change, such as phenolphthalein, is excluded from being present in the emulsions according to granted claim 1.

2.2 *Scope of claim 1 of the main request*

Claim 1 of the main request differs from claim 1 as granted in that the proviso defining the emulsion that "the water-soluble dye being such that the disappearance of color of the sunscreen emulsion is not a result of a change in its pH" is deleted. Furthermore the "water-soluble dye is selected from the group consisting of FDC Blue#1, FDC Blue#2, FDC Green#3, DC Green#5, Ext DC Violet #2, DC Green#8, and mixtures thereof".

With the deletion of the proviso, claim 1 no longer requires that the emulsion is free from a dye such that the disappearance of colour of the emulsion is not the result of a pH change.

The fresh feature in claim 1 of the main request, i.e. that the a water-soluble dye is selected from the group consisting of a list of individual dyes, only requires that at least one of those listed dyes is present in the composition, but does not exclude the presence of pH indicators.

The emulsion according to claim 1, thus, encompasses the presence of pH-indicators, such as phenolphthalein, due to open definition "comprising".

- 2.3 The Board thus holds that the amendment carried out in claim 1 of the main request requiring the presence of individual dyes in the emulsion, without excluding the presence of pH indicators therein has the effect to broaden the scope of that claim vis-à-vis to that of claim 1 as granted.

Accordingly, the Board concludes that claim 1 of the main request extends the scope of protection compared to that conferred by granted claim 1, hence contravening the requirement of Article 123(3) EPC.

Auxiliary requests 1 and 2

3. In claim 1 of auxiliary requests 1 and 2 the same modifications with respect to granted claim 1, i.e. deleting the proviso and introducing a list of individual dyes, have been made. Thus the same considerations and conclusions with respect to Article 123(3) EPC apply as set out in point 2 above.

Accordingly, for the same reasons, claim 1 of auxiliary requests 1 and 2 extends the scope of protection

compared to that conferred by granted claim 1, and these requests must also be refused.

Auxiliary requests 3 to 8

4. *Article 100(c) EPC*

4.1 Claim 1 of these requests is directed to emulsions which comprise the proviso of granted claim 1, which excludes the presence of pH indicators, i.e. the water-soluble dye being such that the disappearance of colour of the sunscreen emulsion is not a result of a change in its pH, and was not to be found in claim 1 as filed.

This proviso provides the claim with a technical contribution, as conceded by the Appellant. It is a rule of selection which determines whether a given water-soluble dye may be present in the claimed invention or not.

4.2 The Respondents opposed the patent in suit on the ground that the subject-matter of the patent extended beyond the content of the application as filed. They objected in particular to that proviso in claim 1 as generating added subject-matter.

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 (see decisions T 288/92, point 3.1 of the reasons; T 680/93, point 2 of the reasons; neither published in

OJ EPO), 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.

4.4 The Appellant referred to page 1, sections entitled "background" and "summary of invention", to page 8, lines 11 to 18 of and to the individual dyes listed in the application as filed as forming the basis for supplementing claim 1 with that proviso.

4.4.1 The section "background" is concerned with sunscreens containing pH colour indicators at a pH greater than 9 and their drawbacks. It is directly followed by the section "summary of invention" which discloses a sunscreen composition containing a water-soluble dye. According to the Appellant, from that sequence, the skilled man would necessarily have considered that the claimed compositions contained water-soluble dyes involving a mechanism of colour disappearance different to that of pH colour indicators, which had nothing to do with a change of pH.

The section "background" concerns the discussion of the prior art and does not form part of the disclosure of the invention. The section "summary of invention" discloses the emulsions according to the invention and indicates those water-soluble dyes which are preferably to be used therein. However, this section nowhere discloses, neither explicitly nor implicitly, any link as regards the composition of the claimed emulsions to the preceding section "background"; in particular both sections comprise no disclosure whatsoever as to the

exclusion of pH indicators from the claimed compositions as required in claim 1 as granted.

4.4.2 The passage of page 8, lines 11 to 18 of the application as filed merely concerns the possibility of adjusting the pH of the formulated emulsion with an acid or a base. There is no disclosure of a relationship between the disappearance of the colour of the emulsion and the change of its pH. Thus, this paragraph also does not support the exclusion of the presence of pH indicators as required in claim 1.

4.4.3 It is true that only water-soluble dyes whose colour disappearance is not a result of a change in pH were exemplified in the application as filed, however, without indicating a pH-independent mechanism for the water-soluble dyes suited for the claimed emulsions.

The dyes to be used in the claimed emulsions are not restricted to those individual dyes found in table 1 on page 3 and 4 of the application as filed, since that table merely "lists some of the currently available water-soluble certified dyes" (page 3, lines 27 and 28). Hence, this list of dyes in the application as filed is not exhaustive.

Furthermore, the exemplification of dyes is not associated with any particular characteristic or property thereof. Hence, when reading the exemplified dyes in the application as filed, the skilled person would not have considered the pH indicators to be excluded from the invention.

4.5 The Board therefore cannot agree with the Appellant's argument that the skilled man when reading the application as filed would have concluded that pH indicators were inevitably and necessarily excluded from the emulsions according to the invention. It follows that there is neither explicitly nor implicitly a disclosure for the proviso of present claim 1 in the application as filed. Hence, the proviso creates fresh subject-matter which is not objectively and unambiguously derivable from the application as filed.

For those reasons, the presence in claim 1 of this proviso is an amendment which extends the subject-matter of that claim beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC.

4.6 Since claim 1 of auxiliary requests 3 to 8 contains this proviso (see paragraphs IV above), the considerations and conclusion drawn in paragraph 4.5 above applies *mutatis mutandis* to any of those auxiliary requests, i.e. the subject-matter claimed extends beyond the content of the application as filed.

Hence, the Appellant's auxiliary requests 3 to 8 must be rejected.

Auxiliary requests 9 to 11

5. In claim 1 of auxiliary requests 9 to 11 the same modifications with respect to granted claim 1, i.e. deleting the proviso and introducing a list of individual dyes have been made. Thus the same

considerations and conclusions with respect to Article 123(3) EPC apply as set out in point 2 above.

Accordingly, for the same reasons, claim 1 of auxiliary requests 9 to 11 extends the scope of protection compared to that conferred by granted claim 1, and these requests must also be refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

P. Cremona

R. Freimuth