

Internal distribution code:

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

D E C I S I O N
of 8 June 2004

Case Number: T 0075/01 - 3.3.2

Application Number: 94303517.0

Publication Number: 0628303

IPC: A61K 7/42

Language of the proceedings: EN

Title of invention:
Compositions containing sunscreens

Patentee:
Imperial Chemical Industries PLC

Opponent:
The Procter & Gamble Company
Merck Patent GmbH

Headword:
Process for the preparation of sunscreens/IMPERIAL CHEMICAL
INDUSTRIES PLC

Relevant legal provisions:
EPC Art.

Keyword:
"Main, first and third requests - inventive step no - the
prior art gives an incentive to use an ingredient in a
specific form in order to achieve an improvement"
"Second auxiliary request - admissibility - no: not in reply
to a ground of appeal/opposition"

Decisions cited:
-

Catchword:
-



Case Number: T 0075/01 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 8 June 2004

Appellant: Imperial Chemical Industries PLC
(Proprietor of the patent) 20 Manchester Square
London W1U 3AN (GB)

Representative: Humphries, Martyn
ICI Group Intellectual Property
P.O. Box 90
Wilton
Middlesbrough
Cleveland TS90 8JE (GB)

Respondent: The Procter & Gamble Company
(Opponent) One Procter & Gamble Plaza
Cincinnati
Ohio 45202 (US)

Representative: Samuels, Lucy Alice
GILL JENNINGS & EVERY
Broadgate House
7 Eldon Street
London EC2M 7LH (GB)

(Opponent) Merck Patent GmbH
Postfach
Frankfurter Strasse 250
D-64293 Darmstadt (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 20 November 2000
revoking European patent No. 0628303 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: G. F. E. Rampold
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

- I. European patent No. 0 628 303, based on European application No. 94 303 517.0 and claiming a priority date of 11 June 1993, was granted on the basis of 18 claims.

Independent claim 1 as granted read as follows:

"1. A process for the preparation of a composition suitable for topical application to human skin characterised in that a dispersion in an oil of particles of a metallic oxide having an average primary particle size of less than 0.2 micrometre is mixed with one or more emulsifiers and an aqueous phase under conditions in which an emulsion is formed and with a hydrophilic organic sunscreen wherein the composition contains up to 10 per cent by weight metallic oxide and up to 7 per cent by weight hydrophilic organic sunscreen."

- II. Oppositions were filed against the granted patent by respondent 1 (opponent 01) and respondent 2 (opponent 02). The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and Article 100(b) EPC for insufficiency of disclosure.

The following documents were cited *inter alia* during the proceedings before the Opposition Division and the Board of Appeal:

(5) GB-A-2 260 130

- (8) Product box of "Marbert sensitive bronzing cream, bearing copyright date of 1991
- (9) Eidesstattliche Versicherung (Statutory declaration) from Prof. Dr Motitschke (10) Recipe sheets, 21 January 1992
- (11) Manufacturing instructions, 21 January 1992
- (12) Data sheets
- (13) Certificates of Analysis 1 and 2
- (18) Cosmetics & Toiletries, 107(10), 1992, pages 136 to 142
- (22) J.P. Hewitt; "Titanium Dioxide: A Different Kind of Sunshield"; DCI; September 1992; pages 26 to 32

III. By its decision pronounced on 11 October 2000, the Opposition Division revoked the patent under Article 102(1) EPC.

It held that the patent in suit did not meet the requirements of inventive step.

In its reason for the decision, the opposition division held that the objection of insufficiency of disclosure raised in respect of the term "hydrophilic sunscreen" used in the claims was ill-founded since the meaning of this term was well-known to those skilled in the art. Moreover, in view of the examples and the explanations given in the contested patent specification it was

entirely clear what was meant by a "hydrophilic sunscreen" in the context of the claimed invention.

The opposition division concluded that all three requests before it were novel since the feature "a dispersion in an oil of particles of a metallic oxide having an average primary particle size of less than 0.2 micrometre" was nowhere disclosed in the cited state of the art in combination with the other features of the claimed process.

In particular, the opposition division considered that the probative value of the pieces of evidence (8) to (13) was sufficient to prove that the "Marbert sensitive" sunscreen was on the market prior to the priority date of the patent in suit but insufficient to prove the allegation of public prior use, namely that the claimed process in the patent was anticipated by the process of producing the known sunscreen product "Marbert sensitive". The items of evidence (8) to (13) produced by respondent 2 included a sample of the sunscreen product "Marbert sensitive", numbered (8) in the proceedings, and documents (9) to (13) relating to its composition and a method for its preparation.

The opposition division was also of the opinion that an analysis of the sunscreen would reveal its components, so that a composition suitable for topical application to human skin characterised in that it contained particles of a metallic oxide (titanium dioxide) having an average primary particle size of less than 0.2 micrometre mixed with one or more emulsifiers (eg glycerol, carbomer), water and a hydrophilic organic sunscreen (Phenylbenzimidazole sulphonic acid) wherein

the composition contains up to 10 per cent by weight metallic oxide (about 5%) and up to 7 per cent by weight hydrophilic organic sunscreen (about 1%) was made available to the public.

As to inventive step, it concluded that the claimed process did not involve an inventive step. It was of the opinion that a person skilled in the art, knowing the method of preparing sunscreens disclosed in citation (5) and also knowing the known sunscreen product (8) or that described on page 141 of citation (18), would have considered it obvious to prepare such sunscreens by forming an emulsion involving the steps of mixing a dispersion in an oil of particles of a metallic oxide of small particle size with one or more emulsifiers and an aqueous phase under conditions in which an emulsion is formed, and adding a hydrophilic organic sunscreen. The more so because no surprising benefit was associated with the claimed process.

In the opposition division's view, the same conclusions applied to auxiliary requests 1 and 2, which did not contain any new inventive features.

IV. The appellant (patentee) lodged an appeal against the said decision.

It filed auxiliary requests A, B and C together with its grounds of appeal.

Claim 1 of the set of claims of auxiliary request A corresponds to claim 1 of the set of claims as granted restricted to the five hydrophilic organic sunscreens recited in the description of the patent application as

filed on page 4, lines 31 to 35, namely Benzophenone-4, p-Aminobenzoic acid, Triethanolamine salicylate, Phenylbenzimidazole sulphonic acid, DEA Methoxy cinnamate.

Claim 1 of the set of claims of auxiliary request B corresponds to Claim 1 of the set of claims as granted restricted to titanium dioxide particles as metallic oxide and containing the additional optional feature that the particles are "optionally coated with inorganic and/or organic material.

Moreover, compared to the set of claims as granted a new dependent claim (claim 5) was added.

Claim 1 of the set of claims of auxiliary request C corresponds to Claim 1 of the set of claims as granted restricted to hydrophilic sunscreen as organic sunscreen.

V. Oral proceedings were held before the Board on 8 June 2004.

VI. The appellant submitted that the conclusions as to novelty reached by the Opposition Division hold good also with respect to document (22) filed by respondent 2 during the appeal proceedings.

In its view, the Opposition Division's reasoning for inventive step was, however, based on an *ex post facto* analysis because, contrary to the Opposition Division's approach, the skilled person had no reason to choose the process of document (5) as closest prior art as this document was not concerned by the preparation of a

sunscreen having a high SPF (sun protection factor) value by mixing two different type of sunscreens, namely a metallic oxide and a hydrophilic organic sunscreen.

As none of the prior art processes were concerned by the preparation of such sunscreen compositions, it considered that there was nothing on file which rendered the process of the contested patent obvious.

In its opinion, the use of a dispersion in an oil of the metallic oxide particles in the process led moreover to unexpected results, as illustrated by the comparative tests filed with its grounds of appeal.

VII. The objection relating to insufficiency of disclosure was not maintained during the appeal proceedings.

Respondent 1 (opponent 1) considered, for the first time during the oral proceedings, that document (22) was novelty-destroying for the process of the patent in suit, mainly because the last paragraph of the article recited that the pre-dispersed titanium dioxide particles described in the article "offer the manufacturers an opportunity to formulate highly effective broad-spectrum products, either alone or **in combination with organic UV absorbers**".

As to inventive step, respondent 1 and respondent 2 (opponent 2) shared the Opposition Division's analysis and conclusions. They submitted moreover that, contrary to the appellant's view, the improved SPF value achieved when using metallic oxide particles as a dispersion in oil could not be regarded as an

unexpected effect as document (22) precisely taught the advantages of using the metallic oxides particles in such a form.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, as auxiliary requests 1 to 3, that the patent be maintained on the basis of one of the auxiliary requests A, B or C, filed with letter dated 19.03.2001.

Respondents 1 and 2 requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.
2. *Public prior use*

The Board agrees with all the findings of the Opposition Division as to the public prior use (see above under III, and the Opposition Division's decision, pages 5 to 8, point 2.2).

In that respect, the Board notes that the appellant has neither denied the Opposition Division's decision in that respect nor provided any reasoned response to the evidence which had been submitted.

Accordingly, in the absence of any element in this respect, there would appear to be no need to develop these aspects further.

3. *Main request*

3.1 Novelty

The Board agrees with the Opposition Division's positive conclusions as to the novelty of the subject-matter of the patent in suit over the then available prior art documents.

The submissions of respondent 1 relating to novelty over document (22) made during the oral proceedings do not contain any new matter not properly dealt with in the Opposition Division's decision.

In particular, document (22) does not concern sunscreens containing metallic oxide in combination with "hydrophilic" organic sunscreens. It cannot therefore describe any process for preparing such compositions either.

Moreover, having regard to the Board's conclusions in the assessment of inventive step (see below, point 3.2), there would appear to be no need to develop these aspects further.

Accordingly, the Board concludes that the subject-matter of the main request fulfils the requirements of novelty (see above under III, and the Opposition Division's decision, pages 5 to 8, point 2.2).

3.2 Inventive step

- 3.2.1 The contested patent relates to a process for the preparation of a composition suitable for topical application to human skin containing a combination of inorganic and organic sunscreen. The process is characterised in that a dispersion in an oil of particles of a metallic oxide having an average primary particle size of less than 0.2 micrometre is mixed with one or more emulsifiers and an aqueous phase under conditions in which an emulsion is formed and with a hydrophilic organic sunscreen wherein the composition contains up to 10 per cent by weight metallic oxide and up to 7 per cent by weight hydrophilic organic sunscreen (page 2, lines 3 and 4, 19 to 23).

The Board considers that the sunscreen "Marbert sensitive" (8), which corresponds precisely to a composition obtainable by the process of the patent in suit, represents the closest prior art.

This sunscreen is a composition suitable for topical application to human skin which contains particles of a metallic oxide (titanium dioxide) having an average primary particle size of less than 0.2 micrometre mixed with one or more emulsifiers (eg glycerol, carbomer), water and a hydrophilic organic sunscreen (Phenylbenzimidazole sulphonic acid) wherein the composition contains up to 10 per cent by weight metallic oxide (about 5%) and up to 7 per cent by weight hydrophilic organic sunscreen (about 1%) (see above under III, and the Opposition Division's decision, pages 5 to 8, point 2.2).

3.2.2 As acknowledged by the Opposition Division, the process for preparing the sunscreen composition is however not disclosed in the available prior art.

Accordingly, the problem to be solved by the subject-matter of claim 1 of the main request of the patent in suit as against document (8) can only be seen in the provision of a process for preparing such a sunscreen composition.

3.2.3 This problem is solved by mixing together a dispersion in an oil of particles of a metallic oxide having an average primary particle size of less than 0.2 micrometre with one or more emulsifiers and an aqueous phase under conditions in which an emulsion is formed and with a hydrophilic organic sunscreen wherein the composition contains up to 10 per cent by weight metallic oxide and up to 7 per cent by weight hydrophilic organic sunscreen.

In the light of the description and examples of the patent in suit, the Board is satisfied that the problem has been plausibly solved.

3.2.4 Thus the question to be answered is whether the proposed solution would have been obvious to the skilled person in the light of the prior art. In fact, in order to prepare a sunscreen such as "Marbert sensitive" containing less than 10 per cent of a metallic oxide having an average primary particle size of less than 0.2 micrometer, less than 7 per cent of a hydrophilic, sunscreen, water and an emulsifier, the skilled person has in fact no other choice than to mix these ingredients together.

This is exactly and merely what the process of claim 1 of the contested patent recites.

The only feature of the process which contains additional technical information relates to the form in which the metallic oxide is used, namely in the form of a dispersion in an oil.

This is therefore the only feature which renders the process novel over the common general knowledge and for which an inventive step has to be assessed.

In that respect, the comparative examples provided by the appellant with its grounds of appeal show that the use in the process of the metallic oxide in the form of a dispersion in an oil rather than in the form of a powder leads to a sunscreen preparation having a greater SPF.

It is however known, for instance from documents (5) and (22), that a greater SPF value is achieved when using the metallic oxide in the form of a dispersion in an oil rather than in the form of a powder ((5) page 11, lines 21 to 25, Example 1; (22) page 26, right column, lines 16 to 21 and 25 to 30).

Accordingly, the Board is satisfied that the skilled person faced with the problem of the provision of a process for preparing a sunscreen composition according to (8) would be able to choose to use the metallic oxide in the form of a dispersion in an oil without inventive activity just by following the teaching of the prior art as illustrated by documents (5) and (22).

3.2.5 The Board therefore does not agree with the main argument submitted by the appellant that the choice of this particular form of the metallic oxide involves an inventive step because it represents a selection among various possibilities, namely as a slurry, as a powder or as a dispersion in water.

As discussed above, the skilled person had a clear incentive to choose this form in the light of the prior art.

As to the argument that a synergetic effect is obtained when a metallic oxide sunscreen is combined with a hydrophilic organic sunscreen, the Board notes that no evidence of any effect in this respect is on file since the closest prior art for any comparison would remain (8), which discloses such a combination, and that this aspect relates moreover to the product *per se* which is not the subject-matter of the patent in suit.

3.2.6 In the light of these facts, the Board can only conclude that the subject-matter of claim 1 of the main request does not involve an inventive step as required by Article 56 EPC.

Under these circumstances, there is no need to consider the remaining claims.

4. *Auxiliary requests*

4.1 First auxiliary request

This request differs from the main request in that claim 1 of the set of claims as granted has been restricted to the five hydrophilic organic sunscreens recited in the description of the patent application as filed on page 4, lines 31 to 31, namely Benzophenone-4, p-Aminobenzoic acid, Triethanolamine salicylate, Phenylbenzimidazole sulphonic acid, DEA Methoxy cinnamate.

Accordingly, in the light of this clear basis in the application as originally filed, the Board does not agree with respondent 1's submission that this claim contravenes the requirements of Article 123(2) EPC because this amendment was equivalent to a positive disclaimer.

This request does not however contain any new feature compared to the main request which distinguishes the subject-matter of claim 1 over the prior art since (8) contains specifically one of the hydrophilic sunscreens recited in amended claim 1, namely Phenylbenzimidazole sulphonic acid.

Accordingly, the conclusions under 3.2.6 hold good for this request as well.

4.2 Second auxiliary request

This request differs from claim 1 of the set of claims as granted in that it has been restricted to titanium dioxide particles as metallic oxide and in that it contains the additional optional feature that the particles are "optionally coated with inorganic and/or organic material".

Moreover, compared to the set of claims as granted a new dependent claim (claim 5) was added.

As, per definition, neither the introduction of an **optional** feature in a main claim, nor the addition of a supplementary dependent claim can restore novelty and/or inventive step of an independent claim which has been attacked under these grounds, this request has to be rejected under Rule 57a EPC since these amendments cannot be considered as having been occasioned by grounds of appeal.

The appellant did not provide any counter-arguments in this respect.

4.3 Third auxiliary request

This request differs from the main request in that claim 1 of the set of claims as granted has been restricted to a hydrophilic organic sunscreen as organic sunscreen.

Accordingly, in the light of the basis for this restriction provided by the examples of the application as originally filed, the Board does not agree with

respondent 1's submission that this claim contravenes the requirements of Article 123(2) EPC because this amendment was equivalent to a positive disclaimer.

In the absence of any element explaining why this restriction would involve an inventive step for the process of the patent in suit, the Board must conclude that this restriction is merely an arbitrary one, which lies therefore within the competence of the skilled person.

Order

For the se reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Townend

G. Rampold