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**Datasheet for the decision
of 22 October 2013**

Case Number: T 0492/10 - 3.3.10

Application Number: 02700177.5

Publication Number: 1361904

IPC: A61L15/58, A61L24/00

Language of the proceedings: EN

Title of invention:

AN ADHESIVE COMPOSITION WHEREIN THE MICROCOLLOID PARTICLES
INCORPORATED THEREIN ARE SPHERICAL IN SHAPE

Patent Proprietor:

Coloplast A/S

Opponent:

Hollister Incorporated

Headword:

Relevant legal provisions:

RPBA Art. 12(4)

EPC Art. 123(2), 123(3), 84, 83, 54, 56, 111(1)

Keyword:

Remittal to the department of first instance - (no)
- no absolute right to two instances
Added subject-matter (no)
Clarity - (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

T 0230/07, T 1233/05, T 1130/09

Catchword:



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Case Number: T 0492/10 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 22 October 2013

Appellant: Hollister Incorporated
(Opponent) 2000 Hollister Drive
Libertyville, Illinois 60048-3781 (US)

Representative: Høiberg A/S
St. Kongensgade 59 A
1264 Copenhagen K (DK)

Respondent: Coloplast A/S
(Patent Proprietor) Holtedam 1
3050 Humlebaek (DK)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
15 December 2009 concerning maintenance of the
European Patent No. 1361904 in amended form.

Composition of the Board:

Chairman: P. Gryczka
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

- I. The opponent (appellant) lodged an appeal against the interlocutory decision of the opposition division to maintain European patent No. 1 361 904 in amended form.
- II. An opposition was filed, on the grounds that the patent in suit contained added subject-matter (Article 100(c) EPC), that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC), and that the subject-matter of the patent as granted was not novel and did not involve an inventive step (Article 100(a) EPC).
- III. The documents filed during the opposition proceedings included the following:
- D1: WO 91/09633
 - D3: US 6 803 400
 - D5: US 4 318 408
- IV. The following documents were filed by the appellant with its statement setting out the grounds of appeal:
- D7: US 5 849 325
 - D8: US 6 264 976
 - D9: US 6 479 073
 - D10: US 4 339 371
- V. The opposition division decided that claim 1 of the then pending main request contained added subject-matter, that the subject-matter of the then pending first auxiliary request was not inventive, but that the then pending second auxiliary request fulfilled the

requirements of the EPC.

- VI. Claim 1 of the main request of the respondent (patent proprietor), submitted during the oral proceedings before the board, is identical to claim 1 of the request which was considered allowable by the opposition division, and reads as follows:

"A pressure sensitive adhesive composition comprising a polymeric matrix and absorbent microcolloid particles incorporated therein, wherein the microcolloid particles are spherical in shape and at least 75% of the microcolloid particles have a particle size below 20 μm ."

- VII. The arguments of the appellant relevant for the present decision were the following:

Documents D7-D10 were filed in reaction to the decision under appeal. The appellant had only recognised the relevance of the emulsion polymerisation for the preparation of the absorbent spherical particles of the adhesive composition of claim 1 after having read said decision, and it had reacted as soon as possible, namely by filing these documents with the statement setting out the grounds of appeal. For these reasons, it was requested that these documents be admitted into the proceedings. Among them, document D7 was particularly relevant.

The application as originally filed disclosed in the last paragraph of page 12 and the first of page 13 different processes for incorporating absorbent particles into the polymeric matrix, as required by claim 1; however, these processes were combined with additional limitations which were not features of said

claim which, thus, contained added subject-matter.

During the examination of the application for the patent in suit, the examining division had replaced the feature "substantially spherical" by "spherical" in order "to clearly and unambiguously distinguish the invention from prior art" (see communication under Rule 51(4) EPC 1973). For this reason, both terms had to have different scopes, with the consequence that the former could not provide a basis for the latter. Claim 1 of the main request contained, thus, also for that reason added subject-matter.

The term "microcolloid particles" in claim 1 did not have a generally recognised meaning and the same held true for the percentage of microcolloids having a particle size below 20 micrometers defined in claim 1. For this reason, claim 1 was not clear. This lack of clarity also amounted to an insufficiency of disclosure of the claimed invention, which could not be put to practice.

The absorbent particles required for preparing the compositions exemplified in the patent in suit were no longer commercially available, and the patent in suit did not provide enough information for obtaining other spherical, absorbent particles required for the adhesive compositions of claim 1, with the consequence that also for this reason the invention was not sufficiently disclosed for it to be carried out by a person skilled in the art.

Document D7 disclosed in example 1 an adhesive composition consisting of an adhesive polymeric matrix blended with polymeric microspheres of an average diameter of about 2 micrometers obtained by emulsion

polymerisation. It was apparent that said particles were absorbent in the light of the results obtained in terms of moisture transmission rate. The subject-matter of claim 1 was, thus, not novel over the disclosure of document D7.

The particle size defined in claim 1 that "at least 75% of the microcolloid particles have a particle size below 20 μm " was not a selection invention within the range of 1-600 micrometers disclosed in D1 (page 36, first paragraph), and all the other features required by claim 1 were also disclosed in D1, with the consequence that claim 1 was not novel.

The particle size defined in claim 1 was not a purposive selection within the broader range 1 to 20,000 micrometers disclosed in D5. Since all the other features required by claim 1 were also disclosed in D5, the subject-matter of claim 1 lacked novelty.

D7 was the closest prior art for the assessment of inventive step. The claimed subject-matter differed with respect to D7 in that the particles in the adhesive composition had to be absorbent. The problem to be solved was providing an adhesive composition capable of absorbing and transporting moisture, and the solution, which was characterised by using absorbent particles, was obvious taking into account the common general knowledge as reflected on page 1, lines 12-19 of the patent application as originally filed, with the consequence that the subject-matter of claim 1 was not inventive.

VIII. The respondent argued as follows:

Documents D7 to D10 were not a timely response to a new

procedural situation, since the request upon which the opposition division maintained the patent in suit had already been filed, with only minor differences, with the response to the notice of opposition. Filing additional documents at such a late stage was an abuse of procedure. Although the relevance of document D7 was not challenged, the respondent requested that none of the late-filed documents be admitted into the proceedings and, should document D7 be admitted, that the case be remitted to the opposition division and that the appellant bear the costs of the respondent for the oral proceedings before the board.

The feature "substantially spherical" was a basis for the feature "spherical", and the feature "incorporated therein" found a basis in the last paragraph of page 12 and the first of page 13 of the application as originally filed, which disclosed methods whose effect was having particles incorporated into the matrix of the adhesive composition, as required by claim 1 which, therefore, did not contain added subject-matter.

Claim 1 was clear, since it defined the feature "microcolloid particles", which were spherical, absorbent particles with a specific size. For the same reason, the skilled person could determine without undue burden the kind of particles suitable for the invention.

The patent application provided sufficient information about the suitable absorbent particles and the methods for obtaining them. The disclosure of a patent application was not limited to its examples, so that the invention was sufficiently disclosed even if the particles used in the examples of the patent in suit were no longer commercially available.

The particle size defined in claim 1 was a sub-range of the broadest range disclosed in D1 (1 to 600 micrometers) which was narrow and far removed from the range preferred in said document, with the consequence that the subject-matter of claim 1 was novel. The same applied with regard to the broad range disclosed in D5.

Document D3 was not a European application and had been published after the filing of the patent in suit, with the consequence that it was not state of the art in the sense of Article 54 EPC.

Lastly, document D7 failed to disclose absorbent particles. The subject-matter of claim 1 was, hence, also novel over D7.

Document D7 was the closest prior art. The problem to be solved was providing an adhesive composition capable of absorbing and transporting moisture, as mentioned in paragraph [13] of the patent in suit, the solution was an adhesive containing absorbent particles, and no indications towards this solution could be found in the art, with the consequence that the subject-matter of claim 1 was inventive.

IX. Oral proceedings before the board took place on 22 October 2013.

X. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside and that European patent No. 1 361 904 be revoked.

- The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed as Request B' during the oral proceedings before the board, or, subsidiarily, on the basis of the auxiliary request, filed as Request F during the oral proceedings before the board. The respondent further requested that the case be remitted to the department of first instance for further examination, should document D7 be admitted into the proceedings.

XI. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of late-filed documents D7-D10:
 - 2.1 Documents D7-D10 were filed by the appellant with the statement setting out the grounds of appeal.
 - 2.2 The board considers that document D7 is *prima facie* very relevant for the claimed invention, and this finding has not been challenged by the respondent. The respondent further acknowledged that its first auxiliary request had been filed *inter alia* in response to D7. In the light of the relevance of the document and since the respondent was not caught unawares by its filing, the board makes use of its discretion under Article 114(2) EPC to admit document D7 into the proceedings.

- 2.3 It has not been disputed by the appellant that the disclosure of document D8 does not go beyond that of document D7 as far as the claimed invention is concerned. Since document D8 is not more relevant than document D7, the board makes use of its discretion not to admit D8 into the proceedings.
- 2.4 Document D9 is not state of the art in the sense of Article 54 EPC since it was published after the filing of the patent in suit and is not a European application, and the appellant could not provide any convincing reason why its content was relevant to the present appeal. Under these circumstances, the board exercises its discretion not to admit D9 into the proceedings.
- 2.5 The appellant acknowledged that the content of document D10 was not *prima facie* relevant for the claimed invention. The board makes, therefore, use of its discretion not to admit D10 into the proceedings.
3. Request that the case be remitted to the opposition division:

The respondent requested that, should document D7 be admitted into the proceedings, the case be remitted to the opposition division to safeguard its right to have all the substantive issues considered by two instances.

According to Article 111(1) EPC, a board may either exercise any power within the competence of the department which was responsible for the appealed decision, i.e. decide on all issues, or remit the case to the first instance for further prosecution. Thus, the EPC does not guarantee the parties an absolute right to have all the issues of a case considered by

two instances.

Although a new novelty objection based on document D7 was raised for the first time with the statement setting out the grounds of appeal, the document itself was filed at the earliest possible stage of the appeal proceedings, and the respondent had not said it was unable to take a position on D7, namely by filing the auxiliary request. For these reasons, the board judges that it is not appropriate to remit the present case to the opposition division.

Since the case is not remitted, the question of the apportionment of costs requested by the respondent if the case was remitted does not arise.

Main request:

4. Amendments:

In claim 1 of the main request the term "substantially spherical" of claim 1 as originally filed was replaced by "spherical".

- 4.1 The appellant argued that the feature "substantially spherical" in claim 1 of the application as originally filed was not a basis for the feature "spherical" in claim 1, since both terms had different scopes, as shown by the comment of the examining division in its communication under Rule 51(4) EPC 1973 that such an amendment was required "to clearly and unambiguously distinguish the invention from prior art".

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.

It is quite common practice in patent claim drafting to use the word "substantially" in order to soften strict mathematical boundaries and, in the field of the present invention, the technical reader further knows that almost no colloidal particle of the size required by claim 1 is perfectly "spherical" in the mathematical sense. Thus, in the present case, the replacement of "substantially spherical" by "spherical" adds no technical information and, for this reason, does not represent added subject-matter.

4.2 Claim 1 requires that the absorbent particles should be "incorporated therein" (in the matrix).

This feature finds a basis in the last two paragraphs of page 12 and the first paragraph of page 13 of the application as originally filed, which disclose different methods for combining the matrix and the absorbent particles, namely:

- "the microcolloid particles are dispersed in one of the components of the polymeric matrix before combining further with the rest of the components of the polymeric matrix",
- "the microcolloid particles may be incorporated into the polymeric matrix in the form of a paste or a liquid dispersion. The dispersing liquid may be removed subsequently", and
- "the microcolloid particles may be incorporated in the form of agglomerates or granules which are broken down before or during the adhesive

manufacturing process".

All these methods for combining the absorbent particles and the matrix result in the absorbent particles being incorporated into the matrix. The feature "incorporated therein" is, thus, disclosed as the result of these processes.

- 4.3 The appellant has argued that these methods were disclosed only in combination with additional features which were not part of claim 1. However, the appellant has failed to indicate which features of said methods are reflected in the product obtained. Although the particles can be added as a paste, as a suspension, or as agglomerates or granules, since the solvent of the suspension is further eliminated and the agglomerates or granules subsequently broken down, the product obtained is, in all cases, merely an adhesive in which the absorbent particles are incorporated into the polymeric matrix. These methods, thus, do not disclose any further feature of the final product.

This argument of the appellant is, therefore, dismissed.

- 4.4 The appellant also argued that the respondent had acknowledged during the oral proceedings before the opposition division that adding powdered microcolloid particles led to dust problems and explosive effects. Since claim 1 included non-workable embodiments while leaving out essential information, the subject-matter claimed went beyond the content of the application as filed.

However, that the claim contains non-workable embodiments could be an objection under sufficiency of

disclosure, but not under added subject-matter. This argument of the appellant is, hence, dismissed.

4.5 The board concludes that claim 1 of the main request finds a basis in the application as originally filed (Articles 100(c) and 123(2) EPC).

4.6 No objection has been raised by the appellant under Article 123(3) EPC against the main request. Claim 1 results from limiting the subject-matter of claim 1 as granted by further defining the required particles as absorbent and by restricting the particle sizes. The board, thus, concludes that the scope of protection of the patent as granted has not been broadened by the amendments made.

5. Clarity, Article 84 EPC:

The appellant has argued that the term "microcolloid particles" in claim 1 lacked a clear definition. For this reason, it was not possible to determine when the feature in claim 1 requiring that at least 75% of the microcolloid particles have a particle size below 20 micrometers was fulfilled. Claim 1 therefore lacked clarity.

However, claim 1 of the main request provides a definition of the term "microcolloid particles", namely "absorbent, spherical particles", without any limitation of size. Thus, the feature "at least 75% of the microcolloid particles" should be determined by reference to the total amount of absorbent, spherical particles. Claim 1 is, thus, clear within the meaning of Article 84 EPC.

6. Sufficiency of disclosure, Article 83 EPC:

6.1 The appellant argued that the lack of clarity of the term "microcolloid particles" also rendered the disclosure of the patent in suit insufficient, since the skilled person could not determine without undue burden which particles should be used to prepare the claimed compositions.

However, since this term is considered to be clear (see point 5.) the objection of the appellant must be rejected.

6.2 The appellant further argued that the particles used in the adhesive compositions of the examples of the patent in suit were no longer commercially available. Since the description of the patent in suit did not provide enough information for obtaining such particles, the claimed adhesive compositions could not be reproduced.

However, page 15, lines 1-19 of the description of the patent in suit discloses materials which could be used for obtaining microcolloid particles and methods suitable for their obtention, so that the skilled person there finds sufficient information to synthesise particles suitable for preparing the claimed adhesive composition. This argument of the appellant is, thus, dismissed.

6.3 The appellant also argued that particles made of naturally or chemically modified natural polymers could not be obtained by an emulsion polymerisation process. For this reason, the claimed invention could not be carried out over the whole scope of claim 1, which included absorbent microcolloid particles without any restriction as to their chemical composition.

However, page 15, lines 10-15 describes alternative methods to emulsion polymerisation such as wet milling, sonication and high shear, and the appellant has not explained why these other methods could not be applied for preparing microcolloid particles from the starting materials mentioned above. This argument of the appellant is also dismissed.

6.4 Lastly, the appellant argued that it was not clear whether other absorbent particles different from those tested in the application would lead to the desired effect. However, since claim 1 is directed to a composition and is not limited by the effect sought, whether other particles could achieve the alleged effect might be an issue for the assessment of inventive step, but not of sufficiency of disclosure.

6.5 The board concludes, thus, that the claimed invention is sufficiently disclosed for it to be carried out by a person skilled in the art.

7. Novelty, Article 54 EPC:

7.1 Novelty over document D7:

Example 1 of document D7 discloses an adhesive composition consisting on an adhesive polymeric matrix blended with polymeric microspheres having an average diameter of about 2 micrometers and obtained by emulsion polymerisation of 232.8 grams of iso-octyl acrylate, 4.8 grams of acrylic acid and 2.4 grams of polyethylene oxide acrylate.

The sole point of dispute between the parties was whether the particles in the adhesive composition of

example 1 of D7 were absorbent, as required by claim 1. Both parties agreed that the term "absorbent" in the field of adhesive compositions for medical devices can only be read as "water-absorbent".

In the light of the chemical composition of the particles, which were obtained from more than 99% of a hydrophobic monomer (iso octyl acrylate) bearing a long, apolar side chain, while the combined amount of hydrophilic monomers (acrylic acid, polyethylene oxide acrylate) was only about 0.5% of the total, it cannot be directly and unambiguously concluded that the microspheres of document D7 are absorbent, as required by claim 1.

For this reason, the subject-matter of claim 1 is novel over D7.

The appellant argued that since the adhesive compositions disclosed in document D7 were capable of moisture transport, the microspheres in said adhesive compositions must necessarily have been absorbent.

However, the adhesive compositions disclosed in document D7 are hydrophilic (see column 3, line 3-15), so that their water transport capacity can reside in the hydrophilicity of the matrix and must not necessarily arise from the presence of absorbent particles. This argument of the appellant is, hence, dismissed.

The subject-matter of claim 1 is therefore novel over document D7, which fails to disclose an adhesive composition containing absorbent particles.

7.2 Novelty over document D1:

The particles disclosed in document D1 have a particle size ranging from 1 to 600 micrometers (page 36, lines 1-6). The interval defined in claim 1 that "at least 75% of the microcolloid particles have a particle size below 20 micrometers" is a narrow selection within the broader range of D1, and is also removed from the preferred embodiments thereof (particle size from 25 to 100 microns, page 36, line 5). The claimed subject-matter is thus at least for this reason novel over document D1.

The appellant did not dispute that the range defined in claim 1 was narrow and far removed from the preferred embodiments of D1, but considered that the range defined in claim 1 did not represent a purposive selection over that disclosed in D1, so that this selection could not impart novelty.

However, the presence or absence of a technical effect within a sub-range of numerical values is not to be taken into account in the assessment of novelty (see T 230/07, T 1233/05 and T 1130/09, not published in the Official Journal of the EPO). Since the particle size defined in claim 1 represents a narrow and far removed selection from the particle size of D1, the subject-matter of claim 1 is at least for this reason novel over D1.

7.3 Novelty over document D5:

Similarly to the situation with respect to D1, the particle size of at least 75% of the absorbent, spherical particles defined in claim 1 being below 20 micrometers is a narrow selection within the range of

size from 1 to 20,000 micrometers disclosed in D5 (column 3, lines 20-21) and is removed from the preferred embodiment represented by the particles used in example VI, Permasorb 10 from National Starch, which do not have any particle smaller than 44 micrometers. This finding has not been challenged by the appellant. Since the presence or absence of a technical effect within the sub-range defined in claim 1 is not to be taken into account in the assessment of its novelty, the particle size defined in claim 1 represents a new selection over the particle size disclosed in document D5 and claim 1 is, at least for this reason, also novel over D5.

7.4 Novelty over document D3:

Document D3 is a US document which was published after the filing of the patent in suit and, hence, is not prior art in the sense of Article 54 EPC. This finding has not been challenged by the appellant.

7.5 The board concludes, therefore, that the subject-matter of claim 1 is novel over the prior art opposed to it.

8. Inventive step:

Claim 1 is directed to an adhesive composition comprising absorbent, spherical microcolloid particles, of which at least 75% have a particle size below 20 micrometers, incorporated into a polymeric matrix.

8.1 Closest prior art:

Both parties agreed that D7 represents the closest state of the art and the board sees no reason to differ.

The opposition division considered that document D3 was the closest prior art. However, D3 is not state of the art in the sense of Article 54(2) EPC and is hence not relevant for the assessment of inventive step of the claimed subject-matter (see point 7.4 supra).

Document D7 discloses an adhesive capable of water transport obtained by blending a polymeric, adhesive matrix and microspheres of an average diameter of about 2 micrometers. Document D7 fails to disclose that said microspheres are absorbent (see point 7.1 supra).

8.2 Technical problem underlying the invention:

The technical problem underlying the claimed invention as defined by the respondent is providing an adhesive composition capable of absorbing and transporting moisture (see paragraph [13] of the patent in suit).

8.3 Solution:

The solution proposed by claim 1 is a composition comprising a polymeric matrix and spherical particles from which at least 75% have a particle size below 20 micrometers, characterised in that said particles are absorbent.

8.4 Success:

The appellant has not raised any objection against the success of the proposed solution for solving the problem as defined in 8.2 above, and the board has no reason to doubt that the claimed adhesive compositions are capable of absorbing and transporting water in the light of the data in the patent in suit, on table 1

with respect to the moisture transmission, and on table 4 with respect to their absorption capacity.

8.5 Finally, it remains to be examined whether the claimed solution was obvious for the person skilled in the art:

No indications have been found in the art which would have led the skilled person to the claimed solution, as none of the documents on file discloses particles with the required shape (spherical) and the required size (at least 75% of said particles have a particle size below 20 micrometers) which are absorbent.

The appellant argued that it was common general knowledge, as reflected in paragraph [3] of the patent in suit, that compositions comprising absorbent hydrocolloids led to the effect sought. Every absorbent colloid would increase the water absorption of an adhesive, independently of its shape and particle size, with the consequence that the claimed solution was obvious.

However, following said common technical knowledge reflected in paragraph [3] of the patent in suit, and seeking to provide an adhesive composition capable of absorbing and transporting moisture, the skilled person would have added *hydrocolloids* to the adhesive compositions of document D7, which are coarse particles of a size between 60 and 100 micrometers according to the definition provided in the patent in suit, paragraphs [32] and [96], and which are different from the particles required by claim 1.

The arguments provided by the appellant are considered, thus, as based on an unallowable ex-post-facto analysis of the prior art.

In addition, the data provided in the examples of the patent in suit (see table 4) show that the absorbency of the claimed adhesive compositions having particles as defined in claim 1 is superior to the absorbency of an adhesive composition containing hydrocolloid particles. Although the latter compositions do not reflect the closest prior art, this data show nevertheless that the claimed solution is superior to the obvious addition of hydrocolloids to the adhesive compositions of D7.

Since the board does not find any indication in the remaining documents on file towards the claimed solution, and document D7 leads the skilled person to a solution different from the one in claim 1 for the reasons given above, the subject-matter of claim 1 and, by the same token, that of dependent claims 2-18 is inventive in the sense of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the following documents:
 - claims 1-18, filed as Request B' (main request) during the oral proceedings before the board;
 - description pages 2-12, as filed during the oral proceedings before the opposition division on 6 October 2009
 - Fig. 1 of the published patent specification.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated