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**Datasheet for the decision
of 17 September 2015**

Case Number: T 2179/13 - 3.3.10

Application Number: 07871278.3

Publication Number: 2091585

IPC: A61L27/34, A61L29/08,
A61L31/10, C08J7/04, C08L33/02,
G02B1/04, C09D4/00

Language of the proceedings: EN

Title of invention:
SURFACE TREATMENT OF BIOMEDICAL DEVICES

Patent Proprietor:
Bausch & Lomb Incorporated

Opponents:
Johnson & Johnson Vision Care, Inc.
Novartis AG

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no) - all requests

Decisions cited:
T 0197/86, T 0020/81

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 2179/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 17 September 2015

Appellant: Johnson & Johnson Vision Care, Inc.
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
4 July 2013 concerning maintenance of the
European Patent No. 2091585 in amended form.**

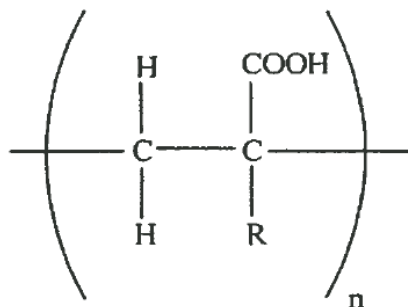
Composition of the Board:

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

Summary of Facts and Submissions

- I. The appellant (opponent 1) lodged an appeal against the interlocutory decision of the opposition division to maintain European patent No. 2 091 585 in the form of the then pending third auxiliary request.
- II. Two notices of opposition had been filed on grounds including that of lack of inventive step (Article 100(a) EPC).
- III. The documents forming part of the opposition proceedings included the following:
- D1: US 6,428,839
D9: US 4,111,922
- IV. The main request in these appeal proceedings corresponds to the third auxiliary request pending during opposition proceedings, on the basis of which the opposition division maintained the patent in suit. Claim 1 of the main request reads as follows:

"A method for improving the wettability of a biomedical device, the method comprising the step of contacting a surface of the biomedical device with a composition comprising a polymer or copolymer having one or more repeating units of the formula:



wherein R independently is a C₂-C₂₀ hydrocarbon radical and n is an integer of 2 to 5000."

Claim 1 of auxiliary request 1, filed with the response to the grounds of appeal, contains, in addition to the features of claim 1 of the main request, the following:

"wherein the biomedical device is a silicone hydrogel contact lens."

Auxiliary request 2 was filed with a letter dated 24 June 2015. Claim 1 of this request differs from claim 1 of auxiliary request 1 in that it further requires that R is, independently, an ethyl or propyl group.

- V. With respect to the third auxiliary request pending during opposition proceedings, which is the main request of the respondent (patent proprietor) in these appeal proceedings, the opposition division considered that document D1 was the closest prior art, that the problem underlying the claimed invention was providing an alternative method for improving the wettability of a biomedical device, and that the solution, which was increasing the length of the hydrocarbon R group of the polymers or copolymers of D1, was not obvious having regard to the available prior art.
- VI. The arguments of the appellant relevant for the decision were the following:

Document D1 was the closest prior art. None of the data on file provided a comparison which reflected the effect of the distinguishing feature, so that the problem underlying the claimed invention was merely the provision of an alternative method for improving the

wettability of a biomedical device. The solution, which was a method including contacting a surface of said biomedical device with a composition comprising a polymer or copolymer characterised in that said polymer or copolymer had 2-5000 units of the structure required by claim 1, was not inventive having regard to D9.

VII. The arguments of the respondent relevant for the decision were the following:

The respondent also considered that document D1 represented the closest prior art, but formulated the technical problem underlying the claimed invention as providing a method for improving the wettability of a biomedical device by forming a polymeric coating thereof according to which said coating remained longer on said biomedical device at the pH required for storage and wear. This problem was credibly solved having regard to the data presented in figures 1 and 4 of the patent in suit.

If, nevertheless, the problem underlying the claimed invention were to be considered as merely providing an alternative method for improving the wettability of a biomedical device, as there was no indication in the prior art towards the claimed solution, and in particular since none of the documents on file other than D1 referred to wettability improvements, the subject-matter claimed was inventive.

VIII. The party as of right (opponent 2) informed the board that it would not be attending the oral proceedings, which took place on 17 September 2015.

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

- The appellant requested that the decision under appeal be set aside and that the patent be revoked.
 - The respondent requested that the appeal be dismissed (main request) or, subsidiarily, that the decision under appeal be set aside and the patent be maintained on the basis of one of the first auxiliary request as filed with letter dated 18 March 2014 and the second auxiliary request as filed with letter dated 24 June 2015.
- X. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Inventive step:

2. Closest prior art

Both parties agreed with the opposition division that document D1 represents the closest prior art, and the board sees no reason to differ.

It has not been disputed that document D1 discloses a method for improving the wettability of a biomedical device comprising the step of contacting a surface of said biomedical device with a composition comprising a polymer or copolymer, and that said polymer or copolymer may comprise polyacrylic acid and polymethacrylic acid.

It has also not been disputed that the polymers and

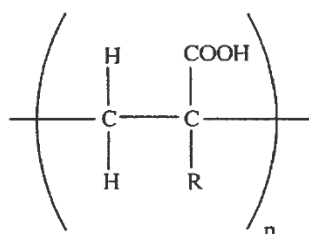
copolymers used in the method of D1 do not have any repeating unit of the formula required by claim 1.

3. Technical problem underlying the invention

The appellant formulated the technical problem underlying the claimed invention as providing a method for improving the wettability of a biomedical device allowing the wettability-imparting coating to remain on the device for a longer period of time at the pH required for storage and wear.

4. Solution

The claimed solution is a method which is characterised in that it requires a polymer or copolymer having at least one repeating unit of the formula



wherein n is an integer of 2 to 5000 and R is a C₂-C₂₀ hydrocarbon radical.

5. Success

The respondent relied on the results obtained in examples 3-6 and summarised in figures 1 and 4 of the patent in suit for showing that the problem formulated in point 3. above had been credibly solved by the features of claim 1.

Example 3 studied the conformation of PAA, PMAA, PEAA and PPAA as a function of pH, PAA and PMAA being embodiments of the polymers used in the prior art, and

PEAA and PPAA being embodiments of the polymer or copolymer required by the claimed method. The results obtained are summarised in figure 1. Although the four polymers studied experience a change of conformation, in the case of PEAA and PPAA said conformation change takes place at higher pH values, closer to those suitable for storage and wear.

According to examples 4 and 5, solutions of PAA, PMAA, PEAA and PPAA were brought into contact with hydrogel lenses, autoclaved, rinsed, submerged into different buffers at different pH values and rinsed again. The surface of the hydrogel lenses were then analysed and the results obtained summarised in figure 4.

The lenses contacted with PEAA and PPAA solutions retained their coatings at pH close to neutral whereas those coatings consisting of PAA and PMAA already rinsed away at acid pH. This result purportedly showed that the claimed method provided an increased adhesion of the polymeric coating to the biomedical device at the pH suitable for storage and wear (i.e. close to neutral) and thus that the problem as defined in point 3. above was credibly solved.

- 5.1 The appellant challenged these results on a number of grounds, including that the tested lenses had been coated at different pH values.

According to example 4, the lenses were coated with aqueous solutions of the polymers tested, whose pH was adjusted as follows: PAA at pH=2.9, PMAA at pH=3.2, PEAA at pH=5.5 and PPAA at pH=6.1. Thus, the embodiments according to D1 (PAA, PMAA) were coated at more acid pH than PEAA and PPAA.

The appellant thus concluded that these data did not allow a direct comparison with D1, since none of the experiments reflected only the effect of the distinguishing feature of the claimed invention.

- 5.2 According to established case law of the boards of appeal, in cases where comparative tests are chosen to demonstrate an inventive step with an improved effect over a claimed area, the nature of the comparison with the closest prior art must be such that the effect is convincingly shown to have its origin in the characterising feature of the invention. For this purpose, it may be necessary to modify the elements of comparison so that they differ only by such characterising features (see T 197/86, OJ EPO 1989, 371, Reasons 6.1.2 and 6.1.3).

If a comparison does not fulfil this criteria, the party relying on that data should explain the reasons for departing from the standard practise of the EPO and why the experiments, notwithstanding it, still allow a comparison showing the effect of the distinguishing features.

- 5.2.1 The respondent argued that the experimental conditions had been chosen taking into account the conformational transition observed and that the different pH values used represented those at which the adhesion was optimised, namely a pH value close but below that required for the conformational transition studied in example 3. The experiments thus provided the best possible comparison.
- 5.2.2 However, the respondent failed to provide reasons why these experiments could not have been carried out at the same pH.

The respondent also failed to provide evidence that the pH values chosen led to the best adhesion, beyond asserting that it was the case. Notwithstanding the conformation change of the coating polymers, there is no apparent technical reason why the adhesion of said polymers should be better at a given pH.

Lastly, the respondent has not provided evidence that these experiments could still show an improved adhesion of the coating derived from the distinguishing feature, for example by showing that the results were independent of the coating method. In fact, the respondent has alleged exactly the opposite, namely that the adhesion was dependent on the pH value during the coating step.

5.2.3 For these reasons, it is concluded that the data provided do not allow a direct comparison with the closest prior art which reflects the effect of the feature distinguishing the claimed invention.

5.3 The respondent argued that the burden of proving that the data presented in the patent in suit did not support an enhanced adhesion at the preferred pH values was on the appellant.

However, if the respondent wishes to rely on comparative tests departing from the standard practice as in the case law, it is its task to credibly show that those examples are still suitable for proving the alleged improvement.

5.4 Since the data provided in the patent in suit does not allow a direct comparison with the closest prior art, as they do not differ solely by virtue of the

distinguishing feature of the claimed invention, the problem as defined in point 3. above is considered as not credibly solved.

6. Notwithstanding the arguments in the previous point, even if it were acknowledged that the tested polymers showed an enhanced adhesion upon conditions of use, irrespective of the pH of the solution used for the coating, the problem as formulated in point 3. above could only be considered as credibly solved if the alleged advantage could be obtained across the subject-matter of claim 1.

The data on file refer to two specific embodiments of the invention, namely a method using a homopolymer in which every R is ethyl (PEAA) or in which every R is propyl (PPAA). However, claim 1 merely requires that the polymer or copolymer used in the claimed method contains two consecutive monomers having a substituent R which is independently a C₂-C₂₀ hydrocarbon radical. Thus, claim 1 is also directed to embodiments according to which the difference with respect to D1 as far as the polymer required is concerned is very small, so that any enhancement which could have been obtained in the case of the tested polymers would not be shared by every polymer required by claim 1.

The respondent argued that it was always possible to envisage a theoretical embodiment within a claim which would not solve the underlying technical problem, but such an approach was too artificial and should be avoided.

However, the embodiment requiring that the polymer or copolymer used in the claimed method contains two consecutive monomers having a substituent R which is

independently a C₂-C₂₀ hydrocarbon radical does not result from an artificial interpretation of claim 1 which the skilled person would never have considered, but is an embodiment which the skilled reader identifies at first sight, as claim 1 explicitly states that it includes embodiments in which n=2.

Also for this reason, it is concluded that the problem as defined in point 3. above is not credibly solved by the features of claim 1.

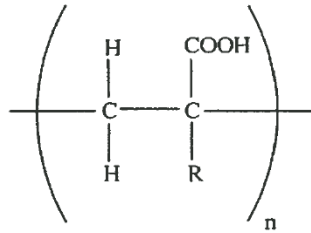
7. Reformulation of the technical problem underlying the invention

According to the case law of the boards of appeal, alleged but unsupported advantages cannot be taken into consideration in determining the problem underlying the claimed invention (see e.g. decision T 20/81, OJ EPO 1982, 217, Reasons 3, last paragraph). As the alleged improvement in terms of enhanced adhesion at the pH suitable for storage and use lacks the required support, the technical problem as defined above needs reformulation.

Thus, in view of the teaching of D1, the problem underlying the claimed invention can only be seen as providing an alternative method for improving the wettability of a biomedical device.

8. Solution

The claimed solution is a method which is characterised in that it requires a polymer or copolymer having at least one repeating unit of the formula



wherein n is an integer of 2 to 5 000 and R is a C₂-C₂₀ hydrocarbon radical.

9. Success

It has not been disputed that the technical problem reformulated in point 7. above has been solved by the method which is the subject-matter of claim 1 and, having regard to the examples of the patent in suit, the board has no objection, either.

10. Lastly, it remains to be decided whether or not the proposed solution to the objective problem underlying the patent in suit is obvious from the prior art.

10.1 Document D1 discloses a method for improving the wettability of hydrogel lenses by contacting their surface with a composition comprising polymers and copolymers of acrylic acid and metacrylic acid (examples). The lenses thus obtained have fair to excellent wettability properties (table 3, table 4).

The skilled person, trying to obtain an alternative method for improving the wettability of lenses, would consider making minor changes to the polymers required by the method of D1 which would not affect the properties of the coating.

Document D9 discloses compositions suitable for contact lenses (column 2, lines 5) which can contain

2-ethylacrylic acid (column 4, line 16). The skilled person thus knows from D9 that polymers containing 2-ethylacrylic acid can be used in contact with the eye. Due to their chemical similarity, 2-ethylacrylic acid can be linked to polyacrylic or polymethacrylic acid. The skilled person would thus consider this monomer as a suitable alternative for either replacing some units of acrylic or methacrylic acid of the (co)polymers disclosed in D1 or for adding to said polymers in order to find an alternative.

At least the embodiments consisting of adding some 2-ethylacrylic acid units to the polymers disclosed in D1 and of replacing some acrylic or methacrylic acid units thereof by 2-ethylacrylic acid, so that the polymeric coating contains a unit required by claim 1 in which $n=2$, are thus obvious for the person skilled in the art.

Since claim 1 contains embodiments which are obvious having regard to the prior art, the subject-matter of claim 1 of the main request lacks the inventive step required by Article 56 EPC.

- 10.2 The respondent argued that none of the documents on file disclosed polymers of 2-ethylacrylic acid in connection with methods for increasing the wettability of biomedical devices, so that the skilled person would not have combined the teaching of any of the documents on file, which referred to different problems, with that of document D1.

However, the skilled person would have considered further monomers not disclosed in D1 as suitable (minor) components of polymers for enhancing the wettability of contact lenses as long as they are

suitable for use in contact with the eye.

- 10.3 The respondent further argued that reading claim 1 as a method which required a polymer containing only two units of C₂-C₂₀ hydrocarbyl acrylate was an artificial interpretation of the claim which could not be justified.

However, contrary to the argument of the respondent, claim 1 has not been interpreted as encompassing a hypothetical embodiment which the skilled reader would never have considered. Claim 1 explicitly requires a polymer or copolymer having 2 to 5 000 units of a specific formula, so that it clearly identifies the embodiment of a copolymer containing only 2 repeating units of that structure.

- 10.4 The respondent also argued that document D9 referred to bacteriostatic compositions and not to methods for increasing the wettability of biomedical devices. For this reason, the skilled person would not have considered combining the teaching of this document with that of document D1.

However, as explained above, in order to find an alternative, the skilled person would not necessarily look for other methods of increasing wettability, but merely for compounds which could be compatible with biomedical devices.

- 10.5 The respondent further argued that the compositions of D9 could be in the form of a gel, powder or film and that ethylacrylic acid was not even the preferred option in D9, so that even if the skilled person took into consideration the teaching of D9 he would not have arrived at an embodiment within the claimed method.

However, the subject-matter of claim 1 does not go beyond an arbitrary selection of those equally suitable alternatives disclosed in D9 and there is no reason why the skilled person would have only taken into consideration the preferred embodiments disclosed therein. In fact, those preferred embodiments correspond to the polymers required by D1, ethylacrylic acid being disclosed as an alternative to the former.

- 10.6 Every other argument presented by the respondent during these appeal proceedings relates to the embodiment within claim 1 according to which all or at least the majority of the units of the polymer required by the claimed method has the formula as in claim 1, which is a different embodiment from that which the board has, for the reasons given above, considered not inventive.
11. It has not been disputed that the arguments set out for the main request apply in the same manner to claim 1 of auxiliary requests 1 and 2, which consequently also lack the inventive step required by Article 56 EPC.

None of the requests on file is thus allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated



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Case Number: T 2179/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of correcting an error in the decision

of 17 September 2015

Appellant: Johnson & Johnson Vision Care, Inc.
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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on

4 July 2013 concerning maintenance of the
European Patent No. 2091585 in amended form.

Composition of the Board:

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

The beginning of point 3. of the decision shall read:

" 3. Technical problem underlying the invention

The respondent formulated [...]."

(instead of "the appellant formulated [...])

The Registrar:

The Chairman



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated