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Datasheet for the decision of 10 May 2017

Case Number: T 1229/13 - 3.3.03

Application Number: 99919853.4

Publication Number: 1090312

IPC: C08F2/48, G02B1/04

Language of the proceedings: EN

Title of invention:
Method for photopolymerizing a monomer mixture to form a lens

Patent Proprietor:
Bausch & Lomb Incorporated

Opponent:
Novartis AG

Headword:

Relevant legal provisions:
EPC Art. 56, 123(2)

Keyword:
Inventive step - (no) - main request, first auxiliary request
Amendments - added subject-matter (yes)- second and third auxiliary requests

Decisions cited:

Catchword:

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Case Number: T 1229/13 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 10 May 2017

Appellant: (Opponent)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Breuer, Markus Henkel, Breuer & Partner Patentanwälte Erika-Mann-Straße 23 80636 München (DE)
Respondent: (Patent Proprietor)	Bausch & Lomb Incorporated 1400 North Goodman Street, Area 62 Rochester, NY 14609 (US)
Representative:	Glas, Holger Maiwald Patentanwalts GmbH Elisenhof Elisenstrasse 3 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 March 2013 rejecting the opposition filed against European patent No. 1090312 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	D. Semino
Members:	M. C. Gordon
	R. Cramer

Summary of Facts and Submissions

I. The appeal of the opponent lies from the decision of the opposition division posted on 21 March 2013 rejecting the opposition against European patent number 1 090 312.

II. The application as originally filed had 12 claims whereby claims 1 and 8 read as follows:

"1. A method for polymerizing a monomer mixture to form a lens comprising:
charging to a mold a monomer mixture including lens-forming monomers, a UV-absorbing compound and a tinting agent; and
exposing the monomer mixture in the mold to a light source including light in the visible region of the spectrum.

8. The method of claim 1 where the lens is a contact lens."

III. The patent was granted with a set of 8 claims, whereby claims 1, 5 and 7 read as follows:

"1. A method for polymerizing a monomer mixture to form a lens comprising:
charging to a mold a monomer mixture comprising lens-forming monomers which polymerize by free radical polymerization, a UV-absorbing compound that, when incorporated in the lens, is capable of reducing at least 70% of light in the region 200 to 400 nm, a tinting agent, and a polymerization initiator comprising a phosphine oxide moiety, and exposing the monomer mixture in the mold to a light source comprising light in the visible region of the spectrum

and filtering UV light from the light source impinging on the monomer mixture to polymerize the monomer mixture and form the lens.

5. A method as claimed in any preceding claim in which the lens is a contact lens.

7. A method as claimed in claim 5 or claim 6 in which the lens is a hydrogel contact lens."

IV. A notice of opposition against the patent was filed in which revocation of the patent on the grounds of Article 100(a) EPC (lack of novelty, lack of inventive step) was requested.

Inter alia the following document was invoked in support of the opposition:

BM1: US-A-5 224 957.

V. According to the decision, the ground of opposition pursuant to Article 100(c) EPC was admitted to the proceedings on request of the opponent with respect to claims 5 and 7. The minutes and decision record that the patent proprietor did not consent to the introduction of the new ground. The opposition division concluded that the ground did not prejudice maintenance of the patent. It was also concluded that in view of this outcome the question of admissibility of the ground did not need to be pursued and that the requests of the patentee for "postponement" (adjournment) of the oral proceedings and an apportionment of costs likewise did not need to be dealt with.

Novelty was recognised, which finding has not been challenged in the appeal proceedings.

Regarding inventive step the closest prior art was BM1, the principal difference being the feature of filtering the UV light impinging on the monomer mixture. Further, multiple selections were required to arrive at the subject-matter claimed from the disclosure of BM1.

The effect of the claimed combination of features had not been demonstrated on a lens formed in a mould, but on hydrogel films. The degree of correlation between the absence of edge curling of a hydrogel film and that of a lens prepared from a monomer cured as defined in claim 1 was not demonstrated in the patent, nor had evidence of this been provided during the opposition proceedings. However, such a degree of correlation was considered plausible. Furthermore the opponent had not demonstrated either experimentally or by appropriate arguments that the effects as determined on the hydrogel films and on a moulded lens were not correlated. In addition, BM1 did not disclose a method wherein both a UV absorbing agent and a tinting agent were simultaneously present in the photopolymerisable composition, which composition according to the operative claim contained monomers (plural) rather than a single monomer. The document BM1 was not suitable to provide a springboard to a solution with problems associated with such a combination of features (UV absorbing agent, tinting agent, lens forming monomers).

Consequently an inventive step was recognised and the opposition rejected.

VI. The opponent (appellant) appealed against the decision, maintaining objections pursuant to Article 100(a) EPC in association with Article 56 EPC and objections pursuant to Article 100(c) EPC. A further written

submission was made with letter of 13 April 2017.

VII. The patent proprietor (respondent) replied, requesting dismissal of the appeal. Three additional sets of claims forming first to third auxiliary requests were submitted.

The first auxiliary request differed from the main request (claims of the patent as granted) by deletion of claims 5-8.

The second auxiliary request, consisting of 7 claims, differed from the main request in that claim 1 was restricted to a method for forming a contact lens. Thus compared to claim 1 of the patent as granted, the first and last occurrences of "lens" were preceded by the term "contact". As a consequence claim 5 had been deleted and the subsequent claims renumbered.

The third auxiliary request consisted of claims 1-4 of the second auxiliary request.

VIII. The Board issued a summons to oral proceedings. In a communication the Board held that the opposition ground pursuant to Article 100(c) EPC had been admitted by the opposition division and hence was to be addressed in the appeal proceedings. The Board expressed doubts that claims 5 and 7 of the main request complied with said provision of the EPC.

Regarding inventive step, it was doubted that there was evidence for a technical effect over the entire scope of the claims, but it was rather considered that the outcome of the method depended on factors other than those specified in the claims, meaning that the objective problem would have to be formulated as the

provision of a further process. The claimed solution to this problem would appear to arise in an obvious manner from the teachings of BM1, being a combination of alternatives taught therein.

IX. Oral proceedings took place on 10 May 2017. As announced in writing on 5 April 2017 the respondent did not attend.

X. The arguments of the appellant can be summarised as follows:

(a) Article 100(c)/123(2) EPC

The subject-matter of granted claim 5 corresponded to an undisclosed combination of features taken from the description and claims of the application as filed. Similarly the subject-matter of granted claim 7 was the result of multiple selections from the application as originally filed.

(b) Article 56 EPC (claims 1-4)

Document BM1 as the closest prior art did not disclose the presence of a plurality of different monomers and of a tinting agent in combination.

The former feature was not shown to give rise to any technical effect and was directly suggested by BM1. The latter feature resulted in a tinted lens, so that the partial problem related thereto was the provision of a tinted lens. However this was explicitly contemplated in BM1.

Regarding the feature of filtering UV light, BM1 taught the need to use a specific wavelength range.

Since it was common general knowledge that halogen lamps produced a range of wavelengths, it would be obvious to use a filter to eliminate the unwanted radiation, in the case that filtering were considered to be a distinguishing feature.

(c) Auxiliary requests

The above objections were relevant also for the auxiliary requests.

XI. The arguments of the respondent can be summarised as follows:

(a) Procedural status of Article 100(c)/123(2) EPC

There had been no justification for the late raising of this ground. The finding of the opposition division that the objections raised under this ground were sufficiently pertinent to be taken into consideration was at odds with the finding - in the absence of any arguments by the patent proprietor - that the ground did not prejudice maintenance of the patent. Therefore the ground should not be admitted.

(b) Main request

The findings of the opposition division with regard to Article 123(2) EPC were correct. The same was true for the conclusions on inventive step based on the arguments submitted during the opposition proceedings.

(c) Auxiliary requests

The second and third auxiliary requests were restricted to contact lenses instead of lenses and were provided for the case that the Board would conclude that the main request and first auxiliary requests did not meet the requirements of Article 56 EPC.

XII. The appellant requested that the decision under appeal be set aside and that European Patent number 1 090 312 be revoked.

XIII. The respondent requested that the appeal be dismissed or alternatively that the patent be maintained in amended form on the basis of one of the first, second or third auxiliary requests, filed with the reply to the statement of grounds of appeal.

Reasons for the Decision

1. Procedural matter - status of Article 100(c)/123(2) EPC

During the oral proceedings before the opposition division the opponent requested that the ground pursuant to Article 100(c) EPC be introduced into the procedure.

According to the minutes (page 1 penultimate paragraph) the opposition division considered:

"that the ground pursuant to Article 100(c) EPC is prima facie relevant and is therefore admitted into the proceedings".

It was then announced that the ground did not prejudice

maintenance of the patent.

According to the written grounds for the decision, (page 6 third paragraph), consistently with the statement in the minutes, the newly raised ground was admitted to the proceedings:

"because, prima facie, this ground would seem to prejudice the maintenance of the European patent in suit."

It was then stated, again consistently with the minutes, that the late filed ground "did not succeed."

Thus the ground pursuant to Article 100(c) EPC was admitted to the proceedings by the opposition division. The manner of its introduction has not been challenged on a procedural basis. Hence the ground is to be dealt with in the present appeal proceedings. In these circumstances the question of whether the Board should admit the ground does not arise.

2. Main request - Article 56 EPC

2.1 Closest prior art

There is consensus between the parties that the closest prior art is represented by the teaching of BM1, and the Board can see no reason to take a different position.

BM1 is directed, according to claim 1, column 1 lines 7-15 and 59-68 and column 2 lines 6-22 to a method of providing a composition for an eye with the steps:

- providing a photopolymerisable composition for preparing an intraocular-lens filling material

- during an operation introducing the composition directly into an eye and
- curing said composition with light in the wavelength range 400-500 nm.

2.1.1 The polymerisable composition consists according to claim 1 and column 2 lines 9-11 of at least one difunctional acrylic and/or methacrylic ester of defined polyhydroxy compounds (i.e. monomer). In each of the examples however only a single monomer is employed.

2.1.2 A photoinitiator, activatable with light in the wavelength 400-500 nm is employed (claim 1, feature b) and column 2, lines 12-14). According to claim 5 and in particular column 3, lines 6-16 "particularly preferred" as photoinitiator are compounds containing phosphine oxide units and consistently with this statement, all examples employ such compounds.

2.1.3 The compositions also contain a UV absorber (claim 1, feature c) and column 2 lines 15-17) which absorbs light in the region <400 nm. According to column 3, lines 25-40 this absorber should ensure "as completely as possible absorption of the wavelength range 400 nm [*sic*] without filtering out the wavelength > 400 nm necessary for polymerisation". It is explained that the purpose of this component is to protect the retina during the irradiation employed in the curing step. The examples of BM1 employ 2-hydroxy-4-methoxybenzophenone as a UV absorber.

2.1.4 Optionally the composition can contain a dye (claim 2 and column 2, lines 19-22).

According to the examples curing is effected by

exposing the compositions to radiation from an "Elipar 2" lamp which, it is stated at column 4 line 53, has a wavelength range 400-500 nm.

2.2 The following features are either not explicitly disclosed in BM1 or require a selection within its disclosure:

2.2.1 "Monomer mixture":

In one approach, the appellant takes the position that the term "monomer mixture" as employed in the operative claim does not require structurally distinct monomers, but would also apply to a plurality of identical molecules.

This interpretation is at odds with what the skilled person would understand from the wording of the claim in the technical field of polymers. Whilst the term "monomer mixture" on its own may in this respect be considered ambiguous, and for example could be interpreted, as postulated by the appellant, as denoting a mixture containing a single type of monomer with other components such as initiators, the further feature of claim 1 "comprising lens forming monomer**s**" (plural - Board's emphasis) in the Board's view imposes unambiguously the requirement that a plurality of distinct types of monomer be present. Accordingly the feature "monomer mixture comprising lens-forming monomers" (plural) provides a distinguishing feature compared to the explicit disclosure of BM1, in particular the examples (see section 2.1.1, above).

In a second approach the appellant takes the position that the general disclosure of BM1 envisages the use of

a combination of monomers. Reference is made to the "at least one" wording in the claim as well as column 3, lines 3-6 where it is stated that different monomers can be mixed for setting various properties.

These passages of BM1 therefore do indeed disclose the use of a plurality of monomers as a possible alternative, but non-exemplified embodiment. Thus the restriction of the operative claim to a plurality of monomers constitutes a selection from the more general disclosure of BM1.

2.2.2 UV-Absorber capable of reducing at least 70% of light in the region 200-400 nm:

As explained in section 2.1.3 above, BM1 requires the presence of a UV absorber which can absorb light in the region 400 nm "as completely as possible". The appellant has submitted that this would anticipate a reduction of at least 70% as required by operative claim 1. Whilst this contention of the appellant would appear - qualitatively - to be reasonable, there is no evidence to support the quantitative limit of operative claim 1 on the extent of UV absorption. Accordingly the degree of UV absorption in the given wavelength range is not explicitly disclosed in BM1 and the defined range of extent of absorption constitutes if not a selection (because no quantitative range for the extent of absorption is given), then a restriction over the generic disclosure of BM1.

2.2.3 Filtering of UV light:

There is no explicit mention in BM1 of whether the UV light generated was "filtered", although the fact that a restricted wavelength range was employed would imply

that some form of restriction or limitation was applied to the light emitted by the lamp. Notwithstanding that the patent in suit does not provide a definition - even in general terms - what steps are implied by "filtering", this step constitutes a distinguishing feature over the explicit disclosure of the prior art BM1.

2.2.4 Tint:

A tint is not employed in the examples of BM1, although a "dye" is envisaged as an optional component (column 2, line 19). Thus the specification of a tint in operative claim 1 constitutes a selection from the disclosure of BM1.

2.3 The technical effect

Only examples 5, 6, 17, 26, 29 and 31 of the patent in suit correspond to the subject-matter of the claims.

Particularly relevant are examples 5 and 6 and reference example 7 which differ in that in examples 5 and 6 the light was filtered, which step was not disclosed for reference example 7 and furthermore in the form of the items produced (film in examples 5 and 6, or contact lens in the case of reference example 7). It appears that the contact lenses produced in reference example 7, despite the absence of any UV filtering, nevertheless exhibited satisfactory properties. In contrast hereto the evidence of examples 28-31 is that omitting the filtering step results in films which were "slightly curly" rather than "flat".

The conclusion is that for the step of filtering - insofar as this is a distinguishing feature - no

consistent effect is shown to occur over the entire scope of the claims.

Regarding the nature of the UV absorbing compound and the degree of absorption in the specified wavelength range (see section 2.2.2 above) only a single UV absorbing agent is employed in the examples of the patent in suit. The only examples which might potentially demonstrate an effect arising from the presence of this compound - examples 1B and 2B - employ neither a tint nor filtering of the light and consequently are not suitable to show any effect associated with the definition of the UV absorber in the context of the claimed subject-matter.

Regarding the other features which are explicitly disclosed as alternatives in BM1 but which are not disclosed in combination, the following conclusions are reached:

As to the presence of a plurality of monomers (monomer mixture), no technical effect has been demonstrated to arise.

As for the tinting agent, the "C" series of examples contain a tint. However the only evidence in respect of these is examples 5 and 6 which relates to films, not lenses. Furthermore reference example 7 which employs the same compositions and does produce lenses omits the step of filtering the UV light. Accordingly there is no evidence to demonstrate that - for the claimed process - the presence of a tint gives rise to any technical effect.

2.4 The objective technical problem

As explained in the foregoing section, there is no evidence that any of the features which provide a distinction over the disclosure of the closest prior art give rise, either singly or in their combination, to a technical effect. Consequently the objective technical problem has to be formulated as the provision of a further method for polymerising a monomer mixture to form a lens.

2.5 Obviousness

As indicated in the above discussion of the closest prior art BM1, many of the identified distinguishing features are disclosed therein as alternative or optional embodiments, or in the case of the filtering of UV light and the extent of the absorption by the UV absorber clearly implied or suggested. Accordingly the objective technical problem was solved compared to the closest prior art by selecting various embodiments which were expressly suggested in the closest prior art or - in the case of the UV absorbing agent - arbitrarily defining a quantitative lower limit for the amount of UV absorbed by acting in accordance the teaching of BM1 (absorption in the specified range "as completely as possible").

Regarding the feature of filtering the light, since BM1 discloses that a restricted wavelength of light was employed the step of filtering would be apparent to the skilled person as one obvious manner of accomplishing this. Therefore the step of filtering the light cannot support an inventive step.

The conclusion is therefore that the subject-matter

claimed according to claim 1 of the main request, constitutes an obvious solution to the objective technical problem, in that it consists of selections of alternatives which are explicitly disclosed in BM1 or by employing features which are clearly implied by the disclosure of BM1 and for which no technical effect has been shown.

Therefore the requirements of Article 56 EPC are not satisfied.

3. First auxiliary request

Claim 1 of this request is identical to claim 1 of the main request and shares the same fate with respect to Article 56 EPC.

4. Second auxiliary request

As explained above, claim 1 of this request differs from the main request by the restriction of the method to "contact lens".

4.1 Article 100(c)/123(2) EPC

In the application as originally filed, claim 8 was directed to the method of claim 1, wherein the lens was a contact lens (see section II, above).

According to the introductory part of the description as originally filed the process of the application is directed to the formation of a lens in general. In the discussion of the prior art in the following paragraphs specific different types of lenses, namely contact lenses and intraocular lenses are mentioned. Thus the application is not limited to or directed to contact

lenses specifically. References to contact lenses are made in the consideration of the prior art (page 2, first complete paragraph and page 10, first complete paragraph).

There is furthermore no general disclosure in the description of the application as originally filed of the process applied specifically to contact lenses. Even the most general statement in the "Summary of the Invention" on page 2 and the following more detailed discussion on pages 3-10 consistently refers to lenses in general rather than contact lenses.

The method of granted claim 1 contains a number of features in addition to claim 1 of the application as originally filed, namely:

- "which polymerize by free radical polymerization";
- "[UV absorbing compound] that when incorporated in the lens, is capable of reducing at least 70% of light in the region 200 to 400 nm";
- "and a polymerization initiator comprising a phosphine oxide moiety";
- "and filtering UV light from the light source impinging on the monomer mixture to polymerize the monomer mixture and form a lens".

The first of these features is disclosed in the final paragraph of page 2 of the application as originally filed. This is disclosed in general, i.e. not associated with any particular type of lens.

The second amendment relating to the UV absorber is disclosed at page 8, third paragraph again with no indication of the type of lens to which this preferred

feature applies.

The definition of the curing agent is disclosed in original claim 2 which being dependent on claim 1 was not restricted to any particular embodiment of lens. A corresponding disclosure is on page 9, starting at the second complete paragraph.

Finally the step of filtering the light is discussed in originally filed claim 7 which was dependent on claim 6 which specified that the monomer mixture was exposed to light "predominantly in the visible part of the spectrum". A corresponding disclosure is to be found in the paragraph bridging pages 10 and 11 of the application as originally filed.

Thus whilst the features introduced into claim 1 have a basis in the description and have been retained in their most generic form, these are disclosed in the application as filed only in association with lenses in general. There is however no basis in the application as filed for this combination of preferred method features wherein the lens to be formed is specifically a contact lens.

Claims 8 and 9 of the application as originally filed are directed to contact lenses, but only in the context of the general process of claim 1 as originally filed.

Only two examples - reference example 7 and example 32 - of the application and patent relate to contact lenses. However these employ specific compositions and a specific form of moulding, and therefore cannot provide a basis for the generality of operative claim 1. Additionally it is not disclosed whether in the method shown in reference example 7 filtering of UV

light has been applied, meaning it is not certain that this example falls within the scope of of claim 1.

Accordingly there is no general basis in the application as filed for a method for preparing contact lenses in combination with the various features introduced into claim 1 of the patent as granted with the result that the second auxiliary request does not meet the requirements of Article 123(2) EPC.

5. Third auxiliary request

Claim 1 of this request is identical to claim 1 of the second auxiliary request so that the above conclusions with respect to Article 123(2) EPC apply.

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:

B. ter Heijden D. Semino

Decision electronically authenticated