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D E C I S I O N
of 28 June 1994

Case Number: T 0855/92 - 3.4.2

Application Number: 84302443.1

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Language of the proceedings: EN

Title of invention:
Tinted hydrogel plastic articles and method of tinting them

Patentee:
Softint Inc.

Opponent:
CIBA-GEIGY AG

Headword:
Tinted hydrogel contact lens/SOFTINT

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

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

Decisions cited:
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Case Number: T 0855/92 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 28 June 1994

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 19 May 1992 posted 20 July 1992 revoking European patent No. 0 122 771 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: E. Turrini
Members: R. Zottmann
B.J. Schachenmann

Summary of Facts and Submissions

I. The Appellant (Proprietor of the patent) lodged an appeal against the decision of the Opposition Division on the revocation of European patent No. 0 122 771 with the application No. 84 302 443.1.

Opposition was filed against the patent as a whole and based on Article 100(a) and 100(c) EPC.

The Opposition Division held that the grounds for opposition mentioned in Article 100(a) EPC prejudiced the maintenance of the patent.

Among others the following documents were cited during the opposition procedure:

(01) H. Rath: Lehrbuch der Textilchemie, third edition, 1972, pages 482-485, 557 and 568-570;
(02) AT-B-245 286;
(03) GB-A-1 583 492;
(03A) DE-A-2 728 613.

II. The Appellant requested that the decision under appeal be set aside and the opposition be rejected.

III. The Respondent (Opponent) requested that the appeal be dismissed. Furthermore, he requested oral proceedings, as auxiliary request.

IV. The Appellant submitted three sets of amended claims. The wording of Claim 1 on file according to the **main request** at the time of the present decision reads as follows:

"1. A process for producing a tinted hydrogel soft contact lens having a pupillary area, an iris area surrounding and contiguous with said pupillary area, and a scleral area surrounding and contiguous with said iris area, which process comprises dispersing a solubilized leuco sulfate ester of at least one vat dye to provide a water-compatible dispersion including an aqueous solution of said solubilized leuco sulfate ester, heating said dispersion to a temperature within the range of 35°C to 85°C and maintaining said dispersion at that temperature, impregnating a hydrogel soft contact lens having a water content within the approximate range of 28% to 79% by weight with a swelling agent which is a polar organic liquid to enlarge the pores of he hydrogel and simultaneously with said dispersion within said iris area, while maintaining said dispersion at said temperature and maintaining said scleral area and said pupillary area clear and untinted, rinsing the impregnated hydrogel soft contact lens, precipitating substantially all of said sulfate ester by oxidation to provide in the lens water-insoluble vat dye substantially all of which is distributed in a subsurface region of the lens and is physically locked within said hydrogel lens, which vat dye is substantially impervious to autoclaving, and rinsing the haydrogel soft contact lens after the sulfate ester has been precipitated."

Claim 1 of the **first auxiliary request** and, respectively, the **second auxiliary request** differs from Claim 1 of the main request only in that "a polar organic liquid" is replaced by "methanol or another mono-alcohol" and, respectively, "methanol".

Claims 2 to 5 are dependent on their respective independent Claim 1.

V. The Appellant's arguing with respect to Claim 1 is summarized as follows:

Maintenance of a certain raised temperature within a given range during impregnation step (features C and E3, see 2. below) can be derived by the skilled person from the application as filed. Such a temperature is applied to obtain an adequate dispersion and it is evident for the skilled person from the description to maintain the dispersion at that temperature to maintain the dye particles dispersed in the liquid. The examples should not be interpreted as limitative in this context.

Document (03) is not clear in its use of term "hydrogel" (feature D1, see 2. below), that is whether the starting material of the process of contested Claim 1 is a resin swollen with water ("hydrogel gel") or unswollen with water ("xerogel"). Methods (i) to (iii) use a xerogel at the start of the treatment and it is unclear which type of gel method (iv) uses.

Example 13 of document (03) is somewhat confusing in terms of the order in which the steps are carried out. It does not make sense first to dip the moulding in solubilized vat dye, then to dip it in a bath of a swelling agent and later to wash off excess vat dye solution. To clarify this aspect, the original Japanese texts on which the English version of (03) is based are to be consulted.

Experiments are carried out to furnish evidence that certain features of Claim 1, particularly simultaneous swelling and impregnating (feature E1, see 2. below), are important to achieve a commercially acceptable tinted soft contact lens and, respectively, that the results of experiments following the teaching of examples of (03) are commercially unacceptable.

VI. The Respondent's arguing with respect to Claim 1 is summarized as follows:

Maintenance of a certain temperature during impregnation step (features C and E3, see 2. below) is disclosed only in connection with the preparation of the dye dispersion and only as an optional feature. In Example II the temperature during the impregnation step lies outside the range indicated in (amended) Claim 1. According to Examples I, III and V, the dye dispersion is heated, but maintenance of the reached temperature is only disclosed in Example IV. However, this example is restricted to very particular process conditions such that abstraction of said feature in a generalized manner, that is application of said feature in a broad claim, is critical.

It cannot be deduced from the use of the expression "hydrogel resin" in (03) that by it only unswollen hydrogel is meant.

Reference is made to (03A) page 10 where the simultaneousness of the swelling step and the impregnating step is disclosed.

Example 13 of (03) shows that not only in method (iv) swelling agents stronger than water are applied and hence that the measures described in connection with the four methods are interchangeable.

The experiments of the Appellant are irrelevant since they do not take into account the nearest prior art that is simultaneously swelling and impregating using an organic solvent following from a combination of methods (i) and (iv) which is illustrated by Example 5.

Reasons for the Decision

1. The appeal is admissible.

2. Claim 1 consists of the following features which are listed separately and numbered to facilitate reference to them:

A) A process for producing a tinted hydrogel soft contact lens;

B) a solubilized leuco compound of at least one vat dye is dispersed to provide a water-compatible dispersion including an aqueous solution of said ester;

B1) the leuco compound is a sulfate ester;

C) said dispersion is heated to a temperature within the range of 35°C to 85°C and said temperature of said dispersion is maintained;

D) a hydrogel is impregnated with a swelling agent to enlarge the pores of the hydrogel;

D1) said hydrogel is a soft contact lens;

D11) said hydrogel has a water content within the approximate range of 28% to 79% by weight;

D12) said lens has a pupillary area, an iris area surrounding and contiguous with said pupillary area, and a scleral area surrounding and contiguous with said iris area;

main request:

D2) the swelling agent is a polar organic liquid;

first auxiliary request:

D2') the swelling agent is methanol or another mono-alcohol;

second auxiliary request:

D2") the swelling agent is methanol;

E) said lens is impregnated with said dispersion

E1) simultaneously with step D;

E2) within said iris area, maintaining said scleral area and said pupillary area clear and untinted;

E3) while maintaining said dispersion at said temperature (35°C to 85°C);

F) said impregnated lens is rinsed;

G) substantially all of said ester is precipitated by oxidation to provide in the lens water-insoluble vat dye;

G1) substantially all of the vat dye is distributed in a subsurface region of the lens;

G2) substantially all of the vat dye is physically locked within said lens;

G3) the vat dye is substantially impervious to autoclaving;

H) said lens is rinsed after said ester has been prepitated.

3. *Allowability of the amendments of Claim 1*

3.1 Features C and E3

The patent application as filed discloses on page 3 last paragraph to page 4 paragraph 1 a process for tinting a hydrogel lens wherein the process comprises

"(1) impregnation pores of the article with a water-compatible dispersion of solubilized leuco sulfate ester of a vat dye and (2) precipitating an insoluble dye within those pores. Warming may be needed to ensure that all of the leuco sulfate ester is dispersed and that the particles of the dispersion are sufficiently fine. A portion of the leuco sulfate ester might otherwise remain on the surface of the hydrogel plastic article and could form an insoluble deposit that would be resistant to the rinsing that preferably follows each of steps (1) and (2)."

Thus warming is mentioned in the same paragraph and immediately after the sentence describing the step of impregnating the article with the solubilized vat dye solution/dispersion and is thus closely related to said steps (1) and (2) (corresponding to features E and G of Claim 1). Moreover, according to the paragraph bridging pages 4 and 5, heating is used to maximize dissolution of the solubilized dye. To maintain the achieved high degree of dissolution until the solubilized dye is precipitated, maintenance of said elevated temperature until the precipitation step seems to be necessary.

It is, however not unambiguously clear whether the reference to warming relates also to step (1) and whether the higher temperature is to be maintained also during said impregnation step (corresponding to feature E of Claim 1). The skilled person would seek to find an answer in the remaining application documents, e.g. in the part describing the examples of the process. Examples I, III, IV an V inform him that the dispersion is prepared at an elevated temperature and that it is also applied to the lens at that temperature (see page 11, lines 17 to 21, page 12, lines 33 to 35 and page 14, lines 1 to 9). Examples I, III and V are silent about the march of the temperature during dispersion preparation and impregnation steps. In Example IV the dispersion is heated to 50°C for at least 5 min to obtain dissolution of as much solubilized dye as possible. The filtered dispersion is maintained at 50°C during the time it is used to tint the contact lens. Since a high dissolution is, apparently, not only desirable during preparation of the dispersion but also during step E, e.g. to maintain the desired high degree of dissolution of the solubilized vat dye and to accelerate the impregnation of the hydrogel soft lens with said dye. Therefore, the skilled person would seriously contemplate specific Example IV as a possible practical embodiment of the described invention and applicable also to the other examples using other solubilized vat dyes (see e.g. decision T 0187/91, to be published, particularly Chapter 4. and Headnote).

With this information in mind, the skilled person would interpret the passage of page 3, lines 31 to 34 in the sense that, at least optionally, the elevated temperature is maintained during steps D and E in order to keep all of the leuco sulfate ester dispersed and, respectively, as far as possible, dissolved.

With respect to possible temperatures to be used for such a dispersion, the application as originally filed mentions in the paragraph bridging pages 4 and 5 a temperature in the range of 35 to 85°C: " ... if an elevated temperature is used, it may range from 35°C to 85°C, ... optimum conditions are established for each individual solubilized leuco sulfate ester."

Taking into account the above considerations, said range is an optional range for the temperature also during the impregnation step.

In Example II, the hydrogel is impregnated with the dispersion (mixed with a swelling agent) at 30°C for 35 s. The text describing said example is, however silent about the temperature during the production of the dispersion. Thus it cannot be deduced from this example that the temperature during production of the dispersion feature B is different from the temperature during the impregnation step E. Moreover, since said temperature range is only optional, a temperature lying outside said range cannot call into question the validity of said range.

Claims 1 do not comprise Examples I, II and V). However, the Board sees no reason why it should not be possible to restrict Claims 1 to an embodiment comprising not all examples and, respectively, why a claim restricted by inserting features which are characterized as optional features in the original application documents should not be allowable (however, deletion of examples not supporting such an amended claim or indication of such a circumstance in the description would be necessary under Article 84 EPC).

Thus the technical information can be taken from the original application by the skilled person that the process comprises the steps of heating the dispersion to a temperature within the range of 35 to 85°C and maintaining said dispersion at that temperature during dispersion preparation (feature C) and during impregnation of the lens (feature E3).

3.2 Features D2' and D2"

However, there is no basis for the use of **mono**-alcohol other than methanol as a swelling agent, since the original application (see p. 4, paragraph 3 and the examples) mentions only a polar organic liquid, a protic solvent, methanol, another **alcohol**, glycol and glycerol as suitable swelling agents.

3.3 The Board finds that a process comprising not only the features C, E3, D2" - and thus D2 since methanol does be a polar organic liquid - but also the remaining features of Claim 1 (which are identical for all requests) is disclosed in the application as filed and that none of said versions extends the protection of Claim 1 as granted. Therefore, said Claims 1 of the main request and the second auxiliary request comply with Article 123(2) and (3) EPC.

However, Claim 1 of the first auxiliary request extends beyond the content of the application as filed and is not allowable under Article 123(2) EPC.

4. *Nearest prior art*

It is undisputed that the nearest prior art with respect to the subject-matter of Claim 1 (all requests) is described in (03) or (03A), both documents belonging to the same patent family and claiming the same priorities.

The Respondent alleges that document (03A) discloses the nearest prior art, since in (03A) method (iv) is not a two stage process as in (03), but is intended by the authors to be a process in which the swelling of the lens and the dyeing takes place simultaneously; reference is made to page 10: "*Ein ... viertes Verfahren ... umfaßt die Stufen der Eintauchung des Hydrogelharzes ... zur Quellung ... des Hydrogelharzes* ***und*** *der Färbung oder des Bedruckens des ... Hydrogelharzes mit ... einer Leukoverbindung* ... ". The German word "*und*" is, in this context, indifferent as to the sequence of the steps: according to said passage, it means only that the process comprises said steps. Moreover, no distinction is made in this passage between dyeing and printing. It is hard to contemplate that the printing of a hydrogel should occur while the hydrogel is immersed in an aqueous solution. The interpretation of said passage that swelling and dyeing are two subsequent steps is supported also by Claim 5 which, apparently, claims process (iv) and discloses that the swelling step is followed by the dyeing step.

Thus, document (03A) does not disclose a prior art which comes closer to the subject-matter of Claim 1 than the prior art of document (03) and, as a consequence, each of said documents can be chosen as nearest prior art.

The four methods used in (03) for impregnating the hydrogel with the solubilized vat dye can be characterized as follows:

method (i): simultaneously swelling the hydrogel in water and impregnating with the solubilized vat dye;

method (ii): first impregnating the hydrogel with the solubilized vat dye and then swelling the resin;

method (iii): first swelling the hydrogel and then impregnating the hydrogel with the solubilized vat dye;

method (iv): first swelling the hydrogel with swelling agent which has a higher swelling power than water and then impregnating the hydrogel with the solubilized vat dye.

5. *Novelty - main request and second auxiliary request*

The nearest prior art of (03) concerns the tinting of articles, particularly soft contact lenses, made of hydrogel resins (see page 1, last paragraph and page 2, lines 11-16) and describes with respect thereto the following manufacturing process steps:

a solubilized leuco compound of at least one vat dye is dispersed to provide a water-compatible dispersion including an aqueous solution of said compound (see page 2, fourth paragraph: "... the water-soluble vat dye ... is in the form of a colourless leuco compound ... "; aqueous solutions **or inks** of the solubilized vat dye are used in all examples; it is well known in the art that an ink is a dispersion);

a hydrogel soft contact lens is impregnated with a swelling agent which may be methanol (and thus a polar organic liquid) to enlarge the pores of the hydrogel (see page 3, lines 71 to 92; as to the subfeature that the lens before the swelling and the impregnation steps is a hydrogel soft material, see particularly Examples 5, 8, 15, 16, Claim 15 and page 3 lines 19 to 26);

said lens has a pupillary area, an iris area surrounding and contiguous with said pupillary area, and a scleral area surrounding and contiguous with said iris area (this is a property of every normal contact lens and thus also of the contact lens of (03));

said lens is impregnated with said dispersion (see all methods (i) to (iv) on page 2, lines 73 to 107 and page 3, lines 71 to 78 and the examples) simultaneously with the preceding step (see method (i) on page 2, lines 76 to 78 and Example 1);

said impregnated lens is rinsed (see Examples 1 and 13); substantially all of said leuco compound is precipitated by oxidation to provide in the lens water-insoluble vat dye (see Claim 7; as to the expression "substantially all": in chemical reactions of this type the reaction is never complete); substantially all of the vat dye is physically locked within said lens (see page 2, lines 67 to 72); the vat dye is substantially impervious to autoclaving (see the dye fixation tests in many examples); and

said lens is rinsed after said leuco compound has been precipitated (see e.g. page 4 and Example 1).

Therefore the features A, B, D, D1, D12, D2, D2", E, E1, F, G, G2, G3 and H individually, even of not in combination, are disclosed in (03), whereas the features B1, C, D11, E2, E3 and G1 are not explicitly disclosed there. Moreover, features D2/D2" and E1 are realized in different methods and examples (D2/D2" in method (iv) and Examples 12 to 18 and E1 in method (i) and Examples 1 to 3) and the rinsing steps F and H are mentioned only in Examples 1 and 13.

Therefore, Claims 1 of main request and second auxiliary request are novel.

6. *Inventive step - main request and second auxiliary request*

6.1 Said distinguishing features and the combination of features of individual examples and methods of document (03) - see last part of the preceding section 5. - result in a process which can be carried out in a shorter time and simpler - due to the simultaneousness of steps D and E (feature E1) - and which leads to a contact lens having a dyeing of satisfactory depth and intensity in the iris area of the eye.

The objective problem to be solved by the invention was therefore to find a process effecting such results.

6.2 Since all the methods and examples of prior art (03) which have been referred to above have the same object, that is a durable and intensive tinting of a hydrogel resin contact lens with a vat dye, the skilled person who wants to find suitable conditions for a process providing such a lens would take into account all the methods and examples disclosed in said prior art. Since, moreover, most of the individual steps, for example preparing the dispersion, swelling, impregnating with

the dispersion, precipitating and rinsing are related to particular and independent problems, the skilled person would consider those steps to be exchangeable between the different methods and examples. This is confirmed by the following fact: The use of swelling agents having a higher swelling power than water is, according to the passage where the four methods of (03) are described (page 2, lines 73 to 107 and page 3, lines 69 to 92), apparently restricted to method (iv). Nevertheless, in Example 13 where the impregnation with the solubilized dye is carried out before the swelling step, a swelling agent (2-ethoxyethanol) having a greater power of swelling the hydrogel than water (and mentioned as such in (03), see page 3, lines 83 to 92) is applied and considerable concentrations of such agents (glycerine, 2-ethoxyethanol) are contained in the printing ink (see Examples 5 to 8, 10, 15, 16, 18 and 19).

Thus it is obvious for the skilled person that use of such stronger swelling agents need not be restricted to method (iv). Starting e.g. from Example 1 of (03), the man skilled in the art, being aware of the effect of such agents on the pore radius of a hydrogel, as explained on page 3, lines 93 to 122 of (03), would expect to obtain an improved result when adding such an agent, as e.g. methyl alcohol, to the swelling solution and/or to the ink. He would then readily recognise that a good result is indeed achieved when adding it to the ink. Vice versa, simultaneous impregnating and swelling according to method (i) could also be applied in method (iv), e.g. in order to accelerate and simplify the latter method. Reference is also made to Claim 13 of the original application of the patent in suit where swelling preliminary to impregnating is mentioned equivalently with simultaneous swelling and impregnating (" ... the hydrogel is treated **before or during** said impregnation to enlarge the pores in the said hydrogel").

Therefore, to solve the above problem, the skilled person would seriously envisage to simultaneously carry out steps D and E and thus to realize feature E1.

The skilled person, when working out the details of a chemical process like that of contested Claim 1, has to determine the conditions for the reactions of such a process in experiments, e.g. concentrations of the reaction partners, time of reaction, pressure and temperature. The skilled person confronted with the problem to choose a suitable temperature for steps B (disperging step), D and E under the conditions that good dissolution, swelling and impregnation in a short time is achieved, would envisage a reaction temperature above room temperature but below the boiling temperature of the solvent (water) and thus a temperature in the range of feature C/E3, since it is well-known in the art that the reaction velocities of chemical reactions and absorbing processes are strongly dependent on temperature. Moreover, use of elevated temperatures in the claimed range is suggested by method (ii) where swelling and impregation is carried at a temperature of between 30 and 100°C.

Regarding feature D11, the Appellant itself stated on page 4, lines 17 and 19 of the application as filed that "Hydrogel soft contact lenses currently on the market have water contents within the approximate range of 28% to 79% by weight ... ". Thus, the skilled person would in the first place use such hydrogel as starting material.

Similar considerations apply to feature B1, since the skilled person knows that one of the most usual methods for solubilizing vat dyes is to transform them into leuco sulfate esters, see for example (01).

In order to obtain a lens having colour effect limited to the iris area of the eye, which is desired e.g. for driving a car at night (see application as originally filed, page 10, second paragraph), it is a trivial measure to restrict the impregnation process to the iris area (feature E2). Reference is also made to document (02), particularly page 2, lines 13 to 16 where such a measure is realized when tinting hydrogel soft contact lenses.

It is not recognizable that feature G1 (the same is true for features G2 and G3) defines more than a result to be achieved when all other features are realized (see the only place of the originally filed application where G1 is diclosed: Example III, page 13, lines 24 to 31).

6.3 The Appellant alleges that (03) is not clear in its use of the term "hydrogel" (feature D1). Reference is made particularly to Claim 15 which refers back to all preceding claims and which states that the hydrogel resin is in the form of a soft contact lens. This means that the material at the start of the dyeing method, in a preferred embodiment of (03), is a hydrated gel.

The Appellant states that Example 13 is confusing in terms of the order in which the steps are carried out. The Board is not able to follow this arguing. Swelling of the hydrogel impregnated with the solubilized vat dye is provided for to cause the dye to permeate the hydrogel (see page 2, lines 96 to 99). It would thus not be advantageous to wash off the solution deposited on the surface before swelling the hydrogel. Therefore, there is no reason why the skilled person should consult the Japanese priority documents.

It follows from the above that the question whether the subject-matter of Claim 1 involves an inventive step has to be answered in the negative.

6.4 Therefore, the subject-matter of Claims 1 of the main request and the second auxiliary request do not involve an inventive step (Article 56 EPC) and said claims are not allowable (Article 52(1) EPC).

7. The remaining claims are dependent on their respective Claim 1 and thus fall together with the latter.

8. Thus the grounds for opposition mentioned in Articles 100(a) and 100(c) EPC prejudice the maintenance of the patent.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Martorana E. Turrini