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Title of invention:
COLORED INK FOR PAD TRANSFER PRINTING OF SILICONE HYDROGEL LENSES

Patent Proprietor:
Novartis AG

Opponent:
Johnson & Johnson Vision Care, Inc.

Relevant legal provisions:
EPC Art. 100(c), 100(b), 54, 56
RPBA Art. 12(4)

Keyword:

Grounds for opposition - added subject-matter (no) - insufficiency of disclosure (no)
Novelty - (yes)
Experimental report not admitted before the opposition division and resubmitted with the statement of grounds of appeal
Inventive step - (yes)

Decisions cited:

G 0002/10, G 0001/03, T 0972/04, T 1009/06, T 0894/07, T 1374/07, T 1710/09, T 0922/10, T 1525/10, T 0409/91, T 0206/83

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Case Number: T 1678/13 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 6 December 2016

Appellant: (Opponent)	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway, Suite 100 Jacksonville, Florida 32256 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Patent Proprietor)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Henkel, Breuer & Partner Patentanwälte Erika-Mann Strasse 23 80636 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 April 2013 rejecting the opposition filed against European patent No. 1735643 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. C. Gordon
Members:	F. Rousseau
	C. Brandt

Summary of Facts and Submissions

I. This decision concerns the appeal by the opponent against the decision of the opposition division posted on 9 April 2013 to reject the opposition against European patent No. 1 735 643, based on international application PCT/EP2005/003382 (published as WO 2005/098478). The opponent had requested revocation of the patent in its entirety on the grounds under Article 100(c) EPC, 100(a) EPC (lack of novelty and inventive step) and Article 100(b) EPC.

II. The patent as granted contained 3 independent claims reading as follows:

"1. A method for making a colored silicone hydrogel contact lens, comprising the steps of:
(a) applying a color coat to at least a portion of at least one of the molding surfaces of a lens mold with an ink, wherein the ink comprises at least one colorant and a binder polymer, wherein the lens mold includes a first mold half having a first molding surface defining the anterior surface of a contact lens and a second mold half having a second molding surface defining the posterior surface of the contact lens, wherein the first and second mold halves are configured to receive each other such that a contact lens forming cavity is formed between the first and second molding surfaces, wherein the colored coat contains a first surface exposed to the interior of the lens-forming cavity and a second surface in contact with the molding surface;
(b) partially or completely curing the ink printed on the mold to convert the colored coat to a colored film;
(c) dispensing a silicone hydrogel lens-forming material into the lens-forming cavity of the mold; and

(d) curing the lens-forming material within the lens-forming cavity to form the contact lens, whereby the colored film detaches from the molding surface and becomes integral with the body of the contact lens, **characterized in that** the binder polymer is a silicone-containing binder polymer, which is a copolymerization product of a polymerizable mixture including
(i) at least one hydrophilic vinylic monomer;
(ii) at least one silicone-containing vinylic monomer or macromer, and
(iii) optionally one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent.

16. A method for making a colored silicone hydrogel contact lens, comprising the steps of:
(a) providing a contact lens constructed of a silicone hydrogel;
(b) applying a color coat to at least a portion of a surface of the lens with an ink, wherein the ink comprises at least one colorant, a binder polymer, an adhesion promoter, and one or more vinylic monomers,
(c) curing the ink, thereby causing the color coat to adhere to the lens,
characterized in that the binder polymer in step (b) is a silicone-containing polymer which is a copolymerization product of a polymerizable mixture including
(i) at least one hydrophilic vinylic monomer;
(ii) at least one functionalizing vinylic monomer containing at least one functional group selected from the group consisting of hydroxyl group -OH, amino group -NHR (wherein R is hydrogen or C_1 to C_8 alkyl), carboxylic group -COOH, epoxy group, amide group -CONHR, and combinations thereof;

(iii) at least one silicone-containing vinylic monomer or macromer; and
(iv) one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent.

28. An ink for making colored contact lenses, comprising at least one colorant, a binder polymer, an adhesion promoter, a solvent, a vinylic-monomer mixture, and a photoinitiator or thermal initiator, wherein the ink has the capability to be cured actinically or thermally to form a colored coat on a contact lens, wherein the colored coat has good adhesion to the contact lens without being covalently attached to the lens material of the contact lens, **characterized in that** the binder polymer is a silicone-containing binder polymer which is
(A) a silicone-containing polyurethane and/or polyurea polymer having at least two functional groups selected from the group consisting of hydroxyl, amino (primary or secondary), isocyanato groups, and combinations thereof, or
(B) a copolymerization product of a polymerizable mixture including
(i) at least one hydrophilic vinylic monomer;
(ii) at least one functionalizing vinylic monomer containing at least one functional group selected from the group consisting of hydroxyl group -OH, amino group -NHR (wherein R is hydrogen or C_1 to C_8 alkyl), carboxylic group -COOH, epoxy group, amide group -CONHR, and combinations thereof;
(iii) at least one silicone-containing vinylic monomer or macromer, and
(iv) one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent,

wherein the silicone-containing polyurethane and/or polyurea polymer is a polymerization product of a mixture containing: (a) at least one aminoalkyl polyalkyleneglycol (a poly(oxyalkylene)diamine) or one polyalkyleneglycol (poly(alkylene oxide)) or one a,w (sic)-dihydroxyl alkyl end-capped polysiloxane (b) optionally at least one compound having at least two hydroxy or amino (primary or secondary) groups, and (c) at least one diisocyanate."

Claims 2 to 15, claims 17 to 27 and claim 29 defined preferred embodiments of the subject-matters of claim 1, claim 16 and claim 28, respectively.

III. Claim 27 of the application as filed read as follows:

"27. An ink for making colored contact lenses, comprising at least one colorant, a silicone-containing binder polymer, an adhesion promoter, a solvent, optionally a vinylic-monomer mixture, and optionally a photoinitiator or thermal initiator, wherein the silicone-containing binder polymer is
(A) a silicone-containing polyurethane and/or polyurea polymer having at least two functional groups selected from the group consisting of hydroxyl, amino (primary or secondary), isocyanato groups, and combinations thereof, or
(B) a copolymerization product of a polymerizable mixture including
(i) at least one hydrophilic vinylic monomer;
(ii) at least one functionalizing vinylic monomer containing at least one functional group selected from the group consisting of hydroxyl group -OH, amino group -NHR (wherein R is hydrogen or C_1 to C_8 alkyl), carboxylic group -COOH, epoxy group, amide group -CONHR, and combinations thereof;

(iii) at least one silicone-containing vinylic monomer or macromer, and
(iv) optionally one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent,
wherein the silicone-containing polyurethane and/or polyurea polymer is a polymerization product of a mixture containing: (a) at least one aminoalkyl polyalkyleneglycol (a poly(oxyalkylene)diamine) or one polyalkyleneglycol (poly(alkylene oxide)) or one a,ω - dihydroxyl alkyl end-capped polysiloxane (b) optionally at least one compound having at least two hydroxy or amino (primary or secondary) groups, and (c) at least one diisocyanate and (d) optionally a polyisocyanate, wherein the ink is characterized by having capability to be cured actinically or thermally to form a colored coat on a contact lens, wherein the colored coat has good adhesion to the contact lens without being covalently attached to the lens material of the contact lens."

IV. The documents submitted during the oral proceedings included:

D1: US 2004/001181 A1
D2: EP 1 262 307 A2
D3: US 5,272,010
D4: US 5,260,000
D5: US 5,120,121
D6: US 5,034,166
D9: WO 01/40846 A2
D10: WO 02/074186 A2
D11: WO 03/040242 A2
D13: US 4,668,240
D14: US 4,857,072
D17: WO 2004/016671 A1

D20: US 5,158,718
D21: USAN-Statement of Adoption on Balafilcon A, 28 September 1994
D22: Excerpt from Toxicological Profile for Hexamethylene Diisocyanate, Agency for Toxic Substances and Disease Registry, August 1998
D23: US 5,070,215
D24: Experimental Report of the opponent submitted with letter of 08 March 2013
D25: WO 2009/124048 A1

V. The opposition division's decision can be summarised as follows:

Documents D20 to D23 were admitted into the proceedings. D24 and D25, however, were not admitted into the proceedings, because they were considered to have been filed too late for the proprietor to react appropriately. Claims 1, 16 and 28 did not extend beyond the content of the application as filed. The objection that the subject-matter was insufficiently disclosed failed to persuade in particular because no evidence had been provided that the numerous methods exemplified in the patent in suit could not be reproduced. The subject-matter of claim 1 was novel over D1, that of claim 16 over D10 and D1 and that of claim 28 novel over any of D4, D10 and D11. The subject-matter of claim 1 was inventive over D1 in combination with common general knowledge and/or D10. D4 was not considered to be a promising starting point leading to the invention. Regarding the subject-matter of claim 16, the skilled person starting from the teaching of D1, D2, D3 or D13 would not be prompted by any of the cited documents to arrive at said subject-matter. As regards claim 28, the skilled person starting from the teaching of D10 or D11, the skilled

person would have to make too many modifications in order to arrive at the ink of claim 28. Neither the general common knowledge nor the teaching of D14 and/or D17 would provide a hint to perform these modifications.

VI. An appeal against that decision was lodged by the opponent (hereafter appellant).

VII. With the statement of grounds of appeal (letter of 19 August 2013) the appellant submitted the following documents:

D26: US 4,139,513
D27: US 3,808,178.

VIII. Further submissions by the appellant were made with letter of 14 July 2014. With letter of 7 November 2016 a summary of the examples of the patent in suit in tabular form (hereafter D29) was submitted by the appellant.

IX. The respondent replied to the appeal with a letter dated 3 February 2014 and submitted therewith auxiliary requests 1 to 7. A further submission was made with letter of 6 October 2016.

X. On 6 December 2016, oral proceedings were held before the Board.

XI. The appellant's submissions, as far as relevant to the present decision, can be summarized as follows:

(a) Article 100(c) EPC

Granted claim 28 differed from claim 27 of the application as filed in that two originally optional components of the ink, a vinylic-monomer mixture and a photoinitiator or thermal initiator, as well as the originally optional feature that one or more components of the polymerizable mixture for making silicone-containing binder (B) could be selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent had been made mandatory. In addition, the definition of the mixture used for preparing the silicone-containing binder (A) had been amended to exclude that it contained a polyisocyanate. In the application as filed a total of 16 different embodiments resulted from the various possible combinations of these four optional features. The selection of one of those 16 possibilities as defined in granted claim 28 was not directly and unambiguously derivable from the application as filed. Moreover, the use of a vinyl-monomeric mixture did not necessarily mean for the skilled person that a photo initiator or a thermal initiator had to be used, because, depending on the choice of the monomers, electron beam could be used to initiate polymerisation. Ink 17, which did not contain a photo or thermal initiator, could not provide a basis for amended claim 28. The Case Law stressed that the claimed subject-matter following amendment must be "individualised" in the application as filed (T 0972/04, T 1009/06, T 0894/07, T 1374/07, T 1710/09, T 0922/10 and

T 1525/10) or that the combination of disparate features added matter (T 0510/10). It was also referred to G 2/10 which made clear that it was not sufficient for meeting the requirements of Article 123(2) EPC that a feature introduced into a claim was disclosed in the application as filed, but also necessary that the resulting combination of features was disclosed. Hence, granted claimed 28 extended beyond the content of the application as filed.

(b) *Article 100(b) EPC*

Example 2, Table 3 showed that it was not possible to obtain a successful coloured contact lens for many binder polymers, diluents and lens forming materials falling within the scope of claims 1, 16 and 28. Only two of the eleven inks tested in Table 3, namely Inks 3 and 11, resulted in good print quality and good print transfer to the lens. As summarized in D29, methods using the steps defined in claim 1 failed to provide a coloured silicone hydrogel contact lens when Inks 5 to 10, 18 and 19, which all fulfill the definition of the ink provided in claim 1, were used. This was sufficient to raise serious doubts in the reproducibility of the claimed subject-matter.

Even Examples 4 and 5, which had been specifically invoked by the opposition division in its findings on sufficiency, did not contain enough information to be exactly and directly repeated as they were originally conducted. Accordingly, the skilled person could not derive any guidance as to which of the many unknown variables would allow successful replication of the examples. Information about the

nitrogen flow and the resulting content of solvent (ethanol) in the ink, which, as stated in paragraph [0096] influenced print quality and adhesion of the ink to the lens, was not provided. Moreover, no viscosity information was provided for the inks of Examples 4 and 5, whereby the viscosity played a crucial role in transfer of the image from the pad to the substrate to be printed. Information about the pad print conditions for which many variables existed e.g. viscosity of the ink, application time, cycle time, humidity, air blow settings, temperature, as indicated in paragraphs [0078] to [0080] was also missing. In addition, no information about the particle size of the pigment used in Examples 4 and 5 was provided, which particle size as indicated in paragraph [0096] could influence print quality and adhesion. Information about the polymerisation conditions in Example 4 and about extraction, plasma treatment, hydration and sterilization in Example 5 were not provided either. Moreover, reproducibility of Examples 2 to 5 was also more difficult because it was not specified whether the amounts of the various compounds used were given in mole % or weight %. Regarding claim 16, the patent in suit did not contain a single example relating to that method. Furthermore, too many variables influencing print quality and adhesion of the ink to a lens were not indicated or not sufficiently elucidated in the specification to permit the invention to be replicated without undue burden within the whole ambit of the claim (with reference to T 409/91). Those variables were *inter alia* molecular weight and molecular weight distribution of the binder, its composition, the polymerization conditions necessary for its preparation, the lens

composition, solvent type and content in the lens and the ink, quantity and particle size characteristics of the pigment in the inks, viscosity of the ink, ink printing technique and conditions and use of a corona treatment. The experimental part of the patent in suit showed that the skilled person would encounter more than occasional failures when trying to repeat the invention (Table 3) and the skilled person was not provided with adequate information to correct those. With experimental report D24 the appellant had attempted to follow the teaching of the patent in suit with respect to the binder to diluent ratio, resulting in viscosity values which were too low and, with reference to the teachings of D25, were not suitable for pad printing. Because D24 represented a serious attempt to reproduce the opposed patent and adequate time had been allowed for the patent proprietor to consider the experimental evidence submitted therewith and to prepare counter-experiments, D24 and the document cited in association therewith - D25 - should be admitted into the appeal proceedings. With respect to claim 28, there was no general guidance how to achieve an ink with "good adhesion to the contact lens" in the whole area claimed without undue burden.

Accordingly, the patent in suit was insufficiently disclosed, because a way of carrying out the invention had not been clearly indicated, and the patent did not enable a skilled person to perform the invention across the whole area claimed without undue burden.

(c) *Novelty*

D1 disclosed coloured contact lenses and methods for their manufacture. Paragraph [0015] disclosed that the hydrogel-forming monomer mixture to be employed for preparing the contact lens material could be silicone-containing monomers, balafilcon being explicitly named as an example. As could be understood from paragraph [0015] of D1 and confirmed by D21 balafilcon was a monomer mixture containing tris(trimethylsiloxy)silyl-propyl vinylcarbamate (TRIS-vc), N-vinyl pyrrolidone (NVP), N-vinyloxycarbonyl alanine (VINAL) and a silicone-containing vinyl macromer (V_2D_{25}). Such a choice from a list of just two options for the lens material could not be regarded as a selection. As to the presence of a binder the method of claim 1 could be construed as encompassing the application of a colour coat to a mould, by forming the ink (i.e. the binder polymer) in the mould. Consequently, the disclosure in D1 of the method described in paragraph [0017] when applied to a hydrogel-forming monomer mixture comprising silicone-containing monomers anticipated claim 1 of the patent in suit.

D6 disclosed in column 1, lines 6-22 and column 4, lines 43-60 a process for the manufacture of a moulded contact lens in which a coloured liquid which was either curable or thermoplastic was coated in a mould for making a contact lens, before charging the mould with a liquid lens-forming mixture. The resins of the curable type could be coated to the surface of the mould in a partially cured stage (B-stage) as described in column 7, lines 48-51, describing thereby an ink comprising a

binder polymer. Furthermore the inks of the curable resin type were most desirably those that were either compatible with or the same as the liquid lens-forming mixture (column 7, lines 42-46). Those included methacrylic and acrylic esters of siloxane monomers, documented in D26 and D27, cited in column 8, lines 30-35 of D6. A partial cure (B-stage) as recommended in D6 of the mixture of monomers of example 1 of D26, which document had been incorporated by reference in D6 would lead to a product comprising a mixture of residual vinylic-monomers, adhesion promoter, and polymerisation initiator, as well as a binder polymer. Furthermore, according to column 6, line 64 to column 7, line 1 of D6 the coating material could also be rendered liquid by the use of a solvent or diluent. Furthermore, the ink was capable of being cured actinically or thermally, with good adhesion to the contact lens without being covalently attached to the lens material (column 4, lines 47-60 and column 9, lines 19-23). Accordingly, the method of claim 1 and the ink of claim 28 lacked novelty over D6.

(d) Inventive step

The closest prior art was represented by D1. The problem solved vis-à-vis that prior art by the subject-matter of claims 1 and 16 or claim 28 was the provision of an alternative method or an alternative ink, respectively, for making coloured silicone hydrogel contact lenses.

In view of paragraph [0017] of D1, it would have been immediately obvious for the skilled person to consider D5 when seeking to find an alternative

method of making a coloured silicone hydrogel contact lens. Column 8, lines 11-14 of D5 disclosed that the coloured liquid comprised a curable liquid which preferably was either compatible with the liquid lens-forming mixture or was the same as the liquid lens-forming mixture. Accordingly, for the moulding of a silicone hydrogel contact lens, it would be most desirable for the colour coat to use a silicone hydrogel binder polymer, such as derived from balafilcon monomer mixture. Column 13, lines 48-52 also disclosed the use of methacrylic and acrylic acid esters of siloxane monomers and polymers. Column 12, line 50 to column 13, line 2 of D5 disclosed that the coloured pattern when coated may already be partially cured (a so called "B-stage"). Therefore, D5 taught that the Balafilcon monomer mixture from D1 should be partially polymerised and comprise a binder polymer before it is deposited onto the mould surface. Moreover, D5 disclosed an ink comprising a binder polymer, because a thermosetting resin was a polymeric compound that had the ability to be crosslinked. Accordingly, claim 1 was not inventive.

D9 disclosed tinted contact lenses, which included polymers, preferably silicones (page 28, lines 10-13). In the case of hydrophilic polymers, the polymer preferably formed a hydrogel (page 27, line 23 to page 28, line 1). According to page 26, lines 9-25 and Figure 6 of D9 the ink could include a monomer and/or a polymer in order to form a composite structure with the lens-forming material. D9 also taught that the inks included polymers or polymerizable monomers, preferably the same monomers used to make the lens (page 5, lines

10-12). The ink could comprise a binder, monomer, polymer, copolymer, initiator and solvent (page 38, lines 15-21). The inks were preferably capable of crosslinking (page 39, line 1). Claim 1 was therefore the obvious result of taking balafilcon from D1 and applying the method of making a coloured lens of D9, including the use of a pre-polymerised balafilcon monomer mixture (i.e. a binder polymer) in the ink.

As to obviousness of claim 16, the ink applied to the surface of the lens in D1 was cured and thus a binder polymer was subsequently formed which had at least an equivalent function to any pre-formed binder polymer in the ink composition of the patent in suit. There was no advantage or technical effect associated with this difference so that the claim was merely an obvious alternative readily contemplated by the skilled person. Accordingly, the subject-matter of claim 16 of the opposed patent lacked an inventive step in view of D1.

Paragraph [0016] of D1 referred to an alternative method of binding a colourant to a lens surface as described in D14 which in column 4, lines 23-46 taught that a binding polymer was present in the colourant, which could be used directly for coating formulations. Polymerization of the binder polymer was preferably carried out in combination with a chain transfer agent and included a solvent and a polymer initiator. The polymeric binder obtained had the proper rheological properties for application of the coating to the lens and usually some residual unreacted monomers remained. It would have been obvious for a skilled person starting from the method of paragraph [0016] of D1 to follow

the teaching of D14 and to prepare a balafilcon-based binder polymer in the ink, before application to the contact lens surface. The ink would also contain unreacted NVP or VINAL monomers as well as an adhesion promoter V_2D_{25}. Accordingly, claim 16 of the opposed patent was not inventive.

The ink defined in claim 28 was essentially the same as the ink used in claim 16, with a slight difference in wording, claim 28 referring to a "vinylic-monomer mixture" rather than "one or more vinylic monomers", implying thereby the presence of more than one vinylic monomer. However, unreacted residual monomers in balafilcon would include NVP and VINAL, so that the difference in wording between claims 16 and 28 was not significant. The result to be achieved defined in claim 28 relating to the ability of the ink to be cured actinically or thermally, with good adhesion to the contact lens without being covalently attached to the lens material was inherently achieved by any ink comprising the other features defined in claim 28. For the same reasons as for claim 16 the solution proposed in claim 28 was obvious to the skilled person in view of D1 and D14. It was also added that D14 taught in the last complete paragraph of column 5 the use of HDI. Accordingly, claim 28 also lacked an inventive step.

XII. The respondent's submissions, as far as relevant to the present decision, can be summarized as follows:

(a) *Article 100(c) EPC*

The optional feature in claim 27 as originally filed of a vinylic-monomer mixture called for a

polymerisation initiator, i.e. a photo or thermal initiator, which was also originally defined as an optional feature. The removal of the optional presence of a polyisocyanate from the definition of silicone-containing binder (A) did not change the scope of original claim 27 or lead to any undisclosed combination of features, since the use of that compound was still possible in view of the wording "containing" which was equivalent to "comprising". With respect to alternative (B) of claim 28, the only remaining optional feature had been made mandatory. The decisions cited by the appellant did not relate to optional features and were not relevant. Moreover, Ink A on page 31 of the application as filed, as well as Inks 11, 12, 15 and 16 provided a basis for the combination of features of granted claim 28. The same held true for Ink 17, even if no initiator was added after preparation of the binder by polymerisation. Polymerisation of further monomers added to the binder solution, which had been kept as it was after preparation, was only possible if residual polymerisation initiator, even if in a small amount, was present in the solution. Hence, granted claim 28 did not extend beyond the content of the application as filed.

(b) *Article 100(b) EPC*

The appellant's submissions were largely speculative. No evidence had been submitted that the invention could not be put into practice and no evidence had been submitted showing that the appellant had made any attempt to reproduce any of the examples of the patent in suit. In this respect D24 did not represent a reproduction of an example

of the patent in suit since a colorant, which would have altered the viscosity of the binder solution, was not added. Hence, the argument that the viscosity of the binder solutions prepared in D24 was unsuitable for pad printing as argued with reference to by D25 (page 14, lines 13-19) because it was too low could not convince. Moreover, D24 did not report that any composition had been printed on a lens mould or a contact lens in accordance with claims 1 and 16.

The issues raised by the appellant did not relate to the core of the invention, but to conventional techniques which therefore did not necessitate detailed explanations.

It was acknowledged that Table 3 of Example 2 of the patent in suit contained inconsistencies (due to typing errors) having regard to the results reported for Ink 9, which the skilled person would immediately identify and correct for. He would recognize in view of the effect of the curing of the ink coating on its transfer to the lens that the "No" and "Yes" indicating the absence of presence of curing, respectively, should be inverted in the second and third lines concerning Ink No. 9. Moreover, the successful examples and those which failed would together guide the skilled person to the claimed methods. Examples 4 and 5, as well as Example 2 (Inks 3 and 11) showed that the method according to claim 1 could be successfully carried out.

Having regard to Tables 1, 4 and 5 in which the values added up to 100 for describing each binder, ink or activation formulation and indication of %

throughout the whole specification, the skilled person would understand that the amounts indicated in those tables were in weight % and not in mole %, as the latter would not only be unusual but would not make sense or would be complex or impossible to define for some of the components, such as the activation solution or siloxane-containing macromer.

The preparation of the binder polymers was shown in Examples 2 to 5, as well as that of the inks, including information on pigment, diluent and the optional adhesion promoter. The amount of pigment was dependent on the colour intensity required and the viscosity of the ink dependent on the printing technique envisaged, which viscosity could be adapted by adding a suitable amount of diluent or removing some solvent.

Pad transfer printing was a well-established technology as indicated in paragraphs [0078] to [0080], as was the optional corona treatment. Such a corona-treatment of the mould-halves before printing with the ink increased the adhesion strength of the printed ink onto the mould, as it resulted in hydrophilic and hydrophobic sites on the normally hydrophobic surface of the mould, therefore allowing enhanced adhesion of the binder that also comprised hydrophobic and hydrophilic parts as compared to prior art hydrophilic polymers. Ink 11 of Example 2 demonstrated that there was no need for corona treatment in order to obtain good print quality and good print transfer to the lens (Table 3).

Ink 17 showed thermal curing of the ink in the presence of an adhesion promoter, whereas Inks 18 and 19 showed how to obtain successful UV curing of the ink on the mould.

Accordingly, the subject-matter of claim 1 was sufficiently disclosed.

As to the method of claim 16 or the ink of claim 28 the appellant had not shown that any doubt existed as to their sufficiency of disclosure.

(c) Novelty

Paragraph [0015] of D1 merely contained a list of monomers but no disclosure of a monomer mixture suitable for making a hydrogel contact lens, which would require making specific selections from the long list of monomers described in that paragraph. Moreover, the disclosure in respect of the monomer mixture referred to in D1 as "balafilcon" was ambiguous, even taking into account the disclosures of D21 or D4 cited in D1. Moreover, D1 did not disclose an ink comprising a binder polymer, as D1 described that in D5 a mixture of monomers was applied on the mould. In addition, paragraph [0017] of D1 did not describe an embodiment of the invention of D1 but an alternative method already known from the prior art for applying a coloured pattern to a contact lens, i.e. that disclosed in D5 to which it was explicitly referred in paragraph [0017] of D1. Moreover, D1 did not disclose either explicitly or implicitly by reference to D5 the use of a second mould half. Hence, claim 1 was novel over D1.

The reading of D6 by the appellant was based on a multiple selection of various alternatives selected within its teaching, in particular with respect to the monomers for the curable coating material and the level of curing of the coating material before being applied (A-stage or B-stage), the combination of which was not directly and unambiguously derivable from that document. In addition, there was no evidence that the B-stage material disclosed in D6 contained a polymer. Accordingly, the subject-matter of claims 1 and 28 was not anticipated by D6.

(d) Inventive step

The closest prior art was represented by D1, which however had not successfully prepared a coloured silicone hydrogel contact lens with an ink comprising a colorant and a monomer mixture. The objective problem solved over D1 by the subject-matter of claims 1 and 16 or 28 was therefore the provision of a method or of an ink, repectively, for making coloured silicone hydrogel contact lenses.

D1 did not disclose a silicone-containing binder polymer, or even an ink comprising a silicon-containing monomer in a process of preparing a coloured silicone hydrogel lens. D5 did not disclose coloured silicone hydrogel contact lenses, but rather referred to lists of monomers generally applicable for preparing lenses. D5 also did not disclose application of an ink comprising a silicone-containing binder. To arrive at such subject-matter, several selections from within the teaching of D5 were required. But even if the

skilled person had selected the same monomer mixture as used for preparing the lens and cured it to the B-stage, which merely means that the curable coating material was partially cured and included oligomeric species, there was no disclosure of formation of a polymer. In addition, the alternatives within D5 regarding the curing stage and the compatibility or identity of the curable coating material and the lens forming monomer mixture were independent of each other. The skilled person could have considered the combination based on several selections but would not have considered it in view of the problem to be solved, as a corresponding teaching was not provided. D9 described that the contact lens could be made of any known material, but was not directed to silicone hydrogel contact lenses. D9 also referred in general to hydrogels, without addressing the separate class of silicone hydrogels. As far as the ink was concerned, D9 taught that an ink could include polymers or polymerizable monomers, preferably the same monomers as used to make the lens, but there was no teaching in D9 that the ink should comprise a binder polymer, let alone a silicone-containing binder polymer. The binder mentioned in D9 was not a binder polymer as required by claim 1 but a low-molecular weight bonding agent, i.e. a cross-linker like HDMI (page 11, lines 13-16). Accordingly, the solution proposed by the subject-matter of claim 1 was not obvious in the light of the cited prior art.

Regarding obviousness of the method of claim 16, D1 disclosed neither a silicone hydrogel contact lens nor a silicone-containing binder. Accordingly, the skilled person applying the method described in

paragraph [0016] of D1 would not arrive in the light of D1 alone at the subject-matter of operative claim 16. The skilled person also would not consider D14 which was not directed to silicone-containing materials, let alone silicone hydrogel materials (column 1, lines 1-5 and column 2, lines 30-55). Moreover, D14 was directed to a colour coat to be applied on contact lenses having high water content upon hydration, i.e. conventional hydrogels based on e.g. NVP. The colour coat comprised a binder polymer with functional groups and an additional compound containing two groups per molecule of -NCO to form covalent bonds, but the contact lens was defined to not comprise corresponding functional groups. Hence, D14 was directed to a different way of applying and fixing a colour coat to a contact lens than D1. This was confirmed by the explicit language of D1 in paragraph [0016] which mentioned an alternate method of binding the colourant to the lens surface when referring to D14. Accordingly, claim 16 involved an inventive step in view of D1 as the closest prior art in combination with D14.

For the same reasons as advanced with respect to claim 1 and claim 16, the solution proposed by claim 28 was not suggested by the cited prior art. Accordingly, the subject-matter of claim 28 involved an inventive step.

XIII. The appellant requests that the decision of the opposition division be set aside and the patent be revoked.

XIV. The respondent requests that the appeal be dismissed, or alternatively that the decision of the opposition

division be set aside and the patent be maintained on the basis of any of auxiliary requests 1 to 7 submitted with letter of 3 February 2014 (reply to the statement setting out the grounds of appeal).

Reasons for the Decision

Main request

Article 100(c) EPC - Claim 28

1. Granted claim 28 differs in substance from claim 27 as filed, i.e. apart from some rearrangement of its wording, in that the claimed ink in addition to a colorant, a silicone-containing binder polymer, an adhesion promoter and a solvent now contains

- (1) a vinylic-monomer mixture, as well as
- (2) a photoinitiator or thermal initiator and
- (3) the polymerisable mixture for preparing the silicone-containing binder polymer (B) contains one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent.

Said features (1) to (3) were defined as optional features of claim 27 of the application as originally filed and are now mandatory features of granted claim 28.

1.1 In accordance with the established Case Law of the Boards of Appeal of the EPO, the relevant question to be decided in assessing whether the subject-matter of

an amended claim extends beyond the content of the application as filed is whether that subject-matter is directly and unambiguously derivable from the whole of the documents of the application as filed, using common general knowledge, and seen objectively and relative to the date of filing (see G 2/10 (OJ 2012, 376), point 4.3 of the Reasons and Case Law of the Boards of Appeal of the EPO, 8th edition, 2016, II.E.1.2). There is no reason to consider that, inevitably, the subject-matter of a claim which results from amendment of an originally filed claim by rendering mandatory a plurality of optional features is implicitly disclosed in the application as filed. It is a matter depending on the facts of the individual case, i.e. taking into account the relationship of the features rendered mandatory with each other and with the other features of the claim as amended, as would be understood by the skilled reader as the date of filing, taking into account the whole content of that claim as filed, the rest of the application documents and the common general knowledge. Decisions T 0972/04, T 1009/06, T 0894/07, T 1374/07, T 1710/09, T 0922/10, T 1525/10 and T 0510/10 cited by the appellant in support of their objection all precede G 2/10, but the rationale behind those decisions has not been put into question by that decision of the Enlarged Board of Appeal. All support the view that it is not sufficient that a specific combination of elements be conceptually included in the scope provided by a disclosure in the original application, but that it is rather necessary that the combination of features resulting from the amendments can be seen to be disclosed in the application as filed.

1.2 The ink of claim 27 as originally filed is defined as having the capability to be cured actinically or thermally. The passage of the application as filed at

page 6, lines 22-23 (hereinafter the passages of the application as filed cited refer to the corresponding passages in the version as published under WO 2005/098478) defines that the wording "vinylic monomer" refers to a low molecular weight compound that has an ethylenically unsaturated group and can be polymerized actinically or thermally. In the light of these two disclosures of the application as filed, the skilled person would understand that the use of a "vinylic monomer mixture", as rendered mandatory in granted claim 28, also necessitates in the context of the invention defined in the application as filed the use of a photo or thermal initiator. Contrary to the submission of the appellant, the skilled person has no reason having regard to the teaching of the application as filed to consider that polymerisation could be started also using electron beam. That option is not disclosed in the application as filed, meaning that the use of a photo or thermal initiator becomes implicit in view of the wording of claim 27 once the use of a vinylic-monomer mixture is made mandatory.

1.3 Furthermore, as far as the additional feature of original claim 27 which defines in general terms in section (iv) that binder polymer (B) may be prepared optionally with one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent, it is implicit for the skilled person in view of the nature of the monomers defined under sections (i), (ii) and (iii) that at least one of the components of section (iv) is preferably employed when preparing binder polymer (B). This constitutes a pointer for the skilled person to render feature (3) mandatory and to apply this to all embodiments of claim 27, i.e. also when features (1) and (2) have been made mandatory.

1.4 Furthermore, Inks No. 11, 12, 15 and 16 in Example 2 (Table 2, page 26), Ink 17 in Example 3 (pages 27 and 28) and Ink A in Example 4, (page 31, last full paragraph) of the application as filed are all in accordance with the definition according to claim 28 as amended, i.e. they do not only use both a vinylic-monomer mixture and a photo or thermal initiator, but they also contain a binder-polymer (B) as now defined in amended in claim 28 by the mandatory use for its preparation of one or more components selected from the groups consisting of a polymerization initiator, a chain transfer agent, and a solvent. More specifically, Inks No. 11, 12, 15 and 16 as disclosed on pages 25 and 26, comprise a pigment as colorant, an adhesion promoter - HDI -, a "Lens formulation #" which comprises ethanol as solvent (page 26, last paragraph), Darocur 1173 as photoinitiator and a mixture of vinylic moonomers TRIS and DMA and a binder polymer, i.e. No. 9 or 11 which are made from a mixture of a hydrophilic vinylic monomer - DMA -, a functionalizing vinylic monomer - HEMA -, a silicone-containing vinylic monomer - TRIS -, a solvent - ethanol -, a polymerization initiator - V68 - and for Binder 11 a chain transfer agent - EtSH -. Ink 17 comprises a pigment, a solvent - cyclopentanone -, a vinyl monomer mixture - HEMA, TRIS and DMA -, an adhesion promoter - HDI - and a binder made from a mixture comprising a hydrophilic vinylic monomer - DMA -, a functionalizing vinylic monomer - HEMA -, a silicone-containing vinylic monomer - TRIS -, a solvent - cyclopentanone -, a polymerization initiator - Vazo 64 - and a chain transfer agent - EtSH - (page 27, last paragraph). Having regard to the fact that (i) no additional polymerization initiator is added after the synthesis of the binder, (ii) Example 3 specifies that the binder

polymer solution is used for preparing the ink without separation and purification of the synthesized binder polymer and (iii) Ink 17 can be successfully cured as shown in Table 6, it is implicit that Ink 17 still contains a polymerization initiator. Finally, Ink A (page 31, paragraphs 2 to 5) comprises pigments, ethanol as solvent (page 31, 3rd paragraph), a vinyl monomer mixture (HEMA, TRIS and DMA), an adhesion promoter (HDI) and a polymerization initiator (Vazo 64) (page 31, 5th paragraph) and a binder made from a mixture comprising a hydrophilic vinylic monomer - DMA -, a functionalizing vinylic monomer - HEMA -, a silicone-containing vinylic monomer - TRIS -, a solvent - ethanol -, a polymerization initiator - AIBN - and a chain transfer agent - EtSH - (page 31, 2nd paragraph). Accordingly, the Inks 11, 12, 15 to 17 and A disclosed in the application as filed provide an additional pointer to use in combination of the optional features defined in claim 27 as filed which have been made mandatory in amended claim 28.

1.5 Finally, the deletion of the wording "optionally a polyisocyanate" in the definition of the silicone-containing binder polymer (A) does not change the meaning of said binder polymer (A), which in view of the wording "polymerization product of a mixture containing" can still be prepared in the presence of a polyisocyanate, and therefore does not contribute to amend the meaning of the claimed ink. That amendment of the wording of original claim 27 is therefore of no relevance for the assessment of whether granted claim 28 extends beyond the content of the application as filed.

1.6 Accordingly, the objection that the subject-matter of claim 28 extends beyond the content of the application as filed fails to convince.

Article 100(b) EPC

2. According to the established jurisprudence of the Boards of Appeal of the EPO a European patent complies with the the requirements of sufficiency of disclosure if a skilled person, on the basis of the information provided in the patent specification and, if necessary, using common general knowledge, is able to carry out the invention as claimed in its whole extent without undue burden, i.e. with reasonable effort. According to the case law (see Case Law, supra, II.C.4.2 and II.C. 4.4), an invention is in principle sufficiently disclosed if in accordance with Rule 42(1)(e) EPC at least one way is clearly indicated enabling the person skilled in the art to perform the invention in the whole range that is claimed. Whether this is the case is a question of fact that must be answered on the basis of the available evidence, and on the balance of probabilities in each individual case. According to the case law (see Case Law, supra, II.C.8) the objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts.

Method of claim 1

2.1 Claim 1 defines a method for making a coloured silicone hydrogel contact lens wherein step (a) relates to the application of a colour coat to at least a portion of at least one of the surface of the mould used to prepare the silicon hydrogel contact lens. That only a portion of the moulding surface of the lens has to be coated is in line with paragraph [0018] of the

specification according to which the colour image can have various forms ranging from cosmetic patterns such as iris-like patterns to various marks for customers such as inversion marks. In a subsequent step (b) of claim 1 the colour coat is partially or completely cured, before in a step (c) a silicone hydrogel lens-forming material is applied into the lens-forming cavity of the mould. In a further step (d) the lens-forming material is cured within the lens-forming cavity to form the contact lens, whereby upon removal of the contact lens from the mould the coloured film must be able to detach from the mould and to adhere to the silicon hydrogel lens material which was applied thereon, becoming integral with the silicone hydrogel body of the contact lens.

The appellant's objections with regard to lack of sufficiency of disclosure of claim 1 were in two parts, one relating to the preparation of the inks themselves (discussed in section 2.6 below). The major part of the objections presented and correspondingly the major part of the response thereto of the respondent which will consequently be dealt with first in the present decision however related to the ability of the skilled person based on the information provided in the patent in suit to apply the ink by pad printing and to obtain good print quality and good print transfer of the coloured film (i.e cured ink coating) to the lens. Whereas claim 1 requires that the coloured film detaches from the moulding surface and becomes integral with the body of the contact lens (which can be understood to correspond to a good print transfer), claim 1 does not contain any feature defining the quality of the image. Accordingly, taking into account that assessment of sufficiency of disclosure is made, as in the case of assessment of novelty or inventive

step, for the invention for which protection is sought, i.e. in terms of the combination of features defining the subject-matter of the claim under consideration (see for example T 0089/13, point 2 of the reasons), the quality of the image resulting from the method of claim 1 is of no relevance for the assessment of sufficiency of disclosure, as long as a coloured image is obtained by said method.

Teaching of the patent in suit and common general knowledge

2.2 The mechanisms underlying the present invention and applied in order to obtain transferability and adhesion of the coloured coating on the silicon hydrogel lens material are explained in paragraphs [0087] to [0090]. According to paragraph [0089], curing of the ink printed on the mould preferably does not consume all ethylenically unsaturated groups in the ink and unreacted ethylenically unsaturated or other cross-linkable groups in the ink can copolymerize with vinylic monomers and/or macromers of the lens forming material when curing the lens forming material in the mould.

Alternatively, as indicated in paragraph [0090] adhesion of the ink to the lens does not require the presence of reactive functional groups in the lens polymer but is believed to result from the ink binder forming interpenetrating networks (IPN) with the lens material of the silicone hydrogel lens after the lens-forming material was allowed to penetrate the cured ink coating during step (c) and subsequently cured in step (d). Since the lens material for the silicone hydrogel lens "*is crosslinked in the presence of a polymer (i.e. crosslinked binder polymer in the ink)*" (see paragraph [0090]), adhesion of the ink to the silicone hydrogel

lens by IPN formation does not require the presence of reactive functional groups in the lens polymer to form chemical bonding. The adhesion of the ink to the lens results from the polymers of the lens and of the ink becoming entangled (i.e. physically bonded).

Accordingly, the skilled person is provided with a general principle and guidance for each of the two possibilities defined in step (b), i.e. either partial or complete curing of the ink printed, for which the patent in suit proposes chemical bonding and formation of IPN, respectively, to make the coloured film adhere on the silicone hydrogel contact lens. The skilled person therefore understands that the method of claim 1 is based on the teaching that sufficient chemical bonding between unreacted ethylenic unsaturations or other cross-linkable groups in the ink and vinylic monomers and/or macromers of the lens or in the alternative sufficient interpenetration of the polymeric binder(s) of the coloured coating and the silicone hydrogel material allows the coloured film to become bonded with the body of the contact lens such that the adhesion between the coloured coating and the silicon hydrogel lens material is stronger than the adhesion between the surface of the mould and the cured coloured coating. That the adhesion of the coloured coating to the surface of the mould is weaker than the adhesion between the coloured coating and the silicone hydrogel material of the lens after curing emerges in view of the nature of the conventional mould material for preparing contact lenses (see paragraph [0036] of the patent in suit, for example polyethylene, polypropylene, and PMMA) and therefore the nature of the strength of adhesion/bond between the mould and the coloured coating.

2.3 The patent in suit does not only provide the skilled person with general principles to be applied, but also with a more concrete teaching having regard to the various steps of the claimed method required to put these general principles into practice. The preparation of the ink for making the colour coat to be applied in step (a) is described in paragraphs [0037] to [0075] and [0100], including the preparation of the silicone-containing binder. Examples of the preparation of an ink formulation are given in paragraphs [0103] to [0109], [0112], [0113] and [0120] to [0125]. Example 2 with Inks 3 and 11 (if no corona pretreatment of the mould takes place), Example 3 with Ink 17 and Examples 4 and 5 show embodiments of the method according to claim 1, i.e. methods for which the coloured film detaches from the mould and has become integral with the silicone hydrogel body of the contact lens and therefore for which the result to be achieved defined in operative claim 1 is obtained. Concerning Examples 2 and 3 the skilled person understands that the values given for the various amounts of compounds used to prepare the inks are necessarily in weight % and not in mole %, contrary to the appellant's submissions. This is, as noted by the respondent, because all amounts indicated in Tables 1, 4 and 5 add up to 100 and because it is technically not feasible or meaningful to define in mole % the amount of binder whose structure is not exactly known or to define in mole % the amount of lens formulation (used as diluent) and the amount of activation solution, which both comprise various components. This is also in line with the general indication of % throughout the whole specification, especially paragraph [0100] which specifies for the type of compounds contained in the ink preferred amounts in % by weight.

2.3.1 The techniques which can be used for application of the coloured coat on at least one portion of the lens mould in step (a) are described in paragraphs [0078] to [0081], including pad printing. The appellant, however, argued that the invention was also insufficiently disclosed with respect to pad printing, because an indication of the viscosity of the ink, which plays a crucial role in the image transfer process of the ink formulation, was missing. However, in the same argument, the appellant itself indicates that in pad printing viscosity is related to ink tackiness, which tackiness allows the image to transfer from the pad to the substrate. This argument based on the common general knowledge in the art shows that the skilled person is well aware that the ink solution has to have sufficient viscosity, which viscosity in the Board's opinion can be adjusted by the skilled person for example by selecting an appropriate amount of diluent or solvent.

2.3.2 Experimental evidence D24 which was not admitted into the proceedings before the opposition division, because it was considered to have been filed too late for the patent proprietor to react appropriately, has been resubmitted with the statement setting out the grounds of appeal and was relied on to demonstrate the unsuitability of the inks taught in the patent in suit for pad printing. The respondent did not object to its admission into the appeal proceedings so that the Board has no reason to exercise its discretion under Article 12(4) RPBA to hold D24 inadmissible. The appellant alleges that D24 shows that by following the teaching of the patent in suit with respect to the binder : diluent ratio one could not prepare a coating composition having a viscosity suitable to apply the coloured ink by pad printing. However, the coating

composition prepared in D24 does not contain any pigment, the presence of which would change the viscosity of the coating solution. Accordingly, D24 does not provide evidence that the teaching of the patent in suit with respect to the binder : diluent ratio is not suitable to carry out the method of claim 1.

2.3.3 The further arguments of the appellant in relation to pad printing, i.e. application time, cycle time between prints, humidity of the environment, air blow settings, temperature rather relate to known parameters affecting the printing step which the skilled person would easily adjust to allow printing on the mould. It is also not contested that pad printing is a conventional technology for applying patterns on contact lenses, as illustrated in D14 (example 1), D5 (column 15, lines 22-35) and D1 (paragraph [0003]).

2.3.4 Considering that the method of claim 1 does not require any specific result in terms of quality of the colour print on the mould, apart from the fact that sufficient coating material should be applied, the Board has no reason to doubt that the skilled person is able to perform step a) using the information contained in the patent in suit and his common general knowledge, if necessary with a reasonable amount of experimentation.

2.3.5 The curing of the coloured coating defined in step (b) is briefly explained in paragraph [0082]. The lens forming material to be dispensed in step (c) and to be cured in step (d) is briefly defined in paragraph [0093] by referring to the knowledge of the skilled person, the fabrication of silicone hydrogel contact lenses being well known in the art as confirmed in paragraphs [0005] and [0006] of the patent in suit.

2.3.6 Concerning step (d) and the ability of the coloured film to detach from the mould surface and become integral with the body of the contact lens, paragraph [0096] indicates that factors which might influence adhesion of ink to the lens include molecular weight, molecular weight distribution, composition of the binder polymer, lens composition, solvent type and content in both the lens and the ink, solvents that swell the lens material being expected to enhance penetration of the binder polymer into the lens. The quantity and particle size characteristics of pigment in inks are also indicated possibly to affect adhesion. Contrary to the appellant's submission and in the absence of any supporting corroborating evidence, the indication in the patent in suit that these factors might influence adhesion of the coloured coating to the hydrogel silicone material does not however mean that it constitutes an undue burden for the skilled person to achieve a level of adhesion between the coloured coat and the hydrogel silicone material which is stronger that the adhesion between the surface of the mould and the cured coloured coating. Examples of a method providing the result defined in claim 1 are given in Example 2 of the patent in suit, i.e. methods using Inks 3 and 11 with and without corona pretreatment, respectively (Table 3), as well as in Example 3 (Ink 17) and Examples 4 and 5 already mentioned in above point 2.3.

2.4 Apart from D24, which as shown in above point 2.3.2 does not in fact constitute a reproduction of the method of claim 1, the appellant did not submit any experimental evidence to show that the process of claim 1 was insufficiently disclosed, but submitted the following arguments:

Experimental part of the patent in suit as evidence for a lack of sufficiency of disclosure?

2.5 The appellant referred to experiments reported in the patent in suit, namely to those of Examples 2 and 3, wherein Inks No. 1 to 19 have been prepared and some of those tested in a method in accordance with claim 1. It is argued by the appellant that the patent in suit shows that applying the method of claim 1 to Inks 5 to 11 and 17 to 19, i.e. pad printing those inks on a base curve portions (male mould halves) of a polypropylene lens mould, thermal or UV curing of the coloured coating, filling the mould with a silicon hydrogel lens forming material and UV curing to form the silicon hydrogel lens, only results in Inks 11 and 17 successfully providing a coated lens as defined in claim 1.

2.5.1 The experiments referred to by the appellant which employ Inks 5 to 9 and 11 all have in common that the male mould half was corona pretreated before applying the coloured inks as indicated in paragraph [0111] and Table 3. The purpose of that pretreatment is explained in paragraph [0141] in the context of example 5: "*Like all other experiments with male mold halves without pre-corona-treatment, all the inks are transferred from the mold to the lens and the printed pattern definition is substantially or completely retained. However, with corona-pretreatment of molds, printed inks tend to substantially stay at or substantially near the base-curve surface of a colored lens so produced. Without corona-pretreatment of molds, printed inks can slightly migrated* [*sic*] *into the bulk material of a coloured lens so produced. It is understood that significant migration of printed inks may affect adversely cosmetic appearance of a colored lens, especially its*

consistency in production. Corona pretreatment of molds before printing may reduce this migration." Hence, in line with the conventional knowledge according to which corona treatment, in particular of plastic surfaces is a known means to increase the surface tension of surfaces for improving their printability or coatability, corona treatment is implicitly recommended in the patent in suit as a route to temporarily increase the adhesion of the coloured ink on the mould avoiding too great migration into the silicone hydrogel material when filled in the mould. However, corona treatment is also taught in Example 3 to possibly lead to a strong adhesion of the coating on the mould, which might render difficult the transfer of the coloured coating on the silicone hydrogel. This is illustrated by the two experiments of Table 3 using Ink No. 11 for which the use of a corona treatment results in the print remaining on the mould half, whereas a good print transfer to the lens is obtained when no corona pretreatment is used.

2.5.2 In other words, the alleged difficulty to achieve a good print transfer of the coloured film is only encountered with those examples when a corona pretreatment which is not a mandatory step of claim 1 is carried out. Furthermore, a corona pretreatment is presented in the patent in suit merely as a means to improve if necessary, depending on the nature of the coloured coating and the curing applied, the quality of the coated print in terms of its cosmetic appearance in the resulting lens, which technical effect also is not a requirement of present claim 1 and therefore of no relevance to the assessment of sufficiency of disclosure. Should a corona pretreatment be considered, the patent in suit indicates that the skilled person should be cautious as it might impair transfer of the

coloured coating on the silicone hydrogel. Moreover, it appears obvious that the intensity of the corona treatment (time, power) can be varied if necessary so as to find a compromise between quality of the print and ability of the coloured lens to detach from the mould.

2.5.3 Having regard to Inks 18 and 19 used in Example 3, it is explained that the print is not completely transferred from the mould to the lens, the majority of the printed ink remaining on the mould, especially in the centre of the pattern, near the optical zone, while the edges undergo better transferring. The incomplete transfer of the cured ink from the mould to the silicone hydrogel body is explained in paragraph [0119] to be due to the use of UV-curing instead of thermal curing and the presence in the latter case of an adhesion promoter such as HMDI for curing the coloured coating in step b). In the case of thermal curing, it is explained that the adhesion promoter reacts with the functional groups of the binder polymer and the vinylic monomers while consuming minimally ethylenically unsaturated groups which can further react with a lens-forming material during the curing step of the lens-forming material to form a lens, yielding a good adhesion of the coloured coat to the lens as well as a good transferability of the coloured coat from the mould to the lens. From Example 3, the skilled person is thus taught that the curing of step (b) might be accomplished with UV or preferably with thermal curing in the presence of an adhesion promoter, depending on the location and form of the coloured coating which is to be obtained on the silicone hydrogel contact lens and what factors influence the outcome in each case.

2.5.4 Accordingly, the experiments contained in the patent in suit to which the appellant referred do not cast doubt on the ability of the skilled person to put into practice the general teaching provided in the patent in suit in order to carry out the method of claim 1, but on the contrary provide additional information for situations that where specific requirements going beyond those defined in claim 1 also have to be fulfilled.

Repeatability of the examples as conducted originally

2.6 The appellant furthermore argue that Examples 4 and 5 of the patent in suit did not include all the necessary detailed information for the skilled person to be able to repeat these as they were originally conducted. It was considered that the skilled person could only establish by trial and error the particular choice of numerous parameters required to provide a satisfactory reproduction of the examples. Thus the requirement of the patent providing at least one way of carrying out the invention were not satisfied.

The potential difficulty of exactly replicating examples of the patent in suit as they were originally conducted is in the present case not decisive for the question of sufficiency of disclosure of the claimed invention and can be left unanswered. Firstly, it is the sufficiency of disclosure of the combination of technical features of the invention, i.e. as defined by the terms of the claims (see Rule 43(1) EPC), which has to be assessed and not that of the specifically exemplified methods, which are not in the present case the subject-matter of a claim. Secondly, according to Rule 42(1)(e) EPC the description shall describe in detail at least one way of carrying out the invention

claimed, using examples where appropriate, meaning that the presence of examples is not a mandatory requirement for meeting the requirement of sufficiency of disclosure. What counts is the information provided by the whole patent, including that provided by the examples, if any. In fact Examples 4 and 5 gives specific details regarding the materials to be used for the synthesis of the ink, including the binder, as well as that of the lens-material. Details of the thermal curing is also indicated. Those examples therefore illustrate the general guidance provided in the rest of the description.

Reproducibility across the full scope of claim 1

3. The appellant referring to the principles of the established case law following the landmark decision T 0409/91 argued that the claimed invention was not reproducible over the whole scope of claim 1. For considering that issue and understanding the rationale behind T 0409/91 and successive decisions relying on its reasoning, it is first necessary to address the situation underlying that decision. In T 0409/91 the Board found that the claim was not supported by the description and lacked sufficiency of disclosure, because it had not been limited to fuel compositions comprising the sole specific additives taught in the application to provide a result to be achieved in respect of the particle size of wax crystals present in the fuel composition, and because neither the patent application nor the common general knowledge provided information allowing the skilled person to find other suitable additives or additive combinations being capable of producing wax crystals having the desired size. That case was said to differ from those cases where a class of chemical compounds was claimed and

only one method of preparing them was necessary to enable a skilled person to carry out the invention, i.e. to prepare all compounds of the claimed class, but was instead comparable to the situation where a group of chemical compounds was claimed, and not all of the claimed compounds could be prepared by the methods disclosed in the description or being part of the common general knowledge (see also T 206/83, OJ EPO 1987, 005). It was in that context that it was held that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art, meaning that the definitions in the claims should essentially correspond to the scope of the invention as disclosed in the description and should not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art.

4. The present case, however, differs from that underlying T 0409/91 in that the patent in suit enables the skilled person to put into practice not only a few specific methods falling within the ambit of claim 1, but rather, as shown above provides sufficient teaching on how the methods in accordance with claim 1 can in general be carried out also in the light of the common general knowledge so as to obtain other suitable contact lenses with which the sought result (i.e. transferability and adhesion of the coloured coating on the silicon hydrogel lens material) is achieved. Accordingly, there is in the present case no reason to conclude that the effect or functional feature to be achieved by the claimed method cannot be reproduced without undue burden over the whole scope of the claimed subject-matter.

5. In view of the above it is therefore concluded that the opponent did not succeed in demonstrating that the skilled person, on the basis of the information provided in the patent specification and the general knowledge common in the art, would not be able to carry out the invention as defined in claim 1 in its whole extent without undue burden.

Method of claim 16

6. According to paragraph [0092] of the patent in suit, an alternative approach to produce a coloured hydrogel silicone contact lens is to print directly with an ink as described in the patent in suit on a preformed silicone hydrogel contact lens to produce a coloured contact lens. The printed ink is allowed to penetrate at least partially into the material of a contact lens and then cured (cross-linked). The curing can be activated by UV radiation or heat. The binder polymer in the ink is cross-linked in the presence of the lens material of the silicone hydrogel to form interpenetrating networks. A method using that approach is defined in claim 16. Compared to the method of claim 1, the method of claim 16 does not require that the ink (colour coat) is cured in the mould but that it be cured only after having being applied on at least a portion of a surface of the lens. Accordingly, the method of claim 16 is even easier to perform than that of claim 1, as the skilled person is no longer concerned with the potential problem of the cured coating adhering more strongly to the mould than to the silicone hydrogel lens material. Furthermore, the definition of the ink formulation, including that of the binder, is more precise (i.e. restricted) than in claim 1. As already indicated in relation to claim 1, although claim 16 is not limited to the use of pad

printing, applying an ink by pad printing is common general knowledge and suitable conditions therefore can be found by routine experimentation. In view of the nature of the material used, the manner in which the two layers are explained to adhere to each other, and the absence of any evidence to the contrary submitted by the appellant, the Board has no reason to put into question sufficiency of disclosure of the method of claim 16, even if the patent in suit does not contain a single example demonstrating that method.

Ink of claim 28

7. Claim 28 defines an ink in terms of its various components and the additional functional requirements that it is suitable for making coloured contact lenses, has the capability to be cured actinically or thermally to form a colour coat on a contact lens, wherein the coloured coat has good adhesion to the contact lens without being covalently attached to the lens material of the contact lens. The appellant objected to sufficiency of disclosure of claim 28 insofar that no general guidance for a skilled person to achieve an ink with "good adhesion to the contact lens" across the full scope of that claim was to be found in the patent in suit. However, the definition in claim 28 that the sought "good adhesion to the contact lens" is obtained without the colour coat being covalently attached to the lens material of the contact lens after it was cured actinically or thermally would be understood by the skilled reader to refer to the formation of interpenetrating networks as taught in paragraphs [0090] and [0092] of the patent in suit as a possibility to provide adhesion of the colour coating and the silicone hydrogel material. Having regard to the broad meaning of the wording "good adhesion to the

contact lens" and in the absence of any evidence to the contrary the Board has no reason to doubt that the skilled person can obtain such a degree of adhesion by selecting ink components which permit formation of an interpenetrating network with the lens material of the silicone hydrogel lens. Hence, the objection that the subject-matter of claim 28 lacks sufficiency of disclosure is not convincing.

8. Accordingly, the argument that the subject-matter of either claim 1, claim 16 or claim 28 lacks sufficiency of disclosure is not found persuasive.

Article 100 (a) EPC - Novelty

Novelty of claim 1 over D1

9. D1, as indicated in its paragraph [0005] and in accordance with the wording of its claim 1 relates to contact lenses having a coloured portion, which coloured portion is covered by a coating layer. D1 although not restricted thereto, is primarily concerned with contact lenses having a hydrogel copolymer as the lens forming material, as shown by dependent claim 8 and paragraphs [0015] to [0017], [0023] and [0026] of that document. D1 also discloses in paragraph [0015] a list of hydrophilic and crosslinking monomers for preparing the hydrogel copolymer, which passage specifies that the monomer mixture may optionally include a silicone-containing monomer in order to form a silicone hydrogel copolymer (paragraph [0015], starting at the top of page 2). A list of suitable silicone containing comonomers is indicated and "balafilcon" is named as a specific example of a silicone hydrogel-forming monomer mixture. Hence, having regard to its paragraph [0005], claims 1 and 8

and paragraph [0015], D1 discloses silicone hydrogel contact lenses, having a coloured portion, which coloured portion is covered by a coating layer.

9.1 D1 also describes in paragraphs [0016], [0017] and [0018] various methods for obtaining the coloured portion on the contact lens generally defined in claim 1. The objection raised by the appellant with respect to novelty of claim 1 over D1 presupposes that D1 does not only disclose a contact lens according to claim 1, made of a hydrogel silicone material, but that a method as defined in paragraph [0017] is used to prepared the latter. The various methods disclosed in D1 for preparing lenses according to claim 1 of that documents are analyzed as follows:

9.2 According to the method described in paragraph [0016], the coloured pattern in the case of a hydrogel contact lens may be applied to the lens surface (prior to hydrating the copolymer) using various methods known in the art, for example by the offset pad printing process. The formulation, applied to the lens surface, includes a colourant, such as a pigment having the form of solid particles or a dye, and a monomeric material, such as compounds containing ethylenic unsaturation and macromonomers. The monomeric material of the ink mixtures may include the "*aforementioned hydrophilic and/or crosslinking monomers commonly employed as lens-forming monomers*", referring therefore implicitly to the monomers defined in paragraph [0015] with the consequence that the monomers for forming the coloured pattern may be the same as the lens-forming monomers. The ink mixtures may optionally further comprise a solvent, a polymerization initiator or a binding agent, the last mentioned being employed to facilitate binding of the colourant to the monomeric material. After

applying the monomeric ink mixture to the lens surface, it is thermally and/or UV cured. D1 also refers in paragraph [0016] to alternative methods of binding a colourant to a lens surface as described in U.S. Pat. Nos. 4,668,240 and 4,857,072, i.e. D13 and D14 in these proceedings.

9.3 Paragraph [0017] describes another way to apply the coloured pattern by reference to U.S. Pat. No. 5,120,121, i.e. document D5 in the present appeal proceedings. Paragraph [0017] of D1 states that "*The contact lenses of this patent are produced by applying a mixture of material to a contact lens front mold surface in a desired pattern. This mixture comprises lens-forming monomers, such as the aforementioned monomers used for hydrogel contact lenses, doped with a tint or colorant*". In D5 the vehicle of the coloured liquid is either preferably a thermoplastic polymeric vehicle or alternatively a curable (thermosetting) resin, which curable resin is either compatible with the liquid-lens forming mixture or is the same as the liquid-lens forming mixture (see D5, column 7, lines 50-52; column 8, lines 6-12; column 12, lines 5-9 and 50-57 and column 13, lines 2-5). In paragraph [0017] of D1, the mixture of material which is applied to the front mould surface is defined to comprise lens-forming monomers, such as the aforementioned monomers used for hydrogel contact lenses, doped with a tint or colorant. Consequently, having regard to the nature of the materials for making the pattern, which are described in [0017] of D1 and in D5, there is no doubt that the wording "*of this patent*" in paragraph [0017] refers to D1 itself, meaning that the passage of paragraph [0017] of D1 is not a mere summary of the invention of D5, as argued by the respondent, but a description of a material containing a monomer and a tint or colorant.

Thus this passage of D1 relates to an embodiment of D1 based on the less preferred coating method of D5, i.e. the method described in paragraph [0017] of D1 represents a selection of the coating material within the teaching of D5 considered to be suitable for the purpose of D1. It is in this respect pointed out that the monomers mentioned in paragraph [0017] to be part of the material mixture to be applied as a pattern on the contact lens merely define the material to be used for this composition doped with a tint or colorant, but not that used for making the contact lens on which the pattern is applied, even implicitly. The reference in paragraph [0017] to "*lens-forming monomers, such as the aforementioned monomers used for hydrogel contact lens*" is a mere reference to the monomers listed in paragraph [0015] of D1 which can be comprised in the patterned/ tinted layer composition applied to the front mould surface, but does not mean that the polymerized product thereof is a hydrogel. This is because whether a hydrogel is formed depends not only on the use of certain monomers employed but on the combination of monomers used and their proportions, as follows from the explanation of the properties of hydrogels in paragraph [0015] of D1 and in paragraph [0019] of the patent in suit.

9.4 According to paragraph [0018] of D1 the coloured pattern may also be applied to the lens surface using an inkjet printer as disclosed in U.S. Ser. No. 10/166,584. Representative inks are described to be mixtures comprising a colorant and a monomeric material, which "*may include the aforementioned hydrophilic and/or crosslinking monomers commonly employed as lens-forming monomers; the ink monomeric material may be the same as a lens-forming monomer, or different monomers may be employed in the ink mixture*

and the lens-forming copolymer." The use of a binder polymer, let alone one comprising the monomeric units defined in claim 1 is not disclosed.

9.5 D1 does not contain a passage indicating any preference for silicone-hydrogel material, which is merely presented as an option in the case that hydrogel contact lenses are used, or any preference for the process described in paragraph [0017], let alone any exemplified embodiment illustrating the invention of D1 in which a silicone-hydrogel contact lens was prepared using a process as defined in paragraph [0017]. Accordingly, D1 has not been shown to contain any pointer to the method specified in paragraph [0017] thereof for preparing a coloured silicone-hydrogel contact lens. Applying the same concept of disclosure used for assessing whether the subject-matter of an amended claim extends beyond the content of the application as filed (see G 2/10, point 4.6 of the Reasons, supra, citing G 1/03, OJ 2012, 436, point 2.2.2 of the Reasons), to the assessment of the disclosure of a prior art document the Board comes to the conclusion that D1 does not disclose to the skilled reader of D1 in a direct and unambiguous manner a process as defined in paragraph [0017] in which the material of the contact lens is a silicone-hydrogel. Furthermore, the objection of the appellant is based on an interpretation of operative claim 1 allowing the binder to be made *in situ*. This, however, is not convincing, because applying a colour coat with an ink which comprises a binder polymer as defined in claim 1 is to be understood according to a normal reading of that claim as meaning that the ink comprises the binder polymer before it is applied, i.e. excluding the possibility that the polymer is formed after application of the coating. However, it is not disputed

that the method described in paragraph [0017] of D1 involves the application of a mixture of monomers and a colourant but does not relate to an ink which comprises a binder, let alone a polymeric binder, before it is applied on the lens mould. Accordingly, D1 has not been shown to provide a direct and unambiguous disclosure of subject-matter falling within the scope of present claim 1. Novelty of claim 1 over D1 is therefore acknowledged.

Novelty of claims 1 and 28 over D6

10. D6 disclosed a process for the manufacture of a moulded contact lens which uses a principle similar to that described in paragraph [0017] of D1, i.e. in which a coloured liquid which is either curable or thermoplastic is coated in a mould, the contact lens material being applied in a second step on the top of the coloured coating (column 1, lines 6-22). The reading of D6 made by the appellant is based on a multiple selection of possibilities encompassed by the general teaching of D6, in particular:

- (i) selection of the vehicle of the colour liquid of curable resin in the B-stage, whereas the colour liquid can also be a thermoplastic or a curable resin (column 7 lines 19-20) including a curable resin in the A-stage i.e. without any cure or in the B-Stage i.e. partially cured (column 7, lines 48-51),
- (ii) selection of a polymerizable mixture of at least one hydrophilic vinylic monomer and at least one silicone-containing vinylic monomer or macromer for preparing the contact lens material from the long list of monomers (column 7, line 65 to column 8, lines 49) and

- (iii) selection of the same material for the vehicle of the colour liquid, although the use of another material compatible with the liquid lens-forming mixture is also described in D6 (column 7, lines 43-46).

A pointer to that combination of features in D6 has not been indicated by the appellant. On the contrary, the preferred monomeric mixtures according to D6 (column 8, lines 36-46) are not described to contain a silicone-containing vinylic monomer or macromer. D6 has not even been shown to contain a direct and unambiguous disclosure of the lens material being formed from a silicone hydrogel. The mere indication in column 8, lines 26-35 that other suitable monomers include methacrylic and acrylic acid esters of siloxane monomers and polymers such as those documented in D26 and D27, cited in said passage of D6, does not mean that any specific monomer mixture used in the examples of those documents, should it be considered to lead to a silicone hydrogel, is disclosed as being employed for preparing a coloured silicone contact lens according to the method of D6, let alone in combination with the same mixture as the liquid vehicle of the coloured coating in the B-stage. Accordingly, the combination of features selected from within the teaching of D6 by the appellant in order arrive at the subject-matter of claim 1 or claim 28 of the patent in suit cannot be objectively considered to emerge in a direct and unambiguous manner from that document.

11. Accordingly, it was not shown that the subject-matter of claims 1 and 28 lacks novelty.

Article 100 (a) EPC - Inventive Step

Closest prior art

12. The closest prior art for the purpose of objectively assessing inventive step is generally that which corresponds to a purpose or effect similar to that of the invention and requiring the minimum of structural and functional modifications (Case Law, supra, I.D. 3.1). It is normally a document that mentions the purpose or objective indicated in the patent in suit as a goal worth achieving (Case Law, *supra*, I.D.3.2). D1 was unanimously considered to represent the closest prior art, and the Board has no reason to take a different view, in particular as in contrast to D6, it was shown to relate to coloured silicone hydrogel contact lenses. Accordingly the disclosure of D1 is taken as the starting point for assessing inventive step.

Problem solved and solution

13. According to the appellant the problem solved vis-à-vis that prior art by the subject-matter of claims 1 and 16 or claim 28 is the provision of an alternative method or an alternative ink, respectively, for making coloured silicone hydrogel contact lenses, whereas the respondent is of the opinion that the problem solved over D1 by the subject-matter of claims 1 and 16 or 28 is the provision of a method or of an ink, repectively, for making coloured silicone hydrogel contact lenses.

14. As shown in the above assessment of novelty over D1, at most D1 envisages the production of coloured silicone hydrogel contact lenses by defining their structure, but cannot be held to describe any specific method for

their preparation. Hence, contrary to what is stated in paragraph [0006] of the patent in suit, which was inserted during examination of the patent application in order to indicate the background art which could be regarded as useful to understand the invention as required by Rule 42(1)(b) EPC, D1 does not in fact disclose a method for making coloured silicone hydrogel contact lenses. Accordingly, the formulation of the problem solved by the claimed subject-matter over D1 proposed by the appellant cannot be adopted because it relies on an incorrect assessment of the disclosure of D1 according to which D1 is held to disclose a method for making coloured silicone hydrogel contact lenses. Thus the problem to be solved must be reformulated in order to objectively assess inventive step.

The methods of claims 1 and 16 per definition lead to coloured silicone hydrogel contact lens and the ink of claim 28 is defined to form a coloured coat having good adhesion to the contact lens without being covalently attached to the lens material of the contact lens (see also detailed consideration of sufficiency of disclosure above in section 2). In contrast thereto, the achievement of a high-quality colour image is not necessarily realised by the method of claim 1 as also shown in above section 2 and no evidence was provided that it would be the case for the method of claim 16 and the ink of claim 28. For this reason, the provision of a high-quality image cannot form part of the problem successfully solved over D1. Accordingly, in line with the problem to be solved set out in the second full paragraph of page 2 of the application as filed, namely "*Therefore, there are needs for a method for making colored silicone hydrogel contact lenses, and for inks suitable for printing a high-quality color-image on a silicone hydrogel contact lens*", the problem considered

to be successfully solved over the disclosure of D1 can be formulated as the provision of a method or of an ink for making coloured silicone hydrogel contact lenses.

15. It remains to be decided whether or not the proposed solution to the above problem, as defined in any of the methods of claims 1 and 16 or the ink of claim 28 is obvious in view of the state of the art.

Obviousness of the method of claim 1

15.1 When seeking to develop a method for preparing coloured silicone hydrogel contact lenses, the preparation of which is envisaged in D1 in the light of a combined reading of claim 1 with paragraph [0015] of that document, the skilled person would turn to the teaching of paragraphs [0016] to [0018] of the same document which as shown in above points 9.1 to 9.4 describe suitable methods for providing the coloured contact lens of D1.

15.2 Paragraph [0017] concerns an embodiment of the invention according to D1 using the same principle as defined in present claim 1 (see point 9.3 above). Paragraph [0017] contains the teaching that "*The contact lenses of this patent*" - meaning D1 itself as indicated in above point 9.3 - *"are produced by applying a mixture of material to a contact lens front mold surface in a desired pattern. This mixture comprises lens-forming monomers, such as the aforementioned monomers used for hydrogel contact lenses, doped with a tint or colorant. Then, the mold and this mixture are subjected to polymerization conditions so as to partially or fully polymerize the pattern on the mold surface, followed by dispensing a conventional lens forming monomer mixture which does*

not contain tint or colorant into the mold such that it submerges the previously polymerized pattern, and polymerizing this mixture to obtain a contact lens." Accordingly, if the skilled person applied the method envisaged in paragraph [0017], he would not find the explicit suggestion to use an ink mixture comprising a polymeric binder, but an ink mixture comprising lens forming monomers, such as those used for forming the hydrogel contact lenses, and polymerize them only once they have been applied on the mould surface. Hence, the mixture containing a tint or colourant addressed in paragraph [0017] is not described to comprise a polymeric binder and is not disclosed to be applied after partial polymerisation of its constituents, so that [0017] cannot be held to explicitly or implicitly suggest the use of a polymeric binder. The other methods described in D1, i.e. in paragraphs [0016] and [0018] concern a method by which - in the terminology of D1 - an "ink", consisting of a monomer and a colourant, is applied on the contact lens, but not a method by which the contact lens is prepared in the lens mould after the ink was printed on a surface of the mould (see points 9.2 and 9.4 above). Accordingly, D1 does not suggest a method falling within the ambit of claim 1 of the patent in suit.

15.3 The appellant argued that claim 1 would be obvious over a combination of D1 with D5. D5 describes from column 13, line 14 to column 14, line 22 a long list of conventionally used liquid lens-forming materials (monomer, prepolymer or vulcanizable components) to prepare contact lenses in accordance with the teaching of D5. The indication that particular suitable components are hydrophilic monomers preferably including those which form slightly or moderately crosslinked three dimensional networks (column 13,

lines 14-19) suggests that D5 is concerned with the coating of hydrogel contact-lenses.

Other suitable monomers include according to column 13, lines 48-51 ethylenically unsaturated monocarboxylic acid esters, in particular "*the methacrylic and acrylic acid esters of siloxane monomers and polymers with/ without a pendant hydroxyl group*" (column 13, lines 50-51). The disclosure of these compounds and the reference to D26 and D27 in lines 54-55 of column 13, which is made in D5 for the purpose of describing other monomers suitable for making the lenses is to be understood as an indication of alternative lens materials (such as those described in D26 or D27) to which the coloured pattern can be applied by the method of D5. It does not however constitute a disclosure that D5 is concerned with silicone hydrogel contact lenses, because those "*methacrylic and acrylic acid esters of siloxane monomers and polymers*" are not disclosed to be used in combination with other contact lens monomers that could form a hydrogel, such as those described in column 13, lines 13 to 47. Accordingly, starting from D1, which already is concerned with tinted silicone hydrogel contact lenses, the skilled person seeking to develop coloured silicone hydrogel contact lens would have no reason to consult D5.

Furthermore, as indicated in above point 9.3 the method described in paragraph [0017] of D1, in which reference is made to D5, is understood by the skilled person reading D5 as a selection of the methods proposed in that document. Accordingly, D1 recommends for the application of a coating to hydrogel contact lenses a selected teaching within the information contained in D5, meaning that the other manners of applying the

coloured coat as described in D5 are implicitly considered to be less preferred for the purpose of D1.

Consequently, because D1 in contrast to D5 is directed to tinted silicone hydrogel contact lenses and already proposes several methods for their preparation, which group of methods is understood to be suitable to prepare silicone hydrogel contact lenses, and D1 already takes into account the teaching of D5 for the preparation of tinted hydrogel contact lenses, there is no objective reason for the skilled person starting from D1 and wishing to provide a method suitable for making a coloured coated silicone hydrogel contact lens to revisit the whole teaching of D5 and to focus on other ways of applying the ink coating described in D5 which were not considered in D1. Accordingly, the skilled person wishing to solve the problem defined above would not be directed to apply the curable liquid resin for forming the coloured pattern in a partially cured but still liquid state (B-stage), which teaching is not provided in D1, but only in column 12, lines 59-62 of D5. Furthermore, the "balafilcon" monomer mixture, whose use is contemplated in D1 for the lens material, would, if it were also selected as a polymeric mixture for the coloured coating, as argued by the appellant and were partially cured to the B-stage as to be still liquid as is taught in D5 for the ink coating would, depending on the intensity of the degree of curing/polymerisation applied, not necessarily lead to a polymer binder. This would require from the skilled person to cure the mixture to a higher extent than that necessary to form oligomers, for which there is also no disclosure in D5. Finally, the argument that D5 would disclose an ink comprising a binder polymer, because a thermosetting resin is a polymeric compound that had the ability to be

crosslinked, must also be dismissed because such an interpretation of the wording "thermosetting resin" cannot be reasonably made in the context of D5. In view of the disclosure in D5 that the most desirable thermosetting resins are those that are either compatible with the liquid lens-forming mixture or are the same as the liquid lens-forming mixture (column 12, lines 50-57), which liquid lens-forming mixture are usually monomeric mixtures as exemplified by D5, D4, D14, D26 and D27, it is concluded that the wording "thermosetting resin" without any level of cure (A-stage) only suggests the use of a monomeric mixture. Accordingly, starting from D1 the claimed solution to the above problem cannot be held to be obvious in the light of D5.

15.4 The appellant argued that claim 1 was the obvious result of taking balafilcon from D1 and applying the method of making a coloured lens of D9, i.e. that described at page 26, lines 9-25 and Figure 6 including the use of a pre-polymerised balafilcon monomer mixture in the ink. However, it was not shown that D9 is directed to application of a coating layer to a silicone hydrogel contact lens. The mere indication in D9 from page 27, line 23 to page 28, line 1 of silicones in a list of preferred materials for making lenses, which list also mentions acrylics, polycarbonates and other known materials in the art and the possibility of the lens material to be hydrophobic or hydrophilic, in which case the polymer is preferably a hydrogel and the indication that the polymer used to make contact lenses results in "hard lenses", "soft lenses" or "hybrid lenses" does not constitute any disclosure that D9 aims at providing tinted silicone hydrogel contact lenses. The description of the contact lens material in that passage of D9 remains general and

does not point to silicone hydrogels. The only more specific description of a contact lens material in D9 is given on page 41 and concerns an acrylic based polymer which does not contain any silicone monomers. Hence, the skilled person seeking to prepare coloured silicone hydrogel contact lens would not be prompted to consult D9.

In addition, the method of D9 referred to by the appellant, i.e. that described at page 26, lines 9-25, does not suggest to apply an ink comprising a pre-polymerized mixture of a monomer mixture. The method of that section of D9 provides a laminate structure (first portion of a structure, a digitally encoded image, i.e. a tinted layer, and a second portion of a structure), the layers of material being applied in a multistage process. The description of said process contains several instances of the expression "*partially polymerized*", also when describing the digitally encoded image (tinted layer). However, all occurrences of the wording "*partially polymerized*", as well as those of the wordings "*non-polymerized*", "*polymerized*", "*optionally spin cast*" and "*optionally polymerized*", do not refer to the state of the material at the time it is applied, but to the absence or presence of a (partial) polymerisation or spin casting step subsequent to the application of the various layers of material. There is therefore no suggestion in that passage of D9 to pre-polymerize a mixture of monomers to an intermedidate stage before its application, let alone for the digitally encoded image (tinted layer).

For these reasons, the argument of the appellant that the skilled person would find it obvious to take balafilcon from D1 and to apply the method of making a coloured lens of D9, including the use of a pre-

polymerised balafilcon monomer mixture (i.e. a binder polymer) in the ink cannot convince.

Method of claim 16

15.5 The question arises if as argued by the appellant the skilled person in an attempt to solve the problem considered to be successfully solved over D1 would have selected the method described in paragraph [0016] of that document, also using an ink formulation based on the balafilcon mixture defined in paragraph [0015], but applied it in a pre-polymerized state as taught in D14, which allegedly would result in applying an ink corresponding to the ink defined in operative claim 16.

According to the method described in paragraph [0016] of D1 the ink to be applied on the surface of a hydrogel contact lens includes a colorant and a monomeric material, which may be the same as a lens-forming monomers and the ink may optionally further comprise a solvent, a polymerization initiator, or a binding agent. The ink is cured after applying the monomeric ink mixture to the lens surface and no pre-polymerization step of the ink before being applied on the lens is disclosed. Accordingly, the method described in paragraph [0016] of D1 does not describe that the ink could contain a polymer, even implicitly, let alone a polymeric binder. The binding agent mentioned in said paragraph of D1 is merely indicated to facilitate binding of the colorant to the monomeric material. Its structure or chemical nature is not specified. Accordingly the method described in paragraph [0016] of D1 cannot suggest the use in the ink of a polymeric binder, let alone those comprising the monomeric units (i) to (iii) specified in operative claim 16. Furthermore, that a binder polymer formed

after application of the ink on the lens has an equivalent function to any preformed binder polymer in the ink composition has not been shown to be suggested in the context of a method of the type defined in paragraph [0016] of D1.

The method of D14 referred to by the appellant is mentioned in paragraph [0016] of D1 as an alternate method of binding a colorant to a lens surface. The chemical nature of the contact lenses of D14 is described in column 2, lines 30-55 of that document and D14 does not disclose that the lens forming material could comprise a silicone containing monomer. The lenses are preferably formed from monomers comprising N-vinyl pyrrolidone (NVP), in an amount from about 50 to about 90 weight percent (claim 1 and column 2, lines 49-55), the contact lens material of the examples being made of about 71 wt.-% of NVP and about 26 wt.-% of methacrylic acid (column 7, Preparative Example No. 1 and column 8, Preparative Example No. 4). Those contact lenses are as a result known to have a very high water content upon hydration (column 1, lines 44-48). In contrast the silicone hydrogel material balafilcon is according to the appellant obtained with a monomer mixture containing TRIS-vc, NVP, VINAL and V_2D_{25}, reference being made to D4 cited in paragraph [0015] of D1 and to D21. That type of material, as illustrated by Formulation A of D4 (column 7) contains a much lower amount of hydrophilic vinyl heterocyclic nitrogen containing monomer (about 30 wt.-%), the rest of the monomers being essentially silicone-containing monomers, which among others are known to have less affinity for water. Accordingly, the contact lens material balafilcon and those described in D14 differ in their chemical constitution and resulting properties.

Furthermore, D14 does not indicate that the pre-polymerization of monomers for forming a binder for the ink, as employed in the specific context of that document, would be generally applicable for coating other types of lenses. There is therefore no reason for the skilled person having regard to the difference in chemical nature and resulting properties between silicone contact lens materials such as balafilcon and contact lens materials of D14 to apply any teaching in respect of D14 to silicone hydrogel contact lenses. Moreover, it is also pointed out that D14 does not even teach the use of the same monomeric mixture for the contact lens material and the binding polymer contained in the ink, this being particularly illustrated by the examples of D14 in which the monomeric mixtures used for making the contact lens and the binding polymer do not even have any monomer in common.

Hence, the appellant's argument that the skilled person would have combined the method described in paragraph [0016] of D1, using an ink formulation based on the balafilcon mixture and applied it in a pre-polymerized state as taught in D14 in order to solve the problem mentioned in above point 14 is not convincing. It is therefore concluded that the method as defined in operative claim 16 has not been shown to arise in an obvious way from the prior art.

Method of claim 28

15.6 As shown in above sections 9.2. to 9.4 D1 describes two types of method for providing coloured hydrogel contact lenses, i.e. suggests two types of method for preparing silicone hydrogel contact lenses, namely (i) a method of the type defined in operative claim 1 in which the ink is applied on the mould for forming the contact

lens and polymerized before applying lens-forming monomers to form the body of the contact lens and (ii) a method by which a colour coating (ink) is applied on an already formed contact lens. In points 15.1 to 15.4 it was concluded that the skilled person using a method of type (i) in order to provide a method for making coloured silicone hydrogel contact lenses would not find it obvious to use an ink comprising a silicone-containing binder polymer as defined in claim 1, which is a copolymerization product of a polymerizable mixture including (i) at least one hydrophilic vinylic monomer; (ii) at least one silicone-containing vinylic monomer or macromer, and (iii) optionally one or more components selected from the group consisting of a polymerization initiator, a chain transfer agent, and a solvent. Considering that the silicone-containing binder polymer defined in claim 1 and consequently the ink defined in claim 1 is more broadly defined than the ink of operative claim 28, it is concluded at least for the same reasons as defined in relation to claim 1, that it would not be obvious for the skilled person to use the ink as defined in claim 28 when seeking to provide an ink for making coloured silicone hydrogel contact lenses by the method of type (i). Furthermore, it was concluded in point 15.5 above that for the method of type (ii) it would not have been suggested to the skilled person to use an ink in accordance with claim 16, an ink which corresponds to the definition of claim 28 as acknowledged by the appellant. Accordingly, it is concluded at least for the same reasons as set out in relation to claim 16, that it would not have been obvious for the skilled person to use the ink as defined in claim 28 when seeking to provide an ink for making coloured silicone hydrogel contact lenses by the method of type (ii). Consequently, starting from D1 and wishing to prepare an ink for making coloured silicone

hydrogel contact lenses, the skilled person being aware only of the two types of methods described in D1 (i) and (ii) would not arrive in an obvious manner to the ink of claim 28.

15.7 Summing up, the appellant did not show that the subject-matter of any of claims 1, 16 or 28 would arise in an obvious way from the prior art.

16. Accordingly, none of the grounds of opposition raised by the appellant prejudices the maintenance of the patent as granted. There is therefore no reason to consider the auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

L. Malécot-Grob M. C. Gordon

Decision electronically authenticated