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**Datasheet for the decision  
of 27 January 2011**

**Case Number:** T 0826/06 - 3.3.02

**Application Number:** 99921291.3

**Publication Number:** 1075285

**IPC:** A61K 49/00

**Language of the proceedings:** EN

**Title of invention:**

The use of a vital dye for facilitating surgical procedures  
for cataract extraction

**Patentee:**

Melles, Gerrit Reinold Jacob

**Opponents:**

Industria Terapeutica Splendore Alfa Intes  
AL.CHI.MI.A. S.r.l.  
FLUORON GmbH  
Arcadophta

**Headword:**

Use of vital dye for facilitating surgical cataract  
extraction/MELLES, G.R.J.

**Relevant legal provisions:**

EPC Art. 53(c), 56  
RPBA Art. 12, 13, 14

**Relevant legal provisions (EPC 1973):**

EPC Art. 52(4), 54

**Keyword:**

"Main request lacks novelty"  
"Auxiliary requests 1, 4, 6 and 7 not admissible"  
"Auxiliary request 5 lacks inventive step"

**Decisions cited:**

G 0001/07, G 0002/08, G 0005/83, G 0006/88, G 0001/04

**Catchword:**

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Case Number: T 0826/06 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 27 January 2011

**Appellant-Opponent OI:** Industria Terapeutica Splendore Alfa Intes  
(Opponent O1) Via Fratelli Bandiera, 26  
I-80026 Casoria NA (IT)

**Representative:** Prato, Roberto  
STUDIO TORTA  
Via Viotti, 9  
I-10121 Torino (IT)

**Appellant-Opponent OII:** AL.CHI.MI.A. S.r.l.  
(Opponent OII) Viale Europa 12/a  
I-35020 Ponte S. Nicolò (PD) (IT)

**Representative:** Ponchiroli, Simone  
Ruffini Ponchiroli e Associati S.r.l.  
via Caprera, 6  
I-37126 Verona (IT)

**Party as of right:** FLUORON GmbH  
(Opponent OIII) Biberkopfweg 1  
D-89231 Neu-Ulm (DE)

**Representative:** Leissler-Gerstl, Gabriele  
Hoefer & Partner  
Patentanwälte  
Pilgersheimer Strasse 20  
D-81543 München (DE)

**Party as of right:** Arcadophta  
(Opponent OIV) 11 rue Antonie Ricord  
F-31100 Toulouse (FR)

**Representative:** Cabinet BARRE LAFORGUE & associés  
95, rue des Amidonniers  
F-31000 Toulouse (FR)

**Respondent:** Melles, Gerrit Reinold Jacob  
(Patent Proprietor) 's Landswerf 69  
NL-3063 GC Rotterdam (NL)

**Representative:** Prins, Adrianus Willem  
Vereenigde  
P.O. Box 87930  
NL-2508 DH Den Haag (NL)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
3 April 2006 concerning maintenance of European  
patent No. 1075285 in amended form.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** M. C. Ortega Plaza  
J.-P. Seitz

## Summary of Facts and Submissions

- I. European patent No. 1 075 285, which was filed as application number 99 921 291.3 based on international application WO 99/58160, was granted on the basis of eight claims.

Claim 1 as granted read as follows:

"1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, for the manufacture of a staining composition for visualizing a lens capsule in an eye during performance of a capsulorhexis."

- II. The following documents and exhibits cited during the proceedings are relevant for the present decision:

(7) Norn M.S., Acta Ophthalmologica, vol. 58, 1980, pages 550-555

(8) Norn M.S., Acta Ophthalmologica, vol. 49, 1971, pages 725-733

(15) Horiguchi M. et al, Arch. Ophthalmol., vol. 116, April 1998, pages 535-537

(32) Study Report, BioScan BV

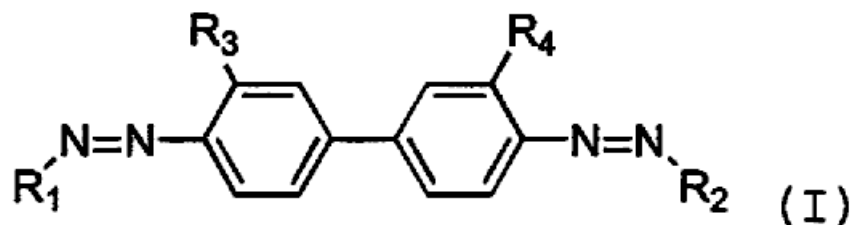
(33) D. F. Chang, EyeNet Magazine online; August 2000, "Cataract Visualization: The Essentials"

(34) A. Oravec, Cataract & Refractive Surgery Today, "Update of VisionBlue" (post-published document)

- III. Oppositions were filed and revocation of the patent in its entirety was requested pursuant to Article 100(b) EPC (insufficiency of disclosure) and Article 100(a) EPC (lack of novelty and inventive step).
- IV. The appeal lies from the interlocutory decision of the opposition division maintaining the patent in amended form on the basis of the main request filed with letter of 25 July 2005 (Articles 102(3) and 106(3) EPC 1973).

Claim 1 of the main request read as follows:

"1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formula (I)



wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate

for the manufacture of a staining composition for visualizing a [sic] the anterior lens capsule in an eye during performance of a capsulorhexis".

- V. The opposition division considered that the main request met the requirements of Articles 123(2) and (3), 84 and 83 EPC.

The opposition division was of the opinion that the Swiss-type form claim was adequate in view of the fact that the surgical method relating to the capsulorhexis could be considered as a method of treatment of the human or animal body under Article 52(4) EPC 1973. As a consequence, the conditions for the legal fiction set out in Enlarged Board of Appeal decision G 5/83 (OJ 1985, 064) directly applied.

In the opposition division's view, novelty was given vis-à-vis document (8) in view of the lack of mention of capsulorhexis in said document.

As regards the issue of inventive step, the opposition division considered document (15) as the closest prior art. The opposition division defined the problem to be solved as to provide another dye as an alternative to indocyanine green which was used in document (15). According to the opposition division's findings, the proposed solution was not obvious since it could not be concluded from the teaching in document (8) that trypan blue was suitable for colouring the anterior lens capsule in capsulorhexis.

- VI. Opponents OI and OII filed appeals against said decision and filed grounds of appeal. Appellant opponent OII filed with its grounds of appeal several declarations and documents.

- VII. The respondent (patent proprietor) filed with its letter dated 22 February 2007 counterarguments thereto, a copy of the main request filed on 25 July 2005, two auxiliary requests and a declaration by Prof. Dr M. Coroneo.
- VIII. A communication expressing the preliminary opinion of the board was sent to the parties as an annex to the summons to oral proceedings to be held on 14 May 2009.
- IX. The respondent filed with its letter dated 27 January 2009 a response to the board's communication. It also filed four auxiliary requests to replace those previously on file.
- X. Oral proceedings took place on 14 May 2009. During said oral proceedings the respondent submitted a first list of questions for referral to the Enlarged Board of Appeal. At the oral proceedings held on 14 May 2009 the board decided to stay the proceedings since Enlarged Board of Appeal decisions G 2/08 and G 1/07 were then pending and likely to affect the case under consideration.
- XI. Summons to oral proceedings to be held on 21 July 2010 were sent on 4 March 2010 with a copy of Enlarged Board of Appeal decisions G 2/08 (date of decision 19 February 2010) and G 1/07 (date of decision 15 February 2010).
- XII. A notice of intervention within the meaning of Article 105 EPC was filed by Arcadophta on 15 April 2010. The intervener requested to be invited to the scheduled oral proceedings as a party as of right.

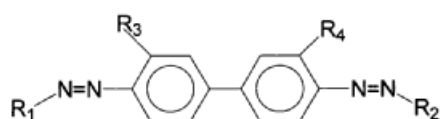


- Moreover, it filed arguments and evidence in order to support its intervention and its opposition against the contested patent.
- XIII. A copy of the notice of intervention and its accompanying annexes was forwarded to the patent proprietor (respondent) on 21 April 2010.
- XIV. The respondent requested with its letter dated 3 June 2010 that the oral proceedings scheduled for 21 July 2010 be postponed in order to have sufficient time to respond to the newly filed intervention.
- XV. Appellant opponent OII contested with its letter dated 8 June 2010 the declaration of Dr Coroneo and his position as an independent technical expert. It filed further documents.
- XVI. With its letter dated 21 June 2010 opponent OIII submitted, *inter alia*, that the main request failed on grounds within the meaning of Article 52(4) EPC 1973 and that the auxiliary requests did not meet the requirements of Articles 123(2) and (3) and 84 EPC.
- XVII. The Board informed the parties that the oral proceedings appointed for the 21 July 2010 were postponed to the 27 January 2011.
- XVIII. The respondent filed a reply to the intervention with its letter dated 1 November 2010. The respondent filed further documents (*inter alia* a second declaration by Dr Coroneo). Moreover, the respondent filed with its letter of 1 November 2010 auxiliary requests 1 to 7, replacing the auxiliary requests previously on file. It

also requested referral to the Enlarged Board of Appeal of some questions of law, which it submitted in two separate pages.

Claim 1 of the first auxiliary request read as follows:

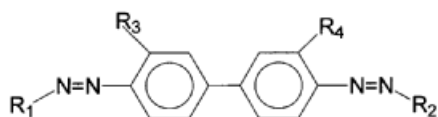
1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formule (I)



- wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate  
for the manufacture of a staining composition for visualizing an anterior lens capsule in an eye during performance of a capsulorhexis, wherein the visualizing facilitates the capsulorhexis.

Claim 1 of the second auxiliary request read as follows:

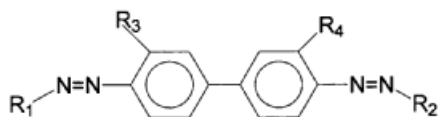
1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formula (I)



- wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate  
for the manufacture of a staining composition for visualizing an anterior lens capsule in an eye during performance of a capsulorhexis, wherein the capsulorhexis is performed as part of a surgical procedure for cataract extraction.

Claim 1 of the third auxiliary request read as follows:

1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formula (I)

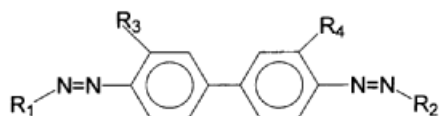


wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate

for the manufacture of a staining composition for visualizing an anterior lens capsule in an eye during performance of a capsulorhexis, wherein the capsulorhexis is performed as part of a surgical procedure for cataract extraction and wherein the anterior lens capsule is stained by applying the composition onto the capsule.

Claim 1 of the fourth auxiliary request read as follows:

1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formula (I)

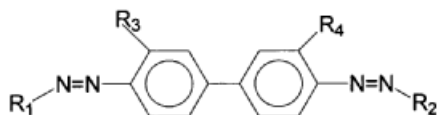


wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate

for the manufacture of a staining composition for use in a surgical procedure for cataract extraction comprising performance of a capsulorhexis, wherein the staining composition is used for visualizing the anterior lens capsule in an eye during performance of the capsulorhexis, and wherein the anterior lens capsule is stained by injecting the composition onto the capsule.

Claim 1 of the fifth auxiliary request read as follows:

1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formula (I)



wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate

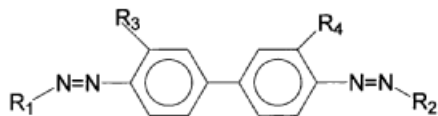
for the manufacture of a staining composition for use in a surgical procedure for cataract extraction comprising performance of a capsulorhexis, wherein the outer surface of the anterior lens capsule is selectively stained by applying the staining composition onto the capsule thereby providing a clear distinction between the portion of the anterior lens capsule that is to be removed and the underlying lenticular material, which distinction facilitates the controlled opening of the anterior lens capsule.

Claim 1 of the sixth auxiliary request read as follows:

1. Use of at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being trypan blue for the manufacture of a staining composition for use in a surgical procedure for cataract extraction comprising performance of a capsulorhexis, wherein the staining composition is used for visualizing the anterior lens capsule in an eye during performance of the capsulorhexis, and wherein the anterior lens capsule is stained by injecting the composition onto the capsule.

Claim 1 of the seventh auxiliary request read as follows:

1. A method for visualizing an anterior lens capsule in an eye during performance of a capsulorhexis, wherein the anterior lens capsule is stained by applying a staining composition onto the capsule, wherein the staining composition comprises at least one dye, which dye is capable of staining tissue without diffusing through said tissue, said dye being represented by the formule (I)



wherein R<sub>1</sub> and R<sub>2</sub> are the same or different aryl groups, and wherein R<sub>3</sub> and R<sub>4</sub> are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate.

XIX. Appellants opponents OII and OI contested the admissibility of the newly filed auxiliary requests and requested that the request for referral to the Enlarged Board of Appeal be refused (letters dated 23 and 27 December 2010, respectively).

XX. Oral proceedings took place on 27 January 2011.

In the course of the oral proceedings the respondent expressly renounced any objection under Rule 106 EPC (and Article 112a EPC) on the ground that auxiliary request 4 filed on 1 November 2010 was not admitted into the proceedings, although it had previously had informed the Board that it intended to file one.

XXI. The arguments submitted by the parties, as far as relevant for the present decision, are summarised in the paragraphs below.

XXII. The appellant opponent OI submitted that although claim 1 of the main request was drafted as a Swiss-type claim, the wording of the claim was not in accordance with the principles set out in Enlarged Board of Appeal decision G 5/83, OJ EPO 1985, 64, since the mandatory mention of the method of treatment of the human body was lacking (either surgical or therapeutic). The expression "during performance of a capsulorhexis" in claim 1 did not signify a method of treatment. Apart from that, "visualizing" implied something the "user" performed subsequently to the "staining". The use of the dye, which was staining, was not linked functionally to the other two steps in the claim (visualizing and capsulorhexis). Thus, even assuming the opposition division's findings that "during capsulorhexis" was a surgical step which allowed the claim be formulated in the so-called Swiss-type form, then said surgical step was not causally linked to the dye and its use for staining. Therefore, the alleged "distinguishing feature" should not be considered either for the assessment of novelty or of inventive step. Moreover, capsulorhexis was not an act of surgery since it merely concerned incision to a lens capsule in an eye, which could be performed *in vitro* (and not necessarily *in vivo*), for example for experimental purposes.

Therefore, claim 1 of the main request lacked novelty vis-à-vis document (8) since some features in claim 1, in particular "during capsulorhexis", could not be considered to be entitled to the legal fiction provided by a Swiss-type form claim. Document (8) did not mention capsulorhexis because it had been published in 1971 and the technique of capsulorhexis was

developed later. Claim 1 of the main request related to the use of the same dye for staining the same tissue as that disclosed in document (8).

As regards paragraph [0007] of the patent in suit, the appellant opponent OI stated that visualization took place when staining and not when cutting. None of the further features specified in claim 1 of the main request could provide novelty.

The appellant opponent OI contested the admissibility of the auxiliary requests filed with the letter of 1 November 2010 since none of the auxiliary requests specifically addressed any new facts and arguments put forward by the intervener. The amended sets of claims addressed objections the respondent had been aware of for a long time from the written proceedings. Thus, said requests could have been filed earlier. Additionally, appellant opponent OI was against a referral to the Enlarged Board of Appeal.

Appellant opponent OI further submitted that the auxiliary requests admitted into the proceedings did not meet the requirements of Article 123(2) and/or Article 84 EPC. The exact meaning of visualization was unclear when taken in combination with the other features in claim 1 of the second auxiliary request. Moreover, the application as filed only disclosed visualization in connection with the defect in the anterior lens capsule. Additionally, visualization was a mental act, not valid as a technical feature for defining a patentable invention.

As regards claim 1 of the third auxiliary request, the appellant opponent OI stated that it related to an unallowable intermediate generalisation of the specification in the application as filed (passage bridging pages 8 and 9). Moreover, the passage on page 8, lines 11-12 did not disclose the feature "applying onto the lens capsule" and it specified the staining composition as a "solution". Several administration modes and several physical forms for the staining composition were possible.

As regards claim 1 of the fifth auxiliary request, the appellant opponent OI raised an objection within the meaning of Article 123(3) EPC. If "during performance of a capsulorhexis" in claim 1 as granted was a functional feature with a temporary meaning, then the object for which protection was sought in claim 1 of the fifth auxiliary request was different in view of the fact that cataract extraction comprising performance of a capsulorhexis constituted a functional feature now linked to the dye.

Appellant opponent OI submitted the following in relation to the inventive step issue for the fifth auxiliary request. Document (15) represented the closest prior art. The only difference was that in document (15) indocyanine green was used as the dye. Document (15) disclosed the same application mode, direct injection onto the capsule, and that the stained anterior capsule became clearly visible, facilitating the capsulorhexis. Document (15) taught that the use of indocyanine green for the selective staining was fully satisfactory in comparison with fluorescein sodium which diffused through the eye, staining several parts.



Hence, the problem to be solved was only to provide another dye which could attain effects similar to those of indocyanine green. Document (8) disclosed the use of trypan blue within the context of cataract extraction. Capsulorhexis was not used as an opening technique in said document since it was not known at that time. However, document (8) gave clear indications to use trypan blue in a similar context, namely cataract extraction. Thus, the skilled person had an incentive to try trypan blue as the dye of choice for staining the same tissue in cataract surgery. Therefore, the proposed solution was obvious. Any other considerations, such as selective staining, were not relevant for supporting the presence of an inventive step since they were already known from document (8).

Appellant opponent OI contested the explanatory statements given by the respondent since they did not reflect the reality of an eye operation. The vital dye trypan blue had been well known for a long time before the filing date of the patent in suit. Thus, the skilled person knew about its low toxicity. Trypan blue was not only a dye obvious to try as a solution to the problem, it was also the dye which the skilled person had a clear incentive to use.

Appellant opponent OI submitted that the improvements alleged by the respondent were dependent on features not reflected by the claim's wording.

Appellant opponent OI also contested the respondent's allegation that the skilled person would have been deterred from considering document (8). It submitted that the relative toxicity of trypan blue in relation

to other dyes such as gentian blue or rose bengal was well known to the skilled person at the time of the priority date of the patent in suit. Document (8) referred to a cataract extraction method which was commonly performed in 1971. This was the only reason why it did not refer to capsulorhexis. Document (8) would have been considered by the skilled person when looking for dyes useful in cataract extraction. The commercial success of trypan blue could not serve to support inventive step of the use claimed. The technical teaching in document (15) concerning the fact that indocyanine green was a dye useful for facilitating capsulorhexis in cataract extraction was not diminished by the outcome of a procedure before regulatory authorities. Additionally, appellant opponent OI stated that the respondent's allegation that the quality of the staining was dependent on the method of operation performed did not have any scientific basis. Document (8) reported a partial staining but did not give any reasons for it.

Appellant opponent OI further contested the admissibility of late-filed documents (67) and (68). Their late filing was not justified. They were no more relevant than documents already on file. The post-published documents (67) and (68) could not serve to establish *ex post facto* the knowledge that had existed at the time of the "invention".

XXIII. Appellant opponent OII agreed with appellant opponent OI in relation to the objections raised against claim 1 of the main request. Additionally, it submitted that the technical effect achieved by the "use of a dye for the manufacture of a staining composition..." was

lacking in the claim. Staining was the natural effect of use of a dye. The other features in the claim were sequential in time and not causally related thereto. Moreover, "visualizing" was an intellectual act of the surgeon. The dye was disclosed in the application as filed for staining the anterior lens capsule. It was not clear what was intended with the expression "for visualizing" in the claim. The expression "for visualizing the anterior lens capsule" was not mentioned in the application as filed. If staining could facilitate a capsulorhexis, this did not mean that the dye participated in the step of capsulorhexis. Thus, "during performance of capsulorhexis" was not a feature justifying a Swiss-type claim. Moreover, if this expression was to be considered as a surgical step, then it was not a method of treatment but just a mode of capsular opening. The treatment concerning cataract extraction was not stated in the claim.

Appellant opponent OII agreed with appellant opponent OI in that document (8) was novelty-destroying for the subject-matter in claim 1 of the main request. It further submitted that document (8) disclosed visualization of the capsule since the anterior lens capsule was stained, as mentioned on page 730 of said document.

Appellant opponent OII submitted that the fact that the claim mentioned an invasive step was clearly insufficient for applying the principles set out in decision G 005/83 for the legal fiction allowing acknowledgement of the novelty of the second therapeutic indication of a known medicament. It further submitted that if a use claim was drafted in a

Swiss-type form everything encompassed thereby had to belong to a medical use in order for this legal fiction to be correctly applied.

Additionally, document (8) (page 726 second full paragraph) disclosed that staining was assessed several times before the extraction of cataract. Thus, document (8) disclosed the same use for trypan blue.

Appellant opponent OII also objected to the admissibility of the auxiliary requests filed with the letter of 1 November 2010, for the same reasons as those stated by the appellant opponent OI. The arguments put forward by the respondent in its letter dated 1 November 2010 did not mention in how far the amendments addressed the grounds in the notice of intervention.

Appellant opponent OII agreed with appellant opponent OI that the auxiliary requests admitted into the proceedings did not meet the requirements of Articles 123(2) and 84 EPC. The application as filed disclosed that the "outline of capsular defect can be visualized during the creation of a capsulorhexis" (page 9, lines 26-27) and page 10 referred specifically to trypan blue. Appellant opponent OII agreed with appellant opponent's OI objection within the meaning of Article 123(3) EPC against claim 1 of the fifth auxiliary request. It also pointed to the fact that the feature "visualizing..." was no longer in the claim. The object of the amended claim was different from that in the granted claim.

Appellant opponent OII agreed with appellant opponent OI's inventive step analysis in relation to claim 1 of the fifth auxiliary request. It further stressed that the claim still encompassed interventions for training purposes in corpses and animals.

The indications in column 5 of the patent in suit that the dye must be safe and able to stain the capsule were of a general nature and self-evident for any vital dye to be used in an eye in a cataract extraction. There was nothing in the patent in suit indicating or referring to improvements or surprising effects to be attained. There was no mention in the patent in suit of a relative better toxicity of the azo-dyes over other dyes, nor did the patent in suit contain any teaching about the amounts or concentrations to be used in order to achieve less toxicity. There was no basis in the application as filed for supporting the problem defined by the respondent in relation to the choice of the azo-dyes in the claim. Therefore, the late-filed and late-published documents (67) and (68) should not be admitted into the proceedings.

Appellant opponent OII also stated that the respondent's argumentation about document (8) almost amounted to an attempt to misinterpret its content. Moreover, if document (8), or another piece of prior art, had disclosed the use of trypan blue in connexion with capsulorhexis in a cataract extraction, then claim 1 of the fifth auxiliary request would have manifestly lacked novelty. The proper reading of document (8) was that trypan blue was able to stain the membrane forming the eye capsule and that it was safe to do so. Furthermore, document (7), which was a document by the

same author as document (8), demonstrated the lack of toxicity of trypan blue. Additionally, the reasons why the staining of the anterior capsule corresponded to the pupil were quite simple: the anterior chamber was filled with the staining composition, thus only the part of the capsule which faced the anterior chamber was stained. The surgeon knew that when he opened the anterior chamber the pressure went down, causing adhesion of the iris to the anterior lens capsule. As a result staining took place through the opening of the pupil.

XXIV. As regards claim 1 of the main request, opponent OIII shared the appellants' submissions and further submitted that the claim contained a mixture of features. The feature "for visualizing the anterior lens capsule" was not disclosed in the application as filed or in the priority document. Moreover, "visualizing" required a subjective observer. What was actually seen was dependent on several conditions. If a red pullover was stained with a red dye, the staining could not be seen. Thus, "visualizing" was not a technical feature, it was an intellectual accomplishment of the observer. The technical effect of a dye was a particular staining, which however was not specified in the claim. The expression "during capsulorhexis" in the claim represented merely an unsuccessful attempt to establish novelty. The dyes were known products and their use in the medical field was also known. Capsulorhexis was a new technique, developed at the beginning of the nineties, which allowed improvements in surgical cataract extraction. It related to a particular form of cutting and opening the lens capsule in the eye for which it was necessary

to know how to cut and observe what was to be cut. However, this technique was known at the effective filing date of the patent in suit. It was also known at that time how to perform capsulorhexis and to use a dye during capsulorhexis. The only difference in the claim was the dye chosen. However, the dye itself had nothing to do with the cutting technique. The capsulorhexis was not functionally linked to the dye since the cutting step took place after the staining; they constituted two separate steps. Assuming that the claim contained all the steps identifying the "invention", it could not merely consist of the step of staining a membrane in the course of cataract extraction, since this was already known from document (8). Thus, the only "distinguishing feature" was the performance of a capsulorhexis as a surgical step. Following the logic in decision G 1/07, such a claim could not be allowed.

Additionally, document (8) (page 725, fourth paragraph) stated the following: "I have vital-stained the anterior chamber during cataract extraction". This passage meant "visualizing" the anterior lens capsule. However, if by some strange mechanism "visualizing" was different in the patent in suit from that in document (8), then said mechanism should have been explained. Paragraph [0007] of the patent in suit mentioned visualization of the defect in the anterior capsule and not visualization of the anterior lens capsule, as stated in the claim. Furthermore, paragraph [0007] was not dedicated to describing the "invention" but related to background knowledge. As regards the disclosure of the "invention" in the patent in suit, paragraphs [0037] and [0038] showed that some other steps, not mentioned in the claim, were required

before capsulorhexis was made. Only then was visualization of the blue stained peripheral portion of the anterior capsule over the gray lenticular mass shown. Furthermore, these two paragraphs specifically related to the use of trypan blue. However, the claim also encompassed other azo-dyes which were not necessarily blue-staining and could stain white or red. In such cases it was unclear what "visualizing" could actually mean.

Opponent OIII shared the appellants' objections against the admissibility of the auxiliary requests filed with the letter of 1 November 2010.

Opponent OIII agreed with the appellants' objections against the auxiliary requests admitted into the proceedings. Claim 1 of the second auxiliary request did not meet the requirements of Articles 123(2) and 84 EPC since visualizing during performance of a capsulorhexis was not a property of the staining composition, and because this feature was not defined in the application as filed in the sense given in the amended claim. If visualizing had to do with homogeneous staining as put forward by the respondent in the written proceedings, then there was a lack of support and a lack of clarity in relation to this term and the azo-dyes encompassed by the claim.

Opponent OIII stated that it had raised objections within the meaning of Articles 123(2) and 84 EPC previously during the written proceedings. Claim 1 of the auxiliary requests did not directly derive from a combination of granted claims but it also included definitions from the description.



As regards the respondent's argument that document (8) did not disclose visualization because washing with alpha-chymotrypsin was required, attention should be given to paragraph [0012] of the patent in suit. Said paragraph mentioned that sodium hyaluronate was used during the operation to fill the anterior chamber of the eye and that it might become stained and then had to be replaced. Thus, the meaning of "visualizing..." in the amended claims was unclear.

Opponent OIII shared with the appellants the objections against claim 1 of the fifth auxiliary request. Additionally, the claim was unclear (Article 84 EPC) and/or not supported by the application as filed (Article 123(2) EPC).

Opponent OIII agreed with the appellants that claim 1 of the fifth auxiliary request lacked an inventive step. Additionally, it submitted that the problem had to be plausibly solved throughout the claimed scope. Since the claim encompassed a group of dyes, and not only trypan blue, it could not be assumed that all these dyes showed the same behaviour as selective vital dyes like trypan blue. Thus, the intended effects had not been shown to be present for the whole scope claimed and the problem of improvement had not been solved. Additionally, document (15) taught the way of handling the vital dye in the cataract extraction comprising capsulorhexis. Thus, the problem was merely to provide an alternative that did not stay long in the tissue after the operation. The solution was provided by document (8) which disclosed selective staining with

trypan blue, wherein the colour faded in the course of the operation (page 727).

Opponent OIII further stressed that although column 5 of the patent in suit referred to "sufficient staining" and "useful colouring to be visible", the patent did not contain any data or any reference to a test for determining these effects. The passages in column 5 could only relate to the general understanding in the field and, thus, such problem was trivial. Another problem was stated in column 4, lines 17-19 of the patent in suit, namely that of providing a dye which was "capable of staining tissue or a tissue component, e.g. a membrane, without diffusing through said tissue or component thereof". Thus, in the light of document (15) the problem was to provide an alternative to indocyanine green. The proposed solution was obvious in view of document (8) since it disclosed that trypan blue met the conditions stated in column 4 of the patent in suit.

XXV. Opponent's OIV submitted that trypan blue was a dye known for a long time (document (8)). Thus, patenting this *per se* known product should not be possible thereafter by delimiting an "invention" according to the development of surgery. The use of the dye had to remain in the public domain. A claim requiring the surgeon to "visualize" the anterior lens capsule should not be allowed, nor should such a claim provide protection against infringement for use of the dye. Claim 1 should not benefit from the exceptional legal fiction within the meaning of G 5/83 since there was no medical treatment reflected by the claim's wording. The Enlarged Board of Appeal decision G 5/83 was limited by

the framework of Article 54(2) EPC 1973 (Article 53(c) EPC 2000). Claim 1 of the main request did not contemplate a treatment, i.e. the use did not involve a patient to be treated. The findings in the rapporteur's communication sent as an annex to the summons for the oral proceedings in May 2009 were correct in this respect.

The fiction implying a medical treatment had been invoked by the respondent in order to overcome an objection of lack of novelty of the use of the dye. However, the intended use "during a capsulorhexis" covered uses *in vitro*, or *ex vivo* and in corpses. For instance, it included the use *in vitro* in a pig eye, or in a corpse eye for the purpose of training of medical students. These uses were far remote from a medical treatment entitled to benefit from the legal fiction recognised in G 5/83. These findings were not contradicted by decisions G 1/07 and G 2/08, OJ EPO, 2010, 456. In particular, G 1/07 established that a surgical step did not necessarily have to be therapeutic to benefit from the legal fiction in G 5/83. Claim 1 of the main request did not only prevent surgeons from treating their patients, it also prevented use *ex-vivo* or in corpses. A lack of identification of the therapeutic treatment inevitably led to a lack of novelty as was the case in decision T 1286/05-3.3.02 of 1 April 2008, since the legal fiction set out in G 5/83 did not apply. The existence of prior-art document (8) did not allow a valid patent merely limited by the surgeon's act of visualizing the anterior lens capsule in an eye. There was an analogy with the situation depicted in decision T 317/95 of 26 February 1999. Moreover, the reasoning in decision

T 566/07-3.3.02 of 17 May 2010, i.e. of the same board as in the present case but in another composition, was directly transposable to the present case. In accordance with said decision T 566/07, a claim which comprised two separate methods, i.e. a diagnostic method followed by a separate method of surgery, could not enjoy the benefits of the notional novelty fiction according to decision G 5/83. Two different and separate activities were specified in claim 1 of the main request in the present case: the visualization and the capsulorhexis. There was a first step which required an evaluation by the surgeon about the state of the anterior lens capsule, the cataract (e.g. mature cataract) and the patient, before he decided to go for a continuous circular capsulorhexis. As stated in the patent in suit, the surgeon might choose other opening techniques such as can-opener technique, capsulotomy, or envelop technique. If following the logic of decision G 1/07 the surgical step of capsulorhexis was a surgeon's act excluded from patentability by the provisions in Article 53(c) EPC 2000, then it could not be relied upon to define the "invention". The reason was that there was no functional link between the use of the dye and the surgical step (G 1/07, point 4.3.2). The term "during" did not change that analysis in any way since "visualizing" necessarily took place after the staining had occurred.

Claim 1 of the main request was not entitled to the benefits conferred by the legal fiction in accordance with decision G 5/83, which could not apply when the use of the dye was "for staining", i.e. as a use that might be other than therapeutic. Thus, claim 1 of the main request in fact related to a method of manufacture

of a staining composition which was known *per se*. Document (8) disclosed the use of a staining composition containing trypan blue. The staining composition was known and its manufacture was also known at that time. Thus the technical construction of the claim ended in a lack of novelty. The statement of a particular purpose could not confer novelty since the use was not made in a method excluded from patent protection under Article 53(c) EPC 2000. The steps specified in claim 1 of the main request did not necessarily pertain by their nature to a therapeutic method and, thus, the findings in decision G 2/08 (point 5.10.9) could not apply. Furthermore, document (8) disclosed the technical function of the staining composition, which was selective staining of the anterior lens capsule (page 730). The expert declarations, even that of Mr Norm, should not be used for a late interpretation of a prior-art document published in 1971, which should be read as it stood. The technical effect which was attained by the dye, i.e. staining, was deprived of any functional link (as expressed in decision G 1/07, point 4.3.2) to the capsulorhexis. Capsulorhexis was dependent on the surgeon. Moreover, the contrast achieved between the stained and the unstained parts in the eye was not mentioned in the claim. Thus, claim 1 of the main request merely related to the use of a known product for the manufacture of a staining composition, which lacked novelty.

Opponent OIV objected to the admissibility of the auxiliary requests filed with the letter of 1 November 2010. They did not clearly overcome the lack of novelty over document (8) since some of them mentioned cataract

extraction as the surgical method and others did not correctly address the problem of non-applicability of the legal fiction. Moreover, these requests raised new issues within the meaning of Articles 84 and 123(2) EPC at too late stage of the proceedings (decision T 1038/02-3.3.02 of 1 March 2005).

Opponent OIV endorsed the other opponents' objections within the meaning of Articles 123(2) and 84 EPC against the auxiliary requests. The definitions introduced in claim 1 of the second and third auxiliary requests did not reproduce all the features appearing in the description of the application as filed. Thus, each claim 1 related to an unallowable generalisation of the original disclosure.

Opponent OIV submitted in relation to claim 1 of the fifth auxiliary request that the wording of the feature "applying onto the capsule" amounted to an unallowable intermediate generalisation. It then objected to the fact that the claim's wording was not a verbatim reproduction of the description (page 5, lines 16-23) and that the term "distinction" was not restricted to taking place after the cutting.

Opponent OIV further questioned that claim 1 of the fifth auxiliary request could benefit from the legal fiction of the Swiss-type form without exclusively relating to a therapeutic treatment (implying an *in vivo* treatment). The method of cataract extraction could be performed for instance on the eyes of dead pigs. Additionally, opponent OIV submitted that claim 1 of the fifth auxiliary request lacked an inventive step.

The mode of application was not a distinguishing feature over document (8) since said document disclosed that the needle of the vital-stain-containing syringe was introduced into the lower half of the anterior chamber in the eye. Thus, the dye was in direct contact with the anterior lens capsule of the eye. Then, the differences were to be found in the following features: "to be removed" and "which distinction facilitates the controlled opening...". However, said "features" were known from document (15), which already disclosed how to use or apply a vital dye for facilitating the controlled opening, a capsulorhexis, in an eye suffering from mature cataract (pages 535, 536). Document (15) further disclosed how to administer the dye by putting one or two drops of the staining solution on the anterior lens capsule after removing the air in the anterior chamber. Moreover, same document (15) also disclosed that easy identification of the anterior lens capsule helped avoid capsular tear.

Opponent OIV then referred to the arguments it had submitted with its notice of intervention, namely that the problem-solution approach was not always appropriate for examining inventive step. It cited decisions T 308/99-3.3.02 of 2 June 2003 and T 465/92, OJ EPO 1996, 32. It further mentioned that trypan blue was known as a selective vital dye for basement membranes, in particular Descemet membrane. Thus, it was obvious to combine this teaching with that of the other cited prior-art documents, in particular documents (15) and (8) and arrive at the claimed invention.

Additionally, opponent OIV cited decision T 296/87, OJ EPO, 1990, 195 and stated that the improvements alleged by the respondent were only quantitative and not qualitative, and thus they were the result of trivial trial and error tests. Moreover, toxicity was dependent on the content of the dye in the staining composition and the amount used. These were features not reflected by the claim's wording.

Opponent OIV acknowledged that if the problem-solution approach was to be applied, then it would agree with the other opponents' presentations. It cited decisions T 400/98 of 19 September 2002 and T 659/00 of 1 July 2003.

Opponent OIV further stressed that there was a reduced number of vital dyes known at the date of filing of the patent in suit and that trypan blue was well known to be suitable to be used in the eye. Furthermore, the claim encompassed the family of azo-dyes and was not limited to trypan blue.

XXVI. The respondent's arguments can be summarised as follows:

As regards claim 1 of the main request the respondent submitted the following. Claim 1 was drafted as a Swiss-type claim on the basis of the principles set out in decision G 5/83, since it addressed subject-matter excluded from patentability (*in vivo* treatment by surgery). A staining composition was not excluded within the sense of Article 52(4) EPC 1973 (Article 53(c) EPC 2000), but it was excluded in the context of its intended use, namely "for visualizing the anterior lens capsule in an eye during



capsulorhexis". Historically, the Swiss-type form originated from the need to protect the use of a known substance for the treatment of a particular disease or disorder. However, there was no requirement to include all method steps in the claim. The opponents had argued that "visualizing" as such was not a therapy, but it was nonetheless the intended use which justified the second medical use claim. The jurisprudence of the boards of appeal had moved forward since Enlarged Board of Appeal decision G 5/83 in year 1985. The Enlarged Board of Appeal decision G 2/08, OJ EPO, 456, 2010 acknowledged the administration regimen of a drug as an allowable feature notwithstanding the provisions in Article 53(c) EPC 2000. The argumentation followed in G 2/08 was applicable to the present case. When looking into G 1/07 for a definition of what is meant by the term "surgery", it became clear that a therapeutic effect was not required. If the health of the patient might be injured, then a method of surgery was implied. The respondent pointed to paragraph [0005] of the patent in suit and submitted that capsulorhexis was not exclusive for cataract extraction. Moreover, it was correct to say that in most cases capsulorhexis was a step for cataract extraction, but capsulorhexis was a far less invasive technique than the old opening technique employed in the cataract operation in document (8). The cataract operation in document (8) was carried out with cryopencil. Said document disclosed that during the removal of full lens mass, the cornea may be damaged. In contrast thereto, capsulorhexis concerned a very small and narrow cut into the cornea and thus, the cornea was still in place and undamaged. Therefore, "visualizing the anterior lens capsule" implied that the cornea remained in place.

The application of the dye *in vivo* to an eye had a medical and surgical character requiring it to be performed by a physician. This prerequisite supported the wording in the Swiss-type form. The feature "visualizing..." imparted novelty to the claimed use when made during performance of a capsulorhexis.

The respondent pointed to paragraph [0006] of the patent in suit in which capsulorhexis was explicitly mentioned, and to paragraph [0007] in which the problems linked to an improper visualization of the anterior lens capsule during the performance of a capsulorhexis were explained. In this context the respondent also cited document (15), left column, lines 15-17, which confirmed that continuous circular capsulorhexis was often difficult to perform because of poor visibility of the anterior lens capsule. Thus, the term "visualization" should be understood within this technical context. The dye for which the use was claimed allowed staining and visualization by only providing colour to the lens capsule. Thus, it was possible to distinguish the capsule from the lens mass during the opening due to the contrast between the stained peripheral portion of the anterior lens capsule and the gray lenticular mass. This constituted the causal link between visualization and capsulorhexis. As the surgeon could visualize the anterior capsule it can provide for means not to damage the eye. Thus, "visualization" was not an intellectual act but reflected actions performed by the surgeon through working in the eye. For assessing novelty and inventive step all features in the claim had to be considered. The distinguishing feature of the use claimed was the visualization during capsulorhexis. None of the

documents provided during the whole proceedings was novelty destroying.

Capsulorhexis was an invasive action requiring a surgeon and, thus, it was an act of surgery according to decision G 1/07. Whether or not the act itself was curative was irrelevant. Visualization was not an intellectual act since "the surgeon sees what he is doing". This was an effect linked to the dye. If the claim also encompassed other uses which were not of a medical nature, such as a capsulorhexis performed on corpses or *ex vivo*, that was irrelevant, because the use addressed in the claim, if claimed *per se*, would contravene Article 53(b) EPC 2000. Thus, the dye facilitated the performance of the incision by the surgeon. The analysis made in decision T 317/95 cited by opponent OIV questioned dosage regimen as a valid distinguishing feature for a second medical use claim. However, decision G 2/08 made it clear that it was possible to acknowledge dosage regimen as a distinguishing feature imparting novelty. As regards the analogy with the case in decision T 566/07, the respondent contested the presentation made by opponent OIV. In the present case there was no diagnosis step involved in the use claimed, since there was no diagnosis of the anterior lens capsule to be made. The anterior lens capsule was present in every eye, except if it had been extracted by surgery. Therefore, there was no need to assess whether the anterior lens capsule was there. The surgeon had to be able to see what he was doing during the performance of capsulorhexis. This use did not involve two separate steps or activities. Therefore, it could not be argued that decision T 566/07 directly applied to the case in suit. The

technical effect of the dye was attained during performance of the capsulorhexis. Thus, there was a temporary and a functional link to the use of the claimed dye.

The respondent further submitted that opponent's OIV arguments did not hold because any method of surgery may be performed on a corpse, by analogy to Rembrandt's "class of anatomy". Even a puncture could be performed in a corpse; however, it was identified in decision G 1/07 as an invasive step for the imaging method. As long as the claim encompassed a step of surgery it had to be classified as a surgical act which came under the provisions of Article 52(4) EPC 1973 (Article 53(c) EPC 2000), in analogy to the use for immunostimulation in decision T 780/89, OJ EPO 1993, 440 (point 6), and in decision T 485/99-3.3.2 of 29 April 2004 where the feature pre-operatively could impart novelty *versus* the feature post-operatively. Therefore, the feature "during capsulorhexis" implied temporarily and causally the visualization of the anterior capsule of the eye. All parties had agreed that capsulorhexis had not been disclosed together with the azo-dyes defined in the claim. As mentioned in paragraph [0007] of the patent in suit, visualization was an important step in the surgical procedure. Document (8) disclosed the partial staining over the area corresponding to the pupil. The claim required staining over the entire anterior lens capsule during a surgical operation involving capsulorhexis. Thus, novelty was given over the content of document (8). Moreover, "visualizing the anterior lens capsule" meant distinguishing the anterior lens capsule from the lens mass when the capsule was opened by capsulorhexis, which required a selective staining.

Histological examination disclosed in document (8) was something different.

Swiss-type form claims were a matter of method policy, since claims should not cover anything which hindered a doctor or physician from treating their patients. If this was the case, the claim could not be directed to the method *per se* and, thus, it had to be drafted in a Swiss-type form. There were many patents granted at the EPO containing claims concerning therapies for which the method could also be applied to corpses. What was relevant for allowing the Swiss-type form was that the claim covered something which was a surgical method.

The respondent further submitted that opponent OIII knew very well in the written submissions what visualization meant. It meant visualization during capsulorhexis, i.e. allowing the differentiation of the anterior lens capsule and the lens mass. If the defect in the anterior capsule could be seen it was because the lens capsule was no longer there and the lens mass could be seen. If the anterior lens capsule was not opened, it could not be distinguished. Document (8) did not disclose visualization. Document (8) disclosed on page 726 that the dye was injected into the chamber and that staining could not be assessed until washing. Washing with alpha-chymotrypsin was something which interfered with the staining. This was something which should not be done during the performance of capsulorhexis. Moreover, in document (8) there was no selective staining since the iris, the capsule and the endothelium of the cornea were stained. In particular, document (8) stated that in some instances trypan blue

stained the nearest portion of the iris, presumably by penetrating through the sclera.

As regards the arguments in favour of the admissibility of the auxiliary requests filed with the letter of 1 November 2010, the respondent submitted the following. The auxiliary requests were filed in response to the notice of intervention. The notice of intervention had been filed in appeal proceedings as oral proceedings were already scheduled for July 2010. As expressed in Article 14 RPBA, Article 12(1) RPBA also applied in case of intervention. The intervener had cited the Enlarged Board of Appeal decisions G 1/07 and G 2/08 and had raised an objection within the meaning of Article 53(c) EPC 2000. The filed amendments were an attempt to defend the respondent's case against the objections raised by a new party to the proceedings. Moreover, it was not a common practice to address every single aspect in the accompanying letter to the filing of auxiliary requests. The auxiliary requests were not complex and had been filed about three months before the oral proceedings. The number of auxiliary requests was also limited. Thus, the auxiliary requests should be admitted into the proceedings since they were in accordance with Rule 13(3) RPBA. Moreover, some corresponding requests had already been on file before.

The respondent further submitted that the discussion as to whether a patent could be maintained in amended form in appeal proceedings had to take into consideration that Article 100(c) EPC was not a ground for opposition in the present case and that no objections were raised with the grounds of appeal in this respect. Thus, the objection against the expression "visualizing..." was

heard for the first time. The attacked expression was present in claim 1 as granted, and the further feature introduced in claim 1 of the second auxiliary request was present in claim 4 as granted. Thus, the discussion about Article 123(2) EPC related to an attempt to introduce a new ground for opposition without the consent of the patentee. Moreover, Article 84 EPC was not a ground for opposition. Therefore the formal objections against the second auxiliary request should not be considered. The fact that the definition of the dye had been specified in relation to its chemical structure did not affect this argumentation.

Additionally, the basis was given, although not as a literal reproduction, on page 5 of the application as filed, as an object of the "invention" was "to visually distinguish the anterior lens capsule from the underlying lenticular material". This meaning corresponded to the "visualization" mentioned on page 2. In fact, the arguments provided by opponent OIII during the oral proceedings against the term "visualization" amounted to arguments within the sense of "undue burden" for the breadth of the claim, and thus corresponded to objections in relation to Article 83 EPC. Article 83 EPC had been a ground for opposition but it had not been pursued by the appellants with their grounds of appeal. The definition of the dye in claim 1 corresponded to that in the claim of the main request which had been maintained by the opposition division. Objections in relation to Articles 123(2) and 84 EPC had not then been raised.

The feature concerning "applying the staining composition onto the capsule" disclosed in the passage

bridging pages 8 and 9 of the application as filed related to the whole disclosure and not to a particular embodiment. Cataract extraction was mentioned everywhere in the application as filed, thus the teaching on pages 8 and 9 directly and unambiguously applied to cataract extraction. The definition of the azo-dyes could be found on page 7 as part of the general teaching. Thus, the amended claims did not relate to an unallowable "cherry picking" from the original disclosure. The technical teaching to apply the staining composition onto the capsule was not limited to the case of solutions.

Claim 1 of the fifth auxiliary request did not contravene Article 123(3) EPC since it was narrower than claim 1 as granted in relation to the dye and to the surgical method (cataract extraction which comprises a capsulorhexis). The expression "visualizing..." had been replaced by the definitions in the corresponding passages of the description. The causal and temporal link to the capsulorhexis was clearly reflected by the wording in the amended claim. The "controlled opening" at the end of the claim corresponded to the capsulorhexis previously mentioned in the claim. The respondent maintained its arguments in relation to the expression "applying..." and the teaching on pages 8 and 9 of the application as filed. Moreover, the content of page 5 was also part of the same generic teaching. The verbal differences in the claim's wording, such as between "to be removed" and "being removed", had only to do with the fact that page 5 defined the method *per se* and the claim defined the use in a Swiss-type form. Additionally, the cause for the distinction was the selective staining. The



distinction between the portion of the anterior lens capsule and the lenticular material could be seen when opening the anterior lens capsule.

The respondent further stated that the discussion whether or not the cataract extraction could be also performed on dead pigs was immaterial for considering the allowability of the therapeutic use in claim 1 of the fifth auxiliary request. Article 52(4) EPC 1973, corresponding to Article 53(c) EPC 2000 prohibited a claim directed to the surgical method (see also G 1/04, OJ EPO, 2006, 334 and G 1/07); thus, the Swiss-type form was mandatory. Claim 1 of the fifth auxiliary request left no doubt about the fact that it related to a use in a method for treatment by surgery.

In relation to inventive step of the fifth auxiliary request the respondent submitted the following. Not until the oral proceedings on 27 January 2011 had opponent OIII alleged that some of the dyes did not solve the technical problem. If the respondent had heard this objection before, then it would have provided further data. Furthermore, if this objection was to be allowed, then the respondent wished to be given an opportunity to restrict the claim of the fifth auxiliary request to trypan blue. The primary consideration when determining the closest prior art for a use claim was the stated utility. Thus, the starting point for the skilled person was the knowledge about the safety and usefulness of indocyanine green for cataract extraction (document (15)). The problem was not merely to provide an alternative to indocyanine green but to provide for better (as regards selective staining) and safer (as regards toxicity) dyes. The

skilled person found no motivation in document (15) to look for other dyes beyond indocyanine green, since on page 537 it was stated that the experiments with fluorescein were not satisfactory. Thus, document (15) taught that some dyes were not satisfactory for use in connection with a capsulorhexis. If the skilled person looked further than indocyanine green and wondered what other dye might achieve better visualization and be less toxic in the context of a capsulorhexis, he would not have looked at document (8).

Asked by the board to complete the problem-solution approach and address the reasons why the problem of providing for an improvement had actually been solved, the respondent referred to post-published documents (33) and (34), and to its written submissions during appeal proceedings in which it had argued that document (33), which disclosed the opinion of Dr Chang, a clinical professor, stated that clinical studies of indocyanine green and trypan blue dye had shown that both were extremely effective in providing anterior capsule visualization with mature white or brown cataracts and that trypan blue produced a more conspicuous and persistent stain since trypan blue created a much darker staining which lasted longer. Additionally, document (34), which referred to Dr Chang's opinion, also included a reference to Dr Masket's opinion that indocyanine green was not as effective as trypan blue in capsular staining. Document (34) stated that Dr Masket's had showed his high esteem for trypan blue by preferring its use (acquiring VisionBlue<sup>R</sup> from Europe), after he had informed his patients that he intended to use a "nonapproved" product in the US.

The respondent further submitted that the problem to be solved was how to provide an improvement and the solution was a dye less toxic and with better staining properties. The context in which those properties were to be looked at was essential, and this context was a capsulorhexis. The skilled person did not have reasonable expectations of success when looking for an improvement over the indocyanine green in document (15). Thus, the argument that the skilled person would look at document (8), published in 1971, was made with hindsight after knowing the claimed "invention". The purpose in document (8) was to stain the corneal endothelium. To the time of document (8) cataract operations were performed in an invasive way, which could injure the cornea. Document (8) reported the results of such operations and assessed the damage to the cornea using cryopencil. Moreover, document (8) reported that trypan blue, rose bengal and fluorescein were equally non-toxic, whereas it had been proven that rose bengal was in fact toxic. The surgical context in the patent in suit was very different from that in document (8). The modern standards and concerns about toxicity were different from those in 1971.

Asked by the board whether toxicity did not rely upon the amounts of dye employed and its concentration in the staining composition, the respondent answered that toxicity did indeed rely on amount and concentration but it was also relative to the efficacy for the required staining. In this context the respondent cited the following passage of the patent in suit "the minimum amount of dye which is necessary to provide sufficient staining" (first paragraph on column 5) and

stated that this was a concern from the beginning when addressing the problem solved by the "invention".

The respondent further argued that document (8) taught away from the proposed solution since it did not disclose specific staining with trypan blue. Moreover, the mode of application in document (8) was to apply the staining composition by filling the anterior chamber. Despite the fact that the anterior capsule had been in contact with the staining composition, only the part corresponding to the pupil was stained. Moreover, alpha-chymotrypsin, which was employed in document (8), was a digestive enzyme that may affect the properties of the capsule. There had been a lengthy dispute among the parties in opposition proceedings about how the skilled person would interpret the phenomenon of a partial staining at the time of the publication of document (8). It could however not be denied that document (8) taught that there was a partial staining of the eye capsule. Thus, starting from document (15) it was not obvious to use the dyes defined in claim 1. There was no incentive to consult document (8) for capsulorhexis. Even if document (8) was consulted, its content taught away since trypan blue may diffuse, not give a selective staining or be too toxic. Furthermore, in document (8) some damage to the edges of the capsule was done caused by cryopencil and/or chymotrypsin.

The respondent further submitted that the commercial success of trypan blue, and the absence of any commercialisation of indocyanine green for capsular staining in cataract surgery, were indirect evidence of the presence of an inventive step.

The respondent also stated that the claim's wording required that the dye was capable of staining tissue without diffusing through said tissue. Thus, if an azo-dye did not fulfil this function its use was not encompassed by the claim. The claim also did not cover toxic dyes. Moreover, the azo-dyes of formula (I) defined in the claim represented a reasonable generalisation from trypan blue. The respondent further submitted that for the phenomenon of diffusion the electrostatic interactions played an essential role and not necessarily the molecular weight. According to document (8) trypan blue could diffuse through tissue, thus the skilled person would have thought that it was not appropriate for the purpose of the "invention". There was even a lack of expectations of success that trypan blue would be as good as indocyanine green, so as to deter the skilled person from trying the product according to the claim.

The respondent objected to opponent's OIV view in relation to inventive step, since it related to an unallowable ex-post-facto analysis (T 710/97 of 25 October 2000). The respondent also referred in this context to its written submissions in letter dated 1 November 2010. It further denied the relevance for the presently claimed use of the arguments submitted by opponent OIV in relation to the staining of basement membranes and Descemet membrane.

Document (15) was a correct choice as closest prior art for the problem-solution approach. Moreover, every feature in claim 1 of the fifth auxiliary request had to be considered for the inventive-step analysis, in particular the following: "which distinction

facilitates the controlled opening of the anterior lens capsule". There was nothing in document (8) in this respect.

During the oral proceedings the respondent also mentioned the late-filed documents (67) and (68). Asked by the board to give reasons for their admissibility, the respondent stated that it had filed them with its letter of 1 November 2011 since the other parties had submitted further arguments in the written proceedings.

The respondent further referred to the questions it had proposed for referral to the Enlarged Board of Appeal in the two pages filed as an annex to its letter dated 1 November 2010.

XXVII. The appellants (opponents OI and OII) requested that the decision under appeal be set aside and that European patent No. 1075285 be revoked.

The opponents OIII and OIV shared the requests of the appellants.

The respondent (patent proprietor) requested:

- 1) that the appeals be dismissed (i.e. that the patent be maintained according to the main request corresponding to the version maintained by the opposition division)
- 2) subsidiarily, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the auxiliary requests 1 to 7 filed on 1 November 2010,

3) further subsidiarily, that questions of law as drafted in its submissions filed on 1 November 2010 be referred to the Enlarged Board of Appeal in case the Board is of the opinion that the main request or any of the auxiliary requests up to the fifth auxiliary request contravene Article 53(c) EPC, or if the Board considers that the claimed features of the previously meant requests cannot be considered for the assessment of novelty and/or inventive step.

## **Reasons for the Decision**

### 1. *Procedural matters*

1.1 The appeals are admissible.

1.2 The intervention filed during the appeal proceedings by Arcadophta is admissible (Article 105 EPC). This has also not been contested by the respondent.

### 1.3 *Admissibility of the auxiliary requests and additional documents*

1.3.1 Article 12(2) RPBA set outs the general principle that the statement of the grounds of appeal and (in the case of *inter partes* proceedings) the reply to the other party's submissions must contain a party's complete case.

However, according to Article 12(4) RPBA everything presented by the parties in accordance with Article 12(1) RPBA shall be taken into account by the board if and to the extent it relates to the case under

appeal and meets the requirements of Article 12(2) RPBA. This is without prejudice to the power of the board to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings.

Article 14 RPBA stipulates that Articles 12 and 13 RPBA applies *mutatis mutandis* to interventions commenced while an appeal is pending. However, the mere statement that the auxiliary requests were filed with the letter dated 1 November 2010 as a reply to the notice of intervention is insufficient for establishing their admissibility.

Article 13 RPBA clearly reflects that any amendment to a party's case may be admitted at the board's discretion, after the circumstances of the case have been examined.

- 1.3.2 Most of the issues raised by opponent OIV in its notice of intervention were long known to the respondent from the written proceedings. In particular, the board's communication sent as an annex to the summons to oral proceedings scheduled for 14 May 2009 indicated that, in view of the absence of functional features in claim 1 of the main request (in particular in relation to the method for treatment by surgery and its causal link to the dye), the legal fiction in G 5/83 could not apply.

The first auxiliary request filed with the letter of 1 November 2010 cannot be considered as a direct response to any new arguments in the notice of intervention. Moreover, the first auxiliary request



raises new issues in relation to the formal requirements of clarity and support and thus, is *prima facie* not allowable. Claim 1 of the first auxiliary request reproduces the wording of claim 1 of the main request with the additional feature at the end of the claim: "wherein the visualizing facilitates the capsulorhexis". This claim's wording opens a new discussion in how far the introduced amendment concerns an allowable attempt under Article 84 EPC to define the protection sought by the claim. Thus, the mere specification that the "intellectual act" of "visualizing" facilitates the capsulorhexis (even if capsulorhexis was to be taken as a surgical step performed by the surgeon) without clearly expressing in the claim a causal link to the dye puts into question the clarity of the subject-matter claimed (Article 84 EPC).

Consequently, the first auxiliary request is not admissible.

The set of claims of the second auxiliary request which corresponds to the set of claims of the first auxiliary request filed with the response to the grounds of appeal is admissible.

The third auxiliary request corresponds to the second auxiliary request filed with the letter of 27 January 2009 as a response to the board's communication mentioned above, and, thus, is admissible.

Claim 1 of the fourth auxiliary request is not identical (only similar) to any of claims in the requests previously on file. The wording of claim 1

manifestly lacks clarity and thus said request is *prima facie* not allowable. In particular, the new claim's construction does not clearly overcome the problems of lack of causal link between the intended use and the azo-dye. On the contrary, it opens new issues of lack of clarity regarding the definition of the use for which protection is sought (Article 84 EPC) since it concerns the use of the azo-**dye for** the manufacture of a staining composition "**for use in** a surgical cataract extraction **comprising** performance of a capsulorhexis" and "wherein said **staining composition is used for visualizing** the anterior lens capsule in an eye **during** capsulorhexis" (emphasis added).

Therefore the fourth auxiliary request is not admissible.

The fifth auxiliary request relates to a clear and fair attempt to respond to the objections raised by the intervener. Thus, the fifth auxiliary request is admissible.

Claim 1 of the sixth auxiliary request is not identical to any claim 1 of requests previously on file. Although it is more restrictive than claim 1 of the fifth auxiliary request in relation to the definition of the dye which is only trypan blue, the rest of the claim's wording (that referring to the definition of the use) is different from that in claim 1 of the fifth auxiliary request. Thus, the amendments in the sixth auxiliary request did not converge, but indeed diverge from the amendments proposed in the previous requests. Moreover, claim 1 of the sixth auxiliary request is *prima facie* not allowable since its wording manifestly

lacks clarity. Consequently, the sixth auxiliary request is not admissible.

Claim 1 of the seventh auxiliary request relates to a method excluded from patentability (Article 52(4) EPC 1973 and Article 53(c) EPC 2000). Therefore, the seventh auxiliary request is clearly not admissible.

1.3.3 As regards the post-published documents (67) and (68) which were filed with letter of 1 November 2010, they are no more relevant than the documents previously on file. Moreover, they do not represent a direct reply to any new objection lately raised by the parties to the present appeal proceedings. The steps forming the logical chain of the problem-solution approach to be applied by the board in the assessment of inventive step should have been known to the respondent.

1.3.4 As regards the admissibility of a full assessment of the requirements within the meaning of Articles 123(2) and 84 EPC for the sets of claims pending in appeal proceedings, it has to be stressed that all the sets of claims serving as the basis for the present decision relate to amended claims. Therefore, the board has the duty to assess whether the amended claims meet the formal requirements within the sense of Articles 123(2) and 84 EPC independently from the opposition division's findings.

Additionally, the amended claims do not derive from a pure combination of granted claims, but include definitions from the description in relation to the dye.

Finally, the amendments have to be examined within the context of the wording in the amended claim.

Therefore, the objections raised under the provisions of Articles 123(2) and 84 EPC, respectively, are admissible for the amended sets of claims.

2. *Main request*

- 2.1 Methods for treatment of the human and animal body by surgery are listed among the methods excluded from patentability according to Article 52(4) EPC 1973 (Article 53(c) EPC 2000). Therefore, the conditions set out in decision G 5/83 for claims directed to further medical indications in methods for treatment by therapy apply in principle to chemical products to be used in methods for treatment by surgery.

Decision G 5/83 institutes the Swiss-type form for claims relating to further medical indications. Thus, the Swiss-type form concerns a legal fiction that allows a specific medical use for a known product to act as a functional feature conferring notional novelty on the use of the product for the manufacture of a medicament which is otherwise known *per se*.

- 2.2 Therefore, the wording in claim 1 of the main request has to be investigated in order to determine whether or not the definitions contained in the claim reflect functional features of the product (in the present case the dye) whose use is addressed.

Formally, claim 1 of the main request is drafted in a Swiss-type form. The claim relates to:

(a) Use of at least one dye..., said dye represented by formula I (the dye is the chemical product)

(b) for the manufacture of a staining composition (the word "medicament" is not appropriate here since the staining composition may be useful in a method for treatment by surgery, but it is not a medicament *stricto sensu*)

(c) for visualizing the anterior lens capsule in an eye **during performance of a capsulorhexis** (emphasis added).

2.3 Capsulorhexis means the controlled opening by making a continuous circular tear in the anterior lens capsule of an eye. Accordingly, capsulorhexis *per se* is not a complete method for treatment by surgery, but it may only be a step in other surgical methods. According to the patent in suit, one complete method for treatment by surgery is the surgical procedure for cataract extraction. However, claim 1 of the main request does not specify the surgical procedure for cataract extraction.

Therefore, in the absence of any specification in claim 1 of the main request in relation to the fact that capsulorhexis is a step of a complete method for a defined treatment by surgery, the legal fiction conferred by the Swiss-type form according to G 5/83 does not apply, and the use claimed is only a method for the manufacture of a staining composition which is known *per se* (see *inter alia* documents (8) and (7) which disclose staining compositions containing the

vital dye trypan blue). Thus, claim 1 of the main request lacks novelty.

- 2.4 Moreover, even assuming in favour of the respondent that capsulorhexis is limited to an act of surgery and thus inevitably part of a method for treatment by surgery, a precise scrutiny of the claim's wording also shows that there is no causal link between the staining function of the dye and the method of opening expressed in the claim by the words "during capsulorhexis".
- 2.5 Leaving aside the parties' dispute whether "visualizing" is merely a mental act performed by the observer (in that case a surgeon), "visualizing" is performed "during capsulorhexis". It has to be recalled that a technical effect may confer novelty on the use of a known product only if there is a causal link between the product and the "new" technical effect for which the use is claimed (see G 1/07, point 5.10.9). Only if such a functional link is shown novelty may be conferred on the use. In the present case the product for which the use is claimed is a dye, thus the technical effect may be a selective dying. The technical effect cannot, however, be a capsulorhexis which is a mode of opening performed by the surgeon. The mention of capsulorhexis in the claim is made only by way of a circumstantial expression "during capsulorhexis" which remains deprived of any causal link to the dye product. Thus, "visualizing" has to be taken in its broadest sense as a synonym (as its direct result) for staining the anterior lens capsule of the eye (to an extent which is not specified in claim 1 of the main request).

2.6 Consequently, the establishment of a temporal condition ("during capsulorhexis") cannot confer novelty on the use claimed by means of providing for a functional feature of the dye, since in the claim the action of staining the anterior lens capsule and the time in which the observer looks at the stained capsule are not causally linked.

2.7 Therefore, document (8) which discloses staining of an anterior lens capsule in an eye by using trypan blue deprives claim 1 of the main request of novelty (Articles 52(1) and 54(2) EPC 1973).

2.8 Decision G 2/08 has put an end to the Swiss-type format (for applications filed after its publication date plus a certain time limit).

Moreover, in the case underlying the referral G 2/08 the claim mentioned hyperlipidaemia as the ailment treated by medicament therapy. Thus, following the logic in decision G 2/08, dosage regimen might be acknowledged as the feature conferring notional novelty on a purpose-related product claim within the meaning of Article 54(5) EPC 2000, since it is a step pertaining by its nature to a therapeutic method concretised by the administration of the medicament containing the product.

2.9 Moreover, even following the respondent's argumentation that, in analogy to decision G 2/08, a particular dosage regimen might also confer notional novelty to the use of a known product in a method for treatment by therapy in a Swiss-type form, there are still insurmountable differences with the present case.

A staining composition is not a **medicament** *stricto sensu*, and capsulorhexis is not necessarily part of a therapeutic treatment attained by the dye product. Capsulorhexis pertains by its nature to a controlled opening technique of the lens capsule which is not inevitably part of a method for therapy resulting from the use of the product mentioned in the claim. Thus, in contrast to the situation with the dosage regimen in which there is a direct link between the administration of the medicament and the product for which the use is claimed, capsulorhexis is an act of the surgeon independent from the application of the dye as a staining composition to an eye. Accordingly, capsulorhexis is causatively and sequentially disconnected from staining in claim 1 of the main request.

2.10 Additionally, the fact that document (8) only reports a partial staining of the anterior lens capsule does not help to overcome the lack of novelty of the claimed subject-matter, since the claim does not clearly define the quality or extension of the staining.

2.11 Consequently, claim 1 of the main request fails for lack of novelty over document (8).

### 3. *Second auxiliary request*

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the following sentence has been added at the end of the claim: "wherein capsulorhexis is performed as part of a surgical procedure for cataract extraction". This



expression, which has been introduced as an attempt to overcome some of the objections against claim 1 of the main request, cannot be taken in isolation but has to be read within the context of the claim. Thus, claim 1 of the second auxiliary request lacks clarity since the subject-matter for which protection is sought is unclear. The purpose of the staining composition is "for visualizing an anterior lens capsule in an eye during performance of a capsulorhexis". Therefore, it is unclear whether a functional causative link exists, or if there is one which can be established, with the dye by mention to the fact that capsulorhexis is part of a surgical procedure.

Consequently, the second auxiliary request fails for lack of clarity (Article 84 EPC).

4. *Third auxiliary request*

Claim 1 of the third auxiliary request differs from claim 1 of the second auxiliary request merely in that the following sentence has been added at the end of the claim: "and wherein the anterior lens capsule is stained by applying the composition onto the capsule". Therefore, the analysis made in relation to lack of clarity for claim 1 of the third auxiliary request applies *mutatis mutandis* to claim 1 of the third auxiliary request since the only difference corresponds to a definition of the application mode of the staining composition, deprived of any causal link to the controlled opening.

Consequently, the third auxiliary request also fails for lack of clarity (Article 84 EPC).

5. *Fifth auxiliary request*

5.1 Having regard to the fact that the fifth auxiliary request manifestly fails for other reasons, the board sees no need to give a full assessment of the formal requirements of the subject-matter claimed therein.

5.2 In contrast to claim 1 of the main request, claim 1 of the fifth auxiliary request relates to a medical indication for which the principles set out in decision G 5/83 for a legal fiction conferring novelty apply.

5.2.1 The method for treatment by surgery in accordance with Article 52(4) EPC (Article 53(c) EPC 2000) is specified in the claim as "surgical procedure for cataract extraction comprising performance of a capsulorhexis".

As regards the technical effect of the dye, it is defined in that "the outer surface of the anterior lens capsule is selectively stained...thereby providing a clear distinction between the portion of the anterior lens capsule that is to be removed and the underlying lenticular material, which distinction facilitates the controlled opening of the anterior lens capsule".

5.2.2 Therefore, claim 1 clearly reflects that the staining facilitates the controlled opening of the lens capsule. The expression "the controlled opening of the lens capsule" can only mean the capsulorhexis within the context of the claim. Thus, the subject-matter of claim 1 is novel over the content of document (8).

5.3 *Inventive step*

- 5.3.1 Document (15) is a publication by the American Medical Association with the heading "Surgical Technique", which relates to "Staining of the lens capsule for circular continuous capsulorhexis in eyes with white cataract".

Document (15) discloses the use of a vital dye, namely indocyanine green, for selectively staining the anterior lens capsule which becomes clearly visible for facilitating a capsulorhexis in eyes with mature cataract and therefore represents the closest prior art.

Document (15) states that the authors "have developed a technique of staining the anterior lens capsule with a solution of indocyanine green that facilitates performance of the circular continuous capsulorrhexis in eyes with mature cataract... Although the safety of indocyanine green dye has not yet been definitively established, the findings of this pilot study suggest that it is safe and useful in visualizing the anterior capsule of a mature cataract during cataract surgery" (headnote on page 535).

Document (15) further discloses that "Clinical studies and an experimental study of cataract surgery have shown that continuous circular capsulorhexis (CCC), a technique introduced by Gimbel and Neubarn, creates an opening in the anterior capsule of the lens that is resistant to tearing during phacoemulsification, cortex removal, and intraocular lens (IOL) implantation... The CCC technique also can be used in planned extracapsular cataract extraction. In eyes with a mature cataract,

and the white lens cortex, however, CCC is often difficult to perform because of poor visibility of anterior lens capsule... To obtain better visibility we have developed a capsular-staining technique using indocyanine green (ICG) that facilitates the CCC (CS-CCC)" (page 535).

Furthermore, document (15) specifically discloses that after a 0.5% solution of ICG was prepared "the sclerocorneal or corneal incision was made, air was used to fill the anterior chamber, and a small amount of viscomaterial was injected around the incision to prevent air leakage. One or 2 drops of the ICG solution was placed on the anterior capsule, and the anterior chamber was replaced with viscoelastic material. After removing the air and redundant ICG, stained anterior capsule became clearly visible and the CCC was easily accomplished... During the phacoemulsification, easy identification of the anterior capsule helped avoid capsular tear" (page 536, left-hand column).

Document (15) expressly states that the results for ICG were satisfactory.

5.3.2 Therefore, in the light of the closest prior art the board considers that the problem to be solved lies in the provision of an alternative vital dye.

5.3.3 The solution as defined in claim 1 of the main request relates to a group of azo-dyes represented by formula I.

The board is satisfied that the problem has been plausibly solved in the light of the description and example in the patent in suit.

5.3.4 It now has to be assessed whether the proposed solution is obvious in the light of the prior art.

The group of vital dyes suitable to be used in the course of an eye operation is not a very broad group of compounds.

Trypan blue (which is an azo-dye of formula I according to claim 1 of the fifth auxiliary request) was well known to the skilled person as a safe vital dye used in a method of treatment by surgery for cataract extraction (document (8), and its follow-up document (7) about safety studies).

Document (8) teaches that trypan blue is suitable for selective staining of the lens capsule since it discloses that "Hystologic examination of a trypan-blue stained cataractous lens showed that **only the capsule became stained, not the cells**" (page 730) (emphasis added).

Therefore, the solution which concerns the choice of trypan blue as a selective dye for staining the anterior capsule in an eye is obvious.

Consequently, claim 1 of the fifth auxiliary request lacks an inventive step (Article 56 EPC).

5.3.5 The respondent had disputed that the skilled person would look into document (8) since it did not refer to capsulorhexis as the opening technique. However, the notional skilled person is not only a surgeon but a team of persons including also a chemist with ample

knowledge of vital dyes. Capsulorhexis was not mentioned in document (8) as the controlled opening technique for cataract extraction simply due to the fact that capsulorhexis was developed at the beginning of the nineties. Document (8) discloses cataract extraction experiments using the surgical methods common in 1971.

However, document (15) clearly teaches the skilled person exactly how to use a vital dye (application mode, method steps) to facilitate the controlled opening by visualising eventual tears. The skilled person nevertheless possesses the knowledge of document (15) when he looks for alternative dyes. Therefore, he will look first for dyes which are known to be safe and which he would reasonably expect to be suitable for staining the anterior lens capsule.

The respondent's argumentation in relation to the paragraph on page 730 of document (8), which reports a partial staining of the anterior lens capsule, amounts to alleging that there was a general technical prejudice, or at least a deterrent, which would discourage the skilled person from using trypan blue in cataract extraction comprising capsulorhexis.

The relevant paragraph of document (8) reads as follows: "The capsule of the cataractous lens became coloured over the area corresponding to the pupil. The rest remained unstained". However, this passage has to be understood within the context of document (8) and the knowledge in 1971. The primary purpose for staining with trypan blue in the classical method for cataract extraction in document (8) was to make visible the

damaged corneal endothelium. Thus, the mode of application of the vital dye and the method steps related to the opening and manipulation of the anterior chamber are very different from those disclosed in document (15). In particular, the method steps relating to the mode of application of the dye disclosed in document (15) make it clear that the anterior chamber has to be kept under a certain pressure (filling with air/viscoelastic material) before removal of the air and the "redundant dye" can be performed. Thus, the starting point of the skilled person involves knowing the whole teaching in document (15). This teaching cannot be diminished by the problems reported in document (8) which were caused by the old operative techniques employed in 1971.

The surgical method disclosed in document (15) teaches the use of a vital dye for facilitating the controlled opening. The reasons are that the dye helps visualising possible tears during the surgical operation. Thus, it is self-evident from the content of document (15) that for attaining this purpose during capsulorhexis it is essential that the dye does not diffuse through the stained membrane which forms the anterior lens capsule. This is the primary requirement (apart from safety) when looking for an alternative vital dye.

Accordingly, what the skilled person is looking for is a vital dye which is known not to diffuse through the membrane forming the anterior lens capsule (i.e. which does not stain the lenticular mass through diffusion). Document (8) teaches that trypan blue is such a dye.

Moreover, the respondent's argumentation that the skilled person looking for a safe dye would have been deterred from using trypan blue in document (8) is disproven by document (7). Document (7) relates to a follow-up study by the same author as document (8) and leaves no doubt about the safety of trypan blue for the eyes of patient undergoing cataract extraction.

It is an undisputable fact that document (15) reports on preliminary experiments in animal eyes in which fluorescein sodium was used instead of ICG and which produced unsatisfactory results since fluorescein diffused throughout the eye and could not be easily removed from the vitreous cavity (page 537, column in the middle).

However, document (15) refers to the molecular weight of fluorescein (lower than that of ICG) as being responsible for the undesirable diffusion.

Although, following the respondent's allegation, the notional skilled person knows that not only molecular weight but also electrostatic interactions are behind diffusion, electrostatic interactions are dependent on the chemical structure of the compound.

Thus, the skilled person knows perfectly well about the very important differences in the chemical structure between fluorescein (which is a 3,6-dihydroxyspiro (xanthene-9,3'-phthalide)) and the azo-dye trypan blue. Accordingly, diffusion behaviour of fluorescein teaches nothing about the diffusion behaviour of trypan blue.

5.3.6 The respondent disputed that the problem to be solved was to provide an alternative dye product and instead



relied on an improvement over ICG and that it had been shown (it cited in particular the post-published documents (33) and (34)) that trypan blue was less toxic and provided for a better staining than indocyanine green.

However, the achievement of an improvement over ICG cannot be taken in the definition of the problem to be solved for very essential reasons. Toxicity depends on amounts of the dye and its concentration in the staining composition which is applied to the eye. Neither the amounts nor the concentration of the dye in the staining composition are defined in claim 1 of the main request. Moreover, one thing is the staining capacity of a particular compound which is inherent to its chemical and physical nature, and the other is the efficacy of a particular staining composition which is dependent on the concentration of the dye in the composition and the physical and chemical form of the composition itself (e.g. aqueous solution, solution or dispersion in a viscoelastic substance, etc).

Therefore, claim 1 of the fifth auxiliary request does not contain the technical features which might have reflected the effects alleged by the respondent.

Finally, the commercial success of VisionBlue<sup>R</sup> cannot be invoked as an indirect indication of the presence of an inventive step, since said commercial product relates to a particular staining composition in a particular chemical and physical form. These features are not reflected by the claim's wording.

5.3.7 Consequently, the fifth auxiliary request fails for lack of inventive step (Article 56 EPC).

5.4 *Request for referral to Enlarged Board of Appeal (Article 112(1) EPC)*

The respondent had requested that questions of law as drafted in its submissions filed on 1 November 2010 be referred to the Enlarged Board of Appeal under certain conditions.

Although conditional requests are in principle not admissible, none of the sets of claims up to the fifth auxiliary request is found to contravene the requirements of Article 53(c) EPC 2000 (Article 52(4) EPC 1973). Under these circumstances the first condition set by the respondent for a referral does not apply.

The second condition relates to the case where the claimed features in the main request or in any of the auxiliary requests up to the fifth auxiliary request cannot be considered for the assessment of novelty and/or inventive step. As becomes evident from the substantive reasoning above, this second condition would apply only to the main request.

*De jure* Article 112(1) EPC provides that in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, the board of appeal may, following a request from a party, refer any question to the Enlarged Board of Appeal for opinion. However, the board shall do so only if it considers that a decision is required for the above-mentioned purposes.

*De facto* in the case in suit the board is able to deal with all the legal issues since decisions G 5/83, G 2/08, G 1/07 and G 6/88 (OJ EPO 1990, 114) already provide sufficient legal teaching of direct applicability to the present appeal case.

Therefore, the respondent's request to refer questions to the Enlarged Board of Appeal is rejected.

## **Order**

### **For these reasons it is decided that:**

- The decision under appeal is set aside.
  
- The patent is revoked.

The Registrar:

The Chairman:

N. Maslin

U. Oswald