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**Datasheet for the decision
of 5 February 2019**

Case Number: T 0403/15 - 3.3.03

Application Number: 07763272.7

Publication Number: 1981438

IPC: A61F2/16, A61F2/14, A61F2/00

Language of the proceedings: EN

Title of invention:
ULTRA VIOLET, VIOLET, AND BLUE LIGHT FILTERING POLYMERS FOR
OPHTHALMIC APPLICATIONS

Applicant:
Key Medical Technologies, Inc.

Relevant legal provisions:
EPC Art. 83, 84

Keyword:
Sufficiency of disclosure - (no)
Claims - support in the description (no) - clarity (no)



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0403/15 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 5 February 2019

Appellant: Key Medical Technologies, Inc.
(Applicant) 2110 Omega Road, Suite F
San Ramon, CA 94583 (US)

Representative: Mewburn Ellis LLP
City Tower
40 Basinghall Street
London EC2V 5DE (GB)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 8 October 2014
refusing European patent application No.
07763272.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman O. Dury
Members: F. Rousseau
W. Ungler

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division posted on 8 October 2014 refusing European application No. 07 763 272.7.
- II. The decision was based on a main request and two auxiliary requests, all submitted with letter of 8 August 2014. According to the reasons for the contested decision, it was in particular held that the claims of auxiliary request 1 fulfilled the requirements of Articles 123(2) and 54 EPC, but their subject-matter lacked an inventive step in view of D2 (EP 0 488 145 A2) alone.
- III. The decision was appealed with letter of 10 December 2014 and the statement setting out the grounds of appeal was submitted with letter of 18 February 2015 to which were attached a main request, a first auxiliary request and a second auxiliary request.
- IV. Claim 1 of the main request, which request was indicated to correspond to the auxiliary request 1 in front of the examining division read as follows:

"1. An acrylic, foldable intraocular lens comprising a copolymer of ophthalmic monomer and a polymerizable orange dye, the lens further comprising:

A substituted hydroxy benzotriazole moiety; or
a substituted hydroxy benzophenone moiety; or
an ethylenically unsaturated anthracene moiety;

wherein the orange dye is selected from the group consisting essentially of:

disperse orange 3 acrylamide, disperse orange 3
methacrylamide disperse orange 25 acrylamide, disperse
orange 25 methacrylamide, disperse orange 25 acrylate,
disperse orange 25 methacrylate, 10-Dodecylacridine
Orange Bromide,
ACID ORANGE 12 (CROCEINE ORANGE C.I. 15970),
ACID ORANGE 128 (MERPACYL ORANGE R) (1),
ACID ORANGE 132 (MERPACYL YELLOW AR),
ACID ORANGE 19 (SUPRAMINE RED GGA),
ACID ORANGE 2 B (1),
ACID ORANGE 3 (C.I. 10385) (1),
ACID ORANGE 33 (C.I. 24780) (1),
ACID ORANGE 34 (CHROMACYL ORANGE GR) (1),
ACID ORANGE 43 (XYLENE FAST ORANGE P) (1),
ACID ORANGE 47 (BENZYL FAST ORANGE G) (1),
ACID ORANGE 5 (ACID YELLOW D C.I. 13080) (1),
ACID ORANGE 51 (1),
ACID ORANGE 60 (CAPRACYL ORANGE R) (1),
ACID ORANGE 62 (NEOLAN ORANGE GRE) (1),
ACID ORANGE 63,
ACID ORANGE 63 (POLAR YELLOW R OR SUPRANOL YELLOW RA)
(1),
ACID ORANGE 64 (CAPRACYL YELLOW 3 RD) (1),
ACID ORANGE 74 (1),
ACID ORANGE 74 (NEOLAN ORANGE G OR GYCOLAN ORANGE GL)
(1),
ACID ORANGE 79 (C.I. 23255) (1),
ACID ORANGE 8 (1),
ACID ORANGE 86 (IRGALAN ORANGE RL) (1),
ACID ORANGE 87 (CIBALAN YELLOW 2 BRL) (1),
ACID ORANGE 94 (IRGANOL ORANGE GRLS) (1),
ACID ORANGE CAPRACYL BROWN HRN (1),
ACID ORANGE GG CRYSTALS (1),
ACRIDINE ORANGE 10-NONYL BROMIDE (2),
AMANIL FAST ORANGE ER (1),
AMIDINE FAST ORANGE 2 RL (1),

ANTHANOL CHROME ORANGE R (1),
ASTRAZON ORANGE G (1),
ASTRAZON ORANGE R (1),
AZOANTHRENE GOLDEN ORANGE R (1),
BASIC ORANGE 21 (GENACRYL ORANGE G) (1),
BASIC ORANGE 22 (GENACRYL ORANGE R) (1),
BASIC ORANGE 24 (SEVRON ORANGE L) (1),
BASIC ORANGE 25 (SEVRON ORANGE CL) (1),
BASIC ORANGE 26 (SEVRON BROWN YL) (1),
BASIC ORANGE 27 (ASTRAZON ORANGE 3 RL) (1),
BASIC ORANGE 28 (ASTRAZON ORANGE RRL) (1),
BASIC ORANGE 29 (ASTRAZON GOLDEN YELLOW GLD) (1),
BASIC ORANGE 30 (ASTRAZON YELLOW BROWN 2 GL) (1),
BASIC ORANGE 4-11 (C.I. 46035) (1),
BASIC ORANGE 43 (DEORLENE FAST ORANGE 2 GL) (1),
BASIC ORANGE 54 (MAXILON ORANGE 4 RL EXTRA CONC.) (1),
BENZANOL ORANGE R (1),
BENZO FAST ORANGE 2 RL (1),
BENZO FAST ORANGE WS (1),
BENZYL ORANGE (1),
BROMOCRESOL ORANGE (1),
BUFFALO DIRECT ORANGE Y (1),
C.I. 326 AMANIL FAST ORANGE S (1),
C.I. 621 AMANIL FAST ORANGE CG (1),
CALCO ACID ORANGE II (1),
CALCOCHROME ORANGE R EXTRA CONC. (1),
CALCOCID FAST LIGHT ORANGE 2 G (1),
CALCOCID MILLING ORANGE 4 R CONC. (1),
CALCOCID ORANGE Y EXTRA CONC. (1),
CALCODUR ORANGE EGL (1),
CALCODUR ORANGE GL (1),
CALCOFAST WOOL ORANGE 4 RN (1),
CALCOFORM ORANGE 5 RE (1),
CALCOLITE FAST ORANGE 3 R (1),
CALCOLOID FLAMING ORANGE 6 RD EXTRA CONC. (1),
CALCOLOID GOLDEN ORANGE 4 RD (1),

CALCOLOID GOLDEN ORANGE GD EXTRA CONC. (1),
CALCOLOID GOLDEN ORANGE RRTD EXTRA CONC. (1),
CALCOLOID ORANGE RD EXTRA CONC. (1),
CALCOMET ORANGE G (1),
CALCOMINE FAST ORANGE 2 RS EXTRA (1),
CALCOMINE FAST ORANGE E3G (1),
CALCOMINE FAST ORANGE EG (1),
CALCOMINE FAST ORANGE ER (1),
CALCOMINE ORANGE 2RS (1),
CALCOMINE ORANGE R SPECIAL (1),
CALCONESE BRILLIANT ORANGE GF CONC. (1),
CALCONESE ORANGE 3 RC (1),
CALCONESE ORANGE G (1),
CALCOSOL GOLDEN ORANGE RRTP (1),
CALCOSOL PRINTING ORANGE RY (1),
CALCOZINE ORANGE RS (1),
CALCOZINE ORANGE YC (1),
CAMACYL BRILLIANT ORANGE JER (1),
CAPRACYL ORANGE RP (1),
CELACYL BRILLIANT ORANGE 3 R (1),
-HYDROXY-1,4-NAPHTHOQUINONE (1),
CHRYSOIDINE G (2),
SUDAN II (1),
TROPAEOLIN 000 NO. 1 (1),
TROPAEOLIN O (1),
TROPAEOLIN O SODIUM SALT (1),
TROPAEOLIN 00 (1),
THIOXINE ORANGE R (1),
TOLUYLENE FAST ORANGE LX (1),
VARINYL ORANGE DAC (1),
VAT ORANGE 1 (C.I. 59105) (1),
VAT ORANGE 24 (PONSOL GOLDEN ORANGE 3 GND EXTRA) (1),
VAT ORANGE 3 (C.I. 59300) (1),
VAT ORANGE 7 (SOLANTHRENE BRILLIANT ORANGE FJRA) (1),
VAT ORANGE 9 (C.I. 59700) (1),
VEGENTINE ORANGE CSW (1),

VERANTHRENE GOLDEN ORANGE 3 G (1),
SUDAN ORANGE G (2),
SULFONINE ORANGE GS CONC. (1),
SULPHUR ORANGE (1),
SUPERLITE FAST ORANGE RT (1),
SUPRAMINE ORANGE G (1),
SUPRANOL ORANGE RA (1),
TANNIN ORANGE (1),
TECTILON ORANGE 2 RT (1),
THIAZOLE ORANGE (2),
SOLVENT ORANGE 1 (NEWPORT OIL YELLOW C.I. 11920) (1),
SOLVENT ORANGE 20 (AZOSOL FAST ORANGE RA) (1),
SOLVENT ORANGE 23 (IOSOL ORANGE) (1),
SRA GOLDEN ORANGE FSI POWDER (1),
SRA GOLDEN ORANGE I POWDER (1),
SRA LIGHT ORANGE FSI (1),
SRA ORANGE BL (1),
SRA ORANGE I POWDER (1),
SRA ORANGE II POWDER ,
SODIUM 4-(3-(2,4-DI-ME-PH-AZO)-2,4-DI-HO-PH-AZO)-
BENZENESULFONATE (ACID ORANGE 24) (1),
SODIUM 4-(4-(BENZYL-ET-AMINO)-PH-AZO)-2,5-DI-CL-
BENZENESULFONATE (ACID ORANGE 50) (1),
SODIUM 5-(4-CL-PH-AZO)-6-HO-NAPHTHALENE-2-
SULFONATE (ACID ORANGE 31 C.I. 15995) (1),
SOLOPHENYL ORANGE TGL (1),
REACTIVE ORANGE 5 (CIBACRON BRILLIANT ORANGE GP) (1),
REACTIVE ORANGE 68 (LANASOL ORANGE R) (1),
REACTIVE ORANGE 70 (CIBACRON GOLDEN YELLOW RE) (1),
REACTONE ORANGE G (1),
RESIST ORANGE N (1),
RESOLIN ORANGE 5 R (1),
RORACYL ORANGE R (1),
ROSANTHRENE ORANGE 3 R CONC. (1),
ROSANTHRENE ORANGE RSS (1),
SETACYL ORANGE P-RFL (1),

REACTIVE ORANGE 13 (PROCION ORANGE H-2R) (1),
REACTIVE ORANGE 16 (1),
REACTIVE ORANGE 2 (CIBACRON BRILLIANT ORANGE 2G-E) (1),
REACTIVE ORANGE 29 (LANASOL ORANGE G) (1),
REACTIVE ORANGE 35 (CIBACRON ORANGE 4 R-A) (1),
REACTIVE ORANGE 44 (CIBACRON PRONT ORANGE G) (1),
REACTIVE ORANGE 45 (CIBACRON PRONT GOLDEN YELLOW
2 R) (1),
REACTIVE ORANGE 46 (CIBACRON PRONT ORANGE BROWN
3 R) (1),
PONTAMINE FAST ORANGE 2 G CONC. (1),
PONTAMINE FAST ORANGE MR (1),
PONTAMINE FAST ORANGE MRL (1),
PONTAMINE FAST ORANGE RGL EXTRA CONC. (1),
PONTAMINE FAST ORANGE S (1),
PROCION ORANGE MX2R (1),
PROCION ORANGE MXG (1),
PYRAMINE ORANGE 3 G (1),
PYRAMINE ORANGE R (1),
PYRAZOL FAST ORANGE RL (1),
POLYDYE HISPERSE ORANGE 5 RH (1),
POLYFORM ORANGE RF EXTRA CONC. (1),
POLYPROPYLENE ORANGE Y (1),
PONSOL BRILLIANT ORANGE RKD EXTRA CONC. (1),
PONSOL GOLDEN ORANGE 4 RD EXTRA CONC. (1),
PONSOL GOLDEN ORANGE G EXTRA CONC. (1),
PONSOL GOLDEN ORANGE GD EXTRA CONC. (1),
PONSOL GOLDEN ORANGE RRTD EXTRA CONC. (1),
PONTACHROME ORANGE 4 G (1),
PONTACHROME ORANGE RL (1),
PARA BRILLIANT ORANGE G (1),
PARANOL FAST ORANGE EG (1),
PARANOL FAST ORANGE ER (1),
PARANOL FAST ORANGE GL (1),
POLAR ORANGE R CONC. (1),
POLY(DISPERSE ORANGE 3 ACRYLAMIDE) (1),

POLY(DISPERSE ORANGE 3 METHACRYLAMIDE) (1),
POLY[METHYL METHACRYLATE-CO-(DISPERSE ORANGE 3
ACRYLAMIDE)] (1),
POLY[METHYL METHACRYLATE-CO-(DISPERSE ORANGE 3
METHACRYLAMIDE)] (1),
ORANGE G (5),
ORANGE G SOLUTION (1),
ORANGE GG (1),
ORANGE GS (1),
MORDANT ORANGE 34 (CHROMAVEN BRILLIANT ORANGE 2 R) (1),
MORDANT ORANGE 8 (OMEGA CHROME ORANGE ML) (1),
NABOR ORANGE G (1),
NABOR ORANGE R (1),
NAPHTHANIL ORANGE R BASE (1),
NATIONAL CHROMOLAN ORANGE R (1),
NATIONAL WOOL ORANGE A CONC. (1),
NATURAL YELLOW 8, 11 (ANRANTINE OSAGE ORANGE C.I.
75660) (1),
NEUTRACYL ORANGE R (1), and
NEUTRAL ORANGE O (1)."

- V. The text of claim 1 of the first auxiliary request was identical to that of claim 1 of the main request, but contained in addition at the end of the claim the additional wording "wherein the orange dye has a coefficient of extinction ("e") of at least $1500 \text{ M}^{-1}\text{cm}^{-1}$ for a region between 350 nm and 500 nm".
- VI. The wording of claim 1 of the second auxiliary request differed from that of the first auxiliary request only in that the wording "An acrylic, foldable intraocular lens comprising a copolymer of ophthalmic monomer" had been replaced by "A foldable, high refractive index intraocular lens comprising: a copolymer of ophthalmic monomer, wherein the ophthalmic monomer is selected from carbazole and/or naphthyl moiety, carbazole,

naphthalene, or a naphthyl group such as vinyl carbazole, vinyl naphthalene, lauryl methacrylate, stearyl methacrylate, methyl methacrylate, 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, 3-hydroxypropyl acrylate, 3-hydroxypropyl methacrylate, n-vinyl pyrrolidone, styrene, eugenol, alpha-methylstyrene, 2-ethylphenoxy methacrylate, 2-ethylphenoxy acrylate, 2-ethylthiophenyl methacrylate, 2-ethylthiophenylacrylate, 2-ethylaminophenyl methacrylate, phenyl methacrylate, benzyl methacrylate, 2-phenylethyl methacrylate, 3-phenylpropyl methacrylate, 4-phenylbutyl methacrylate, 4-methylphenyl methacrylate, 4-methylbenzyl methacrylate, 2-(2-methylphenylethyl) methacrylate, 2-(3-methylphenylethyl) methacrylate, 2-(4-methylphenylethyl) methacrylate, 2-(4-propylphenyl)ethyl methacrylate, 2-(4-(1-methylethyl)phenyl)ethyl methacrylate, 2-(4-methoxyphenyl)ethyl methacrylate, 2-(4-cyclohexylphenyl)ethyl methacrylate, 2-(2-chlorophenyl)ethyl methacrylate, 2-(3-chlorophenyl)ethyl methacrylate, 2-(4-chlorophenyl)ethyl methacrylate, 2-(3-bromophenyl)ethyl methacrylate, 2-(3-phenylphenyl)ethyl methacrylate, 2-(4-phenylphenyl)ethyl methacrylate), 2-(4-benzylphenyl)ethyl methacrylate, including the corresponding methacrylates and acrylates,".

- VII. In its preliminary opinion sent in preparation for the oral proceedings the Board indicated that in addition to various issues concerning the presence of an inventive step over the disclosure of D2, in particular the obviousness of using one of the orange dyes defined in claim 1 of any of the requests, as far as those orange dyes could be considered to be polymerizable, issues concerning clarity, support by the description and sufficiency of disclosure in relation to the

definition of the orange dyes to be polymerizable would arise.

- VIII. In response to the Board's communication the appellant merely announced with letter of 23 January 2019 that they would not attend the oral proceedings. The letter of the appellant did not address any of the issues raised by the Board in its communication.
- IX. Oral proceedings were held on 5 February 2019 in the announced absence of the appellant (Rule 115(2) EPC and Article 15(3) RPBA).
- X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request, or on the basis of the claims of the first auxiliary request, or on the basis of the claims of the second auxiliary request, all requests submitted with the statement setting out the grounds of appeal (letter of 18 February 2015).

Reasons for the Decision

Main request

1. Whereas claim 1 requires in its introductory part that the orange dye should be polymerizable, said dye is also defined to be selected from a list of specific dyes which, apart from the first six dyes mentioned therein, does not define dyes comprising a group susceptible to undergo a polymerization reaction, i.e. in the context of claim 1 a polymerization reaction leading to the incorporation of the dyes in the network

of an acrylic lens. For this group of dyes defined in claim 1, which are enumerated starting with 10-dodecylacridine orange bromide, the appellant failed to provide any indication regarding their ability to polymerize, let alone the nature of the polymerizable group(s) concerned. A common general knowledge in the art in this respect was also not indicated. The Board has therefore no reason to depart from its opinion expressed in its communication of 10 October 2018 (section 10) that the subject-matter of claim 1 lacks clarity as far as the definition of the orange dyes is concerned.

2. According to page 9, lines 14-28 of the description, *"In one variation of this invention, polymerizable orange dyes or chromophores are created or synthesized from non-polymerizable orange dyes by derivatizing the orange dye, e.g., to add a polymerization functionality. In one embodiment of this variation, a non-polymerizable orange dye is reacted with a selected species to add a site of ethylenic or vinylic unsaturation, i.e., double bond functionality. A suitable orange dye may be modified to add multiple reaction sites. Reaction sites, other than free-radically polymerizable sites, also may be added or created depending upon dye characteristics"*. Although based on that passage of the description one would understand that the list of non-polymerizable orange dyes defined in claim 1 (starting with the enumeration of 10-dodecylacridine orange bromide) is an attempt to define polymerizable orange dyes or chromophores which have been created or synthesized by derivatizing the corresponding non-polymerizable orange dyes listed in claim 1, it is established case law (Case Law of the Boards of Appeal of the EPO, 8th edition, 2016, II.A.6.3.5) that the principle of clarity stipulated by

Article 84 EPC requires that it must be possible to understand the claims without reference to the description, or in other words, reliance to the description cannot be considered as a substitute for an amendment which would remove the lack of clarity.

3. Moreover, apart from the general and obvious indication for the skilled person that an ethylenic or vinylic unsaturation could be added (page 9, lines 16-18), as to allow through polymerization the incorporation of the orange dyes in the network of an acrylic lens, the application does not provide any indication on how this could be achieved in a concrete manner for any of the specific dyes mentioned in the list of claim 1 starting with 10-dodecylacridine orange bromide. There is also no indication as to how those dyes should be made polymerizable while remaining orange dyes, as obviously the insertion of a polymerizable group may impact the colour of the dye, which is confirmed on page 9, lines 21-27 of the application. An indication of the common general knowledge in the art in this respect was not provided by the appellant.

4. Accordingly, even if one took the view that claim 1 according to its broadest technical sensible meaning defines the use of polymerizable orange dyes which have been created or synthesized by derivatizing the non-polymerizable orange dyes listed in claim 1 (starting with the enumeration of 10-dodecylacridine orange bromide) one would have to conclude that the claimed invention, as far as it relates to those modified dyes, would not be supported by the description, contrary to the requirements of Article 84 EPC. For the same reasons, the invention defined in claim 1 would not be sufficiently disclosed within the meaning of Article 83 EPC, insofar polymerizable orange dyes were concerned,

which would need to be created or synthesized by derivatizing the non-polymerizable orange dyes listed in claim 1 (starting with the enumeration of 10-dodecylacridine orange bromide).

5. Based on the above findings, the present main request is not allowable. It is therefore not necessary to address whether the claimed subject-matter involve an inventive step over the disclosure of D2 or to deal with the additional various issues under Article 84 EPC raised by the Board in its communication.

First and second auxiliary request

6. The subject-matter of claim 1 of the first auxiliary request differs from that of the main request in that the orange dye has been defined to have a coefficient of extinction ("e") of at least $1500 \text{ M}^{-1}\text{cm}^{-1}$ for a region between 350 nm and 500 nm. The subject-matter of claim 1 of the second auxiliary request differs from that of the first auxiliary request in that the wording "An acrylic, foldable intraocular lens comprising a copolymer of ophthalmic monomer" has been replaced by "A foldable, high refractive index intraocular lens comprising: a copolymer of ophthalmic monomer", whereby the ophthalmic monomer has been specified. As shown by the explanation of the appellant in the statement setting out the grounds of appeal, these amendments were inserted in order to improve the appellant's position with regard to the issue of inventive step over D2. Neither the definition of specific ophthalmic monomers, nor the mere definition that the orange dye exhibits a coefficient of extinction having a minimum value, is related to the clarity issue raised in above point 1 or has been shown to imply any restriction to the subject-matter of claim 1 on the basis of which it

could be concluded that the subject-matter now defined is supported by the description or sufficiently disclosed (sections 2 to 4 above). Accordingly, the conclusion concerning clarity, support by the description and sufficiency of disclosure arrived at for the main request equally applies to the first and second auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:



B. ter Heijden

O. Dury

Decision electronically authenticated