Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 15 November 2022

Case Number: T 0178/19 - 3.3.10

Application Number: 11386025.8

Publication Number: 2604298

IPC: A61L12/08, C11D3/382, C11D3/48, A01N65/12

Language of the proceedings: EN

Title of invention:
Multipurpose solutions for contact lens care comprising chamomile

Patent Proprietor:
DEMO SA Pharmaceutical Industry

Opponent:
Uni-Pharma Kleon Tsetis
Pharmaceutical Laboratories S.A.

Headword:
Multipurpose solutions for contact lens/DEMO

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - multiple selection
Inventive step - non-obvious alternative

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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 0178/19 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 15 November 2022

Appellant: (Opponent)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. 14th Km, National Road 1 145 64 Kifissia (GR)
Representative:	Wibbelmann, Jobst Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstrasse 2 81541 München (DE)
Respondent: (Patent Proprietor)	DEMO SA Pharmaceutical Industry 21st km National Road Athens-Lamia 145 68 Krioneri Attikis (GR)
Representative:	Roukounas, Dimitrios Dietlindenstraße 18 80802 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 15 November 2018 rejecting the opposition filed against European patent No. 2604298 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	J.-C. Schmid
	L. Basterreix

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division rejecting its opposition against European patent No. 2 604 298, independent claim 1 thereof reading as follows:

"1. An aqueous multipurpose solution for cleaning, disinfecting, conditioning, storing and rinsing contact lenses, which comprises the following ingredients:

- a surfactant, for wetting the lenses and removing debris therefrom,

- a cleaning agent, for facilitating protein removal,

- a buffering system, for maintaining the pH of the solution,

- an antimicrobial agent, for disinfecting and preserving the lenses,

- a chelating agent, for binding metal ions,

- a tonicity agent, for adjusting the osmolality of the solution,

characterized in that it further comprises a chamomile extract at a concentration ranging from 0.010 to 0.050 mg/ml."

II. The appellant filed an opposition requesting revocation of the patent-in-suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC). At the oral proceedings before the opposition

division it furthermore requested the introduction of the ground of opposition under Article 100(b) EPC.

Inter *alia*, following documents

(1) WO-A-2007/0042100,
(3) "Oftylla" leaflet by Omisan Farmaceutici,
(7) "Solution Confort Oftyll": leaflet by Contopharma, and
(10) Experimental report filed with letter dated 06.09.2018

were cited in the opposition proceedings.

III. The Opposition Division did not admit the ground of opposition under Article 100(b) EPC, since it was not *prima facie* relevant.

According to the opposition division, the subject-matter of claim 1 of the patent as granted was novel over document (1) and involved an inventive step starting from the commercial product Renu® as the closest state of the art to the invention.

IV. The appellant contests the findings of the opposition division in relation to the issues of novelty and inventive step. In support of its argument, it has filed, *inter alia*, the following documents:

(15) Banin E. et al., "Chelator-Induced Dispersal and Killing of Pseudomonas aeruginosa Cells in a Biofilm", Applied and Environmental Microbiology, 2006, Vol 72. No.3, pages 2064 to 2069,
and

(16) Gil M.L. et al., "Changes in the cell wall glycoprotein composition of Candida albicans associated to the inhibition of germ tube formation by EDTA", Arch Microbiol, 1994, vol. 161, pages 489 to 494.

V. The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be dismissed or, subsidiarily, that the case be remitted to the opposition division for further prosecution on the basis of auxiliary requests 1 to 3, filed with the letter dated 20 July 2018. Should the board decide not to remit the case to the opposition division, it further requested that the patent be maintained on the basis of one of auxiliary requests 1 to 3.

VI. At the end of the oral proceedings held on 15 November 2022, the decision of the Board was announced.

Reasons for the Decision

Main request - patent as granted

1. *Novelty*

1.1 According to the appellant, the compositions disclosed in table I on page 8 of document D1 are novelty-destroying for claim 1.

1.2 Document (1) discloses a sterile eyelid surroundings cleansing composition which is hypoallergenic and which meets standard ophthalmologic requirement (page 6, last paragraph). These compositions are exemplified in table I on page 8 of document (1). They comprise
- Lauryl glucoside (surfactant)

- Polysorbate 20 (surfactant)
- Sodium phosphate monobasic/dibasic (pH modifier)
- 0.01 to 30 mg/ml disodium EDTA (chelating agent)
- Sodium chloride (NaCl)(stabilizer)
- 0.01-50 mg/ml chamomile extract (calmative).

1.3 It is not disputed that the compositions disclosed in table I of D1 comprise all the components required by claim 1 of the patent as granted. It is noted that disodium EDTA and chamomile extracts are known anti-microbial agents.

In this regard, the appellant submitted documents (15) and (16) which show that EDTA provides sufficient inhibition for both bacteria and fungi at concentrations within the range disclosed in document (1). In particular, according to document (15), 50 mM EDTA is the minimal EDTA concentration for maximal killing of *P. aeruginosa* -see page 2, paragraph 5. This concentration, corresponding to a concentration of 16,8 mg/ml EDTA disodium, lies within the concentration range of table 1 of document (1). Document (16) discloses that the addition of 10 mM EDTA to the culture medium at the beginning of the incubation period blocks mycelial growth of yeast cells of *Candida albicans* - see page 2, section results. This concentration, corresponding to a concentration of 3.36 mg/ml EDTA disodium, also lies within the concentration range of table 1 of document (1).

1.4 The respondent requested that this evidence not be admitted in the appeal proceedings. However, it is not necessary for the Board to rule on this issue, as the outcome of the appeal does not change whether or not the evidence is admitted.

1.5 Table I of document (1) discloses concentrations of disodium EDTA ranging from 0.01 to 30 mg/ml. In the composition described in example 1 of document (1), disodium EDTA is present in the solution at a concentration of 0.5 mg/ml.

The patent proprietor submitted an experimental report (document (10)) showing that a composition in which disodium EDTA is used as an antimicrobial agent at a concentration of 0.5 mg/ml is not suitable for the purposes indicated in claim 1 of the patent as granted.

Indeed, the composition of example 1 of document (1) does not meet the criteria for the efficacy test of antimicrobial preservation for contact lenses. The results presented in document (10) show that the reduction in the population of the microorganisms *Aspergillus brasiliensis, Pseudomonas aeruginosa and Staphylococcus Aureus* obtained by using compositions based on example 1 of document (1) comprising 0.5 mg/ml disodium EDTA and having a chamomile concentration of either 0.01 mg/ml or 1 mg/ml is not sufficient for the preservation of contact lenses, in particular with respect to *Pseudomonas aeruginosa* whose population increases after 24 hours.

1.6 Accordingly, disodium EDTA used at a concentration of 0.5 mg/ml as in exemple 1 of D1 does not have sufficient antimicrobial activity to be used in a multi-purpose solution as an anti-microbial agent for disinfecting contact lenses.
Since the claimed compositions must be suitable for disinfecting contact lenses, the person skilled in the art must first select from the range of 0.01 to 30 mg/ml disclosed in D1, a concentration of EDTA at which

ETDA exhibits suitable antimicrobial activity, which is in any case greater than 0.05 mg/ml.
In addition, the results presented in document (10) also show that at a concentration of 0.1 mg/ml or 1 mg/ml, an extract of chamomile does not have sufficient antimicrobial activity to be used in a multi-purpose solution as an anti-microbiological agent. Therefore even if the chamomile extract disclosed in Table 1 of D1 for calmative purposes would count also as an anti-microbial agent, an appropriate range of concentration must be selected from the range of 0.01 to 50 mg/ml disclosed in D1.

1.7 The claimed compositions also require 0.010 to 0.050 mg/ml of chamomile extract in addition to the anti-microbial compound.

To arrive at the multi-purpose solution of claim 1, starting from the disclosure of Table I of document (1), the person skilled in the art must therefore also select a chamomile extract concentration of 0.010 to 0.050 mg/ml from the disclosed range of 0.01 to 50 mg/ml.

Therefore, since at least a twofold selection from the disclosure of document (1) is necessary to arrive at the subject matter of claim 1 of the patent as granted, the board arrives at the conclusion that the claimed multi-purpose solutions are novel over the eyelid surroundings cleansing compositions of document (1) (Article 54 EPC).

2. *Inventive step*

2.1 *Closest prior art*

The board considers, in agreement with the opposition division and the appellant that the commercial multi-purpose solution Renu® Multi-Purpose Solution represents the closest state of the art to the invention. It is not contested that this product and its composition as described in the patent specification in paragraph [0005] was available to the public before the filing date of the patent in suit. This commercial solution comprises all the components of the solution of claim 1 of the patent as granted, except chamomile extract.

2.2 *Technical problem underlying the patent-in-suit*

Regardless of the alleged improvements put forward by the respondent, which are contested by the appellant, the technical problem to be solved by the invention is, at the least, the provision of a further multi-purpose solution for cleaning, disinfecting, conditioning, storing and rinsing contact lenses.

The Board will therefore consider, in favour of the appellant, that the technical problem to be solved is the provision of a further multi-purpose composition for cleaning, disinfecting, conditioning, storing and rinsing contact lenses.

2.3 *Solution*

The solution proposed by the patent-in-suit is the multi-purpose solution of claim 1 of the patent as granted, characterized in that it further comprises a chamomile extract at a concentration ranging from 0.010 to 0.050 mg/ml.

2.4 *Obviousness*

It remains to be decided whether or not it is obvious in the light of the prior art to add 0.010 to 0.050 mg/ml chamomile extract in the multi-purpose solution Renu® in order to provide a further multi-purpose solution for cleaning, disinfecting, conditioning, storing and rinsing contact lenses.

According to the appellant the solution is obvious in the light of documents (1) or (3).

2.4.1 Document (1) relates to the field of personal hygiene, more particularly, to the treatment of eyelid inflammation, and maintenance of eyelid hygiene (see page 1, first paragraph).

This document describes a hypoallergenic eyelid and eyelid surroundings cleansing composition for preparing a non-discolouring, essentially purely white cleansing pad for hygiene maintenance of the eyelid and eyelid surroundings , which meets standard ophthalmologic and dermatologic requirements (see page 6, last paragraph). The cleansing solutions described in this document comprises from 0.01 to 50 mg/ml, preferably from 0.5 to 5 mg/ml of chamomile extract as a calmative agent (see page 8, table 1).

However, when seeking to provide an alternative to the commercial Renu® multi-purpose solution for lens care, the person skilled in the art will consider the prior art which relates to solutions for contact lens care. The skilled person will therefore not turn to document (1), which does not relates to contact lens care solutions, but to cleansing solutions to wet pad.

2.4.2 The appellant's argument that the person skilled in the art would nevertheless take account of document (1) because of its disclosure of the calmative ingredient is irrelevant, as this argument overlooks the fact that document (1) does not relates to aqueous solutions for contact lenses. Combining the teaching regarding the presence of chamomile extract in the aqueous cleansing solution of document (1), preferably present at a concentration of 0.5 to 5 mg/ml, with the commercially available Renu® multi-purpose solution, and then taking the concentration of chamomile extract at the extreme lower end of the disclosed broad range of 0.01 to 50 mg/ml to a concentration of 0.01 to 0.05 mg/ml can only be done with the benefit of hindsight.

2.4.3 Accordingly, document (1) does not render the proposed solution obvious.

2.4.4 Document (3) relates to a natural, sterile product, namely Oftylla malva e chamomile, which is used to lubricate and hydrate all types of contact lenses. It gives a feeling of freshness, and makes wearing all types of contact lenses more comfortable, which is attributed to the chamomile extract known for its calming properties. This document also reveals that chamomile is traditionally used to treat conjunctivitis, bloodshot and tired eyes.

The product, Oftylla malva e chamomile, comprises 1 g of a liquid extract of Matricaria Camomilla per 100ml solution, i.e. a concentration of 10 mg per ml (see document (7)), which is far above the concentration required by claim 1 of the patent as granted.

Accordingly, by applying the teaching of document (3) to the commercial Renu® multi-purpose solution for lens

care, the skilled person will not obtain a composition according to claim 1 of the patent as granted. The proposed solution is therefore not obvious in the light of document (3).

2.5 Consequently, the board arrives at the conclusion that having regard to the state of the art represented by documents (1) or (3), the subject-matter of claim 1 of the patent as granted is not obvious.

2.6 Consequently, the subject-matter of claim 1 of the main request and, for the same reason, that according to the dependent claims involve an inventive step within the meaning of Article 56 EPC.

Auxiliary requests 1 to 3

3. Since the main request is considered to be allowable, it is not necessary to decide on the lower-ranking auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated