Internal distribution code:

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

Datasheet for the decision of 24 November 2020

Case Number: T 2534/18 - 3.3.07

Application Number: 13768403.1

Publication Number: 2830637

IPC: A61K33/18, A61K38/44, A61K9/08, A61K9/14, A61K9/06, A61P27/02

Language of the proceedings: EN

Title of invention:
COMPOSITIONS AND METHODS FOR TREATING OR PREVENTING DISEASES ASSOCIATED WITH OXIDATIVE STRESS

Applicant:
CXL Ophthalmics, LLC

Headword:
COMPOSITIONS AND METHODS FOR TREATING OR PREVENTING DISEASES ASSOCIATED WITH OXIDATIVE STRESS/CXL Ophthalmics, LLC

Relevant legal provisions:
EPC Art. 123(2), 111(1)
RPBA Art. 11

Keyword:
Amendments - allowable (yes)
Remittal to the examining division

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 2534/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 24 November 2020

Appellant: (Applicant)	CXL Ophthalmics, LLC 4354 Manchester Avenue Encinitas, California 92024 (US)
Representative:	FRKelly 27 Clyde Road Dublin D04 F838 (IE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 29 May 2018 refusing European patent application No. 13768403.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	P. Schmitz

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse European patent application n° 13 768 403.1. The decision was based on a set of 8 claims filed with letter of 4 April 2017 as main request.

Claims 1 and 2 of the main request read:

"1. A pharmaceutical composition for use in photochemical cross-linking of corneal collagen, comprising (a) 0.015% sodium iodide by weight, (b) 0.5% riboflavin by weight, and (c) a pharmaceutically-acceptable excipient, wherein the composition has a basic pH that permits iodide ion to catalytically break hydrogen peroxide into water and oxygen.

2. The pharmaceutical composition for use according to claim 1, wherein the basic pH is between 7 and 8.4."

II. According to the decision under appeal, claims 1-8 did not meet the requirements of Article 123(2) EPC. The presence of riboflavin in the claimed composition was not directly and unambiguously derivable, in particular in combination with an ion iodide, and, in the dependent claims, in combination with the features relating to the pH and to the presence of a reducing agent.. There was also no basis for the feature "by weight".

III. The patent applicant (hereinafter the appellant) filed an appeal against said decision.

IV. A communication expressing the Board's preliminary opinion was sent to the appellant, wherein the Board confirmed that some of the claims of the main request did not meet the requirements of Article 123(2) EPC.

V. A telephone conversation between the rapporteur and the appellant took place on 13 November 2020.

VI. With a letter dated 15 November 2020, the appellant submitted a new main request with 2 claims corresponding to claims 1 and 2 of the request on which the examining division based its decision.

VII. The appellant's arguments can be summarised as follows:

The only reference to pH of the compositions of the invention was in relation to the embodiments and referred to a basic pH and a preferred basic pH was referred to as between 7 and 8.4. No other pH was mentioned.

Similarly, the only reference to percentage amounts of ingredients in the specification referred to amounts of ingredients percentage by weight, "% weight".

The only example describing 0.5% riboflavin and 0.015% sodium iodide clearly provided basis for claim 1 as relating to a composition comprising 0.5% by weight of riboflavin and 0.015% by weight of sodium iodide. The description would not use % weight for iodide and intend something else to be used for riboflavin. A skilled person, reading the application and the example on the date of filing would have no doubt about the % by weight intended in the example and now claimed.

VIII. Requests

The appellant requests that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the the basis of the set of claims filed as main request with letter of 15 November 2020.

Reasons for the Decision

Main request - Amendments

1. Independent claim 1

1.1 The feature **"a pharmaceutical composition for use in photochemical cross-linking of corneal collagen, comprising (a) 0.015% sodium iodide by weight, (b) 0.5% riboflavin by weight"** finds a direct basis in the unique example of the application in paragraph [83], which is the only passage disclosing the simultaneous concentration of 0.015% by weight of sodium iodide and 0.5% by weight of riboflavin. Said passage reads: "[83] Corneal collagen cross-linking utilizing 0.5% riboflavin and 0.015% (1 mmol) sodium iodide was performed in over 200 eyes".

Said example discloses therefore the specifically claimed composition comprising riboflavin and sodium iodide and relates also to the use in collagen cross-linking as claimed.

This disclosure is confirmed by the disclosure in paragraph [0043], which relates also to a combination of riboflavin and sodium iodide for use in photochemical crosslinking and reads:

"[43] Described herein are compositions for photochemical crosslinking comprising (1) riboflavin, and (2) an iodide ion and/or catalase".

1.2 It remains to be determined whether the disclosure of the specific embodiment of the application's only example can be generalized to the subject-matter of claim 1 in particular in combination with the other features of claim 1. Said other remaining features should in particular not be exclusively associated with other different embodiments disclosed in the application as filed.

In the present case, said example does not specify the pH of the composition comprising both sodium iodide and riboflavin, the presence of an excipient, and the concentration units, all these features being present in claim 1.

1.2.1 With regard to the presence of an excipient, the only composition constantly disclosed in the application as filed is a composition with an excipient.

The presence of "(**c) a pharmaceutically-acceptable excipient**" in association with sodium iodide is disclosed in claim 1 as originally filed, and also for instance in paragraph [03] of the application as filed, which specifies further what is meant by excipient, namely "the pharmaceutically-acceptable excipient is a thickener, an oil phase, a surfactant, a preservative, or a pH adjusting agent". Dependent claim 8 as originally filed gives the same definition of the excipient namely, "a thickener, an oil phase, a surfactant, a preservative, or a pH adjusting agent".

Further passages of the description mention also the presence of an excipient in the compositions according to the invention, such as paragraphs [09] and [31] .

It is obvious, in view of these disclosures, that the presence of an excipient is linked to all compositions or embodiments as originally disclosed, and that the incorporation of this characteristic and its combination with the remaining features of claim 1 is unambiguously derivable from the application as filed.

1.2.2 A basis for the feature **"basic pH that permits iodide ion to catalytically break hydrogen peroxide into water and oxygen"** can be found in paragraph [34], which reads "iodide ion is a catalyst to break hydrogen peroxide into water and oxygen in non-acidic solutions". Said disclosure is an explanation of the action of the composition which is applicable to all compositions of the application comprising sodium iodide.

The incorporation of the feature **"basic pH that permits iodide ion to catalytically break hydrogen peroxide into water and oxygen"** and its combination with the remaining feature of claim 1 is therefore directly and unambiguously derivable from the application as filed.

1.2.3 With regard to the concentration unit, the only unit which is constantly used in the application as filed is a concentration **"by weight"**; there is therefore no doubt that the concentration given in the unique example also refers to "% by weight". This feature is therefore also directly and unambiguously derivable from the application as filed.

1.3 Consequently, the subject-matter of claim 1 is an allowable generalisation of the example.

2. Dependent claim 2

2.1 A basis for a pH composition between 7 and 8.4 can be found in original claim 5, and in paragraphs [03], [09] and [31] all relating in general to a composition comprising sodium iodide, and in paragraphs [08] or [57] relating generally to a method for photochemical cross-linking of collagen. Paragraphs [31]-[34] give further explanations about the pH of the composition, in particular why it should be basic, and more particularly comprised between 7.0 and 8.4.

Consequently, the subject-matter of claim 2 is derivable directly and unambiguously from the application as filed.

3. Consequently, the main request meets the requirements of Article 123(2) EPC

4. Remittal to the examining division

The only grounds for the refusal set out in the decision under appeal, namely objections under Article 123(2) EPC, are no longer justified .

The examining division has not yet examined the patentability requirements and no reasons as to this regard are included in the decision under appeal.

Under Article 111(1) EPC, the Board may either proceed further with the examination of the application, in particular with respect to Articles 54 and 56 EPC, or remit the case to the examining division for further prosecution.

Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

The Board holds that such special reasons are apparent because the examining division has not taken an appealable decision on essential outstanding issues. As recalled in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of the application.

Under these circumstances, the Board considers it appropriate to allow the appellant's request for remittal of the case to the examining division (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated