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Submission in opposition proceedings

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- representing the proprietor(s):	ALLERGAN INDUSTRIE, SAS
Proprietor/representative's reference	147 001 u3/bst

The information given below is pertaining to the following patent in opposition proceedings:

Patent No.	EP2323617
Application No.	EP09785852.6
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	18 January 2017
Title of the invention	Hyaluronic acid-based gels including lidocaine
Proprietor of the patent	ALLERGAN INDUSTRIE, SAS

Documents attached:

	Description of document	Original file name	Assigned file name
1	Reply of the patent proprietor to the notice(s) of opposition	Response to oppositions.pdf	OBSO3.pdf
2	Auxiliary request in opposition	Auxiliary request 1.pdf	AUXREQ-1.pdf
3	Auxiliary request in opposition	Auxiliary request 2.pdf	AUXREQ-2.pdf
4	Auxiliary request in opposition	Auxiliary request 3.pdf	AUXREQ-3.pdf
5	Any annexes (other than citation) to an opposition letter -	List of Documents.PDF	OTHER-1.PDF
6	Clean copy of amended description	Amended description page 10.pdf	DESC-CLEAN-R82.pdf

Evidence filed subsequently:

Exhibit 1109

		technical terms" The McGraw-Hill Companies Inc., 2003 original file name: D62 Dictionary.pdf attached as: Published-Evidence-1.pdf
D63	Other evidence	Experimental Data original file name: D63 Experimental Data (revised).pdf attached as: Other-evidence-1.pdf
D64	Other evidence	Allergan Report original file name: D64 Allergan Memo.pdf attached as: Other-evidence-2.pdf
D65	Non-patent literature - book	Eskes and Mieczyslaw, "Drug Therapy During Pregnancy" Butterworth, 1985 original file name: D65 pKs lidocaine.PDF attached as: Published-Evidence-2.PDF
D66	Other evidence	Calculations based on Henderson-Hasslbalch-equation original file name: D66 lidocaine calculation based on pka.pdf attached as: Other-evidence-4.pdf
D67	Non-patent literature - book	Sadick, "Augmentation Fillers" Cambridge University Press, 2010 original file name: D67.PDF attached as: Published-Evidence-3.PDF

Signatures

Place:	**München**
Date:	**04 June 2018**
Signed by:	**/Dr. Peter Klusmann/**
Association:	**HOFFMANN EITLE PATENT- UND RECHTSANWÄLTE PARTMBB**
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Place:	**München**
Date:	**04 June 2018**
Signed by:	**/Dr. Katrin Dörfel/**
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Munich, June 4, 2018

Our Ref.: 147 001 u3/u18
European Patent 2 323 617
ALLERGAN INDUSTRIE, SAS

In response to the Communication of Notices of Opposition pursuant to Rule 79(1) EPC dated November 23, 2017, we hereby file our observations on behalf of Patentee.

1 Requests

We request:

- Rejection of the oppositions and maintenance of the opposed patent, EP 2 323 617 B1, as granted.
- In the event that the Main Request cannot be granted, maintenance of the opposed patent in amended form on the basis of the enclosed Auxiliary Requests 1-3.
- Oral proceedings in the event that the Opposition Division is unable to grant the Main Request on the basis of the written proceedings.

2 The Cited Documents

We suggest referring to the documents cited by the Opponents (OPP) and filed by Patentee (PI) herewith according to the table filed herewith in order to simplify the discussion.

We note that **D1**-**D5** have already been cited and considered in the EP examination proceedings (as **D1**-**D5**).

3 Content of the Opposed Patent

The present invention concerns a process for preparing a soft tissue filler composition as defined in claim 1 which solves the problem that hyaluronic acid (HA)-based compositions which incorporate lidocaine HCl during the manufacturing process are prone to partial or almost complete degradation prior to injection, particularly during high temperature treatment and/or when stored for any significant time (see paragraphs [0012], [0039] and [0048] of the opposed patent). This problem was solved by applying specific process conditions, and in particular a specific pH adjustment step, during the manufacturing process.

As a result, the claimed process provides hyaluronic acid (HA) compositions which include a therapeutically effective amount of lidocaine as its HCl salt and which have an enhanced stability, relative to conventional HA-based compositions including lidocaine HCl, when subjected to sterilization techniques and/or when stored over a long period of time at room temperature (see also paragraph [0039] of the opposed patent).

In and for the following substantiation, the technical features of independent claim 1 of the opposed patent are grouped and designated as follows:

1. *A method of preparing a soft tissue filler composition, the method comprising the steps of:*
2. *providing a hyaluronic acid component crosslinked with at least one crosslinking agent selected from the group consisting of 1,4-butanediol diglycidyl ether (BDDE), 1,2-bis(2,3-epoxypropoxy)ethylene and 1-(2,3-epoxypropyl)-2,3-epoxycyclohexane, or combinations thereof;*
3. *adjusting the pH of said hyaluronic acid component to an adjusted pH above 7.2; and*

4. *adding a solution containing at least one anesthetic agent to said hyaluronic acid component having said adjusted pH to obtain a hyaluronic acid-based soft tissue filler composition,*
5. *wherein the at least one anesthetic agent is lidocaine HCl.*

Claim 1 may be interpreted in accordance with the guidance provided in the Guidelines, F-IV, 4.2 which reads as follows:

> "*Each claim should be read giving the words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise. (…) The claim should also be read with an attempt to make technical sense out of it.*" (emphasis added)

When interpreting feature 2 in accordance with the Guidelines, F-IV.4.2, paragraph [0065] provides guidance that "*providing a HA component crosslinked…*" concerns the provision of a hydrated, alkaline NaHA gel in a first step which may then be crosslinked:

> "*The next step in the manufacturing process involves the step of crosslinking the hydrated, alkaline NaHA gel with a crosslinking agent selected from 1,4-butanediol diglycidyl ether (or 1,4-bis(2,3-epoxypropoxy)butane or 1,4-bis-glycidyloxybutane, all of which are commonly known as BDDE), 1,2-bis(2,3-epoxypropoxy)ethylene and 1-(2,3-epoxy-propyl)-2,3-epoxycyclohexane. The use of more than one crosslinking agent or a different crosslinking agent is not excluded from the scope of the present disclosure.*" (Emphasis added)

In and for the following substantiation, the technical features of independent claim 8 of the opposed patent are grouped and designated as follows:

A. *A method of preparing a cohesive hyaluronic acid-based filler composition, the method comprising the steps of:*
B. *providing dry uncrosslinked sodium hyaluronate material and hydrating said dry uncrosslinked sodium hyaluronate material in an alkaline solution to obtain an alkaline, uncrosslinked sodium hyaluronate gel;*
C. *crosslinking said uncrosslinked sodium hyaluronate gel with BDDE to form a crosslinked alkaline hyaluronic acid composition with a pH above 7.2;*

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