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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
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CONFIRMATION NO. 7372

51957
ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599

FILING RECEIPT

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Date Mailed: 09/02/2008

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Applicant(s)

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If Required, Foreign Filing License Granted: 08/28/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/087,934**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
Title

Cross-Linked Cohesive Hyaluronic Acid With Lidocaine Gel

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CROSS-LINKED COHESIVE HYALURONIC ACID WITH LIDOCAINE GEL

By Inventor Pierre Lebreton

The present invention generally relates to injectable soft tissue fillers and more specifically relates to hyaluronic acid-based dermal and subdermal fillers including lidocaine gel.

As a person ages, the face begins to show the effects of gravity, sun-exposure, and years of facial muscle movement, such as smiling, frowning, chewing and squinting. The underlying tissues that keep the skin appearing youthful begin to break down, often resulting in laugh lines, smile lines, "crow's feet" and facial creases.

Soft tissue fillers have been developed to help fill in facial lines and depressions, and for restoring volume of tissues due to fat loss, thereby temporarily restoring a smoother, more youthful appearance.

Ideally, a filler will be long-lasting, soft, smooth and natural appearing when implanted in the skin or beneath the skin. Further, the filler will be easy to implant into a patient using a fine gauge needle and will require low extrusion force for injection. Ideal fillers would also cause no adverse reaction of effects, and would be injectable with minimal or no discomfort to the patient.

For more than 20 years, bovine collagen-based fillers were the only U.S. Food and Drug Administration (FDA)-approved dermal fillers. Because these dermal fillers are bovine based, one of the main disadvantages has been the potential for allergic reaction in patients. It is believed that approximately 3-5% of human subjects show serious allergic reactions to bovine collagen, thus requiring careful testing before using these fillers in any particular person. In February 2003, human derived collagens received FDA approval. These collagens provide the advantaged a significantly reduced risk of allergic reactions.

The search for fillers that do not provoke allergic reactions has brought about the development of hyaluronic acid (HA)-based products. In December 2003, the first HA-based filler was approved by the FDA. This was soon followed by other HA-based fillers.

Hyaluronic acid, also known as hyaluronan, is a naturally occurring, water soluble polysaccharide, specifically a glycosaminoglycan, which is a major component of the extra-cellular matrix and is widely distributed in animal tissues. Hyaluronic acid has excellent biocompatibility and does not cause allergic reaction when implanted into a patient. In addition, hyaluronic acid has the ability to bind to large amounts of water, making it an excellent volumizer of soft tissues.

The development of HA-based fillers which exhibit ideal *in vivo* properties as well as ideal surgical usability has proven difficult. For example, HA-based fillers that exhibit desirable stability properties *in vivo*, can be so highly viscous that injection through fine gauge needles is difficult. Conversely, HA-based fillers that are relatively easily injected through fine gauge needles often have relatively inferior stability properties *in vivo*.

Crosslinked HA is formed by reacting uncrosslinked HA with a crosslinking agent under suitable reaction conditions. Methods of preparing HA based soft tissue fillers including both crosslinked and uncrosslinked HA are well known.

It has been proposed to incorporate certain therapeutic agents, for example, anesthetic agents such as lidocaine, into injectable HA-based compositions. Unfortunately, HA-based injectable compositions which incorporate lidocaine during the manufacturing process are prone to partial or almost complete degradation prior to injection, particularly during high temperature sterilization steps and/or when placed in storage for any significant length of time.

Sadozai et al., U.S. Patent Application Publication No. 2005/0136122, discloses a process for making an HA-based composition including lidocaine which includes hydrating dried HA particles with a phosphate buffer containing lidocaine.

Wohlrab, U.S. Patent Application Publication No. 2006/0122147 discloses a combination preparation comprising hyaluronic acid and a local anesthetic for example lidocaine, and further

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