

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of)
 Bengt ÅGERUP)
 Patent No. 5,827,937)
 Issued: October 27, 1998)
 FOR: POLYSACCHARIDE GEL)
 COMPOSITION)

MAIL STOP: PATENT EXTENSION

RECEIVED

FEB 10 2004

REEXAM UNIT

VIA HAND-CARRY TO USPTO

TRANSMITTAL LETTER FOR APPLICATION FOR EXTENSION
OF PATENT TERM UNDER 35 U.S.C. § 156

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Enclosed is an Application for Extension of Patent Term Under 35 U.S.C. § 156 (an original and three copies) for the above-identified patent.

Also enclosed with the original and each of the three copies are the following documents:

1. Attachment A (Copy of Product Information About RESTYLANE® Injectable Gel)
2. Attachment B (Copy of Approval Letter from the FDA for RESTYLANE® Injectable Gel)
3. Attachment C (Copy of U.S. Patent No. 5,827,937)
4. Attachment D (Copy of Statutory Disclaimer of Claim 4 for U.S. Patent No. 5,827,937)
5. Attachment E (Copies of Maintenance Fee Statement for U.S. Patent No. 5,827,937)
6. Attachment F (Copy of Recorded Assignment Document for U.S. Patent No. 5,827,937)
7. Attachment G (Copy of Authorization from Q-MED Scandinavia to Q-MED AB to Rely Upon Activities of Q-MED Scandinavia Before the FDA in Making Its Applications for Extension and Extension of Patent Term)

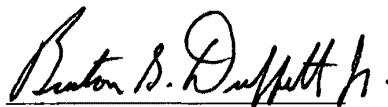
8. Attachment H (Copy of Power of Attorney).

Please charge the requisite fee in the amount of \$1,120.00 to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, LLP



Benton S. Duffett, Jr.
Registration No. 22,030

P.O. Box 1404
Alexandria, Virginia 22313-1404
(838) 838-6620

Date: February 10, 2004

#18

Patent
Attorney's Docket No. 003300-356

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of) MAIL STOP: PATENT EXTENSION
Bengt ÅGERUP) RECEIVED
Patent No.: 5,827,937) FEB 10 2004
Issued: October 27, 1998) REEXAM UNIT
For: POLYSACCHARIDE GEL)
COMPOSITION)

APPLICATION FOR EXTENSION OF
PATENT TERM UNDER 35 U.S.C. § 156

MAIL STOP: PATENT EXTENSION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 35 U.S.C. § 156 and 37 C.F.R. § 1.710 *et seq.*, the owner of record of U.S. Patent No. 5,827,937 requests that the term of this patent be extended by 879 days to expire on **December 12, 2017**.

U.S. Patent No. 5,827,937 was filed on July 17, 1995 and issued on October 27, 1998 for "POLYSACCHARIDE GEL COMPOSITION," listing Bengt Ågerup as the sole inventor. The term of U.S. Patent No. 5,827,937 will expire, unless extended, on July 17, 2015 (*i.e.*, twenty years from the date on which the application for the patent was filed in the United States).

Application For Extension Of
Patent Term Under 35 U.S.C. § 156
for U.S. Patent No. 5,827,937
Attorney Docket No.: 003300-356

Q-MED AB, a Swedish corporation, is the assignee of the entire right, title and interest in U.S. Patent No. 5,827,937, granted to Bengt Ågerup, on October 27, 1998 for POLYSACCHARIDE GEL COMPOSITION, by virtue of an assignment from the inventors to Q-MED AB, Upsala, Sweden, recorded on September 8, 1997 at Reel 8741, Frame 0942.

Q-MED AB submits this application for extension of the patent term of U.S. Patent No. 5,827,937 by providing the following information in accordance with 35 U.S.C. § 156 and 37 C.F.R. § 1.710 *et seq.*, and follows the numerical format set forth in 37 C.F.R. §1.740(a)(1)-(15)

(1) COMPLETE IDENTIFICATION OF PRODUCT

The product presently subject to regulatory review is RESTYLANE® Injectable Gel (trade name). Product information from the U.S. Food and Drug Administration website regarding RESTYLANE® Injectable Gel is attached at ATTACHMENT A.

RESTYLANE® Injectable Gel contains 20 mg/ml of non-animal stabilized hyaluronic acid (hereinafter "NASHA") in buffered physiological sodium chloride solution pH 7. RESTYLANE® Injectable Gel is a sterile, transparent, viscous gel supplied in a 1 ml disposable glass syringe filled with 0.4 or 0.7 ml gel. The syringe is equipped with a tip cap, finger grip, plunger stopper and plunger rod. The product is for single use only. A sterile 30G needle is supplied in the package.

Hyaluronic acid is a polymer containing alternating units of glucuronic acid (GlcUA) and N-acetylglucosamine (GlcNAc). NASHA is a generic name for the stabilized forms of Hyaluronic Acid (hereinafter "HA") from Q-MED. The HA in RESTYLANE® Injectable Gel is stabilized by adding a minimum amount of 1,4-butanediol diglycidyl ether to allow formation of a 3-dimensional HA molecular network (gel). The patented chemical stabilizing process used by Q-MED does not change the polyanionic character of the polysaccharide chain. As only about 1% of the polysaccharide has been stabilized the substance remains biocompatible.

Hyaluronic acid belongs to a group of very few substances, which are identical in all living organisms. It is a natural polysaccharide that is present throughout the tissues of the body.

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