



PATENT  
CASE PHAR-1550

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 6, 031,007

Granted February 29, 2000

Patentees Arne Brodin, Raymond Fynes, Lars Heijl, Adela Nyqvist-Mayer, Marie Scherlund

Assignee Maillefer Instruments Trading S.a.r.l.

FOR NEW PHARMACEUTICAL COMPOSITION WITH ANESTHETIC EFFECT

Date February 13, 2004

Commissioner for Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
**Mail Stop Patent Extensions**  
Ms. Karin Forritter, Esq.  
Crystal Plaza Three, D09  
Arlington, VA 22202

**Request for Extension of Patent Term Pursuant 35 U.S.C. § 156**

Sir

Applicant Maillefer Instruments Trading S.a.r.l. of Ballaigues, Switzerland (MITS), the owner of record of US 6,031,007, an indirect wholly owned subsidiary of DENTSPLY International Inc., a Delaware corporation, herewith applies for an Extension of Patent Term under the provisions of 35 USC 156. MITS changed its name from Dentsply Anaesthetics S.a.r.l. effective January, 2001 and was the assignee of US 6,031,007 from Astra Zeneca AB recorded in the US Patent and Trademark Office September 10, 2001 at Real/Frame 012153/0068, which changed its name from Astra AB in accord with a letter to the US Patent

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and Trademark Office dated July 28, 2000. Dentsply Pharmaceutical is an operating division of Dentsply International.

We include in our Application the enclosed exhibits which we believe, in addition to the remarks below, are sufficient to meet the requirements of 37 CFR 1.740(a). 37 CFR 1.740(a) requires, under the indicated subsection:

- (1) A complete identification of the approved product, by appropriate chemical and generic name, physical structure or characteristics. Applicant submits as Exhibit 1 its FDA approved ORAQIX package insert which provides the required information;
- (2) A complete identification of the Federal statute, including the applicable provision of law under which the regulatory review occurred. Applicant submits as Exhibit 2 the FDA's approval letter for the ORAQIX NDA 21-451 which approved the ORAQIX product under Section 505(b) of the Federal Food Drug and Cosmetic Act;
- (3) An identification of the date on which the product received permission for commercial marketing or use. Applicant submits as Exhibit 3 the results of an on-line search of the FDA's Orange Book which shows the approval date of December 19, 2003 for the ORAQIX product, NDA 21-451;
- (4) In the case of a drug product, an identification of each active ingredient in the product and a statement ...of when the active ingredient was approved, either alone or in combination with other active ingredients, and the provision of the law under which it was approved. Applicant submits as Exhibit 4, the ORAQIX Composition and a summary identification of when each ingredient was approved. The Exhibit was earlier submitted to the FDA as part of our NDA application.
- (5) A statement that the application is being submitted within the 60 day period permitted for submission pursuant to Section 1.720(f) and an identification of the date of the last day on which the application could be submitted. Applicant submits as Exhibit 5 the required

statement, to the effect that our submittal is timely and is before the last day of permitted submission, February 17, 2004;

- (6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue and the date of expiration. Applicant submits as Exhibit 6 a complete copy of the United States patent, which shows that the inventor is Brodin et al, the patent number is US 6,031,007, said patent issued February 29, 2000 and shall expire April 1, 2017;
- (7) A copy of the patent for which the extension is being sought. As noted above, Application submits Exhibit 6 which is a complete copy, including the entire specification and claims. There are no drawings to the patent;
- (8) A copy of any disclaimers, certificate of correction, receipt of maintenance fee payment or re-examination certificate issued in the patent. In response, Applicant submits as Exhibit 7 a USPTO Maintenance Fee Statement showing that the first maintenance fee was paid;
- (9) A statement that the patent claims the approved product or a method of using or manufacturing the approved product and a showing which lists each applicable patent claim and demonstrates the manner in which, at least one such patent claims reads on: (i) the approved product, method or using and/or method of manufacturing. Applicant submits that claims 1, 3, 4, 5, 6, 8-12 and 16 of US 6,031,007 read on the composition of the ORAQIX product. Applicant further includes Exhibit 8, a claim chart which lists the applicable claim limitations and demonstrates how each claim reads on the product by reference to the Package Insert of Exhibit 1 and Composition of Exhibit 4;
- (10) Requires a statement, beginning on a new page, of the relevant dates and information pursuant to 35 USC 156(g) in order to enable the Secretary of Health and Human Services to make a determination of the applicable regulatory review period for (i) a patent claiming a human drug, including (A) the effective date of the investigational new drug (IND) application and the IND number; (B) the date on which a new drug application (NDA) was

initially submitted and the NDA number; and (C) the date on which the NDA was approved. Applicant submits as Exhibit 9 the required statement, the dates of which are extracted from Exhibit 10 described below;

(11) Requires a brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and significant dates applicable to such activities. Applicant submits as Exhibit 10 a chronology beginning with the IND 52,677, continuing as NDA 21-451 which was approved by the FDA as ORAQIX;

(12) Requires a statement beginning on a new page that in the opinion of the Applicant the patent is eligible for the extension and a statement of the length of extension claimed, including how the length of extension was determined. Applicant submits as Exhibit 11 a statement that the patent is eligible for extension and claims an extension of time of 1040 days calculated in accord with 35 USC 156.

(13) Requires a statement by the Applicant acknowledging a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of the entitlement to the extension sought.

Applicant herewith acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of the entitlement to the extension sought.

(14) Requires that the prescribed fee for receiving and acting on the Application for Extension under Section 1.20(j) of \$1,120.00 be provided.

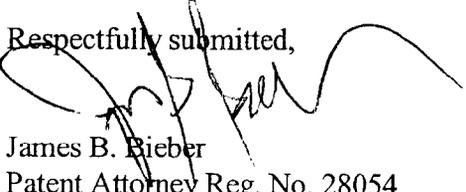
Applicant herewith approves payment of the fee and any additional required fees and requests that all fees or credits be charged to our Deposit Account 04-0780; and

- (15) Requires that the name, address and telephone number of the person to whom inquiries and correspondence relating to the application for Patent Term Extension are to be directed.

Applicant states that such inquires and correspondence be directed to:

James B. Bieber Esquire  
DENTSPLY International Inc.  
570 West College Avenue  
P.O. Box 872  
York, PA 17405-0872

Respectfully submitted,



James B. Bieber  
Patent Attorney Reg. No. 28054

February 16, 2004

Address of signer:

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570 West College Avenue  
York, PA 18405-0872  
(717) 849-4466