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Stephen G. Baxter
Jacob A. Doughty
Oblon Spivak McClelland Maier & Neustadt LLP
1940 Duke Street
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,856,336

mailed by
AUG
OPLA

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,856,336, claims of which cover the human drug product LIVALO® (pitavastatin calcium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,823 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,823 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 20, 2010 (75 Fed. Reg. 79382). Under 35 U.S.C. § 156(c):

Period of Extension	=	RRP - PGRRP - DD - ½ (TP - PGTP)[1]
	=	3,341 - 0 - 0 - ½ (3,036 - 0)
	=	1,823 days

Since the regulatory review period began June 12, 2000, after the patent issued (January 5, 1999), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

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[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,856,336
Granted:	January 5, 1999
Original Expiration Date[2]:	January 5, 2016
Applicant:	Yoshihiro Fujikawa et al.
Owner of Record:	Nissan Chemical Industries Ltd.
Title:	Quinoline Type Mevalonolactones
Product Trade Name:	LIVALO® (pitavastatin calcium)
Term Extended:	1,823 days
Expiration Date of Extension:	January 1, 2021

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: LIVALO® (pitavastatin calcium)
Docket No.: FDA-2010-E-0042

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,856,336

APR 29 2013

Dear Mr. Baxter:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,856,336 for a period of 1,823 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: LIVALO® (pitavastatin calcium)
Docket No.: FDA-2010-E-0042

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

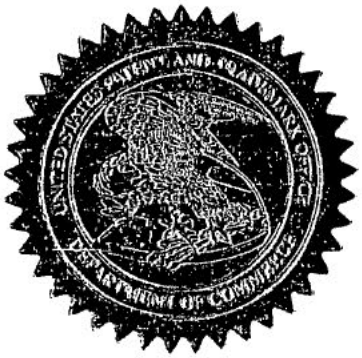
(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68)	PATENT NO.	:	5,856,336
(45)	ISSUED	:	January 5, 1999
(75)	INVENTOR	:	Yoshihiro Fujikawa et al.
(73)	PATENT OWNER	:	Nissan Chemical Industries Ltd.
(95)	PRODUCT	:	LIVALO® (pitavastatin calcium)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,856,336 based upon the regulatory review of the product LIVALO® (pitavastatin calcium) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,823 days

from January 5, 2016, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156.



I have caused the seal of the United States Patent and Trademark Office to be affixed this 1st day of April 2013.

Teresa Stanek Rea
Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office

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