



MAR 14 2005

Mailed: March 14, 2005

Beth Burrows
Foley & Lardner
Washington Harbour, Suite 500
3000 K Street NW
Washington DC 20007-5109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,079,262

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,079,262, which claims the method of use of the human drug product Levulan® Kerastick (aminolevulinic acid HCl), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,525 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 such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,525 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 April 1, 2003 (68 Fed. Reg. 15730). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,007 - 0) + 521 \\ &= 1,525 \text{ days (4.2 years)} \end{aligned}$$

Since the regulatory review period began January 2, 1993, after the patent issued (January 7, 1992), 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).

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to further reduce the period of extension determined above.

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

U.S. Patent No.:	5,079,262
Granted:	January 7, 1992
Original Expiration Date ¹ :	July 28, 2009
Applicant:	James C. Kennedy, et al.
Owner of Record:	Queen's University at Kingston
Title:	Method of Detection and Treatment of Malignant

¹Subject to the provisions of 35 U.S.C. § 41(b).

and Non-Malignant Lesions Utilizing
5-Aminolevulinic Acid

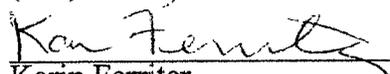
Classification: 514/561
Product Trade Name: Levulan® Kerastick (aminolevulinic acid HCl)
Term Extended: 1,525 days
Expiration Date: September 30, 2013

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

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7744
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at
(571) 272-7744.



Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: Levulan® Kerastick (aminolevulinic acid HCl)
FDA Docket No.: 00E-1404

Attention: Claudia Grillo

Determination of Patent Term Extension Under 37 CFR 1.775

Enter the number of days for the testing phase defined in 37 CFR 1.775(c)(1)	
Or Enter the Beginning of the Testing Phase	1/2/1993
Enter the Day the NDA was filed	7/1/1998
Calculated Testing Phase using Dates	2007
Enter the number of days for the approval phase as defined in 37 CFR 1.775(c)(2)	
Or Enter the Day the NDA was approved	12/3/1999
Calculated Approval Phase Using Dates	521
Add the Testing Phase to the Approval Phase (or Enter total Regulatory Review Period)	2528
Enter the Issue Date of the Patent	1/7/1992
Enter the Number of Days of the Testing Phase which Occurred On or Before the Issue Date of the Patent	0
Enter the Number of Days of the Testing Phase in which the Applicant failed to Act with Due Diligence as defined in 37 CFR 1.775(d)(1)(ii)	0
Add Lines 13 and 14 and Enter Total	0
Subtract Reductions (line 15) from Testing Phase (line 1 or b4)	2007
Half of Testing Phase (must round down, see 37 CFR 1.775(d)(1)(iii))	1003
Enter the Number of Days of the Approval Phase which Occurred On or Before the Issue Date of the Patent	0
Enter the Number of Days of the Approval Phase in which the Applicant failed to Act with Due Diligence as defined in 37 CFR 1.775(d)(1)(ii)	0
Add Lines 19 and 20 and Enter Total	0
Total of Reductions to Regulatory Review Period Line 15 plus line 21)	0
Subtract reductions and half of testing phase from total RRP (this number is the Projected Patent Term Extension (PPTE) based upon the RRP)	1525.00
(Approval Phase less any reductions) plus one half (testing phase less any reductions) rounding up (for comparison purposes)	1525
PPTE in years	4.2
Enter the Earliest US nonprovisional filing date	
	x
Original Expiration Date	28-Jul-09
Terminal Disclaimer, if any	x
Add the PPTE to the Expiration Date	30-Sep-13
Enter the Approval Date	03-Dec-99
14 Year Limit	03-Dec-13
Number of Days Between 14 Year Limit and Patent Expiration Date	1589
2 or 5 Years, Depending Upon Issue Date	5 years
Add to Expiration Date of Patent	7/28/2014



MAR 14 2005

Mailed: March 11, 2005

Robert B. Murray
Nikaido Marmelstein Murray & Oram LLP
Metropolitan Square
Suite 330 - G Street Lobby
655 Fifteenth Street NW Washington DC 20005-5701

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,808,616

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,808,616, which claims the human drug product AROMASIN® (exemestane), and a method of use of said product is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,729 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 such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,729 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 April 28, 2003 (68 Fed. Reg. 22390). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (2,848 - 0) + 305 \\ &= 1,729 \text{ days (4.7 years)} \end{aligned}$$

Since the regulatory review period began March 11, 1991, after the patent issued (February 28, 1989), 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 the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

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

U.S. Patent No.:	4,808,616
Granted:	February 28, 1989
Original Expiration Date ¹ :	July 7, 2006
Applicant:	Franco Buzzetti, et al.

¹Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Pharmacia Itailia S.p.A.
Title: 6-SUBSTITUTED ANDROSTA-1,4-DIENE-3,17-DIONES
Classification: 514/177
Product Trade Name: AROMASIN® (exemestane)
Term Extended: 1,729 days
Expiration Date: April 1, 2011

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

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7744
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: AROMASIN® (exemestane)
FDA Docket No.: docket no