



Mailed: July 28, 2004

Thomas D. Hoffman
Schering-Plough Corporation
Patent Department (K-6-1-1990)
2000 Galloping Hill Road
Kenilworth NJ 07033

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,260,291

A determination has been made that U.S. Patent No. 5,260,291, which claims the drug product TEMODAR® (temozolomide) 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 1,006 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 1,006 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 6, 2003 (68 Fed. Reg. 6176) and under 35 U.S.C. § 156(c) would be:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (1,668) + 364 \\ &= 1,198 \text{ days}\end{aligned}$$

Since the regulatory review period began January 19, 1994, after the patent issue date (November 9, 1993), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,198 days, would extend the patent from November 9, 2010 (35 U.S.C. § 154) to February 19, 2014, which is beyond the 14-year limit (the approval date is August 11, 1999, thus the 14-year limit is August 11, 2013). The period of extension is thus limited to August 11, 2013, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, November 9, 2010, to and including August 11, 2013, or 1,006 days.

The limitations of 35 U.S.C. § 156(g)(6) do not 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:

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|------------------|---------------------|
| U.S. Patent No.: | 5,260,291 |
| Granted: | November 9, 1993 |
| Applicant: | Edward Lunt, et al. |

Owner of Record: Cancer Research Campaign Technology Limited
Title: Tetrazine Derivatives
Classification: 514/183
Product Trade Name: TEMODAR® (temozolomide)
Original Expiration Date: November 9, 2010
Term Extended: 1,006 days

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

By mail: Mail Stop Patent Ext. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.
By FAX: (703) 872-9411

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

/s/

Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

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

RE: TEMODAR® (temozolomide)
FDA Docket No. : 00E-1238

Attention: Claudia Grillo