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SEP - 8 1997

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,047,407

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,047,407, which claims the human drug product EPIVIR™ (lamivudine), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 282 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 14, 1996 (61 Fed. Reg. 24316). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,448 - 51) + 134 \\ &= 833 \text{ days} \end{aligned}$$

Since the regulatory review period began July 21, 1991, before the patent issued (September 10, 1991), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 21, 1991 to September 10, 1991 is 51 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $1,448 - 51 = 1,397$ days.) 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 because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (November 17, 1995) when added to the period of extension calculated above (833 days) cannot exceed fourteen years. The period of extension is thus limited to November 17, 2009, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of twenty years after the filing date (35 U.S.C. § 154) would expire on February 8, 2009, the period of extension is the number of days to extend the term of the patent from its expiration date to and including November 17, 2009, or 282 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

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 Commissioner will issue a certificate of extension, under seal, for a period of 282 days.

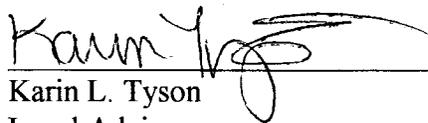
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,047,407
Granted:	September 10, 1991
Applicant:	Bernard Belleau, et al.
Owner of Record:	BioChem Pharma Inc.
Title:	2-Substituted-5-Substituted-1,3-Oxathiolanes with Antiviral Properties
Classification:	514/274
Product Trade Name:	EPIVIR™ (lamivudine)
Term Extended:	282 days

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

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

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



Karin L. Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
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RE: EPIVIR™
FDA Docket No.: 96E-0043