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Washington, D.C. 20231

Joseph J. Ruch, Jr.
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2100 Pennsylvania Ave., NW
Suite 800
Washington, DC 20037-3202

Re: Patent Term Extension
Application for
U.S. Patent No. 4,943,569

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,943,569, which claims the human drug product MERREM® I.V. (meropenem) and a method of use of MERREM® I.V. (meropenem), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,063 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 Commissioner will issue a certificate of extension, under seal, for a period of 1,063 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 February 11, 1997 (62 Fed. Reg. 6261). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,640 - 447) + 968 \\ &= 1,565 \text{ days}\end{aligned}$$

Since the regulatory review period began May 3, 1989, before the patent issued (July 24, 1990), 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 May 3, 1989 to July 24, 1990 is 447 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, 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 plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,565 days, would extend the patent from July 24, 2007 (35 U.S.C. § 154) to November 5, 2011, which is beyond the 14-year limit (the approval date is June 21, 1996, thus the 14 year limit is June 21, 2010). The period of extension is thus limited to June 21, 2010, 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, July 24, 2007, to and including June 21, 2010, or 1,063 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:

U.S. Patent No.:	4,943,569
Granted:	July 24, 1990
Original Expiration Date ¹ :	July 24, 2007
Applicant:	Makoto Sunagawa, et al.
Owner of Record:	Sumitomo Pharmaceuticals Company, Ltd.
Title:	β-Lactam Compounds
Classification:	514/210
Product Trade Name:	MERREM® I.V. (meropenem for injection)
Term Extended:	1,063 days
Expiration Date of Extension:	June 21, 2010

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

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

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
Senior 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)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: MERREM® I.V.
FDA Docket No.: 96E-0388