



MAY 31 2000

Mr. Howard R. Lambert
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

Re: Patent Term Extension
Application for
U.S. Patent No. 4,898,461

#30

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,898,461, which claims the medical device Silicone AMO® ARRAY® multifocal intraocular lens (Model SA40N AMO® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,557 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 1,557 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 17, 1998 (63 Fed. Reg. 69632). Under 35 U.S.C. § 156(c):

$$\begin{aligned}
\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\
&= \frac{1}{2} (2,478 - 76) + 368 \\
&= 1,569 \text{ days}
\end{aligned}$$

Since the regulatory review period began November 22, 1989, before the patent issued (February 6, 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 November 22, 1989 to February 6, 1990 is 76 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.

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, 1,569 days, would extend the patent from June 1, 2007 (35 U.S.C. § 154) to September 17, 2011, which is beyond the 14-year limit (the approval date is September 5, 1997, thus the 14 year limit is September 5, 2011). The period of extension is thus limited to September 5, 2011 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, June 1, 2007, to and including September 5, 2011, or 1557 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.: 4,898,461
Granted: February 6, 1990
Original Expiration Date¹: June 1, 2007
Applicant: VALDEMAR PORTNEY
Owner of Record: VALDEMAR PORTNEY
Title: MULTIFOCAL OPHTHALMIC LENS
Classification: 351/169
Product Trade Name: Silicone AMO® ARRAY® multifocal intraocular lens
Term Extended: 1,557 days
Expiration Date of Extension: September 5, 2011

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 or (703)872-9411
Attn: Karin Tyson

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

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: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: Silicone AMO® ARRAY®
FDA Docket No.: 98E-0227

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