



NOV 18 2004

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Re: Patent Term Extension
Application for
U.S. Patent No. 5,192,319

REQUIREMENT FOR INFORMATION

This is in response to the application for patent term extension, filed November 12, 2004 (with a certificate of mailing dated November 8, 2004).

For the claims to claim the Phakic Intraocular Lens approved by the Food and Drug Administration, the iris tissue support fixation must have a gap positioned between two pincer arms. From the drawings of Models 204 and 206, the Office is unable to determine whether the approved device includes such a gap. Items 39 and 39 appear to reference the thickness of the support, or a midline. Furthermore, further details of the lateral side gates 36 are required. The gates are not clearly illustrated in the figures provided.

Applicant is required to submit further details of the approved device to assist the Office in determining whether the patent claims the approved product.

Applicant has **TWO MONTHS** from the date of this letter to file the required information. The time period is extendable pursuant to 37 CFR 1.136(a). Failure to reply will result in a determination that the patent does not claim the approved product.

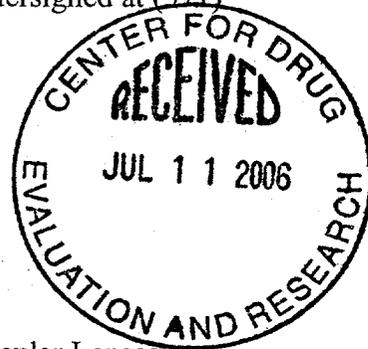
Any correspondence with respect to this matter should be addressed as follows:

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

By FAX: (571)273-7744

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


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: Phakic Intraocular Lenses

Attention: Claudia Grillo

2006E-0282

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