



Hilary Dorr Lang
Patterson Intellectual Property Law, PC
Roundabout Plaza
1600 Division Street, Suite 500
Nashville, TN 37203

In Re: Patent Term Extension
Application for
U.S. Patent No. 7,473,678
Filed: October 31, 2015

JUN 14 2016

ORDER TO SHOW CAUSE

This is an order to show cause based on the apparent untimely filing of the present application for patent term extension of U.S. Patent No. 7,473,678 (“the ‘678 patent”) under 35 U.S.C. § 156.

In section 156(a) of title 35, several eligibility requirements for a patent term extension are found. In addition to the requirements found in section 156(a), the PTE application must be timely filed. Section 156(d)(1) provides, in relevant part:

To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period *beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred* for commercial marketing or use.

35 U.S.C. § 156(d)(1) (emphasis added). The “beginning on” language makes clear that the triggering date for filing a PTE application is the day of FDA approval, *i.e.*, the date of the PMA approval letter. The triggering date is not the day after FDA approval. In other words, the first day of the sixty-day period within which an applicant must submit a PTE application is the day of FDA approval. The day after FDA approval is considered to be the second day in the sixty-day application window.

Additionally, the USPTO’s regulation implementing section 156(d)(1) mirrors the language of section 156(d)(1): “The application is submitted **within the sixty day period beginning on the date the product first received permission for commercial marketing or use** under the provision of law under which the applicable regulatory review period occurred” *See* 37 C.F.R. § 1.720(f) (emphasis added).

Based on the plain language of section 156(d)(1) and Rule 1.720(f), the FDA’s grant of permission for commercial marketing or use triggers the time period for submission of a patent term extension application. The phrases used in section 156(d)(1) and Rule 1.720 to define the time period for submitting a patent term extension application, *i.e.*, “within” and “beginning on,” are clear. *See Unimed, Inc. v. Quigg*, 888 F.2d 826, 828 (Fed. Cir. 1989) (characterizing the language used in section 156(d)(1) as “crystal clear”). Thus, under both section 156(d)(1) and Rule 1.720(f), a PTE applicant has sixty days to submit a PTE application; the first day of that

sixty day period begins on the date granted permission for commercial marketing or use of the product which was subject to the applicable regulatory review period.

Here, Applicant received FDA approval on September 1, 2015, triggering the start of the sixty-day period for filing its PTE application and making its PTE application due on or before October 30, 2015. Applicant did not, however, file its PTE application until October 31, 2015, one day late.

In order to determine when the sixty-day time period begins, the following sentence was added to 35 U.S.C. 156(d)(1) as part of the America Invents Act:

[f]or purposes of determining the date on which a product receives permission under the second sentence of 35 U.S.C. 156(d)(1), if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.

Here, no evidence has been made of record indicating that Applicant received notice of its PMA approval from FDA after FDA's close of business, *i.e.*, after 4:30 PM EST. Therefore, without any such evidence, the USPTO presumes that the notice of PMA approval was transmitted to Applicant on September 1, 2015 during FDA's normal business hours. Thus, Applicant filed its PTE application one day late, and the eligibility requirement set forth in section 156(d)(1) does not appear to be satisfied and the '678 patent appears ineligible for patent term extension for this reason.

Applicant has **ONE MONTH** from the date of this letter in order to file a response indicating that the application has been timely submitted. Extensions of time under 37 CFR 1.136 are available. Failure to respond will result in the application for patent term extension being dismissed as untimely under section 156(d)(1).

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

By mail: Deputy Commissioner for Patents
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Telephone inquiries related to this notice should be directed to Ali Salimi at (571) 272-0909.



Mary C. Till

Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg 51, Rm. 6250
Silver Spring, MD 20993-0002

RE: Augment® Bone Graft
FDA Docket No.:

Attn: Beverly Friedman