



JUL 24 2000

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,296,100

NOTICE OF FINAL DETERMINATION

This is in response to the application for interim patent term extension under 35 U.S.C. § 156(d)(5) of U.S. Patent No. 4,296,100, filed June 20, 2000 (certificate of mailing June 15 2000). The application, filed by Wayne P. Franco, requests an interim extension due to the regulatory review of the human drug product rFGF-2.

A determination has been made that U.S. Patent No. 4,296,100 is NOT eligible for interim patent term extension under 35 U.S.C. § 156(d)(5) based upon the filing of only an Investigational New Drug Application (IND) for rFGF-2.

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 applicable to this time period. See 37 CFR 1.750.

35 U.S.C. § 156(d)(5)(A) states, in part (emphasis added):

If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii)...or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may be extended beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Commissioner for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire.

35 U.S.C. § 156(g)(1)(B)(ii) states:

the period beginning on the date an application is initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date the such application was approved under such section.

An application for interim extension under 35 U.S.C. § 156(d)(5) may only be filed after the approval phase of a regulatory review period of a product has begun. The approval phase of a product is defined in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) of 35 U.S.C. § 156(g). See also 37 CFR 1.790(a). The approval phase of a new drug or human biological product is defined in 35 U.S.C. § 156(g)(1)(B)(ii) and begins with the date an application with respect to the new drug or biologic (a New Drug Application (NDA) or Biologic License Application (BLA)) is initially submitted under section 505 of the Federal Food, Drug and Cosmetic Act. Since applicant has not submitted a initially submitted an application under section 505 of the Federal Food, Drug and Cosmetic Act, the application for patent term extension is premature and must be dismissed.

DECISION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,296,100 is not eligible for interim extension of the patent term under 35 U.S.C. § 156(d)(5). Accordingly, the application for extension of the patent term is dismissed

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) 872-9411
 Attn: Special Program Law Office

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



Karin Tyson
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for Patent Policy and Projects