

Mailed: February 27, 2002

Steven M. Odre
Vice President, Intellectual Property
AMGEN INC.
1840 DeHavilland Drive
Thousand Oaks, CA 91320

Re: Patent Term Extension
Application for
U.S. Patent No. 4,695,623

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,695,623, which claims the drug product INFERGEN (interferon alfacon-1 or consensus interferon 1) has been determined to be 5 years.

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 Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 14, 2001 (66 Fed. Reg. 24389). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3849 - 725) + 545 \\ &= 2,107 \text{ days (5.8 years)}\end{aligned}$$

Since the regulatory review period began September 27, 1985, before the patent issued (September 22, 1987), 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 September 27, 1985 to September 22, 1987 is 725 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 five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,695,623
Granted:	September 22, 1987
Original expiration date:	September 22, 2004

Applicant: Norman K. Alton, et. al.
Owner of Record: Amgen, Inc.
Title: Consensus Human Leukocyte Interferon
Classification: 530/351
Product Trade Name: INFERGEN (interferon alfacon-1 or consensus interferon 1)
Term Extended: 5 years
Extended Expiration Date: September 22, 2009

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

By mail: Commissioner for Patents By FAX: (703) 872-9411
 Box Patent Ext. Attn: Karin Tyson
 Washington, D.C. 20231

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

/s/

Karin L. Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read RE: INFERGEN
 Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 98E-0476
 Food and Drug Administration
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