



Exhibit 11

Statement That The Patent Is Eligible For Extension and Length of Extension Claimed

Applicant is of the opinion that US Patent 6,031,007 is eligible for extension under 35 USC 156, because it satisfies all the requirements under 35 USC 156, including claiming the approved product. Applicant notes that the term of the patent has not expired before this Application for Extension has been submitted; that the patent term has never before been extended; that the Application for Extension is being submitted by the owner of record of the patent; that the product has been subject to a regulatory review period before its commercial marketing or use; and that the regulatory permission is the first permitted commercial and marketing for use of the provision of law under which such regulatory review period occurred.

Statement as to the Length of Extension Claimed and Calculation thereof under 35 USC 156

Applicant claims an extension of patent term of: 1040 days, calculated as follows:

- Allowed extension is the sum of (1) IND period and (2) NDA period

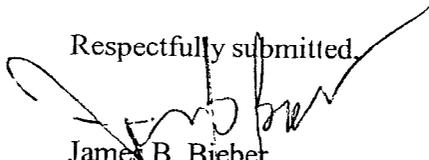
$$\begin{aligned} (1) \text{ IND Period} &= 1791 \text{ days (date of NDA filing - date of IND filing)} \\ &- \underline{1100} \text{ days (date of issue of patent - date of IND filing)} \\ &691 \div 2 &= 345 \text{ days} \end{aligned}$$

and

$$\begin{aligned} (2) \text{ NDA Period} &= 695 \text{ days (date of NDA approval - date of NDA filing)} = \underline{695} \text{ days} \\ &\Sigma \quad 1040 \text{ days} \end{aligned}$$

* IND effective filing date: February 24, 1997
NDA effective filing date: June 22, 2002
NDA approved: December 19, 2003
Patent Issue Date: February 29, 2000

Respectfully submitted,



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[patent term extension exhibits]