

2.5.21 Required Reduction Basis

Applicant's delay for failure to engage in reasonable effort to conclude the prosecution of the application is subtracted from GAB1-3: failure to reply within 3 months to any notice from the office making any rejection, objection, argument, or other requests (even though the applicant pays for and receives extension), days in excess of 3 months are deducted; reinstatement of deduction of up to 3 months can be made by applicant, showing that "in spite of all due care, the applicant was unable to reply," due perhaps to testing to demonstrate unexpected results, death of applicant's sole practitioner, or a natural disaster. (Do not confuse the 3 months' concession with 3 months required to respond.) Additional required reduction bases (RRBs) are generated because of suspension of action under Rule 1.103, deferral of issuance under Rule 1.3114, abandonment or late payment of issue fee, petition to revise more than 2 months after the notice of abandonment, conversion of provisional to nonprovisional, preliminary amendment within 1 month of office action that requires supplemental office action (i.e., a response is sent when an office action is to come within 1 month)*, inadvertent omission in reply to office action*, supplemental reply not requested by examiner*, submission filed after BPAI or court decision within 1 month of office action that requires supplemental office action*, submission filed after the notice of allowance*, and filing a continuing application to continue prosecution. Note that in instances marked with an asterisk (*), information disclosure statement submission will not create reduction if information is received from foreign patent office within the last 30 days (i.e., the applicant responds within 30 days of receiving such information).

Summary: Patent term begins on the day of patent issuance; terminal disclaimer date ends patent term; failure to pay a postissuance maintenance fee ends patent term (notice: no such fee is required for design and plant patents); term extension beyond statutory period is only through private congressional legislation or by showing government agency delays (e.g., the FDA); 20-year term begins from the earliest ancestral application from which priority is claimed (does not include provisional application or a foreign application for term running purpose); design applications excluded from URAA and AIPA, as they have a fixed 14-year term from issue.

2.6 Food and Drug Administration

A listing of drugs for which the patent term had been extended by the U.S. FDA is available at the website mentioned in Ref. 20. The longest patent term extension given by the U.S. FDA to any drug belongs to U.S. Patent 3,737,433 for 2494 days.

The point in the development program at which a patent application is filed will vary somewhat from company to company but will normally be at an early stage in the process, when the substance has been made and been shown to be active in early screening. For a patent with a nominal term of 20 years from filing, the effective term during which the patentee has exclusive rights to a marketed product is only 8–12 years. This explains the importance attached by the pharmaceutical industry to provisions to extend the patent term, whether directly, as in the United States and Japan, or indirectly by way of the supplementary protection certificate (SPC), as in Europe, in order to compensate for this loss of effective patent term. It also explains