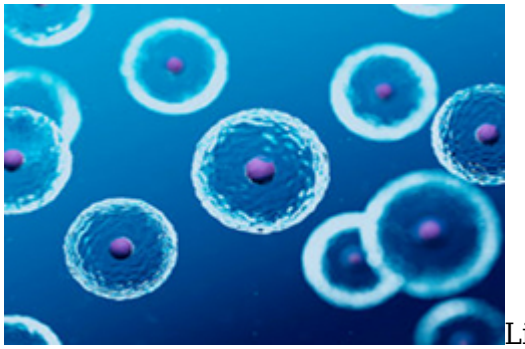
Strategic Considerations for Seeking Patent Term Extension (PTE) and Its Scope for Drug Products



Life science companies developing new therapeutics – both small molecule and biologic – know that obtaining long patent term for their products is a key driver of valuation and revenue. A particular challenge in this respect is minimizing the loss of patent term during drug development. Fierce competition in the marketplace often requires that innovators patent their drug products as early as possible in the development process, but because the clock on a United States (patent's lifespan starts running the moment it is filed, years of valuable patent term are often lost as a product navigates the regulatory approval process. An important method to mitigate these losses can be found in the Patent Term Extension ("PTE") provisions of 35 U.S.C § 156, which provide statutory compensation for the substantial time and resources expended by an innovator to bring a new drug to market. In a nutshell, PTE restores a portion of the patent term, up to five years, that is lost during the period a new drug or medicinal product is awaiting pre-market regulatory approval in the U.S.. When a new chemical entity ("NCE") – either a small molecule or a biologic – is approved by FDA as a therapeutic, a patent claiming either the NCE or its method of use may be entitled to PTE.

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