

Summary and comparison of key PTE provisions in Australia, Canada, Europe, Israel, Japan, and the United States

	Australia (PTE)	Canada (CSP)	Europe (SPC)	Israel (PTE)	Japan (PTE)	United States (PTE)
What is the maximum term of extension?	5 years.	2 years.	5 years.	5 years.	5 years.	5 years.
Are there further considerations on the maximum term of extension?	<p>The duration of the PTE cannot result in an effective patent life exceeding 15 years from the first Market Authorisation of that product in Australia.</p> <p>The PTE's exact duration is determined as the period between the filing of the patent and the first Market Authorisation.</p> <ul style="list-style-type: none"> If this period is less than 5 years then no PTE will be provided. If the period between the two dates is greater than 10 years, then the PTE will be set at the maximum term of 5 years. 	<p>The duration of the extension is first determined as the period between the filing of the patent and the first Market Authorisation of the product in question in Canada.</p> <p>A period of 5 years is then subtracted from this calculation to determine the CSP duration.</p> <p>There is a cap of a maximum 2 years for an extension, irrespective of whether the calculation was higher</p>	<p>The duration of the SPC cannot result in an effective patent life exceeding 15 years from the first Market Authorisation of that product in a contracting state of the European Medicines Agency (EMA).</p> <p>The date of approval is taken as the earliest Market Authorisation in any of the EMA contracting states, regardless if that date is shared between all states.</p>	<p>The duration of the PTE cannot result in an effective patent life exceeding 14 years from the first Market Authorisation of that product in Israel.</p> <p>The PTE's exact duration will take into consideration any extensions on an equivalent reference patent in a recognised designated state (e.g. US or EPO designated state) and will not exceed the shortest of these extensions.</p>	<p>There is no further restriction on the extension of term beyond the limit of 5 years.</p> <p>The exact duration of the PTE will be determined by the length of time the patented invention "could not be worked", due to requiring a Market Authorisation in Japan.</p>	<p>The duration of the PTE cannot result in an effective patent life exceeding 14 years from the first Market Authorisation of that product in the United States.</p> <p>The exact duration of the extension will take into consideration several factors during the regulatory review period including:</p> <ul style="list-style-type: none"> Grant date of the patent. Submission date of the Investigational New Drug (IND) application and New Drug Application (NDA). FDA approval date.

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What types of patents are eligible for extensions?	<p>There are two eligibility criteria in Australia, which include patents where:</p> <ol style="list-style-type: none"> 1. The product is disclosed in the specification 'per se' (e.g. not qualified by a process, method, or use), and falls in substance within the scope of the claims. 2. A process of manufacture where the product is produced via recombinant DNA technology, where the substance is disclosed in the specification, and the product/process in substances falls within the scope of the claims. 	<p>Patents which claim the product itself or a product-by-process are eligible for extension. Medical use patents are also eligible, even if the claimed use is not yet authorised.</p> <p>Patents claiming combinations of products are also permissible, if the combination in question is approved.</p>	<p>A patent is eligible if it claims an approved medical product(s).</p> <p>Patents concerning medical devices are not eligible for extensions, regardless if they define an approved product.</p> <p>A medical product is taken to refer to a product that treats or prevents diseases, as well as, any substance administered to humans to restore, correct, or modify physiological functions.</p>	<p>Patents which claim the product as an active pharmaceutical ingredient are eligible if the product has been approved for use in Israel.</p> <p>Patents relating to medical devices concerning these products are also eligible for extension.</p>	<p>Any patent can potentially be eligible for extension as long as a Market Authorisation requirement prevented the patent from being workable. This allows both process and medical device patents to also be eligible for extension.</p> <p>Subsequent amendments or updates to a product's Market Authorisation can provide additional eligibility for extension(s) as this represents a new period of time the invention "could not be worked".</p>	<p>Patents which claim the product, manufacture of the product, or a medical use of the product are eligible for extensions.</p> <p>A "product" is also taken to refer to a medical device, food additive, or a colour additive.</p>
Is it possible to obtain multiple patent term extensions per patent application?	<p>No, only one extension is allowed per patent. In the event a claim encompasses two products, both products will be protected during the extension period. However, if the products are entitled to different extension terms, then the shorter of the two terms must be taken.</p>	<p>No, only one extension is allowed per patent.</p>	<p>Yes, a patent can be subject to multiple SPCs, covering different products.</p>	<p>No, only one extension is allowed per patent.</p>	<p>Yes, a patent can be subject to multiple PTEs.</p> <p>The patent in question can also be extended multiple times for the same product as well as for different products.</p>	<p>No, only one extension is allowed per patent.</p>

	Australia (PTE)	Canada (CSP)	Europe (SPC)	Israel (PTE)	Japan (PTE)	United States (PTE)
Is it possible to obtain multiple patent term extensions for a product?	Yes, it is possible for multiple patents to receive an extension for a product.	No, only one extension is allowed for the product overall.	Yes, it is possible for multiple patents to receive an extension for a product. However, this has been interpreted as being limited to one SPC, per product, per patentee.	No, only one extension is allowed for the product overall.	Yes, it is possible for multiple patents to receive an extension for a product.	In general no, only one extension is allowed for the product overall. In some very limited circumstances subsequent extensions for a product may be permissible.