

# THE IP ACADEMY

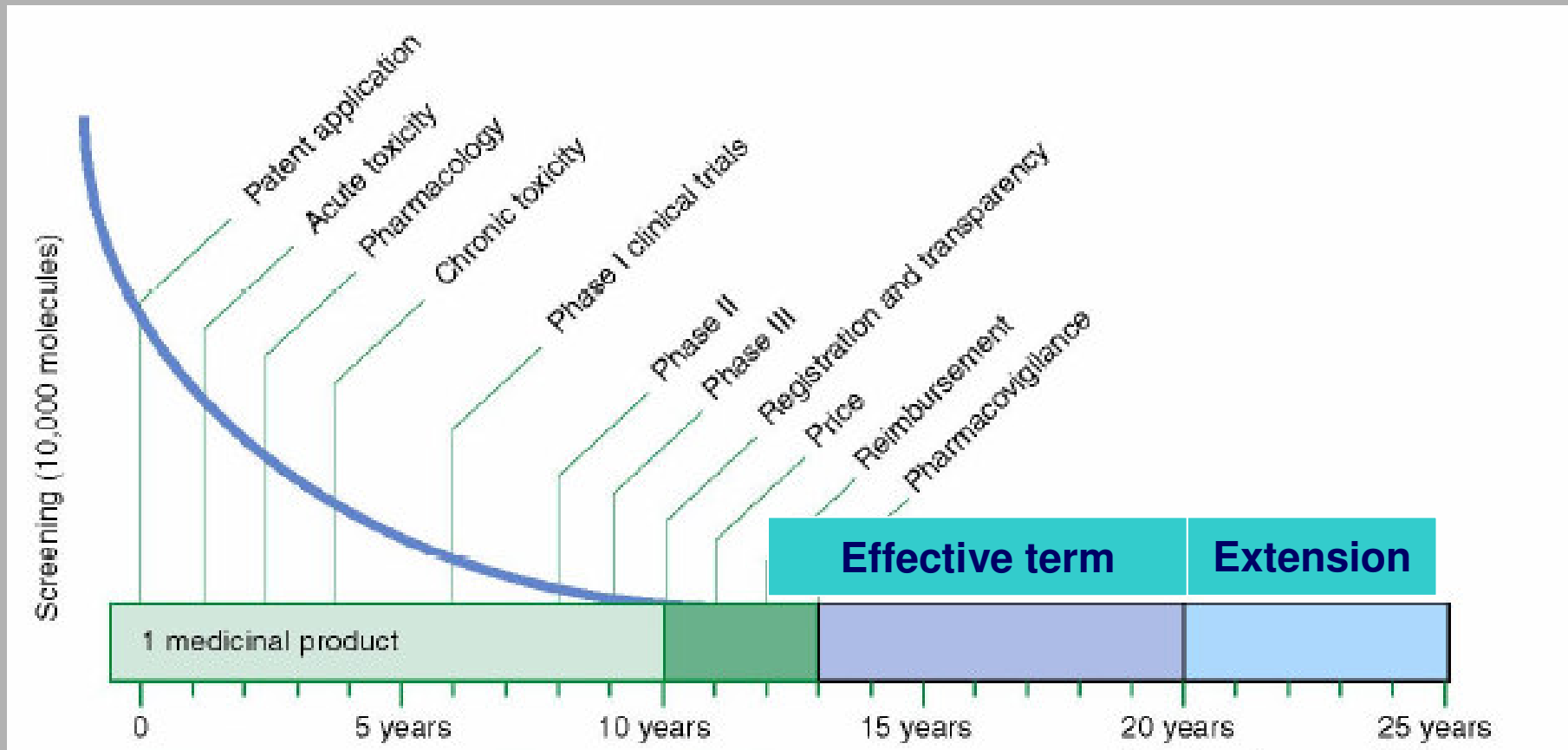


## Overview and comparison of patent term extensions (PTE) in Israel and in selected - OECD countries

International Standards Group

25 April 2007

# Effective Commercial Patent Life



NCE

**Protection**

MEDICINE

**Exploitation**

## PTE as a Formula

**Coverage**: the extent to which extension terms is give to a patent or is it given to a pharmaceutical product covered by a patent? (the latter will extend the patent as long as the specific pharmaceutical product is in the market...)

**Maximum extension term**: The maximum period allowed by the law to extent the patent beyond the expiry date of its basic term

**Maximum term of market exclusivity**: The maximum period of product market exclusivity allowed by the law from the date of grant of marketing approval for that pharmaceutical product.

**Calculation**: How is the PTE for a given patented pharmaceutical product is calculated?

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
<p><b>United States</b> Federal Food, 35 U.S.C. 155A Patent term restoration &amp; 156 - Extension of patent term.</p>	<p>14 Years from the date of product approval</p>	<p>5 years from the date of basic patent expiry  + 6 months extension for pediatric drugs</p>	<p>Shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued:</p> <p>Period of Extension = 1/2 (Testing Phase) + Approval Phase</p> <p>= ____ days</p>	<p>Extension is granted to a <u>Patent</u> - on an “approved” FDA product that has not been subject to patent extension before</p> <p>Close collaboration between FDA and USPTO!</p> <p>FDA provides the time of the testing phase and approval phase</p>

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
<p><b>European Union-</b> Council Regulation EEC No 1768/92 of 18 June 1992</p>	<p>15 Years from the date of product approval*</p> <p>* Date of First authorization to place the product on the market in a state which is Contracting Party to The European Economic Area Agreement.</p>	<p>5 years from the date of basic patent expiry in each EEA country</p> <p>+ 6 months extension for pediatric drugs</p> <p>(The Pediatric Medicines Regulation)</p>	<p>Extension = period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market, reduced by a period of five years.</p> <p>Period of Extension = 5- (date of product Approval – date of patent application)....</p>	<p>*Extension is granted to a an approved Product (by the EMEA) with a valid* patent in each EEA country</p> <p>* In the EU SPC needs to be secured in every EEA member.</p>

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
<p><b>Japan</b> Sections 67(2), 67bis, 67bis-bis, 67ter, and 67quater of the Japanese Patent Law</p>	<p>No cap</p>	<p>5 years from the date of basic patent expiry</p>	<p>Extension = the period from the commencement of testing for approval or registration of the patent, whichever is later, to the day approval is granted.</p> <p>Period of Extension = Date of product approval - date of testing or patent grant ( whichever is later)</p>	<p>Extension is granted to a <u>Patent</u> - on an “approved” Product (drugs approved under Cabinet Order” – Section 67(2).)</p>

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
<p><b>Australia</b> Sections 70 - 79A of the Australian 1990 Patent Act (1998 Amendments)</p>	<p>20 Years from the date of product Approval</p>	<p>5 years from the date of basic patent expiry</p>	<p>The period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years.</p> <p>The period beginning on the date of the patent and ending on the first regulatory approval in Australia</p>	<p>Extension is granted to a <u>Patent</u> - on an “approved” Product (by the Australian Register of Therapeutic Goods)</p>

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
<p>S. Korea* - Patent Act 1991, Extension Term of Patent Right, Articles 89-95</p>		<p>5 years from the date of basic patent expiry</p>	<p>A period, up to five years, during which the patented invention could not have been worked.</p> <p>“ The extended period of time to complete the activity test, the Safety tests, etc., necessary to obtain such authorization or registration</p>	<p>Extension is granted to a <u>Patent</u> - on an “approved” Product (under the Presidential Decree)</p>

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
<p>Israel* - Amendment no. 7, to Article 64 (December 19th 2005)</p>	<p>5 years</p> <p>But, linked to the <u>earliest expiry date</u> of a parallel extension granted in countries recognized by the Pharmacist Ordinance for the purpose of registering a new pharmaceutical Product</p> <p>For the sake of calculating the PTE term the list of Recognized Counties shall include: the US, EU-15, Switzerland, Norway, Iceland Japan and Australia.</p>	<p>14 years of the first date of product approval obtained in any of the Recognized Countries, as defined above</p>	<p>Find the shortest PTE in terms of Date of expiration</p>	<p>Extension is granted to a Patent - on an “approved” Product ( based on the Pharmacist Ordinance)</p>

# OECD Countries – PTE legislations

Country	Maximum exclusivity Period	Maximum extension	Calculation	Granted to patent or a product?
Canada	None			
New Zealand	None			
Mexico	None			

# Analysis of PTE Amendments in Israel

Component	Final PTE Amendment
<p><b>ITEM -1 Expiry of term of a PTE in Israel</b></p>	<p>Linked to the earliest expiry date of a parallel extension granted in countries recognized by the Pharmacist Ordinance for the purpose of registering a new pharmaceutical product.*</p> <p>With the exception OF ITEM III below, The PTE term be linked to parallel extensions that were <u>actually</u> granted by Recognized Countries, and will not take into account countries in which an application for a PTE was not submitted or that a PTE was not granted</p> <p>* For the sake of calculating the PTE term the list of Recognized Counties shall include: the US, EU-15, Switzerland, Norway, Iceland Japan and Australia.</p> <p>Total= 21 countries.</p>
<p><b>ITEM II - Maximum term of a PTE in Israel</b></p>	<p>14 years of the first date of product approval obtained in any of the Recognized Countries, as defined above.</p>
<p><b>ITEM III - Pre condition for the submission of a PTE.</b></p>	<p>An application for PTE in Israel can be submitted and approved only after a <u>reference PTE</u>* application was approved in the US and in one member country of the EU-15.</p> <p>* <u>Reference PTE</u> - a PTE that refers to any patent claim of a pharmaceutical product, which has been granted a PTE by a Recognized country, and which is used as a basis for a PTE application in Israel.</p> <p>In other words PTEs, in Recognized Countries, as defined above, do not need to refer to the same patentable subject matter of a PTE in Israel</p>

# Analysis of PTE Amendments in Israel

<p><b>ITEM IV- Procedural process for applying for a PTE and discretionary powers of the Patent Registrar</b></p>	<p>An application for a PTE in Israel should be submitted within 90 days of obtaining product marketing approval in Israel.</p> <p>The Patent Registrar will have the <u>power to extend the above deadlines</u> in cases that concerns delays that are beyond the control of the patentee.</p>
<p><b>ITEM V - Opposition procedures</b></p>	<p>The Patent Registrar may nullify a PTE or shorten the term of a PTE on the basis of a request by any third party, if he finds that such a request for opposing the grant of a PTE or the term of a PTE is valid.</p>
<p><b>Applicability of the amendment</b></p>	<p>Subject to two exceptions (outlined below) the amendment will apply on <u>all the applications for a PTE</u>, including PTE application that were approved and granted by the Patent Office, that were <u>submitted prior of to the date of entry into force of the amendment</u>.</p> <p>Exception 1 – the amendment will not apply on PTEs that have already begun their extension.</p> <p>Exception 2 – the amendment does not require the implementation of ITEM III above - that an application for PTE in Israel can be submitted and approved only after a <u>reference PTE</u> application was approved in the US and in one member country of the EU-15</p>

**United States** - United States Federal Food, 35 U.S.C. 155A Patent term restoration & 156 - Extension of patent term.

[http://www.uspto.gov/web/offices/pac/mpep/consolidated\\_laws.pdf](http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf)

[http://www.uspto.gov/web/offices/pac/mpep/documents/2700\\_2750.htm#sect2750](http://www.uspto.gov/web/offices/pac/mpep/documents/2700_2750.htm#sect2750)

<http://www.uspto.gov/web/offices/pac/mpep/documents/2700.htm>

[http://www.uspto.gov/web/offices/pac/mpep/documents/appxr\\_1\\_750.htm#cf37s1.750](http://www.uspto.gov/web/offices/pac/mpep/documents/appxr_1_750.htm#cf37s1.750)

[http://www.fda.gov/cder/about/smallbiz/patent\\_term.htm](http://www.fda.gov/cder/about/smallbiz/patent_term.htm)

**EU** - Council Regulation EEC No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products

[http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg\\_1992\\_1768/reg\\_1992\\_1768\\_en.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_1992_1768/reg_1992_1768_en.pdf)

<http://www.ipo.gov.uk/practice-spc.pdf> (p.22)

**Japan** - Sections 67(2), 67bis, 67bis-bis, 67ter, and 67quater of the Japanese Patent Law

[http://www.wipo.int/clea/does\\_new/pdf/en/jp/jp006en.pdf](http://www.wipo.int/clea/does_new/pdf/en/jp/jp006en.pdf)

<http://www.wipo.int/ipstats/en/resources/pdf/japan.pdf>

<http://www.law.washington.edu/CASRIP/Harmonization/PDF/ExperimentalUse.pdf>

**Australia** - Sections 70 - 79A of the Australian 1990 Patent Act

<http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilationLnsi/frame lodgment attachments/D585C9E4CA3E5EBFCA2570450020B36B>

S. Korea – Patent Act 1991, Extension Term of Patent Right, Articles 89-95

[http://www.wipo.int/clea/does\\_new/pdf/en/jp/jp006en.pdf](http://www.wipo.int/clea/does_new/pdf/en/jp/jp006en.pdf)