AN INSIGHT ON THE PATENT TERM ADJUSTMENT PROVISIONS IN VARIOUS COUNTRIES

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ABSTRACT

Before the implementation of TRIPS agreement, the term of a patent was usually expressed in a number of years either starting from the filing date of the patent application or from the date of grant of the patent. Significant international harmonization of patent term across national laws was transpired in the 1990s by the implementation of the WTO and TRIPS Agreements. As the patent term is now based on the filing date instead of the patent issue date; delays in prosecution may reduce the term of a granted patent. Patent Term Adjustment (PTA) could effectively reduce any possible patent term reduction caused by Patent Office delays. PTA provision is very well established in USA and available in the public domain. This article provides the details of various statutory provisions in other countries including United States of America, compensating the term of a granted patent, reduced by patent office delays, in the form of Patent Term Adjustment (PTA).

Key words: Patent term adjustment (PTA), Patent Act, Examination, Timelines for applying PTA, Relevant Section.


1. INTRODUCTION

A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent. “Invention” means a solution to a specific problem in the field of technology [1]. Most of the jurisdictions provide for a standard patent term of twenty years.

Patents are frequently referred to as “monopolies”, but a patent does not give the right to the inventor or the owner of a patented invention to make, use or sell anything. The effects of the grant of a patent are that the patented invention may not be exploited in the country by
persons other than the owner of the patent unless the owner agrees to such exploitation. Thus, while the owner is not given a statutory right to practice his invention, he is given a statutory right to prevent others from commercially exploiting his invention, which is frequently referred to as a right to exclude others from making, using or selling the invention. The right to take action against any person exploiting the patented invention in the country without his agreement constitutes the patent owner’s most important right, since it permits him to derive the material benefits to which he is entitled as a reward for his intellectual effort and work, and compensation. Simply put, a patent is the right granted by the State to an inventor to exclude others from commercially exploiting the invention for a limited period, in return for the disclosure of the invention, so that others may gain the benefit of the invention. The disclosure of the invention is thus an important consideration in any patent granting procedure.

In order to be eligible for patent protection, an invention must fall within the scope of patentable subject matter. Patentable subject matter is established by statute, and is usually defined in terms of the exceptions to patentability; the general rule being that patent protection shall be available for inventions in all fields of technology [2].

The term of a patent is the maximum period during which it can be maintained inforce. It is usually expressed in a number of years either starting from the filing date of the patent application or from the date of grant of the patent. In most patent laws, renewal annuities or maintenance fees have to be regularly paid in order to keep the patent in force. Otherwise the patent lapses before its term. The term of a patent or specific "claims" in a patent may also be curtailed by judgment of a court, as where a claim or patent is held "invalid" under the relevant law, and thus no longer enforceable.

Significant international harmonization of patent term across national laws was provided in the 1990s by the implementation of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Article 33 of the TRIPS Agreement provides that "The term of protection available [for patents] shall not end before the expiration of a period of twenty years counted from the filing date". Consequently, in most patent laws nowadays, the term of patent is 20 years from the filing date of the application.

As the patent term is now based on the patent filing date instead of the patent issue date; delays in prosecution may shorten the effective term of a granted patent. Patent term adjustment (PTA) could effectively reduce any possible loss of patent term caused by Patent Office delays. For biotechnology and pharmaceutical inventions, the term of a patent is of particular importance because commercialization often occurs long after the patent application is filed and because research and development costs are often high. Every day in the term of a patent behind a successful product can be highly valuable. PTA leads the term of patent beyond 20 years (normal case).

Patent Term Adjustment (PTA) is one of the alternate mechanism for extending the term of a patent apart from the other provisions such as Patent Term Extension (PTE), Supplementary Protection Certificate (SPC), Pediatric Exclusivity (PED) etc. The extension of patent term in case of PTE, SPC, PED etc. will be possible only if the patents relate to the products that are approved through a regulatory body/mechanism. Further, in these scenarios, in most of the countries, the term of the patent extension is limited to certain category of patents covering the approved product. Unlike the regulatory approval restriction in these cases, the PTA provides extension of the term of the patent primarily delays in issue of patent by the patent office. Further, extension of the term of the patent through PTA may be possible for patents where the patent term extension is not possible with PTE, SPC and PED routes. Therefore, PTA is an assured tool to get term extension of the patent for any category of
patents when the delay occurred from the patent office side in the countries where such provision is applicable.

The PTA provision is very much established in United States and well known in the public domain. There are some established case laws in USA decided by different legal bodies [district courts, court of appeals for federal circuits (CAFCs)] defining the provisions of determining the PTA in various situations. In addition to USA, some other countries also have amended their patent laws to include PTA provisions in their Patent laws. Such countries are viz, South Korea, Singapore, Columbia, Republic of El Salvador, Chile, Republic of Costa Rica, Guatemala, Chile, Honduras and Nicaragua. The objective of this article is to provide more details about the statutory provisions related to PTA in these countries.

2. USA

2.1. Relevant section of Patent Act


This PTA provision applies to original (i.e., non-reissue) utility and plant applications filed on or after May 29, 2000, which include continuation (e.g., a continued prosecution application (CPA)), divisional, or continuation-in-part applications.

2.2. Time line for requesting

USPTO automatically calculate the necessary delays and provide the number of days eligible as PTA. There is no requirement of making request for PTA by the applicant which is unlike to the other countries where applicant has to make a request for granting the PTA within stipulated timeline as defined in the particular country law.

However, if the applicants want that USPTO reconsider the determination of PTA, in that case the applicant has to request within 2 months from the issue date of the patent.

2.3. Rules for applying PTA

As per the American Inventors Protection Act of 1999, there are three main bases for adjusting the term of a utility or plant patent;

(1) If the USPTO fails to take certain actions within specified time frames;

(2) If the USPTO fails to issue a patent within three years of the actual filing date of the application; or

(3) For delays due to interference, secrecy order, or successful appellate review.

2.4. Calculation of PTA period

PTA is calculated based on the rules formed under Patent Term Guarantee Act of 1999, i.e., 35 U.S.C § 154 (b) and 37 CFR §§ 1.702-1.704.

PTA = A delay + B delay + C delay - Applicant Delay - Overlapping delays

14-4-4-4-4 rule - “A delay”

- Failure of the USPTO to issue the first office action within 14 months of filing of the application and all other office actions within 4 months of receipt of an applicant response.

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Year rule - “B delay”
- Failure of PTO to issue a patent within 3 years from filing and the delays are calculated under 35 U.S.C. §154(b)(1)(B)

Rule - “C delay”
Delays due to PTAB appeals, interferences, and secrecy orders are calculated under 35 U.S.C. § 154(b)(1) (C) (i) - (iii)

Rule - Applicant delay
- Delays due to failure of applicant to respond within 3 months of mailing of an office action are calculated under 37 C.F.R. §1.704(b)
- Delays due to abandonment of the application are calculated under 37 C.F.R. §1.704(c)(3)
- Delays due to submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or notice of allowance are calculated under 37 C.F.R. §1.704(c)(6)
- Delays due to submission of a reply having an omission are calculated under 37 C.F.R. §1.704(c)(7)
- Delays due to submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed are calculated under 37 C.F.R. §1.704(c)(8)
- Delays due to submission of an amendment under §1.312 or other paper, other than a request for continued examination in compliance with §1.114, after a notice of allowance are calculated under 37 C.F.R. §1.704(c)(10)
- Delays due to failure to file an appeal brief in compliance with §41.37 of this chapter within three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed are calculated under 37 C.F.R. §1.704(c)(11)
- Delays due to submission of a request for continued examination under 35 U.S.C. 132(b) after any notice of allowance are calculated under 37 C.F.R. §1.704(c)(12)

Rule – Overlaps
The number of days that are overlapping between the A and B delays or A and C delays are calculated under 35 U.S.C. §154(b)(2)(A).
- The number of overlapping days of delay is subtracted from the PTA so that the same day is not counted twice as a delay.

3. SOUTH KOREA

3.1. Relevant section of Patent Act
Article 92(2) of the Korean Patent Act [4] deals with the patent term adjustment (PTA). The PTA system was introduced in Korea in 2012 as a result of the Korea-US Free Trade Agreement. It applies to all patent applications filed (or internationally filed, in case of PCT applications) on or after March 15, 2012.

3.2. Time line for making request
PTA can be granted only upon a request by the patentee, which must be made within three months from the date patent, is issued. The Korean Intellectual Property Office (KIPO) does not notify patentees of the PTA eligibility of patents of the PTA period that can be granted for

http://www.iaeme.com/IJIPR/index.asp  4 editor@iaeme.com
the patents. Thus, patentees need to check whether their patents are eligible for PTA and be cognizant not to miss the 3-month deadline for requesting PTA.

3.3. Rules for applying PTA

If a patent is issued more than four years after the filing of the patent application and more than three years after a request for examination, the patent will be eligible for PTA.

In the case of a PCT national phase application, the base date for calculating the 4-year period is the national filing date. In the case of a divisional application, the base date for calculating the 4-year period is the actual filing date of the divisional application.

3.4. Calculation of PTA period

The basic calculation of PTA is the number of days beginning the day after 4 years from filing date of the patent application (or in the case of PCT applications, 4 years after entering the Korean national phase) or 3 years after the request for examination (whichever is later) and ending on the date the patent is registered. This period is then reduced by the number of days of delay that are attributable to the applicant rather than KIPO.

\[
[\text{Extendable Patent Term}] = \left[ \text{Period from the extension reference date to the patent issuance date} \right] - \left[ \text{Delay by the applicant} \right]
\]

“Extension reference date” refers to the latter of four years from the filing of the patent application or three years after the filing of a request for examination.

“Patent issuance date” refers to the date of the payment of the issuance fee.

“Delay attributable to the applicant”

The Enforcement Decree of the Korean Patent Act gives the following examples of delay attributable to the applicant:

- Any period of time taken by the applicant to respond to an office action or notice from Korean Intellectual Property Office (KIPO) rejecting the application, unless the asserted rejection grounds are overcome without any amendment to the application (in which case there is no applicant delay);
- Any extension of a designated deadline that is requested by the applicant (though only the time actually taken by the applicant to respond will be counted as delay, if the applicant responds prior to the extended deadline); and
- The period between the date the notice of allowance is received to the date the registration fee is paid.

4. SINGAPORE

Singapore enables patent owners extend the life of a patent directed to any kind of subject matter, not just pharmaceuticals. This extension is similar to the patent term adjustment (PTA) available in the US in many ways.

4.1. Relevant section of Patent Act

Section 36 of the Singapore Patent Act (Chapter 221) deals with term of the patent and section 36A of the Act deals with the provisions related to patent term adjustment [5].

4.2. Time line for making request

PTA can be granted only upon a request by the patentee, which must be made within six months from the date of the patent grant. The Singapore patent office does not notify
patentees of the PTA eligibility of patents or of the PTA period that can be granted for the patents.

4.3. Rules for applying PTA
   (a) There was an unreasonable delay by the Registrar in granting the patent; and
   (b) The proprietor of a patent has made an application, within six months from the grant of the patent, for PTA and has satisfied the Registrar that there was in fact an unreasonable delay.

The Unreasonable Delay:
A delay by the Registrar in granting a patent shall not be treated as an unreasonable delay unless the patent is issued more than four years after the filing of the patent and more than two years after a request for examination. In the case of a PCT national phase application, the base date for calculating the four year period is the national filing date. In the case of a divisional application, the base date for calculating the four year period is the actual filing date of the divisional application.

4.4. Calculation of PTA period
The Registrar shall extend the term of the patent by the period in which
(i) the date of filing of the application for the patent and the date of issue of the certificate of grant, excluding any period attributable to an act or omission of the applicant, exceeds 4 years; or (ii) the interval between the date on which the applicant filed a request for a search and examination report and the date of issue of the certificate of grant, excluding any period attributable to an act or omission of the applicant, exceeds 2 years; whichever is the longer period.

5. COLOMBIA

5.1. Relevant section of Patent Act
On September 29, 2014, the Colombian Government issued Decree 1873 [6] providing patent term adjustments to compensate patent owners in the event of unjustified delays by the Colombian Patent Office in issuing patents. The decree was issued in order to comply with the regulations established by the Andean Community of Nations, the ADPIC (known as TRIPS in English) and the United States–Colombia Free Trade Agreement.

This compensation does not apply to pharmaceutical patents.

Pharmaceutical patent applications are an exception for this regulation, is because in case of extending the protection period for more than 20 years, it would not allow third parties to obtain access, domain or simply a greater exploitation of said pharmaceutical products, which might be crucial for public health.

5.2. Time line for requesting
A patent owner must request restoration of the patent term within two months of the date of issuance of a patent, indicating the PTO delay and the corresponding patent term adjustment being requested.

5.3. Rules for applying PTA
According to the decree, a patent term is extendible for each day of “unreasonable delay” in the granting of a patent. An “unreasonable delay” exists when a decision to grant a patent takes longer than; unreasonable delays over 5 years from the application’s filing date or over
3 years from the request of the patentability examination, whichever is the latest, always that the periods related to the applicant’s actions, are not included for the delayed periods determination”.

5.4. Calculation of PTA period
In case the PTA request is accepted, it would be added one calendar day to the restoration period, for each calendar day of unreasonable delay, which would be counted from the next calendar day in which the patent’s protection period has expired. Lastly, it is important to point out that that the fact of applying the restoration term, does not avoid the patent holder for continue paying the annuities for the granted patent maintenance.

6. REPUBLIC OF EL SALVADOR

6.1. Relevant section of Free Trade Agreement
The Government of the Republic of El Salvador, allow patent term adjustment as per article 15.9(a) [7] of the free trade agreement between the Dominican Republic, Central America and the United States. PTA is available for any patent application filed after January 20, 2006 [8].

6.2. Rules for applying PTA
PTA is available for any patent if the registration of a patent is delayed more than;
(i) Five years from the filing date of the application; or
(ii) Three years from the date of filing a request for examination.

It is possible to request PTA of a patent in El Salvador for up to an additional 550 days due to delays in the granting of a patent by the Patent Office in El Salvador.

7. REPUBLIC OF COSTA RICA

7.1. Relevant section of Patent Act
Article 17 [9] - Duration of patent protection

1. Patents shall be valid for twenty (20) years, beginning from the date on which the application is filed with the Industrial Property Registry or, in the case of patents processed under the Patent Cooperation Treaty, from the date of international filing (as amended by LAW No. 8686 of November 26, 2008).

2. Notwithstanding the provisions of paragraph 1 above, if the Industrial Property Registry takes more than five (5) years to grant a patent, beginning from the date on which the application is filed with it, or takes more than three (3) years, beginning from the application for the substantive examination of the patent provided for in Article 13 of this Law, whichever comes last, the owner shall be entitled to petition the Industrial Property Registry for compensation for the period of patent validity. Said petition shall be filed in writing within three (3) months following the grant of the patent (as amended by LAW No. 8686 of November 26, 2008).

7.2. Timeline for Requesting
Art. 17(2) petition shall be filed in writing within three (3) months following the grant of the patent.

7.3. Rules for applying PTA
Art. 17(3) after receiving such a request, the Industrial Property Registry shall provide compensation for the period of the patent, by granting one day for every day over the periods of time referred to in paragraph 2. However, periods of time ascribable to actions taken by the
applicant shall not be included in the determination of such delays. Notwithstanding the above, total compensation for the patent term may under no circumstances exceed 18 months.

8. REPUBLIC OF GUATEMALA

Article 126 bis [10] Term of the patent for arrears not attributable to the applicant, patent has been granted, its owner may request that the Registry adjust the term of the validity of the patent established in the previous article, if one of the cases occurs following not attributable to the applicant:

a) When, during the processing of the patent application, the Registry suffers an unjustified delay,

When the Registry issues the patent in a term greater than five (5) years from the date of the presentation of the patent application, or within a period of more than three (3) years from the date on which the interested party requested the substantive examination, whichever is later; or

b) When the patent refers to a pharmaceutical product and the authority administrative authority issues the authorization to market the product within a period exceeding three (3) months from the date of the presentation of the patent application.

The extension of the term of the patent must be equivalent to the amount of time for which the period established in the previous paragraphs was exceeded.

The term provided in article 126 of the present law, may only be adjusted in the terms expressly provided for in this article.

9. CHILE

Chile also enables patent owners extend the life of a patent directed to any kind of subject matter, not just pharmaceuticals.

9.1. Statutory provisions related to PTA


9.2. Patents Eligible for PTA

(a) There was an unjustified administrative delay by the Registrar in granting the patent; and

(b) The proprietor of a patent has made an application, within six months from the grant of the patent, for PTA and has satisfied the Registrar that there was in fact an unreasonable delay.

9.3 Extendable Patent Term:

There has been an unjustified administrative delay in the grant of the patent and the term for grant was more than five years from the date of filing of the application or three years from the request for examination was made, whichever comes later. The PTA shall only cover the period proved to be an unjustified administrative delay.

10. HONDURAS AND NICARAGUA

The Government of the Republic of Honduras, the Government of the Republic of Nicaragua, also allows patent term adjustment as per article 15.9(a) [7] of the free trade agreement between the Dominican Republic, Central America and the United States.
10.1. Rules for applying PTA

PTA is available for any patent if the registration of a patent is delayed more than;

(i) Five years from the filing date of the application; or
(ii) Three years from the date of filing a request for examination.

The following table (Table 1) summarizes the details of the Patent Term Adjustment (PTA) in various countries discussed in this article for ready reference.

Table 1 Brief summary of Patent Term Adjustment (PTA) provision in various countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Statutory Provision</th>
<th>Effective date</th>
<th>Rules for applying PTA / Patents eligible for PTA</th>
<th>Time line for requesting</th>
<th>Limit on number of days for PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>35 U.S.C. § 154(b)</td>
<td>29 May 2000</td>
<td>if the USPTO fails to take certain actions within specified time frames;</td>
<td>USPTO automatically calculate the necessary delays</td>
<td>No such limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>if the USPTO fails to issue a patent within three years of the actual filing date of the application; or for delays due to interference, secrecy order, or successful appellate review.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Korea</td>
<td>Article 92(2) of the Korean Patent Act</td>
<td>15 March 2012</td>
<td>Patent is issued more than four years after the filing of the patent application or more than three years after a request for examination</td>
<td>Patentee must make a request within three months from the patent issue date</td>
<td>No such limit</td>
</tr>
<tr>
<td>Singapore</td>
<td>Section 36 of the Singapore Patent Act (Chapter 221)</td>
<td>14 February 2014</td>
<td>There was an unreasonable delay by the Registrar in granting the patent; and</td>
<td>Patentee must make a request within six months from the patent issue date</td>
<td>No such limit</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>The proprietor of a patent has made an application, within six months from the grant of the patent, for PTA and has satisfied the Registrar that there was in fact an unreasonable delay.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Columbia*</td>
<td>As per Decree 1873 issued by the Colombian Government</td>
<td>29 September 2014</td>
<td>Unreasonable delays over 5 years from the application filing date or over 3 years from the request of the examination, whichever is later</td>
<td>Patentee must make a request within two months from the patent issue date</td>
<td>No such limit</td>
</tr>
<tr>
<td>El Salvador</td>
<td>As per article 15.9(a) of the free trade agreement between the Dominican Republic, Central America and the United States</td>
<td>20 January 2006</td>
<td>delay more than 5 years from the filing date of the application or delay more than 3 years from the date of filing a request for the examination</td>
<td>-----</td>
<td>Not more than 550 days</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>Article 17 (2) of Law on Invention Patents, Industrial Designs and Utility Models As amended by LAW No. 8086 of November 26, 2008</td>
<td>26 November 2008</td>
<td>more than five (5) years to grant a patent, beginning from the date on which application is filed with it; or takes more than three (3) years from the application for the substantive examination.</td>
<td>Patentee must make a request within three months from the patent issue date</td>
<td>Not more than 18 months</td>
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</tr>
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<tbody>
<tr>
<td>Guatemala</td>
<td>Article 126 bis</td>
<td></td>
<td>when the Registry issues the patent in a term greater than five (5) years from the date of the presentation of the patent application, or within a period of more than three (3) years from the date on which the interested party requested the substantive examination, whichever is later;</td>
<td>----</td>
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</tr>
<tr>
<td>Chile</td>
<td>Article 53 bis1</td>
<td>20 January 2007</td>
<td>There has been an unjustified administrative delay in the grant of the patent and the term for grant was more than five years from the date of filing of the application or three years form the request for examination was made, whichever comes later.</td>
<td>Patente must make a request within six months from the patent issue date</td>
<td>---</td>
</tr>
<tr>
<td>Honduras &amp; Nicaragua</td>
<td>As per article 15.9(a) of the free trade agreement between the Dominican republic, central America and the united states</td>
<td></td>
<td>delay more than 5 years from the filing date of the application or delay more than 3 years from the date of filing a request for the examination</td>
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*does not apply to pharmaceutical patents.

### 11. CONCLUSION

The provision of Patent Term Extension (PTA) in the countries where it is applicable is beneficial to the patentee for enhanced patent term which increase the monopoly and by not allowing the third parties to access. However, such PTA extension may avoid the generic player entry in to these markets, which might be crucial for public health in case of biotechnology and pharmaceutical patents. Therefore, the countries where the PTA provisions are applicable must be vigilant particularly in case of biotechnology and pharmaceutical patents by avoiding the patent office delays which in turn restrict the patent life term to 20 years even if the patent application is granted and maintained.

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States, available at http://www.wipo.int/edocs/lexdocs/treaties/en/cafta-
do/trt_cafta_do.pdf


http://www.wipo.int/edocs/lexdocs/laws/es/gt/gt041es.pdf

by Decree-Law No.3), available at