

TRANS-PACIFIC PARTNERSHIP AGREEMENT (TPPA)

跨太平洋伙伴关系协定（跨协）

Changes Required to Accede to the TPP: Intellectual Property (IP)

就加入跨协所需的修改：知识产权

In collaboration with:
联合著作：



社会经济研究中心
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Intellectual Property (IP) under TPPA

The TPP sets a strong standard for the protection and enforcement of IP rights to give traders and investors the confidence that they will face the same set of rules across all TPP countries. Some of these provisions, no doubt have somewhat exceeded the WTO Agreement on Trade-Related Aspect of Intellectual Property (TRIPS Agreement), but are intended to help streamline IP transactions, increase transparency and lower the costs of doing business, while providing incentives for businesses to invest in creative industries.

This Chapter highlights the key areas of IP protection, namely on copyright, geographical indications, industrial designs, patents, trade marks, etc. The additions in TPP Agreement includes IP provisions for pharmaceuticals, and technological issues related to cybersquatting and internet services.

KEY POINTS

1. Copyright - Provides protection and enforcement of copyrights and related rights, building upon the World Intellectual Property Organization Internet Treaties.
2. Geographical Indications - Includes rules to promote transparent and fair administrative systems for the protection of geographical indications.
3. Industrial Designs - Protects industrial designs against unauthorized use, consistent with the Hague Agreement.
4. Patents - Ensures patent protection for inventions in all fields of technology; and promotes transparent and efficient patent administration systems.
5. Pharmaceuticals – Progression of existing regimes, systems and laws on Patent linkage; Data protection; and availability of early working exceptions.
6. Trademarks - Provides protection against infringement; and fosters transparent and efficient rules and procedures across the TPP region.



TRIPS Agreement

- Set forth the minimum standards for intellectual property (IP) protection among WTO members.
- Any provisions that require more stringent protection than those set in the WTO TRIPS Agreement are known as TRIPS-plus (TRIPS+) measures.
- TRIPS has provisions that allow a degree of flexibility and room for countries to adapt their own patent and intellectual property laws to accommodate their developmental needs.

Changes Required to Ratify TPP Agreement

Some of the TPP provisions compel Malaysia to make amendments to its national laws before we can ratify TPP. These can include changes to *Patent Act 1983*; *Copyright Act 1987*; *Trade Marks Act 1976 (TMA)*; *Control of Drug & Cosmetics Regulations 1984*; *Geographical Indications Act 2002*; and *Communications and Multimedia Act 1998*;

Copyright Term Extension

- Under Article 18.63, the TPPA requires minimum copyright terms of 70 years, or the author's life plus 70 years for literary works, performance, musical, or artistic works.
- Compared with Malaysia's Copyright Act 1987, this provision extends the term of copyright by 20 years. Malaysia needs to amend its current law, thus bringing it to be on par with that of US and Europe.
- While increasing returns to holders of valuable work, the extension may provide disincentive for software and/or communications related businesses in terms of creation of new works, and likely to have impact on software and communications-related businesses.

Trademark Terms of Protection

- Signatory countries shall provide a minimum 10 years trademark terms of protection. TRIPS sets the minimum term at 7 years; renewable indefinitely.

Malaysia's Trade Marks Act 1987 (TMA) already affords registered trademark holders 10 years protection, renewable every 10 years in perpetuity.

- Article 18.18 opens up the scope for easier registration of non-traditional trademarks, such as sound. Signatories must not require a sign to be "*visually perceptible*" as pre-requisite condition for trademark application.

This new obligation requires Malaysia to amend its TMA to recognize and allow the registration of non-traditional trade marks. The present section 3(2)(a) of TMA defines trademark use as "*use of a printed or other visual representation of the mark*".

- Well-known Marks: TPP countries are required to provide measures to reject application or cancel the registration of a trade mark, if it is identical or similar to a well-known trademark. No details were given in TPPA Agreement on the standards to apply in the assessment of well-known trademarks.

For Malaysia, well-known trademarks are already being recognized under section 14(1)(d) of TMA.

- Article 18.19 of TPPA also mandates the inclusion of collective marks and certification marks as trademarks. Section 56 of TMA already has provision for certification trade marks. However, obligation of collective marks required under TPPA is new to the current legislation, hence shall require inclusion of this provision in the Trade Marks Act 1976 (TMA).

- TPP members are committed to provide transparent systems for registering trademarks, including electronic application systems and online databases of registered trademarks.

The Intellectual Property Corporation of Malaysia (MyIPO), which is empowered with matters relating to IP in Malaysia, has establish online search, registration, filing and tracking system.

Geographical Indications (GIs)



- Geographic indications (GIs) are marks that identify product as coming from a specific territory or region.

Article 18.30 grants each Party the flexibility to protect GIs through a trademark system, a *sui generis* legislative system or through legal means.

- TRIPS Agreement does not require signs serving as GI to be protected under trademark system.
- Malaysia's TMA 1976 excludes geographical names from registration of trademark.
- GIs is govern under the Malaysian Geographical Indications Act 2000, where a registered GI is granted a 10-year protection from the date of filling, renewable every 10 years.

Trade Marks Act 1976 (TMA)

Section 10(1)(d):

In order for a trade mark (other than a certification trade mark) to be registrable, it shall contain or consist of at least of the following particulars:

“a word having no direct reference to the character or quality of the goods or services not being, according to its ordinary meaning, a geographical name or surname.”

Industrial Design

- In consistent with TRIPS, the TPP has in place provision for an extension protection duration of no less than 10 years.
- Malaysia's Industrial Designs Act 1996 allows an extension of duration of protection to 25 years, thus fully comply with TPPA obligation.

Domain Names

- TPPA Article 18.28 requires signatories to enact anti-cybersquatting remedies to protect trademark holders against registration or use of domain names that are identical or similar to the trademarks with intent to profit.
- Hence, for their top level country-code top-level-domain (ccTLD)*, signatories shall provide:

Note:

* Malaysian Network Information Centre Berhad (MYNIC), an agency under the Ministry of Science, Technology and Innovation (MOSTI) is the sole administrator and registrar for web addresses that bear the country code ".my". MYNIC administers 8 domain name categories, including ".my", ".com.my", ".net.my", ".org.my", ".edu.my" and ".gov.my".

Domain Names

- a dispute resolution procedure based on or modelled along the principles in UDRP, and
 - a reliable online database of contact information for those who have registered domains,
- in accordance with each Party's law.
- For Malaysia, MYNIC is the sole administrator that manages the top level country domain name in the country**.
 - All domain disputes are governed by MYDRP (Domain Name Dispute Resolution Policy).
 - MYNIC has appointed Kuala Lumpur Regional Centre for Arbitration (KLRC) as the independent dispute resolution service provider for the “.my” domain name.

Cybersquatting

- Most domain name disputes are due to cybersquatting.
- Cybersquatting is the practice where third party registers trademark, or names of famous people or businesses, with which they usually have no connection as domain names.

Uniform Domain Name Dispute Resolution Policy (UDRP)

- UDRP has been adopted by the Internet Corporation for Assigned Names and Numbers (ICANN).
- Under UDRP, most types of trademark-based domain-name disputes must be resolved by agreement, court action, or arbitration before a registrar will cancel, suspend, or transfer a domain name

Liability for Internet Service Provider (ISP)*

- Internet service providers can face risks of copyright liability resulting from actions of their users. The TPPA provides safe-harbor protection to ISPs when they store content on-line or link to third-party content.
- TPP signatories shall provide a mechanism for ISPs, without a court order, to expeditiously remove or disable access to allegedly copyright infringing material on their networks or systems upon obtaining knowledge of the infringement. This provision, however, does not require ISPs to monitor the uploads on their networks to receive this safe-harbor protection
- Under present Malaysian copyright law, ISP is not required to disable or remove materials that infringes copyright in its network, unless being notified by the copyright owners (section 43H of Copyright Act).

Notes:

- Internet service providers (ISPs) include firms that provide services for assessing and using the Internet, including e-commerce services to users for free (such as Dropbox, Facebook, or Google or free apps).

Patent Related Provisions

Patentability

- TPP signatories shall ensure patents are available for any inventions (both products and processes) which are new, involve inventive step and capable of industrial application.

New Use of known product is Patentable

- Under TRIPS, members have the flexibility to establish its own standard of patentability criteria to grant patents.
- Under TPPA, one of the following is patentable:
 - new uses of a known product;
 - new method of a known product;
 - new process of using known product
- The wider scope of patentability under TPPA can probably open up floodgates for “ever-greening” practices of pharmaceuticals. Such manipulations may limit the access to affordable medicine.

Malaysia Patents Act 1983 Patentability

An invention is patentable if it is new, involves an inventive step and is industrially applicable (s.11). An invention may be or may relate to a product or process (s.12).

Inventive step implies improvement or advancement over and above what is already known or obvious (s.15), i.e. the idea permitting in practice the solution to a specific problem (s.12)

12-month Grace Period for Prior Art

- Article 18.38 introduces a 12-month grace period protection to certain public disclosures that limiting patentability. This means than an invention can be made public and shall be protected under a patent filed up to 12 months later.
- Such provision allows safety net for researchers or SMEs to publish their findings or invention before filing for patent.
- Malaysia has established similar provision under Section 14, 14(2)(a) and 14(3).

Publication of Patent Application

- To promote transparency about new inventions, member countries undertakes to publish pending patent applications promptly after the expiry of 18 months from the filing date, or as soon as practicable (Article 18.44).
- According to Malaysia’s Patents Act 1983 under Section 34(1) and (2), information relating to patent application shall be made for public inspection after 18 months from filing date and upon payment of prescribed fee.

Enhanced Protection – Patent Term Adjustment

Patent Term Adjustment (PTA)

- Article 18.46 of TPPA requires parties to extend the 20-year patent term to compensate the patent holder if there is “unreasonable delay”.
- There are no such provision in TRIPS Agreement nor in Malaysia’s current regulatory practice.
- Unreasonably delay in granting of the patent can be defined as:
 - If patent has not been granted within 5 years from the date of filing; or
 - If patent has not been granted within 3 years after a request for examination has been made.

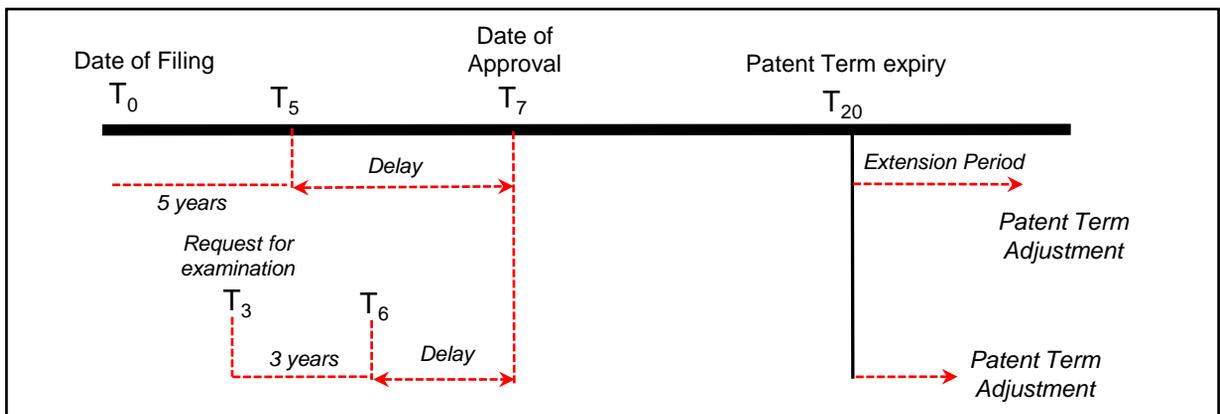


Pharmaceutical Extension of Patent Term

- For pharmaceutical products, patent adjustment is required to compensate patent holder for delay or unreasonable curtailment resulting from marketing approval process.

Patent Term

- In invention of medical drugs or pharmaceuticals, the patent term is crucial because the process of commercialization usually only takes off long after the filing.
- USA already has PTA to allow for delays in patent application, while patent laws in Australia and Japan currently allow an extension of up to 5 years for regulatory delays.
- Under Singapore-EU FTA, the extension may not exceed 5 years.
- TPP may require legislative changes in countries that do not have this mechanism, e.g. New Zealand and Malaysia.



- No maximum extension term is specified in TPPA for compensating patent or marketing approval delays. But, the likelihood of extending the patent term is minimal for Malaysia. The Ministry of Health client charter for registration of drugs by the Drug Control, Authority is set as 245 working days.
- The extension obligation can be met within the current practice given the improvement and efficiency in the patent registration process of approval authorities such as BPFK (National Pharmaceutical Control Bureau) and MyIPO (Intellectual Property Corporation of Malaysia).

Enhanced Protection - Data Exclusivity (DE)

Data Exclusivity

- Data exclusivity (DE)* is the time period when imitation drugs or 'generic'*** medicine cannot rely or piggy back on innovator's test data to support registration and approval of similar products..
- Under TPPA, protection of undisclosed test data submitted for marketing approvals is granted at least 10 years for agricultural chemicals, and 5 or 8 years for pharmaceuticals.
- In Malaysia, the DE directive under Regulation 29 of the Control of Drugs and Cosmetics Regulation 1984 came into force on 1 March 2011. It allows protection of small-molecule*** drugs or pharmaceuticals test data for a period of 5 years. Biologics are however not stated in this directive.

Regulation	Patent Granted in Malaysia	Data Exclusivity (DE)			DE Expiry in Malaysia under TPPA	Patent Expiry in Malaysia
		Granted in Origin country	Granted in Malaysia	DE Expiry in Malaysia		
Present Malaysia Law	31.3.2010	21.9.2010	19.1.2012	21.9.2015	-	7.4.2024
						<i>Patent granted extended beyond data exclusivity by 103 months</i>

Regulation	Patent Granted in Malaysia	Data Exclusivity (DE) under TPPA			DE Expiry in Malaysia under TPPA	Patent Expiry in Malaysia
		Granted in Origin country	Granted in Malaysia	DE Expiry in Malaysia		
TPP Agreement	31.3.2010	21.9.2010	19.1.2012	19.1.2017	7.4.2024	
						<i>Patent term granted extended beyond DE by 87 months</i>

Notes

- Patent term protection safeguards the original innovation while DE protects the innovator's investment in getting marketing approval. Although DE is complementary, both patent and DE may or may not run concurrently. Article 18.54 affirmed that the Party shall not alter the DE period of protection in the event that the patent protection terminates on a date earlier than DE.
- ** Generic is the copy of same active chemicals of the patented medicine which are allowed to be marketed when the patent expires. Cost of generics are usually lower.
- *** Small molecules pharmaceuticals are derived from simple chemical synthesized compounds with small molecular weight. These conventional drugs that currently make up large proportion of the pharmaceutical market.

Market Exclusivity for Biologics

Market Exclusivity for Biologics

- TPPA provides explicit protection for biologics* by granting market exclusivity (inclusive DE). This may appear as market barrier entry to *follow-on products*, hence potentially hindering access to affordable medicine.
- Signatories have a choice between: (i) an 8-year data exclusivity period for biologic medicines; or (ii) at least 5 years with possible additional measures that could deliver a comparable market outcome.
This provision appears that regardless of the option chosen, the selected option must provide “comparable outcome” in the market.
All Parties agrees to consult again after 10 years on the period of exclusivity.
- Malaysian law currently has no protection for biologics, but opts to place 5 years of DE and provide market protection through other measures.
- Malaysia’s registration records show that existing biosimilars were registered between 6 - 13 years after the first marketing approval of their biologics. This implies that the impact on public’s access to cheaper alternative medicine is minimal.
- Malaysia requires filing of market approval within 18 months from the first approval anywhere in the world, otherwise the exclusivity will be deemed forfeited..
- Malaysia is granted transition period of 5 years to introduce data protection for biologics.

	Patent Granted in Malaysia	Market Exclusivity for Biologics		5-Year Exclusivity under TPPA	8-Year Exclusivity under TPPA
		Origin country	Approval filing in Malaysia		
TPPA	31.3.2017	21.9.2017	21.3.2019	21.3.2024	21.3.2027

Notes:

* *Biologics - Biotechnology has created the biologics. Biologics are biological medicines consisting of large molecule usually derived from cell cultures. The general characteristic of biologic medicines is the conditions of the manufacturing process. Evaluating and monitoring the quality, safety and efficacy of the process imprint unique characteristics into biologics, hence “the process is the product”. Examples of biologics include vaccines and medicines used in cancer treatment.*

Biosimilar or Follow-on Biologic

When the patent protection for biologic ends, rival firms are allowed to sell the equivalent version, known as biosimilar. Biosimilar is “similar” but not identical version of a biologic after the innovator patent has expired. Producing a biosimilar (*also known as follow-on biologic*) is far more complicated due to the complex molecular structure and the unique manufacturing process of biologic medications.

Patent Linkage

- Under TPPA, parties agree to put in place a system that enable patent owner be notified if a generic version (which relies on evidence of the patented product) has been submitted and seeking approval during the term of the applicable patent.

This system provides the patent holder the remedy to enforce its actions against validity or infringement prior to the marketing of the generic product.

- Provision of linkage in TPPA can create delays or limit generic competition which are relatively more affordable medicines.
 - TRIPS Agreement does not have patent linkage system; hence WTO members have the right to grant regulatory approval of generic medicines independent from patent status.
 - The Malaysian law contains no provision that links the patent system to marketing approval process.
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TPPA IP – The Way Forward for Malaysia

Summary for Intellectual Property (IP) Obligations

- In general, the TPP's chapter on intellectual property (IP) sets the new norm not only for member countries, but for future bilateral and regional trade agreements.
- Malaysia seems to be in compliance with most requirements, but there are issues which have generated much concern, e.g. patent term extensions and data exclusivity for biologics, that need to be addressed in order to accede to the TPPA formally.
- Malaysia has been granted transition periods to apply most of these TPP's obligations.

TPPA Obligations	Article in Chapter 18	Transition Period
Ratify or accede to international conventions and protocols	18.7.2 (a),(b),(c),(d)	4 years
Trademarks - Types of Signs Registrable as trademarks	18.18	3 years
Patent Term Adjustment (PTA)	18.48.2	4.5 years
Protection for Biologics	18.51.1(b)	5 years
Patent Linkage	18.53	4.5 years
Copyright Term extension	18.63(a)	2 years
Special Requirements Related to Border Measures – provide for applications to suspend the release of, or to detain, suspected counterfeit or confusingly similar trademark or pirated copyright goods that are imported	18.76	4 years

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