

# The importance of Intellectual Property Rights for progress

A reform agenda for ASEAN countries

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**Geneva Network, United Kingdom**



**Institute for Democracy and Economic Affairs, Malaysia**



**Minimal Government Thinkers, Philippines**



**Paramadina Public Policy Institute, Indonesia**



**Siam Intelligence Unit, Thailand**



**Viet Nam Institute for Economic and Policy Research**

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## Summary

- In order to secure sustainable economic growth and achieve high-income status, ASEAN countries need to shift from basic manufacturing and the export of commodities towards innovation and higher-value knowledge-based goods and services. To achieve this ASEAN countries will need to integrate deeper into global R&D networks and manufacturing value-chains, which are increasingly knowledge-based.
- A strong framework for the protection of intellectual property rights is key to this transition, as it gives certainty to foreign investors, who bring with them valuable knowledge, technology and technical capacity that may be missing locally. Strong Intellectual Property Rights (IPRs) also help local businesses and entrepreneurs develop goods and services, and enter into cross-border alliances and partnerships.
- ASEAN countries are well-placed to move up the value-chain and become more innovative, thanks to their strong human resources and their existing strengths and capabilities.
- In order to build upon these considerable strengths and accelerate the transition towards more innovative, knowledge-based economies, ASEAN governments will have to reform their IPR systems to the highest global standards. This process has already begun, but there is still some distance to travel.
- According to international comparative indices the strength, scope and efficiency of the IP framework in Malaysia, Indonesia, Viet Nam, Thailand and the Philippines is still well below the highest global standards.
- Our report identifies major issues within these countries' IPR frameworks and makes suggestions for reform.
- **Patents.** As ASEAN countries shift from low-value manufacturing towards value-added manufacturing and R&D activities in knowledge-based sectors, a strong framework for the protection and enforcement of patents is crucial. Patents are central to the business models of the highest-value industrial sectors, including the life sciences, semiconductors, manufacturing of all kinds of electronic equipment and appliances, and natural gas extraction. ASEAN countries should focus on the following areas:
  - » Delays in examining patents: All ASEAN countries in this report undermine the value of patents through delays and backlogs in their national patent offices, which eats into the twenty-year term of a patent. Delays in Thailand are particularly severe.
  - » Granting patents for useful inventions: Indonesia and the Philippines have created uncertainty within their patent systems by making it more difficult to secure patents for a range of important innovations.
  - » Clarity over the use of compulsory licenses: Malaysia, Indonesia and the Philippines have shown willingness to issue compulsory licenses for medicine patents, creating great uncertainty within their framework of IPRs.

- **Copyright** is crucial to ASEAN'S growing creative and ICT industries, yet copyright infringement is widespread, particularly online. Although some countries have taken steps to improve their copyright laws, enforcement is difficult. Often there is no injunctive relief that enables rights holders to disable infringing content online pending adjudication, and a lack of mechanisms to allow cooperation between authorities and rights holders against online piracy.
- **Trademarks.** Despite the importance of strong trademark protection to local business and economic development, trademarks are routinely infringed throughout ASEAN with counterfeit goods available across a wide range of products including consumer goods, semi-conductors and electronics, spare parts, chemicals, IT goods, luxury items, pharmaceuticals and food and drink. While many countries have recently strengthened trademark laws, legal and procedural obstacles still exist to securing trademark rights. Customs officials also often lack the authority to act against infringing goods in transit.
- **Trade secrets.** As business increasingly becomes digitised, trade secret laws are vital to protect companies from theft of valuable know-how, plans, technical and customer information. ASEAN governments have recognised the importance of trade secret laws to the overall innovation ecosystem and have taken steps to improve laws in this area.
- **Regulatory data protection.** The data produced during the development of medicines, veterinary medicines and agricultural chemicals is valuable, and its protection from use by competitors is an increasingly important form of IPR. Most ASEAN countries either provide insufficient terms of protection for this data, or none at all. This hampers the ability of ASEAN companies to participate in global Research and development (R&D) networks and high-tech manufacturing.

## SUMMARY OF RECOMMENDATIONS

- |  |   |
|--|---|
| ✓ Put strong IPRs at the centre of national economic development and investment promotion strategies | ✓ Enable courts and officials to act against goods that infringe trademarks, including those in transit between countries |
| ✓ Speed up the examination of patents  | ✓ Raise awareness of the importance of trade secret protection amongst the business community                             |
| ✓ Do not discriminate against specific technologies in the granting of patents                       | ✓ Provide sufficient terms of regulatory data protection for medicines, veterinary medicines and agricultural chemicals   |
| ✓ Restrict the use of compulsory licensing of patents to true emergencies                            |   |
| ✓ Strengthen the enforcement of copyright, particularly online                                       |   |

## Introduction – Why intellectual property rights matter to ASEAN countries

**Economists agree that sustainable economic growth depends on higher-value, knowledge-based services, high-tech manufacturing, research and development, and less reliance on the export of commodities and natural resources. Domestic manufacturing sectors within ASEAN member states, while increasingly diversified, are largely focused on the assembly of products designed and manufactured elsewhere. There is also too much reliance on the export of natural resources. For ASEAN countries to join the ranks of high-income countries, they need to continue to commit and invest in the building of a knowledge economy.**

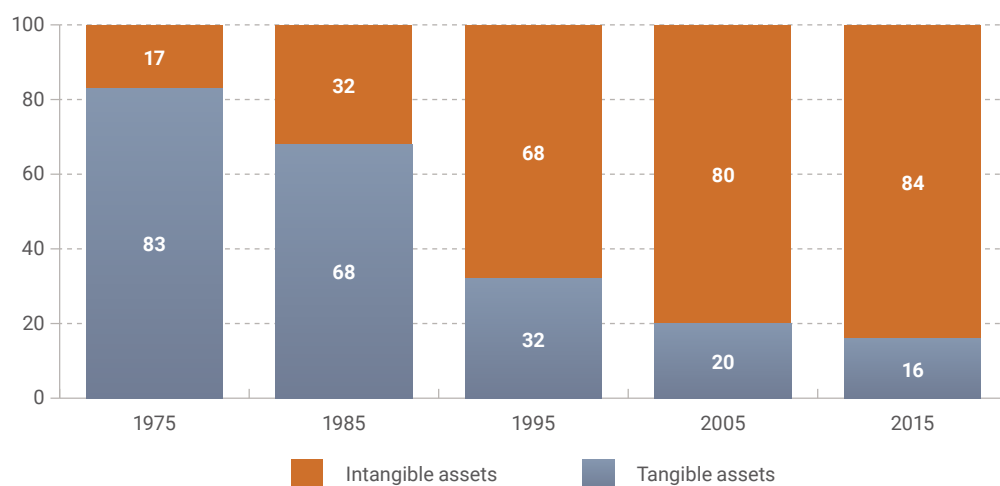
Innovation-led industries such as biopharmaceuticals, information technology, chemicals and entertainment underpin sustainable growth and employment in the economies of most high-income countries. Consider the United States. In 1975, 83 percent of its 500 biggest companies were focused on “tangible assets” in the areas of manufacturing, agriculture and commodities. Very much like ASEAN countries today (with the exception of Singapore).

Today, the reverse is true. By 2015, 85 percent of the value of these companies came from “intangible assets”. Simply put, the most successful US companies make almost all their money through ideas, concepts, brands and innovative products and processes (Figure 1). Advanced Asian economies – Japan, South Korea, Hong Kong, Singapore and Taiwan – have also taken this path, moving over recent decades from agriculture to manufacturing to knowledge-based industries.

ASEAN countries can no longer rely on low-wage, labour-intensive manufacturing for their competitive edge, especially in the context of rapidly rising wages in countries like Thailand and Malaysia, and rising rates of automation. The development of knowledge-oriented sectors and processes will be crucial for ASEAN countries to continue their economic transition.

**Figure 1: The biggest US companies are increasingly knowledge-based**  
Components of S&P500 market value

*Source: Ocean Tomo*



Economic openness and international collaboration are key. Few countries have developed thriving knowledge-based industries purely from domestic resources. Today, scientific knowledge, technological know-how and the required R&D capital are dispersed globally. It is no longer the case that “vertically integrated” R&D companies, for example industrial giant General Electric or tech behemoth Samsung, research, develop, manufacture and market products in-house from start to finish. Today, multinational companies collaborate with small companies, academia and the public sector at all stages of the R&D cycle, across borders and continents. Meanwhile, innovative, high-tech products are increasingly manufactured by several companies in different countries in globalised manufacturing value-chains. These global value chains have created cheaper consumer goods and reduced poverty by helping to integrate developing countries into the global economy.

The challenge for ASEAN countries is to become more meaningful participants in global innovation networks and knowledge-intensive manufacturing value chains. In order to upgrade their innovation capacity and boost economic growth, ASEAN countries must attract innovative multinational companies to their shores to conduct R&D and build high-tech manufacturing capacity, bringing with them the capital, skills and technological know-how that are missing locally.

The potential prize is enormous: China now captures more foreign direct investment in R&D than the US. The pharmaceuticals sector leads the way with investments totalling \$1.6 billion between 2010 and 2015, according to FDI Markets. Intangible, knowledge-intensive capital accounted for a third of the value of all goods manufactured globally between 2000 and 2014, according to WIPO.<sup>1</sup>

While tax, regulatory and skills policy all play an important role in the development of national innovation ecosystems, both local and foreign investors need certainty over their intellectual property rights, including clearly defined and easily enforceable patent rights, trademarks and copyright. If this protection is weak or enforcement is poor, local companies will be unlikely to invest in developing their own new technologies and creative outputs, while international companies will be less likely to enter into partnerships with local companies for R&D or manufacturing.

Crucially for ASEAN countries at the beginning of their innovation journeys, insufficient frameworks for the protection and enforcement for intellectual property rights means there will be fewer opportunities to participate in knowledge-intensive manufacturing value chains, and the consequent loss of technology transfer, jobs and economic growth. Uncertainty over IP rights will also delay the launch of innovative products, services and medicines, denying citizens access to new technologies, medicines and their productivity-enhancing potential.

This report is a collaborative effort between five ASEAN think tanks from Malaysia, Indonesia, Philippines, Viet Nam and Thailand. It makes the case for a strong framework of intellectual property rights as a cornerstone of sustainable economic development. It gives an overview of the strengths and weaknesses of each country’s IP framework, and makes suggestions for reform.

## | Building ASEAN knowledge economies

**Although they find themselves at different stages of development, ASEAN countries are well-placed to capitalise on the growth of global innovation networks and manufacturing value-chains. According to the Economic Research Institute for ASEAN and East Asia:**

- **Singapore** is the regional leader in the “frontier phase” of innovation, thanks to its strong local R&D capabilities.
- **Malaysia** and **Thailand** are in the “catch-up phase” and have significant potential to grow their already high innovation capabilities as their economies grow.
- **The Philippines, Indonesia** and **Viet Nam** have made significant progress in recent years, particularly in terms of their high-tech and creative goods exports. These countries are in the ‘learning’ phase of innovation, which is characterised by the acquisition of innovation capability. The potential for future innovation from these countries is very high.<sup>2</sup>

ASEAN countries are performing increasingly well in terms of innovation outputs, with Malaysia and Viet Nam this year entering the top third of the world’s most innovative countries (Figure 2).

ASEAN member states have great potential for improvement in future thanks to their existing strengths and successes in terms of both policy frameworks, human resources and specific sectoral strengths. Figure 3 shows the specific strengths of ASEAN countries in innovation, suggesting areas of capability that can be leveraged as economies develop.

**Figure 2: Innovation output rankings, 2019 Global Innovation Index**

Source: 2019 Global Innovation Index

Overall rank	Country	Score
1	Switzerland	63.5
2	Netherlands	57.5
3	Sweden	56.9
4	United Kingdom	54.4
5	China	52.8
6	United States of America	52.6
7	Finland	51.6
8	Israel	51.6
9	Germany	51.1
10	Ireland	50.1
15	Singapore	44.6
37	Viet Nam	33.9
39	Malaysia	32.4
42	Philippines	30.7
43	Thailand	30.7
78	Indonesia	20.8
84	Cambodia	19.7
120	Brunei Darussalam	13.0

**Figure 3: ASEAN innovation strengths**

Source: Adapted from 2019 Global Innovation Index



## | The role of IPRs in economic development

**In order to build upon their considerable strengths illustrated in Figure 3 ASEAN countries require the correct policy incentives. While tax, regulation and infrastructure are all key, intellectual property is particularly important to foster innovation and knowledge-based industries due to three distinct characteristics:**

- Knowledge-based industries compete by inventing next generation products and services, rather than competing on price and commodification.
- They are characterised by very high initial fixed costs (for example R&D and design), but relatively low marginal costs of production.
- They embody and depend on intellectual property in order to justify risk investments in innovation.

As such, intellectual property is increasingly vital as global trade becomes more about “intangible” products and services, based on research and development efforts, brands, and patented or licensed technology, rather than about moving physical goods from their point of manufacture to customers in different countries. The enabling role of IPRs is laid out more specifically below.

- **IPRs drive innovation:** comparing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that countries with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.<sup>3</sup> Evidence shows that strong patent protection in a given jurisdiction not only attracts technologically-rich exports into that jurisdiction but, in the longer term, promotes indigenous innovation by firms located in that jurisdiction (provided that it has reached a certain level of economic development).<sup>4, 5</sup>
- **IP drives economic growth.** The IP system is a significant driver of competition and economic growth in modern, knowledge-based economies. Innovation is responsible for almost three-quarters of the U.S. growth rate after World War II, along with additional benefits such as high-paying jobs.<sup>6</sup>
- **IPR rights help countries participate more meaningfully in global value chains.** Goods are increasingly manufactured in many different countries, with increasing amounts of their economic value attributable to knowledge-based capital. Intellectual property rights allow countries to attract investment into high-tech manufacturing, thereby accelerating the move upstream from basic manufacturing.
- **Patents promote competition** by sharing the knowledge behind an invention with the world. Patent applications, which must include detailed information about new products and processes, are freely searchable by the public – even before patents expire. This disclosure accelerates innovation and empowers potential competitors to design around inventions without “re-inventing the wheel”. One example is the multitude of new patented Hepatitis C cures that have been launched since 2013, providing unprecedented choice and competition in this therapeutic area.

- **Robust intellectual property protection drives Foreign Direct Investment**, with the OECD finding that a one percent increase in the strength of patent protection equates to a nearly three percent increase in FDI across all countries.<sup>7</sup>
- **IPRs promote the international diffusion of new technologies.** IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.<sup>8,9</sup> A country's level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.<sup>10</sup> Numerous econometric analyses have found that stronger IP protections are associated with speedier in-country launches of new drugs; and conversely, weak IP rights being associated with new drug launch delays of many years.<sup>11, 12, 13, 14</sup>
- **IPRs help start-ups and Small and Medium Enterprises (SMEs) secure investment.** IPRs are especially important for start-ups, which tend to have few assets and need investors. A patent is a signal and guarantee of value since it improves the expected profitability of a project, it also provides a signal of the quality of the innovation and can provide a rescue asset if the company fails. Evidence shows, for example, that venture capital firms are more likely to invest in a biotech start-up if it is able to secure its intellectual capital with a robust patent portfolio.<sup>15</sup>

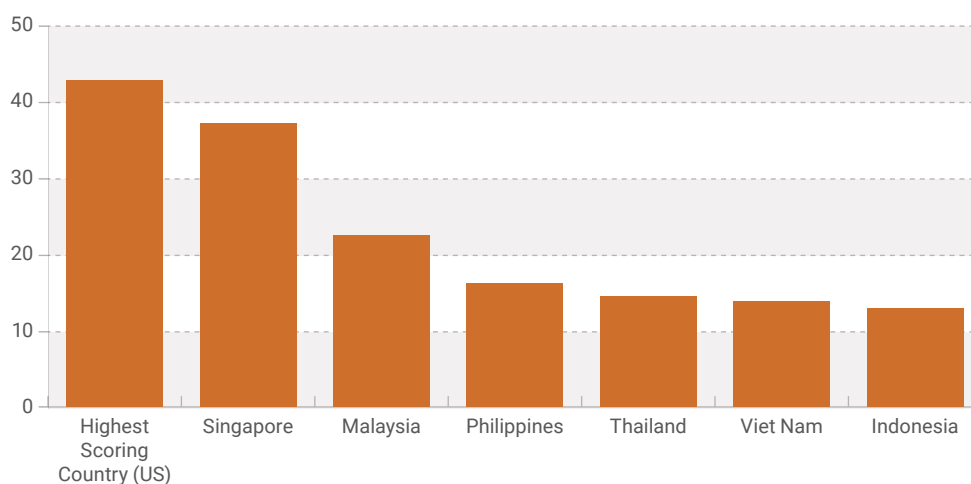
## The status of IP protection in ASEAN

**ASEAN has long identified the important role of IPRs to achieving its economic and social objectives. It has identified IP as a fundamental element of the ASEAN Economic Community Blueprint 2025, which sets out specific steps to be taken by member countries to transform ASEAN into a highly innovative and competitive region. The reform agenda includes the upgrading of national IP offices, greater technical and policy cooperation and harmonisation, and promoting awareness of the importance of IP.<sup>16</sup>**

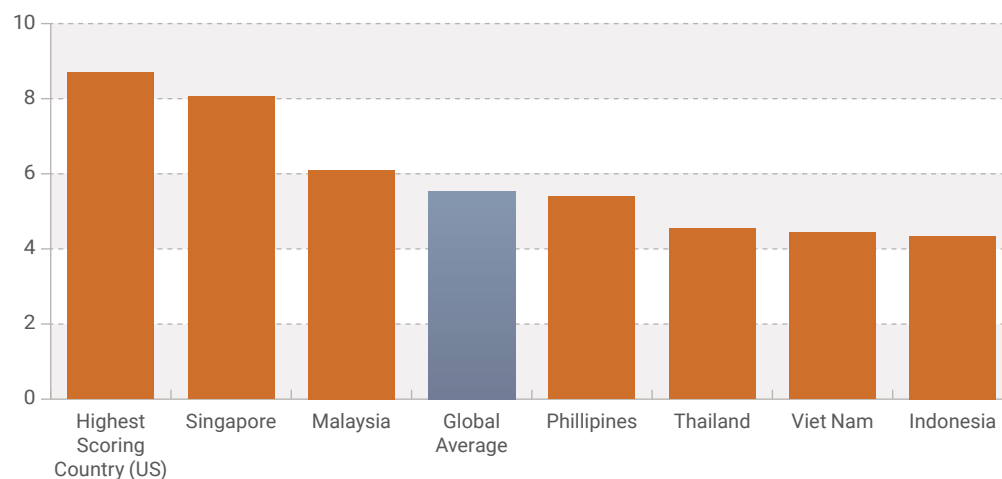
Likewise, many ASEAN member states have recognised the importance of IPRs to their economic and social development goals and have committed to reforming policies and laws in this crucial area. Thailand is notable in this regard for the high-level political support it has placed behind upgrading its IPR system, with the Prime Minister and Deputy Prime Minister chairing the National Committee on Intellectual Property Policy and a subcommittee on enforcement of IP protection laws.<sup>17</sup>

Nevertheless, there is still far to travel before ASEAN countries benefit from IP frameworks of the highest global standards. According to international comparative indices, the strength, scope and efficiency of the IP framework in Malaysia, Indonesia, Viet Nam and Philippines is still well below the highest global standards (Figures 4 and 5), despite improvements in recent years.

**Figure 4:** 2019 International IP Index Score



**Figure 5:** 2018 International Property Rights Index (IPR sub-component)



- **Malaysia** has strengthened certain IP laws since 2011. In particular, copyright reforms have improved Malaysia's environment for creative artists and software developers. But key issues remain, including relatively widespread availability of pirated and counterfeit products in Malaysia, high rates of piracy over the Internet, and continued concerns over the compulsory licensing of medicine patents. Forthcoming patent law changes will be a test of Malaysia's commitment to innovation.
- **The Philippines** IP protection framework has been strengthened in recent years, placing it above Thailand and Indonesia. However, weak enforcement continues to be an issue. IP infringement is not considered to be a serious crime and is therefore often a low priority for the authorities and judiciary. Life science patents are becoming more difficult to obtain and there are concerns that compulsory licensing could become more widely used.
- **Thailand** holds a relatively low position in international IP indices, reflecting an insufficient enforcement system for intellectual property. The amendments to the Computer Crime Act of 2007 and the Specialised Court of Appeals reflect a renewed commitment by the government to address problems related to the increased infringement of online content. Thailand has suffered from extreme delays in the examination of patents, something the government has started to address through reforms to the patent office. The Prime Minister and Deputy Prime Minister have taken leadership of various national IP committees, reflecting serious political commitment to increasing the protection of IPRs.
- **Indonesia** has many reasons for its low IP protection performance. Indonesia geographically consists of more than 17,000 islands, which has made it challenging to control its borders and prevent any potential IPR infringement. Indonesia also faces a number of other challenges, including ineffective enforcement mechanisms, and an insufficient framework for the protection and enforcement of life science patents. However, some significant steps are being taken to improve Indonesia's IP environment, including a new law on trademarks and improvements to IPR enforcement agencies and institutions. Potential patent law changes are an opportunity to correct past problems and further improve IP protection and enforcement.
- **Viet Nam's** IP system has undergone rapid improvement over the last ten years, although there are still gaps and challenges in the enforcement of patents and copyright (particularly online). There are high physical counterfeiting rates and online infringement with an estimate software piracy rate of 74%. The enforcement of life sciences patents is a concern. However, basic IP protection and enforcement frameworks are in place, with stronger penalties now applicable for commercial scale infringement. Viet Nam's government is pursuing an IP strategy that is integrating Viet Nam into the global IP framework, and efforts are being made to better coordinate domestic IP enforcement efforts amongst different agencies.

## | Principles for a high-standard IP system

**As this report has highlighted, there are many positive reasons to improve the quality of the overall framework for the protection of IPRs. According to Global Innovation Policy Center, those countries in the top third of the International IP Index rankings are 38% likelier to get innovation funded and 39% likelier to attract foreign investment.<sup>18</sup>**

**For an intellectual property system to be effective, there are three key elements:**

- ✓ It must provide fair and effective incentives for innovation
- ✓ It must provide innovators certainty regarding their rights
- ✓ It must offer rights holders strong enforcement tools for defending infringed IPRs

ASEAN countries have the IP basics in place in line with their commitments under the WTO TRIPS Agreement, including providing patent protection for eligible inventions for a term of 20 years. Beyond that, there is considerable variation from country to country in the scope of IP rights provided, the ease with which they can be registered, and their enforcement.

The following section provides an overview of the main forms of intellectual property (patents, copyright, trademark and trade secrets). It provides a brief assessment of each country's performance in protecting these rights, identifies some major issues, and sets out some principles for reform.

## Patents

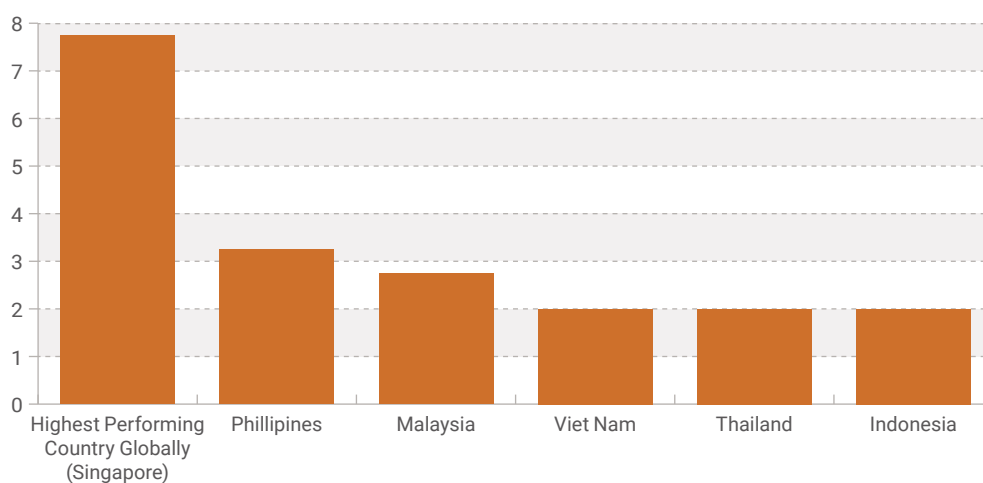
As ASEAN countries look to shift from low-value manufacturing towards value-added manufacturing and R&D activities in knowledge-based sectors, a strong framework for the protection and enforcement of patents is crucial. Patents are central to the business models of the highest-value industrial sectors, including the life sciences, semiconductors, manufacturing of all kinds of electronic equipment and appliances, and natural gas extraction. In the European Union, patent-intensive sectors are responsible for 17% of all employment and 15% of total GDP.<sup>19</sup> This suggests that ASEAN countries stand to gain considerably from a high standard of patent protection and enforcement. While all countries provide the basics of patent protection, there are several specific areas of weakness, reflected in the region's poor scores for the protection of patent rights relative to global best practice (Figure 6).

### Efficient and timely examination of patents

Under the WTO TRIPS Agreement, to which all ASEAN members are signatories, the 20 year term of a patent starts when the application is filed with the patent office, not when a patent is granted.<sup>20</sup> Patents are granted on a national basis, and the process typically falls under the purview of national patent offices. Ideally, patent offices should examine applications swiftly and efficiently, in order to not eat into the patent life and undermine its value.

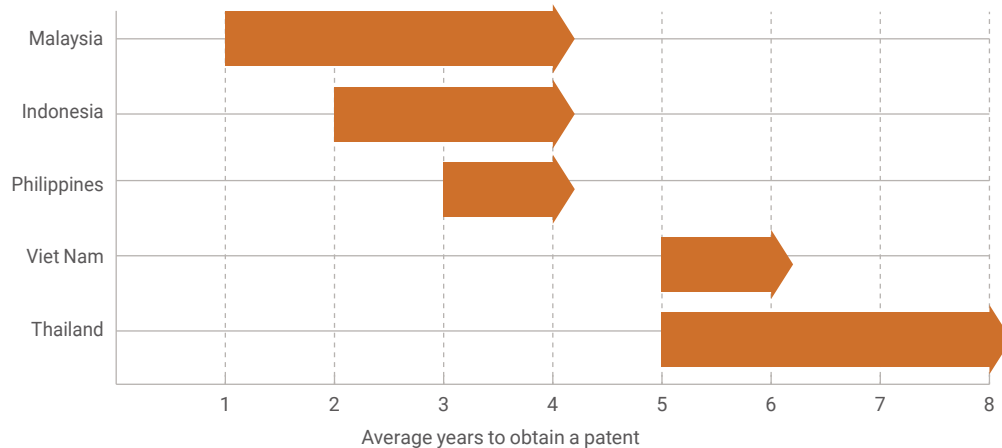
Unfortunately, certain ASEAN patent offices have significant backlogs of patent applications, leading to delays in granting patents (Figure 7). A detailed survey of this issue by the Center for the Protection of Intellectual Property found patent pendency to be a global problem that it is particularly acute in Thailand, where it takes more than 14 years on average to get a life sciences patent.<sup>21</sup> In fact, Thailand regularly issues patents with only months or weeks of life left before expiration (although the Thai Department of Intellectual Property has recently hired additional patent examiners, helping reduce the patent backlog by 20% in 2018).

**Figure 6:** Patent system strength according to the 2019 International IP Index



**Figure 7: Patent examination delays in ASEAN**

Source: *Mirandah Asia*,<sup>22</sup> *Centre for Protection of Intellectual Property*



Delays in examining patents matter for three reasons.

- Delays hurt entrepreneurs and undermine the ability of new businesses to develop and grow.<sup>23</sup>
- They hurt consumers and patients by delaying the market entry of new products, technologies and medical treatments.
- Delays also hurt society. According to the UK Intellectual Property Office the combined losses of backlogs in the US Patent and Trademark Office, Japan Patent Office, and the European Patent Office cost the global economy over \$10 billion a year through lost investment, jobs and products.<sup>24</sup>

Patent examination delays particularly hit those products with long R&D timelines (such as pharmaceuticals), and those products with short lifecycles (such as ICTs).

### Principles for reform

In order to preserve the integrity and purpose of the patent system, the proper functioning of patent offices should be a policy priority.

- ✓ National patent offices should hire more and better qualified examiners to tackle patent delay and backlog problems.
- ✓ Patents are increasingly filed in multiple jurisdictions, so to avoid duplication patent offices should share work or fast-track applications that have already been granted by recognised jurisdictions. One example is the Patent Prosecution Highway (PPH), in which different countries expedite patent examination if it has already been successfully submitted to a partner patent office in another country with similar patentability criteria. Intellectual Property Corporation of Malaysia (MyIPO) is notable in this regard by having PPH agreements in place with both the European Patent Office and the Japan Patent Office.
- ✓ The ASEAN Patent Examination Co-operation (ASPEC) shows promise as a regional patent examination work sharing initiative, and ASEAN member states should commit to its successful operation particularly by raising awareness among potential users.

## ■ Granting patents for useful inventions

Countries that are successful in innovation allow patents for all forms of invention that meet patentability criteria, without discrimination by sector or technology. However, a number of countries do not allow patenting of software (for example Indonesia and India), while others restrict the patenting of improvements to existing medicines (see below).

Examples of follow-on innovation in medicine include new forms of a drug with improved safety-efficacy profiles, new formulations and dosages providing improved patient adherence and outcomes, and new methods of using an established drug more safely (for example an orally-administrable formulation of the antibiotic cefuroxime which was originally only administrable by injection<sup>25</sup>).

Another important form of follow-on innovation is when new uses are found for existing medicines. This is particularly important form of innovation and is responsible for many of today's most important treatments (Figure 8). Research suggests that up to 15% of given indications for drugs on the WHO List of Essential Medicines are follow-on innovations.<sup>26</sup> According to some estimates, approximately 90% of medicines most used by patients are approved by the US Food & Drug Administration (FDA) for diseases other than their original approval.<sup>27</sup> The repurposing of a drug cannot take place until it has undergone the full suite of clinical trials, which requires significant investment – hence the importance of patent protection for this category of invention.

Despite the importance of follow-on innovation, certain ASEAN countries specifically prevent the patenting of these kind of pharmaceutical innovations.

- In the **Philippines**, national law limits patentability of new formulations and new uses of existing medicines.

**Figure 8:** Drugs that have been successfully repositioned

Drug	Original Indication	New Indication
<b>Amphotericin B</b>	Fungal infections	Leishmaniasis
<b>Aspirin</b>	Inflammation, pain	Antiplatelet
<b>Bromocriptine</b>	Parkinson's disease	Diabetes mellitus
<b>Finasteride</b>	Prostate hyperplasia	Hair Loss
<b>Gemcitabine</b>	Viral infections	Cancer
<b>Methotrexate</b>	Cancer	Psoriasis, rheumatoid arthritis
<b>Minoxidil</b>	Hypertension	Hair loss
<b>Raloxifene</b>	Cancer	Osteoporosis
<b>Thalidomide</b>	Morning sickness	Leprosy, multiple myeloma
<b>Sildenafil</b>	Angina	Erectile dysfunction, pulmonary hypertension

- **Indonesia** adopted a new patent law in 2016 that also disallows patents for new formulations and new uses of existing medicines. 2017 amendments to the patent law require that innovators demonstrate “increased meaningful benefit” for certain kinds of pharmaceutical innovation such as new dosage forms. These laws inject new and heightened criteria into the Indonesian patent system and create uncertainty for investors.

The ASEAN countries that currently deny patent protection to key follow-on innovations have much to gain by reversing course. R&D into follow-on innovation can act as an entry into fully-fledged de novo drug R&D – fledgling ASEAN companies could undertake proof of concept studies on existing molecules and license them out to more established R&D companies, or alternatively in-license molecules from established pharma companies, screen and validate them, and license them back to the parent companies for development. The management of clinical trials is also a growth area for many ASEAN countries. These business models help local industries move up the value-chain and in turn generate high quality jobs and sustainable economic growth.

**India** provides a case study in the negative impacts of restrictive patentability criteria on domestic innovation. India’s patent law prevents the patenting of new formulations, compositions, and combinations of existing medicines. Data shows that Indian generic pharmaceutical companies (several of whom are beginning to innovate), are increasingly filing patents, undertaking R&D and commercialisation abroad rather than in India – meaning that the Indian economy and patients do not benefit.<sup>28</sup>

### Principles for reform

The patent system was built on principle of non-discrimination – applying the same rules to everybody instead of discriminating against particular types of technologies, industries, or the physical location of invention.<sup>29</sup> Each invention should be judged on its individual merits based on neutral and internationally accepted rules for patentability.

- ✓ In order to meet international standards for patentability, governments should ensure that all inventions are assessed by applying the internationally recognised patentability criteria of novelty, inventive step, and utility without discrimination or interference from government agencies other than the patent office.
- ✓ Ensure new forms and new uses of existing medicines, and eligible software inventions, are eligible for patent protection, as long as they meet these recognised criteria for patentability.

## Providing clarity over the use of compulsory licenses

A compulsory license is when a government allows a third party to produce a patented product or process without the consent of the patent owner. The TRIPS agreement allows countries to invoke compulsory licenses for any patent, either for local manufacture or importation. Given the gravity of compulsory licenses for international economic relations and investor perceptions, few countries have been prepared to deploy this tool except in exceptional circumstances. For example, several compulsory licenses were issued by African and Latin American countries in response to the HIV/AIDS pandemic in the late 1990s to mid 2000s.<sup>30</sup>

However, recent years have seen more willingness amongst ASEAN countries to consider this tool to reduce medicine costs:

- **Malaysia** in 2017 issued a compulsory license for an innovative Hepatitis C drug.
- **Indonesia** has issued compulsory on nine patented pharmaceutical products (in 2004, 2007 and 2012). Additionally, Indonesia has passed legislation that would justify a compulsory license if the patent holder does not manufacture the product in Indonesia within 36 months of the patent being granted.
- **The Philippines** is preparing guidelines that would broaden the scope of compulsory licensing as part of its Cheaper Medicines Act.

The threat and use of compulsory licenses can paradoxically reduce choice in the medicines available and undermine access. If a country regularly resorts to or threatens compulsory licenses, manufacturers will be unlikely to consider it a priority country for the launch of new medicines. Without an initial local launch of the innovative product, generic companies may not be able to obtain the necessary regulatory approvals to sell their products, unless they are willing to shoulder this significant cost themselves. Generic companies might also be unable to afford the significant costs of medical education necessary for the appropriate use of the products by the healthcare community and undertake the necessary steps to ensure the product is listed in public sector reimbursement lists. This is particularly true of medicines with smaller patient populations. It is also unlikely that companies will invest in R&D activity, such as clinical trials, in countries that routinely annul intellectual property rights.

**Indonesia's** new regulation that requires the compulsory licensing of any pharmaceutical product not being manufactured in the country is particularly troubling. It will reduce the numbers of drugs available in the country, as few companies will want to take part in a risky joint venture in which IP is not properly respected. Without these ventures, Indonesia lacks the expertise necessary to set up reliable facilities to realise its potential as a knowledge-based economy.

### Principles for reform

In the past, compulsory licenses have often been used as a price bargaining tool, rather than a means of responding to legitimate public health crises. In other cases, notifications to the rights holders and processes have been non-transparent. Undermining intellectual property rights in this way deters private sector investment in the healthcare ecosystem, which undermines choices for patients. Governments should therefore:

- ✓ Limit the use of compulsory licenses to truly extraordinary circumstances, rather than making them standard government practice.
- ✓ Compulsory licenses should not be issued for vague justifications such as “public interest”. The proper functioning of intellectual property rights requires certainty, clarity and predictability.
- ✓ Compulsory licenses should be issued rarely and in a fair, transparent and predictable manner, including undertaking proper efforts to gain authorisation from the rights holder on reasonable commercial terms and conditions.
- ✓ Pursue as a matter of principle voluntary rather than coercive solutions to government procurement issues.

## Copyright

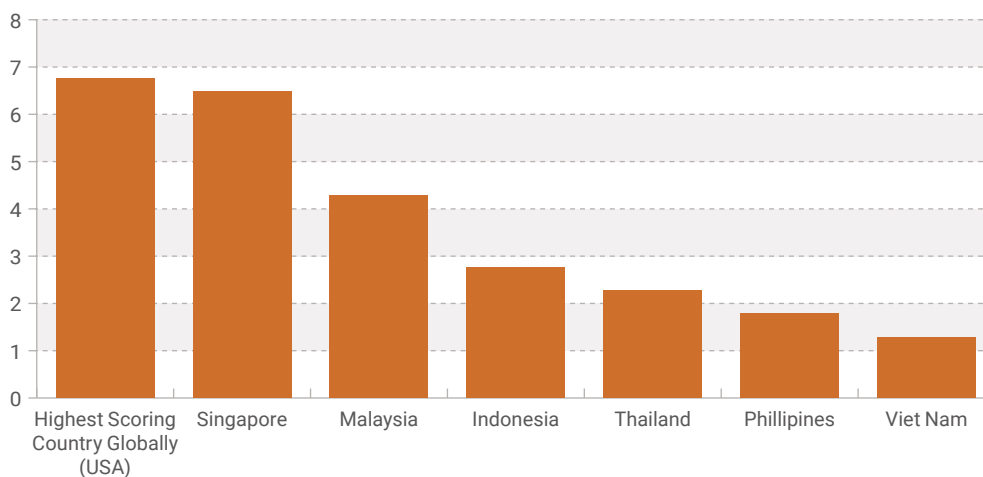
**The primary objective of copyright is to encourage and reward authors, through the provision of property rights, to create new works and to make those works available to the public to enjoy. By granting certain exclusive rights to creators that allow these creators to protect their creative works against theft, they receive the benefit of economic rewards and the public receives the benefit of the creative works that might not otherwise be created or disseminated. Aside from literary works, copyright can be used to protect, inter alia, music; motion pictures and other audio-visual works; sound recordings; and computer programming code.**

Copyright is particularly important to ASEAN countries, with the creative industries set to be major growth areas. In 2018 the Philippines produced its highest-ever grossing movie,<sup>31</sup> whilst it is building on its digital strengths originally developed in Business Process Outsourcing to grow high-value activities such as graphic design, online marketing and web development. The Indonesian creative industries constituted 7.4% of the country's GDP in 2017, with the movie industry poised for regional expansion thanks to the widely understood Bahasa language.<sup>32</sup>

Unfortunately, copyright theft continues to be a major problem in South East Asia, with all countries except Singapore and to an extent Malaysia with copyright frameworks well below the highest international standards (Figure 9). Online piracy in ASEAN takes many forms including:

- Unauthorised retransmission of live sports programming online;
- Cloning of cloud-based entertainment software, through reverse engineering or hacking, onto servers that allow users to play pirated content online, including pirated online games;
- Stream ripping to illegally distribute music over the internet;
- “Camcording”, in which filming devices are taken into cinemas and the resulting footage distributed online.

**Figure 9:** Copyright system strength according to the 2019 International IP Index



## ASEAN COPYRIGHT BLACKSPOTS

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- ✗ Indonesia's online markets Tokopedia, Bukalapak, and IndoXXI.com were included in USTR's Notorious Markets list in 2018
- ✗ The rate of unlicensed software use in Viet Nam is 74 percent, according to the Software Alliance
- ✗ Online piracy cost the Malaysian film and TV industry 2,012 jobs and a further 1,327 jobs in its supporting value chain in 2018

Despite the prevalence of online copyright infringement, ASEAN countries tend to lack sufficient rules and capacity for online enforcement. Often there is no injunctive relief enabling rights holders to disable infringing content online pending adjudication, and a lack of mechanisms to allow cooperation between authorities and rights holders against online piracy, according to the International IP Index.

For example, the Philippines E-Commerce Act and IP Code provide a wide safe harbour for ISPs, limiting their role in combating infringement. ISPs are only required to block access to content if there is a court order.<sup>33</sup>

Thailand, however, has recently bolstered its Copyright Act to enable rights holders to work directly with ISPs to take down infringing content,<sup>34</sup> as part of its wider strategy to improve IPR enforcement.

### Principles for reform

- ✓ Extra resources should be devoted to training and capacity building, to ensure the courts and judiciary are able to successfully enforce existing copyright laws.
- ✓ Raise awareness of the impact and illegality of online piracy among the public
- ✓ Investigate the use of technological solutions to enforce copyright
- ✓ Ensure the body of copyright jurisprudence stays up to date and is adapted to new forms of media as they emerge
- ✓ Introduce effective legislation to require Internet Service Providers to remove IP infringing content from the internet as quickly as possible

## Trademarks

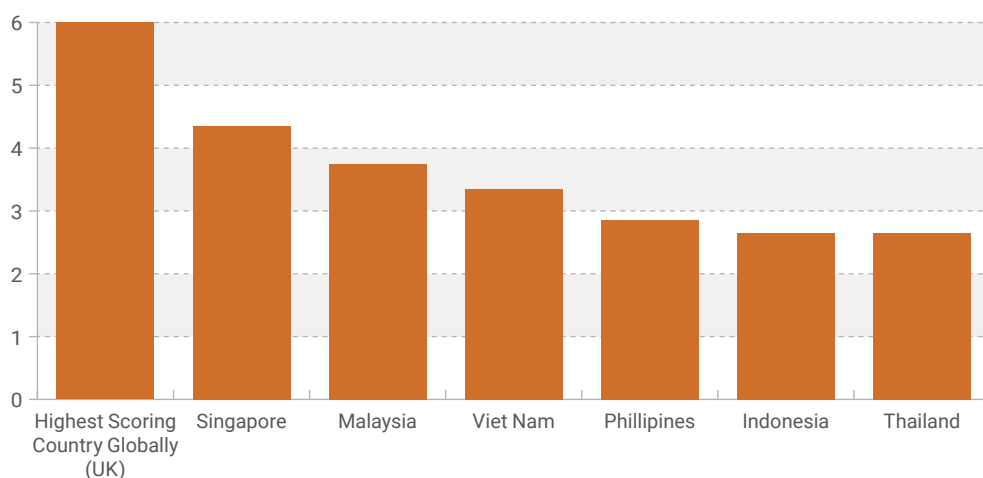
Trademarks have two objectives. One is to prevent unfair competition by allowing consumers to distinguish between and identify different services and goods. The second is to provide information to the public about the quality and origin of products and services. Trademark protection is therefore crucial for the development of local industries, for foreign investment and international trade, and the proper functioning of a competitive market economy. ASEAN member states have a wide range of rapidly growing and popular indigenous brands that are contributing to economic development. These brands rely on trademark protection for their success (Figure 10)

Despite the importance of strong trademark protection to local business and economic development, trademarks are routinely infringed throughout ASEAN with counterfeit goods available across a wide range of products including consumer goods, semi-conductors and electronics, spare parts, chemicals, IT goods, luxury items, pharmaceuticals and food and drink.<sup>35</sup> This is reflected ASEAN countries' relatively poor scores in trademark protection relative to global best practice (Figure 11), and in the overall policy environment to counter trade in illicit goods (Figure 12).

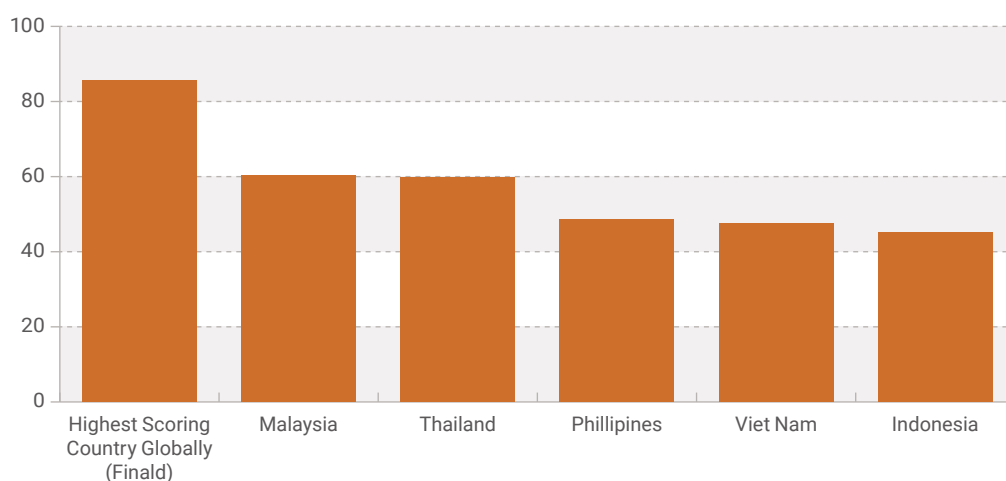
Figure 10: Major South East Asian consumer brands



**Figure 11:** Trademark system scores according to the 2019 International IP Index



**Figure 12:** Global Illicit Trade Environment Index 2018



While China is identified by the OECD as by far the largest producer of counterfeit goods,<sup>36</sup> Malaysia, Viet Nam and Thailand are also significant producers in certain categories.<sup>37</sup> Meanwhile, many shipments of counterfeit products pass through transit hubs such as Singapore and Hong Kong.

In order to address the economic and social harms associated with counterfeit products, all countries in ASEAN have in place basic frameworks for the protection of trademarks, and in recent years many countries have directed extra resources and new reforms to better protect and enforce these rights:

- **Thailand** has amended its Trademark Act to clarify some procedural aspects and potentially shorten prosecution times, while the 2017 Customs Act brings new penalties for the importation of counterfeit goods, also covering goods in transit. The Department of Intellectual Property (DIP) recently introduced an intellectual property roadmap that calls for intensifying efforts to combat piracy and counterfeiting.

- The **Philippines** has determined to make continuous improvement in fighting against counterfeiting as the biggest IP issue faced by the country
- **Malaysia** has recently introduced IP enforcement coordination mechanisms and agreements to enhance interagency cooperation in the fight against trademark infringement.
- **Indonesia** has ratified the Madrid Agreement Concerning the International Registration of Marks and has passed a new law on trademarks, which strengthens considerably the current levels of protection.<sup>38</sup>
- **Viet Nam** in 2016 updated its criminal code to make the manufacturing and trading of IPR infringing goods a criminal offence.<sup>39</sup>

Despite these promising initiatives, there are lacunae in the protection of trademarks that make enforcement challenging.

- In numerous countries, legal and procedural obstacles exist to securing trademark rights. For instance, USTR reports that Malaysia and the Philippines have slow opposition proceedings which limits the abilities of companies to enforce their trademarks.
- In many countries, customs officials are not given ex officio powers to seize suspected goods, or if they do have the power, cannot use it for goods in transit.

#### Principles for reform

- ✓ Adopt best practice on customs including investment in capacity at border and customs operations including the use of latest technology;
- ✓ Ensure sufficient penalties for importers of counterfeit products, including those in transit;
- ✓ Enact reforms to courts to accelerate opposition proceedings.

## Trade Secrets

**Trade secrets are a highly valuable form of intellectual property that nearly all businesses in all industries and sectors possess. Trade secret law covers three categories of information: (1) technical information, such as industrial processes and blueprints; (2) confidential business information, such as customer lists; and (3) know-how, such as business methods for efficiency.**

Where effective trade secret laws exist, a business owner can use the legal system to protect secrets. It can stop an unscrupulous former employee or competitor from taking the secret and using it as their own. With the digitisation of information, however, trade secrets have become more vulnerable to misappropriation. Trade secret laws have thus come into prominence as the digital age has made information easier to steal. For governments, effective trade secret laws are an important part of a well-functioning, national innovation system. For businesses, protecting trade secrets has become increasingly important to investment decisions and success.

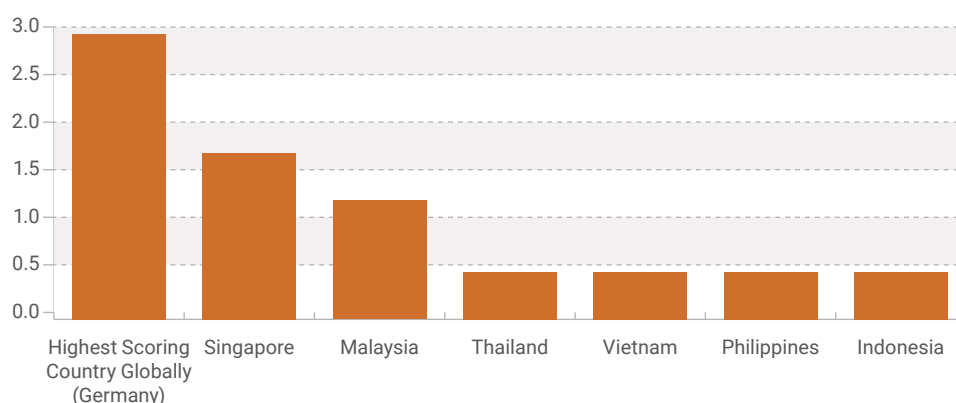
Many countries now understand that effective trade secret protection is a key competitive advantage and have been upgrading their laws accordingly (Figure 13).<sup>40</sup>

- **Malaysia** in particular has a robust framework where trade secrets are a recognised IP right and qualify for protection and enforcement
- In **Indonesia**, the aggrieved party has to prove that confidential business information has been unlawfully obtained by the suspected party, making litigation difficult.
- While the **Philippines** IP law include ‘protection of undisclosed information’ as one of the intellectual property rights, it does not define it, leaving great uncertainty around the protection of trade secrets.
- **Viet Nam** has recently updated its IP code to include trade secrets, although the authorities lack experience in dealing with infringement cases.
- The protection of trade secrets was incorporated into **Thai** law in 2002.

### Principles for reform

- ✓ **Raise awareness of the importance of trade secret protection amongst the business community**

**Figure 13:** Protection of trade secrets and confidential business information according to the 2019 International IP Index



## Regulatory data protection

**Regulatory data protection is an increasingly important form of intellectual property right to encourage investment in veterinary medicines, agricultural chemicals and biologic medicines.**

Regulatory data protection prevents competitors from relying on the data generated in clinical trials by the original developer of the medicine or agricultural chemical, which they are obliged to disclose to regulators in order to gain regulatory approval for the new product. Clinical trials are becoming increasingly costly and complicated and add significantly to the cost of developing a new medicine or chemical.

A sufficient term of regulatory data protection therefore gives innovators enough time over which they have the opportunity to recoup the costs of compiling clinical trials data, before that data is made available to generic or biosimilar manufacturers to use in their own marketing approval applications.

In the case of biologic medicines, the protection of clinical trial data is also important since patents alone may provide insufficient protection. This is because the molecular structure of biologics is far more complex than “traditional” chemically-synthesized drugs, making it impossible to replicate an original biologic precisely. Given that each biosimilar is slightly different from the originator, patents may offer only limited protection, as patents are granted for specific inventions and do not cover the variations that will inevitably arise in the process of developing a biosimilar.

As such, the most innovative countries in biotechnology, chemicals and veterinary medicines all have clear, legally binding rules to protect these data. This form of intellectual property right is particularly important for countries looking to enter the R&D value-chain through the provision of clinical trials and related services. Many ASEAN countries provide do not provide this form of intellectual property protection (Figure 14).

### Principles for reform

- ✓ Provide sufficient terms of regulatory data protection for chemically-synthesised and biologic medicines, veterinary medicines and chemicals.

**Figure 14:** Regulatory data protection around the world

*Source: Mirandah Asia; Thomson Reuters Practical Law; China IP Legal Report.*

Country	Regulatory data protection
United States	12 years
European Union	11 years
Japan	8 years
China	Proposes increasing from 6 to 12 years for certain biologic drugs
Malaysia	5 years; no protection for biologic drugs
Viet Nam	5 years
Indonesia	Not available
Thailand	Not available
Philippines	Not available

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