Chapter 5

Intellectual Property Harmonisation under the Trans-Pacific Partnership Agreement: Issues and Challenges

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Introduction

The Trans-Pacific Partnership Agreement (TPP) was negotiated by 12 Pacific-rim countries, namely: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. Intellectual property (IP) is one of the most important issues in the TPP negotiations. The Agreement will introduce higher standards of IP protection than required in the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) TRIPS (so called TRIPS-Plus provisions). The international agreements on IP like those contained in the proposed TPP will bind the participating countries and oblige them to provide more extensive IP protection. The IP chapter under the TPP would undermine countries' substantive ability to deal with public health problems. First, the proposed rules would have negative implications for access to medicines by limiting flexibilities that the countries currently have under the WTO/TRIPS Agreement, e.g. restricting the right of governments to allow the production, marketing, and import of generic medicines. The treaty has introduced language that will undermine the ability of the participating countries to make use of compulsory licensing as a means to obtain differentially priced generic products and to restrict the measures it can take to pursue affordable drugs. In making decisions with respect to whether or not a country should join the TPP, its policymakers will have to weigh, based on empirical evidence, the economic benefits of such a treaty against the importance of protecting health and social interests of their population.

I. General background of TPP

In the late 1980s, a number of countries, including Taiwan, Korea, India, Thailand and Indonesia, were placed under tremendous pressure by developed countries to improve their

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laws for the protection of IP. Particularly, the United States, the world's largest trading nation exerted bilateral pressure, by withdrawing or threatening to withdraw trade privileges they gave to developing countries under the Generalized System of Preferences (GSP). The developed countries also threatened to impose trade sanctions on the countries that failed to provide adequate and effective IP protection. Because of this pressure, those countries decided to revise their IP laws to increase the protection level even before the adoption of the WTO TRIPS Agreement in 1994. In addition to the aggressive unilateralism and bilateralism, the industrialized countries' IP norm-setting activities also take place on the plurilateral level. For example, when a country's government has decided that it wishes to apply for membership of the WTO, it has to make a large number of commitments. Accession to the WTO involves a complex technical process and negotiations with existing members. The country has to adopt domestic laws and regulations to implement WTO obligations, including improving IP protection, even before the final accession terms and commitments are presented to the WTO body for a vote.

The years from 2000 onwards saw the proliferation of free trade agreements (FTA). In recent times, the United States and the European Union have launched their negotiation campaigns for an FTA with certain countries. The countries that have signed or are in the process of negotiation of a bilateral and regional trade agreements with two of the world's economic superpowers include Australia, the Andean Community countries, Bahrain, the Central American countries, Chile, India, Jordan, Morocco, Panama, Singapore, Southern African countries, South Korea, Thailand, Vietnam, etc. Larger economies like China and Japan are also engaged in negotiating free trade agreements with their trading partners. China, the world's second largest economy, is working toward an FTA with ASEAN (called ASEAN+3). Japan has so far concluded an FTA with Indonesia, Malaysia, Mexico, Philippines, Singapore, and Thailand. Negotiations for an FTA are also underway among Australia, Chile, India, Japan and South Korea.

There are several reasons for the expansion of the FTAs. First, the success of the North American Free Trade Agreement (NAFTA) and the moves toward a Free Trade Area of the Americas (FTAA) motivated other countries to adopt FTAs. Secondly, the United States and the European Union aim to dominate rule-setting in the global trading system. Those countries have realized the need for stepping up the pace of economic integration. FTAs can help insure against the periodic difficulties of multilateral trade liberalization. These two

giant trading blocs became weary of the slow progress in multilateral trade negotiations. Since trade liberalization was getting more difficult under the WTO framework, the trade negotiators of the United States and Europe have used bilateral and regional trade fora to achieve what they could not in the multilateral WTO forum, namely, *inter alia*, enforcing an inflexible, high level IP protection in developing countries. The developed countries can easily manage to set benchmarks with respect to all their trade objectives that will be difficult to achieve at the WTO.[1]

One of the most significant free trade agreements is the Trans-Pacific Partnership (TPP) Agreement. The TPP Agreement was negotiated by 12 nations, including Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. It has been concluded on 5 October 2015. Once entered into force, the TPP Agreement will tie together the Pacific's largest economies and will set standards of trade measures that cover a broad range of traditional and non-traditional trade and investment issues, such as local-content requirements in government contracts, higher standards of IP protection, the roles of state enterprises, liberalization of telecommunications, labour and environment standards and e-commerce. The TPP Agreement is expected to be the world's highest standard agreement and perhaps will become the most important trade agreement in the 21st century.[2] Due to its rule that allows for membership expansion, the Agreement will create the largest and most important trading bloc which includes several of the Pacific's largest economies such as the United States, Japan, Canada, Australia, New Zealand, Indonesia, the Philippines, Singapore and perhaps China.

From the perspective of the negotiating countries, the regional and bilateral deals will increase the volume of international trade and investment.[3] The signing of non-multilateral trade agreements is the crucial economic factor for creating growth, efficiency and stability in their economy.[4] A unified and borderless economic entity will present greater business challenges and opportunities for enterprises and investors of the signatory countries. It will

[1] Kilic, B. "Defending the Spirit of the DOHA Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines, 12 Loyola University of Chicago Int'l Law Review, (2014), pp. 23–57.
[2] Backer, L.C. "The Trans-Pacific Partnership: Japan, China, the U.S., and the Emerging Shape of a New World Trade Regulatory Order", 13 Washington University Global Studies Law Review, (2014), p.49.
[3] Gantz, D.A., Liberalizing International Trade after Doha: Multilateral, Plurilateral, Regional, and Unilateral Initiatives, Cambridge University Press, New York, 2013.
[4] Matsushita, M, Proliferation of Free Trade Agreements and Development Perspectives, 2010, http://www.lawanddevelopment.net/img/matsushita.pdf

also give exporters and investors from those countries greater access to lucrative integrated markets. However, it has been argued that the benefits derived from the trade agreements seem unbalanced, due to the fact that such agreements are negotiated by parties of unequal bargaining power. The power asymmetry is likely to influence the bargaining outcomes and will lead to unequal distribution of benefits causing unfairness and inequity in trading relations. Bilateral and regional trade deals will bring about several negative consequences for the smaller economies, particularly when they restrict those countries' ability to use the relevant policy space to implement their national development policies. The prospective costs of the bilateral trade treaties include various problems relating to monopoly, public health, education, food security, environment, labour rights, technology transfer, biodiversity management, etc.[5]

Before beginning to develop legal agreements regarding IP protection under the TPP, let us briefly examine some other issues contained in the Agreement. It may be noted that commitments under the TPP are extended to cover several essentially non-trade issues – principally investment, competition policy and government procurement. In many countries, there is widespread public concern over the adoption of looser rules on investment. The TPP investment chapter offers some truly novel features on investment rules, including the followings: the right to private ownership and establishment (permitting 100 per cent foreign ownership of companies); fair and equitable treatment; no restrictions on the free flow of capital into and out of the country; no performance requirements; investor-state-dispute mechanisms, etc. For a developing country, incorporating such investment rules into national legislation would have severe consequences. The government would lose the right to regulate the entry of foreign investors. It would no longer be able to give preferences or protection to local firms or even farmers. Local producers would disappear or be taken over by larger foreign firms. Foreign competitors would have full rights to own land and real estate and to receive government aid, subsidies and contracts, just like the locals. Any attempt by the government to regulate investment activities, such as imposing high environmental standards, could end up with the government paying millions of dollars in compensation to foreign investors, as has happened in the NAFTA countries.

[5] Fazzone, P.B. "The Trans-Pacific partnership—towards a free trade agreement of Asia-Pacific?", 43 Georgetown Journal of Int'l Law (2012), p. 695.

With the competition policy proposed in the TPP, member countries are obliged to establish domestic competition policies and laws of a certain type, which would restrict the sovereign right of each state to adopt laws preventing companies from resorting to practices which are prejudicial to the interests of the host country. Regarding government procurement, it is clear that the TPP would introduce a process whereby foreign bidders and contractors would be entitled to obtain a large share of the lucrative business of state projects in the host country. Many WTO members currently have no obligations to provide government contracts to foreigners as they do not join the WTO's plurilateral agreement on government procurement. Winning government contracts is undoubtedly lucrative in view of the fact that up to a significant proportion of countries' GNP goes to state projects. If that is the case, the liberalization of government procurement raises the question of why this domestic spending should be treated as a trade issue.

A further concern over the TPP, and other free trade agreements, is that bilateral trade negotiations are generally being conducted in a most non-transparent manner. The FTA negotiating process of the United States has been criticized for lacking openness and transparency. The trade negotiators of the economic superpower are mandated to negotiate trade deals in secret. They usually demand for a closed and secretive bilateral trade negotiation from their negotiating partners. Public access to draft agreement texts and other documents is restricted throughout the negotiation process. American public do not have knowledge about the details of the negotiations and are not aware of the proposals made by their government. It may be noted that the United States uses a confidential trade advisory committee system, which consists of 28 trade advisory committees. These committees are largely dominated by industries. For example, the members of the Trade Advisory Committee on Intellectual Property Rights are mostly the representatives of US major research-based pharmaceutical companies and entertainment industry. They are the only interested private parties that are allowed to access to and contribute comments on US proposals on IP matters.[6] The information that has been made publicly available is generally one-side information, coming mainly from the government and those private groups. Public demands in the United States have called for a system of transparency, collaboration and participation of broader interest groups in this public policy making. It was claimed that the closed-door policy not

[6] US Department of Commerce and the Office of the USTR, *Charter of the United States Trade Advisory Committee on Intellectual Property Rights* (2010) http://www.trade.gov/itac/committees/Charters/Intellectual_Property_Rights_ITAC.pdf.

only prevented the vast majority of the public from fully comprehending the content of the negotiations, but also denied trade negotiators the opportunity to listen and exchange views with the public members.[7]

The secret nature of the bilateral and regional negotiations is contrary to the more open and transparent practice adopted by the WTO and the WIPO in their multilateral negotiations. The two organizations generally make all country proposals available to the public as a formal part of the negotiation process. They from time to time publish updates on the status of negotiations that generates public debates regarding various aspects of the negotiated issues. Major developed countries are dissatisfied with the transparency in the norm-making process of the multilateral organizations. It was perhaps one of the reasons why those countries have shifted their policy towards pursuing bilateral trade.

The secrecy in trade negotiations allows the developed countries to establish acceptable higher trade standards. It also helps them to escape social movement attention and to avoid growing public opposition against international norm-making at the multilateral level.[8] As pointed out by Flynn et al, "[T]he strategy appeared tailored to avoid an open debate over the standards being proposed in the agreement."[9] The United States and the European Union are pushing for poor countries to accept trade issues that will have public interest implications, such as threatening access to affordable generic medicines or generating environmental and resource depletion effects. It is probably the main reason why US and EU trade negotiators are reluctant to reveal its negotiating position to the public.[10]

So far the trade liberalization policies of most governments have deepened inequalities between different interest groups within a country. Most key decisions are worked out by a group of bureaucrats and business people. The vast majority of the population has very little real say in trade negotiations. Governments of the negotiating countries never allow the

[7] Flynn, S. "Law Professors Call for Trans-Pacific Partnership (TPP) Transparency" *Infojustic* 9 May 2012 http://infojustice.org/archives/21137.
[8] Morin, J. "Multilaterlising TRIPs-Plus Agreements: Is the U.S. Strategy a Failure?" *Journal of World Intellectual Property* 12 (2009), p. 175; Gervais, D. "Of Clusters and Assumptions: Innovation as Part of a Full TRIPS Implementation" *Fordham Law Review* 77 (2009) 2353.
[9] Flynn, S. *et al* "U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement", American University International Law Review, Vol. 28, (2012), pp.105-205 at 110.
[10] ICTSD, *Bridges Weekly Trade News Digest*, International Centre on Trade and Sustainable Development, 18 February 2011.

public to participate in the many formal and informal meetings to which business people and trade councils are invited. As a result, the issues put up for negotiation, and the decisions made by the government, tend to be biased against grass-roots interests. By excluding the very people who have so far failed to benefit from trade liberalization, corporate-driven bilateral trade deals like the TPP effectively undermine the sustainable development all governments say they are aiming for.

2. Country case study: Thailand

2.1 Economy

Thailand was one of the fastest-growing economies in the late 1980s. In 1988 and 1989, the Thai economic growth rate reached a remarkable figure of 11 per cent.[11] The country's high-growth economic boom during that period had led many people to believe that Thailand had the resources to become a developed country with a high per capita income. However, the economic crisis in the late 1990s had brought Thailand back to earth. The economic bubble that had grown for almost a decade finally burst in 1997 with the crash of the property market and the plunge in the baht value, which it subsequently spread from Thailand to other countries and became the East Asian financial crisis. However, the Thai economy has recovered quickly from the crisis and renewed its growth.

Currently, the economy of Thailand is an emerging economy with solid growth from 2000 to 2008, averaging more than 4 per cent per year. In 2010, it enjoyed the total GDP of US$ 580.3 billion.[12] Thailand is ASEAN's second largest economy after Indonesia. It is the fourth highest per capita GDP in ASEAN after Singapore, Brunei and Malaysia. Agriculture makes up 10.4 per cent of the country's GDP, industry 45.6 per cent and services 44 per cent.[13] Thailand's major trading partners are the United States (10.9%), China (10.6%), and Japan (10.3%). The EU, other ASEAN countries, Australia and New Zealand are also Thailand's significant trade partners. Thailand has always enjoyed a substantial trade surplus. As the 2010 figure shows, its exports were worth US$ 191.3 billion and imports were

[11] NESDB, *Annual Report*, National Economic and Social Development Board, Bangkok, 1991.
[12] *Thailand's Economy*, Asian Info, Bangkok, 2012. http://www.asianinfo.org/asianinfo/thailand/pro-economy.htm, accessed 17 July 2012.
[13] Ibid.

US$ 156.9 billion.[14] Primary destinations of Thai exports include the United States (10.9%), China (10.6%) and Japan (10.3%), and the major import partners are: Japan (18.7%), China (12.7%), Malaysia (6.4%), the United States (6.3%), United Arab Emirate (5%), Singapore (4.3%), and South Korea (4.1%).[15] The followings are the country's major export products: textiles, footwear, fishery products, rice, rubber, jewelry, automobiles, computer parts and electrical appliances. Capital goods, intermediate goods, raw materials, consumer goods and fuels are among Thailand's principal imports.

2.2 IP law

Thailand up to now is a party to the TRIPS Agreement and the Berne Convention. It joined the Paris Convention in August 2008, and subsequently ratified accession to the PCT in September 2009. It is currently considering joining the Madrid system for the international registration of trade marks. Currently, there are seven legislations protecting intellectual property rights in Thailand, including the Patent Act B.E. 2522 (1979), the Trade marks Act B.E. 2534 (1991), the Copyright Act B.E. 2537 (1994), the Plant Variety Protection Act B.E. 2542 (1999), the Protection of Layout-Designs of Integrated Circuits Act B.E. 2543 (2000), the Trade Secrets Act B.E. 2545 (2002), and the Geographical Indications Protection Act B.E. 2546 (2003). Apart from law protecting internationally recognized IP rights, Thailand has adopted a law to protect traditional knowledge in the field of medicines. The Traditional Medicine Act B.E. 2542 (1999), which is under the administration of the Ministry of Public Health, lays down conditions on access to herbal resources and Thai traditional formulations. The law establishes the rights of traditional healers to retain control over traditional medicinal knowledge through public registry.[16]

2.3 Research policy and technology diffusion

The Thai Government has financed a number of research programmes in various universities, public research institutes and private companies in order to encourage the development of local technology. In spite of this effort, the country still has a relatively low level of science and technology. Thailand's R&D expenditures are small compared to those of industrialised countries. The amount of research spending in Thailand in 2009 accounted for 0.12 per cent of

[14] Ibid.
[15] Ibid.
[16] Kuanpoth, J. "Thailand", in Heath, C. (ed.), *Intellectual Property Law in Asia*, Kluwer Law, The Hague, 2002, pp. 337-362.

national Gross Domestic Product (GDP),[17] which was smaller than those spent by Japan (3.4%), the United States (2.7%), Germany (2.5%), France (2%), Republic of Korea (1.8%) and China (1.4%).[18] Apart from smaller R&D budget, Thailand also has shortage in skilled scientists and engineers to undertake the R&D. According to the 2007 World Bank statistics, in Thailand there were 316 researchers in R&D (per million people), compared to 5,409 in Japan, 4,673 in the United States, 3,525 in Germany, 3,593 in France, 4,672 in Republic of Korea, and 1,077 in China.[19]

2.4 Patent office

The Department of Intellectual Property (DIP), established within the Ministry of Commerce in May 1992, is in charge with the implementation of IP laws in Thailand with the exception of the Plant Variety Protection Act B.E. 2642 (1999), which is administered by the Ministry of Agriculture. The DIP is a government agency. Its duties and responsibilities are: registering patents, trade marks and licensing of IP rights; developing systems, patterns and means to protect IP; promoting effective use of IP and technology information for the purposes of education, research and development, commercialization, and studying, analyzing and recommending policies on IP to the Thai Government.[20]

Establishing an effective patent system is a challenge for developing countries like Thailand. Like most developing-country patent offices, the patent office administered by the DIP does not have adequate skilled personnel and sufficient institutional capacity to perform necessary patent examination. While an efficient patent office generally requires at least 200 examiners to guarantee proper examination in all technical fields,[21] there are currently 42 patent examiners at the Thai Patent Office. Although the number of patent examiners employed by the DIP Patent Office has increased in recent years, from 24 in 2001 to 42 in 2010, the number is still too small to guarantee the quality and efficiency of patent examination. The situation is even worse considering the fact that only 17 out of the total 42 examiners are involved in examination of patent applications for invention in the fields of chemistry,

[17] ONRCT, *Annual Report*, Office of the National Research Council of Thailand, Bangkok, 2010.
[18] UNESCO Institute for Statistics (August 2010) www.uis.unesco.org.
[19] World Bank, *Data: Researchers in R&D*, World Bank, http://data.worldbank.org/indicator/SP.POP.SCIE.RD.P6.
[20] DIP, *Annual Report*, Department of Intellectual Property, 1999, p. 16.
[21] Sherwood, R.M., V. Scartezini and D. Siemsen, 'Promotion of Inventiveness in Developing Countries through a More Advanced Patent Administration', *IDEA: The Journal of Law and Technology*, 39 (1999), 480.

biotechnology, pharmaceuticals, and engineering. The rest are involved in examining applications for designs and petty patents.[22]

It is to be noted that the recruitment of experienced engineers and scientists as patent authorities to examine increasingly complex applications is a serious problem for developing countries' patent office. In Thailand, for example, 11.9 per cent of the patent examiners currently employed by the DIP have a bachelor's degree in science, and the remaining holds a master's of science degree. The majority has little experience in patent examination. Of the total, 35.7 per cent have between 10 and 15 years experience, and the rest has work experience of less than 10 years.[23]

Experienced patent examiners cannot be hired quickly in the labour market. The problem is more acute as the DIP is not a self-financing executive agency. Patent examiners at the DIP are hired at government pay scale, which are uncompetitive with non-governmental jobs. For example, the starting salary of a DIP's patent examiners is THB 12,000 (approximately US$ 300) per month, while an examiner with 5-10 year experience receives the maximum salary of THB 50,000 (approximately US$ 1,666) per month.[24] The DIP enjoys less flexibility than its counterparts in some other ASEAN countries such as Singaporean and Malaysian patent offices, which are now an autonomous organisation. The DIP is still regarded as a source of income for the Thai government, and most of its income generated from application and maintenance fees must be remitted to the Revenue Department. It is unable to use the surplus income for providing pay incentives to well performing examiners. Because of its limitations, the Thai Patent Office has struggled to recruit competent examiners, and as a result it is unable to deal with dramatic increases in the number of applications.

2.5 Backlog of applications and incomplete patent documentation

Like Thailand, many countries do not have sufficient expertise necessary to maintain a modern patent office with full capability for thorough technical examination in all fields, particularly in new areas of technology such as biotechnology and pharmaceuticals. In recent years, patent offices around the world are facing the patent backlog problem due to dramatic

[22] Kenan Institute, *Comparative Assessment Study of Patent and Trademark Offices in Southeast Asia,* Kenan Institute Asia, Bangkok, 2012.
[23] Ibid.
[24] Ibid.

increases in the number of applications.[25] As a result, a number of patents being issued for inventions do not meet the patentability criteria. In the United States, for example, very few patent claims reach the trial phase, and "about 30–35% of patents brought to trial are found invalid or unenforceable".[26]

The problem of patent backlog for developing countries like Thailand has become even more acute due to the weak institutional capacity in patent administration. It has become obvious that the DIP has struggled to cope with the increasing volume of patent applications. From 2005 to 2010, the DIP received approximately 10,000 patent applications each year. The majority of the applications were design patent applications. Only about 15 per cent were applications for a patent on the invention. The period of patent granting in Thailand is, on average, from 3 to 5 years, which can be much longer for patent applications in complex fields. It is estimated that the period taken to obtain a patent for invention in areas of physics and biotechnology generally takes 5-9 years due to the lack of examiners in those fields of technology. The number of applications per examiner is also growing in recent years. In 2009, each examiner was expected to process an average of 254 applications per year at an approximate rate of an application for every working day.

Thailand has attempted to increase its patent quality and reduce administrative burden on the Patent Office by seeking international collaboration. The DIP has outsourced search and examination of patents to foreign patent offices, such as the Australian Patent Office, with additional fees incurred on applicants. While the outsourcing option provides relatively low-cost, high-quality examination, it has created a language problem, as the patent law of Thailand requires all applications to be drafted in Thai. In practice, the DIP, due to limited resources and facilities, gives greater weight to the patent grants for the same invention in other countries. Because of this practice, a claimed invention that has been granted a patent by a foreign patent office, particularly that of developed countries that are considered more capable of thoroughly examining applications, is almost guaranteed a patent right in Thailand.

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[25] London Economics, *Economic Study on Patent Backlogs and a System of Mutual Recognition*, Report submitted to the UK Intellectual Property Office, Intellectual Property Office, London, 2010. http://www.ipo.gov.uk/p-backlog-report.pdf; The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*, The Royal Society, London, 2003.

[26] Abbott, F.M. "Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines", in Maskus, K.E. and J.H. Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge University Press, Cambridge, 2005, p. 408.

In principle, patent database and patent documentation provide a wealth of information for local scientists. In reality, the patent specifications provided by the applicant are generally a translation of the patent application filed in a foreign country by the same applicant. The DIP's patent examiners have faced difficulties dealing with the large number of translated documents. A number of patent applications filed in Thailand are technically incomplete and poorly translated, which makes it difficult for the examiners to read and understand the technical descriptions of the applications. It is interesting to note that specialised profession of patent attorneys does not exist in Thailand. The law is silent about what type of qualifications the patent representative has to possess. As a result, attorneys at law are the only ones qualified to represent clients in the prosecution of patent applications. Those patent attorneys generally are law graduates and most of them do not have a technical degree, and there is no graduate school for the professional training of patent attorneys.

The importance of essential details of the patented invention is crucial. The inadequate and incomplete disclosure in patent applications makes it impossible for the public to utilise the patented information efficiently. Poorly translated applications may also lead to errors in the determination of the patent examiner and may result in an invalid patent being granted.

2.6 Specialised IP court

In Thailand, a special court for IP was set up by the Act for the Establishment of and Procedure for Intellectual Property and International Trade Court B.E. 2539 (1997). At the same time, the Office of the Attorney General also established a special division to deal with litigation involving IP and international trade. It was an aim of Thailand to have a special court equipped with specialised expertise to handle cases pertaining IP and international trade matters.[27] A quorum of the Intellectual Property and International Trade Court (IP&IT Court) comprises two career judges and an associate judge who is an expert in the relevant field. The Court has its own procedural rules, which can be issued by the Chief of Justice of the IP&IT Court, with the approval of the President of the Supreme Court. An appeal against any judgment of the Court is filed directly to the Supreme Court. A new procedural law was also developed. The new rule authorises a use of deposition and affidavit of foreign witness in lieu of hearing of witness residing overseas. A hearing of evidence by means of video-

[27] Ariyanuntaka, V. "TRIPs and the Specialised Intellectual Property Court in Thailand", *International Review of Intellectual Property and Competition Law*, 30/4 (1999), pp. 360-376; Legomsky, S.H., *Specialised Justice*, Oxford University Press, Oxford, 1990.

conferencing is also allowed, in order to facilitate the conduct of the trial. According to the Rules for Intellectual Property and International Trade Cases B.E. 2540 (1998), various enforcement measures are available including a preventive injunction (i.e. an injunction granted to prevent an IP infringement prior to instituting an action) and an *Anton Piller* order (i.e. an order granted to preserve relevant evidence concerning the alleged infringement). The changes in procedural law are expected to provide a speedy, efficient and fair trial.

The establishment of specialised IP court in Thailand was in response to the issue of lack of judicial expertise in IP, which was viewed as a major problem in handling contentious IP matters. However, the IP&IT Court still lack sufficient judges with IP expertise. Since the IP&IT Court is a specialised court under the general administration of justice, its career judges are still under the rotation system imposed by the Judicial Commission of Thailand. IP&IT Court judges generally move from the court to another court every two to three years in order to gain promotion. When a judge that has developed IP expertise and has learnt all aspects of IP&IT court practice is transferred, it would be difficult to replace him or her with another judge who has specialised knowledge of IP issues. No doubt, when the institutional deficiencies and a lack of IP resources and expertise are not addressed, the establishment of specialised courts would be of little benefit.

2.7 IP and technical assistance

Developing countries' requirements for IP technical assistance is obvious. Foreign agencies have provided technical assistance on IP law and policy to Thailand. The aim of the provision of technical assistance is for strengthening Thailand's capacity in handling IP-related matters. The Thai agencies that are the major recipients of technical assistance are: the IP&IT Court and the DIP.[28]

Each year, the IP&IT Court receives a number of technical assistances. Offers come from different foreign organisations. The followings are some of assistances provided to the Court:

- The United Kingdom: The British Council offers several scholarships for studying in the UK. It also funds academic seminars, and sponsors resource persons coming from a foreign country.

[28] Kuanpoth, J. *Intellectual Property- Related Technical Assistance, Collaboration, and Capacity Building: The Thailand Experience*, Paper Presented at ICTSD Dialogue on Technical Collaboration for IP Policy in Developing Countries, International Centre on Trade and Sustainable Development, Geneva, 2005.

- The United States: The US Embassy organises meetings between American resource persons and lawyers with judges from the IP&IT Court through teleconferences. This is to allow both sides to share experience and clarify certain issues. USAID also co-funds the Court to attend an annual symposium in every December. It also sponsors judges from Vietnam to train and share experience at the IP&IT Court.
- France: INPI Division of France Embassy invites resource persons from France to share experience with Thai judges.
- Australia: Australia in several occasions supported the organisation of IP seminars.
- Germany: Germany offers one scholarship per year for judges to undertake research at the Max Planck Institute in Munich. The scholarship is for a 2-3 month stay in Germany.
- Japan: Japanese granting agencies like JETRO, JICA, and JAI, provide technical assistance to the Court in several forms, including funding seminars, offering field trips to Japan, and sponsoring judges to train in Japan for 2-3 weeks. The IP&IT Court has also entered into a technical collaboration with Waseda University to develop a database containing court decisions.
- Through the ECAP Project (EC-ASEAN Intellectual Property Rights Collaboration Program), the EU provides different from of assistance to the Court, including organising meetings to raise awareness, field trips, seminars and developing IP database.

The DIP has engaged in technical collaboration with foreign agencies at three levels: multilateral, regional and bilateral. The multilateral collaboration mostly comes from the World Intellectual Property Organisation and the World Trade Organisation. The DIP also enters into regional collaboration with APEC countries and ASEAN countries. It also receives bilateral technical assistance from Japan, the EU, the United States, Australia, Korea, China and individual members of APEC. These collaborative projects appear in the forms of academic and educational collaboration on different IP-related issues, technical assistance in the drafting and amendment of laws and for the development of the IP system, training in the patent application process, etc. To date, the majority of technical collaboration provided to Thailand is mostly related to IP protection and enforcement. Support provided to the DIP is mainly focused on IP enforcement with an emphasis on training police, judges, and customs

officers. Some donor agencies see the benefit in assisting the DIP in developing its own IP system, as they expect that in return Thailand will have better enforcement.

It can be seen that technical assistance is mainly provided to Thailand for raising awareness of IP protection and for increasing enforcement of IP rights. Specific programmes have focused on the training of judges and officers in agencies responsible for IP enforcement. Existing collaborations is also concentrated in amending existing and drafting new legislation to comply with international rules. It is to be noted that developing countries like Thailand have urgent needs in management or commercialisation of IP, rather than IP enforcement. They also require supports for raising awareness of the social and developmental impact of IP and advanced technologies such as biotechnology and information and communication technology. Technical collaboration should be available to developing countries to promote the legal, commercial and economic exploitation of IP rights. Training assistance should be provided to assist the local entrepreneurs in commercialising their innovations and creations or in finding markets for their innovative products. Assistance is also needed in the restructuring of national agencies, such as the reorganisation of the IP office to facilitate the better management of IP, to improve efficiency of the office, and to review the process for patent granting and repealing in order to improve the country's IP system.

2.8 Opposition proceedings

Examination of patent applications requires two things: competent patent examiners, and access to the body of scientific and technical knowledge. It is extremely costly for a country to carry out accurate patent examination. The US, for example, spends more than US$ 1 billion per year to do exhaustive searches of the prior art and to carry out substantive examination of patent applications. Patent offices in developing countries do not have sufficient resources and qualified staff. Its staffs are generally under-trained and have less access to technological materials on prior art.[29] It is possible that many patents granted by patent offices of the developing countries are invalid. Granting a bad patent will not stimulate public interests, but can generate very negative consequences to the country, particularly if an invalid patent is granted to a powerful economic actor like a multinational pharmaceutical company. Thus, it is extremely important that patent challenge proceedings are available in

[29] Kanter, J. "A New Battlefield: Ownership of Ideas", International Herald Tribune, 3 October 2005.

order to detect an application's weaknesses and allow competitors to oppose the grant of a patent to such an application.

There are two types of opposition proceedings: pre-grant and post-grant. The former is the system that opposition is considered by the national patent office during the examination process, and the latter refers to the proceedings brought by the opponent of a patent holder before the patent office or the courts. The post-grant procedure comes after the decision on the examination leading to official grant of the patent and the opposition is filed to challenge the decision. Challenging a patent before it is issued is an administrative process, and is generally faster and cheaper than post-grant court proceedings. While a successful opposition in a pre-grant procedure will prevent the entire issuance of the patent or limit the scope of the opposed patent claims, the post-grant patent challenge can result in one of these solutions: rejection of the opposition, nullifying the granted patent, and amending the patent.

The TRIPS Agreement is silent on the issue of procedures for patent opposition. The Japanese law, the EPC and law of the countries brought in line with the European Convention (e.g. that of the UK, the Netherlands, Germany, Sweden, Denmark, etc.) provide for a post-grant opposition procedure.[30] The current law of India is unique as it is the only patent law that provides for both pre- and post-grant opposition.[31] The patent systems of other developing countries seem to prefer a pre-grant opposition. Section 31 of the Thai Patent Act, for example, permits oppositions to be filed after the applications are published. Any person, without restriction as to their nationality or connections with the applicant, may initiate proceedings to oppose the grant of a patent within ninety days from the date of the publication. There are two reasons on which oppositions may be based: (1) lack of patentability; and (2) the applicant is not entitled to apply for a patent application. Other grounds likely to affect the validity of a patent (e.g. insufficient disclosure) cannot be raised as grounds for opposition under Thai law.

[30] See Beier, F.K. "The Remedies of the Patent Applicant and His Competitors in Comparison - Balance or Imbalance? A Comparative Law Study" 20 IIC 407 (1989) at 438; Pagenberg, J. "Different Level of Inventive Step for German and European Patents? The Present Practice of Nullity Proceedings in Germany" 22 IIC 763 (1991).

[31] Dhar, B. and K.M. Gopakumar, Post-2005 TRIPS Scenario in Patent Protection in the Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India, ICTSD-UNCTAD Project on IPRs and Sustainable Development, Geneva, 2006. Available at http://www.iprsonline.org/unctadictsd/regional_research.htm

Thailand is currently under pressure from the US and the EU to discard its pre-grant opposition proceedings. Those countries are very skeptical about the negative effects of such pre-grant opposition, particularly the very considerable delay in achieving the grant of a patent. Such procedures, they maintain, are unnecessary and done at the wrong time. Since the only document available after the date of publication would be the specification as filed, the person who lodges an opposition might not be certain as to what exactly he is opposing.[32]

From the public health perspective, the repeal of the present system for post-grant opposition may not benefit the developing countries like Thailand wishing to increase access to medicines. It will be much more difficult for the competitor to oppose patents after grant as the patents are in force while the opposition litigation is pending. The pre-grant patent challenge is the best way to limit the number of granted invalid patents. It provides some form of low cost administrative procedure for the manufacturers of generic medicines, who are in a better position to check a drug's patentability than the patent office as they operate in the same field and are aware of evidence that the medicine has already been used by someone else before the applicant. However, since the pre-grant opposition proceedings can be used by third parties to delay the grant of a patent, it is necessary that the process is run in a transparent manner. It is equally important that the process for oppositions is independent, and fair and equitable to all parties.

3. Impact of TPP IP on Health

The debate on IP protection consistently touches upon the problems that are being faced by developing countries and the impact that intellectual property implementation has on these countries. In particular, the impact and ability for local industries to use and produce new products are particularly felt in emerging economies as their growth is being slowed down because of patent protection. It is universally accepted that access to good quality essential medicines could make a vital contribution to improving health and reducing mortality and morbidity. However, those essential medicines would save lives and improve health only if they were available and affordable. However, many people in the developing world have not yet had regular access to the medicines they need. This had a major impact on health, since most common illnesses in developing countries could be treated or alleviated with simple

[32] Helfgott, S. "The Declining Use of Patent Oppositions", 16 IIC 178-9 (1985).

essential medicines. Trade globalization and the controversial TRIPS-plus issues under various FTAs including the TPP have made the issue of access to essential medicines, and especially to patented medicines such as antiretroviral agents, more acute than ever. Therefore, it is necessary for a country to understand the depth of IP before it decides to sign on the treaties with TRIPS-plus obligations such as the TPP.[33]

The followings are the summary of the TPP IP issues that may hinder accessibility to essential medicines.

- Patents on new uses, new methods of use, and new process for using known products will flood national patent office with patents on incremental inventions and prolong the monopoly the life of medicines that are supposed to enter into the public domain after their patents have expired.
- Requirements on data exclusivity will create entry barriers for generic medicines, as the generic manufacturers are prohibited from accessing clinical and test data. The generic firms will have to enter into a long and costly testing process before the marketing approval of a generic drug can be obtained. It will also restrain the effectiveness of the compulsory licence system by forcing the person to whom a compulsory licence is granted to come up with their own test data required for marketing approvals of medicines.
- Patent term extensions for delays in granting patents as required under the TPP will give compensation for delays in issuing patents for pharmaceuticals. It will allow the manufacturers of medicines to control the market longer than the conventional patent rule, despite the fact that those companies are generally compensated by *de facto* deterrent effect of pending patents on generic producers. The original companies can also use various marketing techniques, such as brand name advertisement and trade mark protection, to secure their monopoly position even after the expiration of the patent term. Extending patent term will delay the potential introduction of affordable generic medicines and defer the day when consumers can reap the benefit of generic competition.
- The TPP text mandates patent linkage, whereby the national drug regulatory is under obligation to inform the holder of patents relating to medicines sought registration by

[33] Baker, B.K. "Patents, Pricing, and Access to Medicines in Developing Countries", 11 Virtual Mentor 527, 527 (2009); Mitchell, A.D., T.S.L. Voon and D. Whittle "Public Health and the Trans-Pacific Partnership Agreement, 5 Asian Journal of Int'l Law, (2015) pp. 279–309.

a generic company. The authority is also required to withhold marketing approvals of the said medicine while the patent holder exercises his/her patent rights through judicial or administrative procedures. The linkage of drug registration with the patent status will impose an unnecessary burden on the drug authority and unnecessarily restrains the entry of generic medicines. The practice of linking patent status to registration obviously provides stronger protection for IP rights than any other rights of the private party.[34]

- The previously mentioned TPP provisions, together with other provisions contained in the TPP text, including a strong enforcement mechanism of IP rights and the availability of so-called investor state dispute settlement that gives IP owners broad rights to bring claims for private arbitration directly against the State, will deter governments from using the flexibilities that TRIPS provides – for example compulsory licensing, thus inhibiting countries' ability to access generic and patented medicines.

Asian countries, particularly Thailand, have experiences in dealing with pressure tactics from pharmaceuticals and other countries. Thailand's experience with trying to provide access to HIV/AIDS and other drugs for its poorer population groups highlights the difficulties a country can face when life-saving and essential medicines are protected by patents. HIV/AIDS is one of the leading causes of death in Thailand. An estimated 610,000 Thais are currently living with HIV. The widespread transmission of HIV in Thailand occurred in the late 1980s. Between 1988 and 1989, rapid transmission was apparent among injecting drug-users, with over 50 per cent HIV prevalence among injecting drug-users in some provinces. From 1993 to 1997, 8325 cases were reported, with HIV infections believed to have rapidly spread among sex workers. It was found that during the early 1990s almost half of sex workers in Chiang Mai, a northern province of Thailand, were infected with HIV.[35] The high rate of infections among sex workers led to the rapid transmission of HIV/AIDS to their male clients, and from infected males to their wives and partners, and their children, particularly in a country where 20 per cent of adult males are reported to use the services of a sex worker at last once per year.[36] Despite greater condom use

[34] Bhardwaj, R. *et al* "The Impact of Patent Linkage on Marketing of Generic Drugs", Journal of Intellectual Property Rights 18(4), 316-322 (2013).
[35] Weniger, B.G. *et al* "The epidemiology of HIV infection and AIDS in Thailand", AIDS, Supp 2, S71-S85 (1991).
[36] UNAIDS, Redefining AIDS in Asia – Crafting an effective response, Oxford University Press, New Delhi, 2008, pp. 33-38. http://www.hivpolicy.org/Library/HPP001470.pdf

by sex workers, this remains a prime transmission path, with female and male sex workers and injecting drug users particularly at risk.

In response to AIDS epidemic in the early 1990s, the Thai Government launched large-scale preventive action. In 1991, the Anand Punyarachun Administration declared that HIV/AIDS was a government priority. The National AIDS Prevention and Control Committee (the Committee) was set up and the AIDS control programme was transferred from the Ministry of Public Health to the Office of the Prime Minister. The Government also increased the 1993 budget for HIV/AIDS to USD 44 million, almost a twenty-fold increase from the previous year.[37] The top-level political commitment helped to mobilize not only financial resources but also a wide range of sectors of government and society to fight against HIV/AIDS.

The initial policy response was limited to preventing the spread of the epidemic. Medical treatment was for the prevention of opportunistic infections only. No ARV treatment was provided to HIV-related patients at the early stage of the HIV/AIDS campaign. The Thai Government subsequently realized that while preventing new HIV infections was crucial, it also needed to treat those who had already contracted the virus. In 1992, the Ministry of Public Health shifted the HIV/AIDS policy from prevention to the subsidization of ARV treatment and the introduction of locally produced low cost ARVs.[38] At the beginning of the campaigns, only mono-ARV therapy (that is, AZT or zidovudine) was prescribed free of charge for a small number of selected HIV patients. However, when drug resistance occurred as the virus evolved to escape the inhibitory effects of the drug, it required a change of medication. The Ministry was forced to switch to the combination therapy of using two or three drugs, which is more potent in suppressing the virus but also more expensive than a single therapy.

In 2000, the Ministry of Public Health created a project 'National Access to Antiretroviral Program for People living with HIV/AIDS' (NAPHA), which provided a wide range of triple drug ARV therapy. Under the project, around 400 public hospitals are dispensing ARV drugs to selected HIV-infected people. The Committee based its selection of HIV-related patients on clinical grounds (for example, a patient with a CD4 count of less than 200). Those selected

[37] UNDP, Thailand's Response to HIV/AIDS: Progress and Challenges, United Nations Development Programme, Bangkok, 2004, pp.16-17.
[38] Ibid.

would receive free ARV drugs, which the Ministry of Public Health allocated to the hospitals based on a quota system. Each small state-funded hospital (that is, a 60 bed hospital) received ARV drugs for 20 persons at a time. Larger hospitals received a quota of drugs for 40 persons. This was inadequate to cope with the increasing number of infected persons.

It may be noted that the Constitution of Thailand adopted in 1997 for the first time recognized the people's right to health care and social welfare. This subsequently led to the introduction of the universal healthcare system. The health insurance system or the '30 baht' scheme, which currently covers approximately 95 per cent of the population, was introduced in April 2002 by the Thaksin Shinawatra government. But the universal healthcare system did not include ARV treatment, due to the country's financial constraints and the high cost of the relevant medicines. As a result, only a very small percentage of Thai AIDS patients were receiving the drug therapy under the Government hospital-based programme.

In the early stages, most of the drugs distributed under NAPHA were branded drugs which cost more than THB 380 000 (USD 11,875) per person per year, far beyond the limited government budget. Due to the success of the Government Pharmaceutical Organization (GPO) in producing GPO-vir, a fixed-dose combination of stavudine, lamivudine and nevirapine, the Thai Government could expand its ARV treatment programme providing ARV drugs to a large number of HIV-infected people. Currently there are six triple ARV therapies being used under the Ministry of Public Health's NAPHA programme, including GPO-vir (stavudine+lamivudine+ nevirapine), d4T+3TC+EFV (stavudine+lamivudine+efavirenz), AZT+3TC+NVP (zidovudine+lamivudine+nevirapine), AZT+3TC+EFV (zidovudine+lamivudine+ efavirenz), d4T+3TC+IDV/RTV (stavudine+lamivudine+indinavir/ritonavir), and AZT+3TC+IDV/RTV (zidovudine+lamivudine+indinavir/ritonavir).

In the six triple drug therapies, there are seven ARVs (each a different chemical entity). Among these, only two chemical entities (efavirenz and indinavir) are patented in Thailand. One formulation (namely GPO-vir) is under a petty patent, which is owned by the GPO. There are no patents over lamivudine, nevirapine, ritonavir, stavudine, and zidovudine. The lack of patents on the majority of ARV drugs makes it possible for the GPO to produce cheaper generic medicines. For example, GPO-vir pills can be produced because stavudine, lamivudine and nevirapine are not under patents in Thailand. With the use of GPO-vir, which

costs around THB 1200 (USD 37) per patient per month compared to THB 18,620 (USD 582) per patient per month for the imported drugs, the Thai Government can run its ARV treatment programme successfully as it can obtain the generic versions of the drugs at far lower prices than those for the brand pharmaceuticals offered by the MNCs.

However, the government programme faced difficulties in 2007 when the Ministry of Public Health had to switch a large percentage of patients to considerably more expensive second-line therapy because those patients became allergic to the first-line drugs or when the HIV virus became resistant to the current drugs. Several WHO-recommended second-line drugs are currently under patent protection in Thailand. Only two of seven second-line drugs (abacavir and ritonavir) are not patented. Three important second-line ARVs (didanosine, lopinavir, and lopinavir/ritonavir) are all patented. The other two compounds (tenofovir and saquinavir) are at the time of writing still the subject of pending applications, to which patents can be granted in the near future. It means that five of the seven WHO-recommended second-line ARVs will be under patent protection in Thailand.

Available data indicate that the prices of branded and patented ARVs are generally much higher than those offered by the generic companies. For example, the prices of two non-patented first-line ARVs currently used by the Ministry of Public Health (namely, lamivudine and stavudine) are considerably lower than those offered by the originator companies. While the originator's lamivudine 150 mg and stavudine 40 mg are priced at THB 6,046 (USD 189) per 60 capsules and THB 5,660 (USD 176) per 60 capsules respectively, the same drugs are available in the same quantities from the GPO at much cheaper prices: THB 600 (USD 19) for lamivudine and THB 270 (USD 8.44) for stavudine. As regards the patented drugs, the price differentiation is much greater. For example, lopinavir/ritonavir 113.3/33.3 mg, a WHO-recommended second-line ARV, is sold in Thailand by the originator company at THB 17 762 (USD 555) per 180 capsules, while the same drugs could be imported from an Indian generic company at the price of THB 5930 (USD 186).[39]

In November 2006 and January 2007, the Thai Ministry of Public Health decided to issue government use licences against patents over three medicines: (1) efavirenz, Merck's anti-HIV drug; (2) clopidogrel, an anti-clotting drug sold by Sanofi-Aventis and Bristol-Myers

[39] Kuanpoth, J. "Patents and Access to Antiretroviral Medicines in Vietnam after WTO Accession", Journal of World Intellectual Property, 10(3/4) (2007), pp. 201–224.

Squibb; and (3) lopinavir/ritonavir (branded 'Kaletra'), an ARV distributed by Abbott Laboratories. Although the past decade has seen a number of developing countries granting compulsory licences, Thailand was the first developing country that issued a license for a non-HIV medicine, which reflected that compulsory licences can be issued for patented medicines treating all sorts of ailments, not only HIV/AIDS. Clopidogrel, which is sold under a brand name 'Plavix', is one of the world's biggest-selling heart disease medicines, with annual sales of USD 6 billion. Around 200,000 Thai patients suffer from heart conditions and blood clotting problems that could be treated with the drug. As for drugs required for the treatment of HIV/AIDS, the Public Health Ministry claimed that only 20 per cent of infected people or about 20,000 were able to access the HIV treatment.[40]

The Government pointed to high drug prices as the main factor for its inability to provide health-care coverage. In the 2007 fiscal year, for example, public health accounts for 9.5 per cent of the total public expenditure, which is equivalent to THB 4,373 million (about USD 112 million).[41] With this amount, the Government claimed that it could afford to provide medicines to one-fifth of the 500 000 people living with the HIV/AIDS in Thailand at the companies' price. The issuance of government use licences would allow the Ministry of Public Health to treat many more patients because it could switch to a generic version of the drugs that cost on average only one-seventh to one-tenth the prices of the patented and branded products, cutting the drug bill by two-thirds.[42]

The Thai Government has two options to deal with the excessive price problem. First, it may grant a compulsory license for government use allowing the GPO to manufacture generic drugs. It can also authorize the Ministry of Public Health to import generic versions of the patented medicines from the countries where the prices are lower.[43] It should be no surprise to find political factors playing an important part in the granting of non-voluntary licences. The grant of compulsory licences by the Thai Government has attracted a variety of reactions. The owners of the affected patented brand drugs expressed their concerns about the process

[40] UNAIDS, op.cit.
[41] Ministry of Public Health and National Health Security Office (2007) 'Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand', Document to Support Strengthening of Social Wisdom on The Issue of Drug Patent, Bangkok, http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf
[42] Ahuja, A. "Thailand to Break Two Drug Patents", Business Week, 29 January 2007.
[43] Abbott, F.M. and J.H. Reichman "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions", Journal of International Economic Law, 10 (2007), p. 953.

of grant of compulsory licences. They maintained that the Ministry did not give advance notice of the decision, causing the compulsory use of the patents by the Thai Government to be in violation of WTO/TRIPS intellectual property rules. They also claimed that the licences would reduce their profits, thereby decreasing the incentive to continue research and development.

Thailand's justification for issuing the compulsory licence is based on WTO rules that allow for compulsory licensing on patents when a patent holder violates the public interest by charging an excessive price for its product. The Ministry of Public Health also contended that it was engaged in extensive discussion with the right holders for more than two years before it finally decided on government use licensing. The use of the drugs by the State, according to the Ministry, would not affect the patented market as the medicines distributed under the non-voluntary licensing scheme would be for those unable to pay, most of whom already covered by the universal coverage.[44]

It is interesting to note that the move by the Thai Government brought an angry response from the Office of the United States Trade Representative (USTR). In its 2007 and 2008 review, the USTR exerted extraordinary pressure on Thailand by placing Thailand on the Priority Watch List (PWL) under Special 301 of the Omnibus Trade and Competitiveness Act of 1988. It also threatened to revoke the trade privileges it grants to Thailand under the Generalized System of Preferences (GSP). The leverage, which was previously successfully applied by the United States on Thailand in 1992 and which caused Thailand to amend its patent law to protect pharmaceuticals, is clearly threatened in an attempt to discourage government use licensing. Furthermore, the fear of government intervention in patent matters caused the USA to limit the application of a compulsory licensing scheme under the bilateral free trade agreement (FTA) it had been negotiating with Thailand since 2003. In the FTA negotiations, the USTR demanded Thailand implement stricter laws concerning the licensing scheme including, *inter alia*, narrowing the situations in which non-voluntary licences could be issued. However, the Thai-USA FTA negotiations were suspended due to the political crisis in Thailand that led to dissolution of the Thai parliament in February 2006.[45]

[44] Ministry of Public Health and National Health Security Office, op.cit.
[45] Arunmas, P. "Thai Traders Urge 'Extreme Caution' on CL", Bangkok Post, 14 February 2008; Sell, S.K. "TRIPS and the Access to Medicines Campaign", Wisconsin International Law Journal, 20 (2002), pp.481-522.

Thailand is renowned for its success in tackling HIV/AIDS, its efforts resulting in a ten-fold drop in new infections.[46] It has incorporated ARV treatment into the national AIDS plan by providing free and universal access to ARV treatment for people living with HIV/AIDS. This achievement stems from the fact that Thailand has been able to build its local manufacturing capacity to produce a fixed-dose generic combination drug like GPO-vir. Thailand was also successful in using flexibilities available under WTO/TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health to negotiate lower prices for patented drugs. The country's success in improving the availability of essential HIV/AIDS medicines is related to many factors. First, it was able to determine the patent status of the needed product both in Thailand and in the country from which it wanted to import the generic drug. This understanding allowed Thailand to apply the appropriate mechanism to make the patented drug available at appropriate prices. More importantly, Thailand was prepared to resist and finally overcome political pressure from multinational pharmaceutical companies and its major trading partners. UNAIDS has praised the commitment of Thailand in providing ARVs for people living with HIV/AIDS. The 2008 report says: '… there is a compelling argument for providing antiretroviral treatment for all households as a public good. Thailand has shown this can be done within the ambit of a national social insurance system, where more than 80 per cent of people in need of antiretroviral therapy could be provided treatment."[47]

Several success factors have contributed to improve access to medicines in Thailand. Those factors include: the country's relatively good health-care and reliable supply systems, and the Public Health Ministry's policy that enhances rational selection and use of drugs. Finally, a combination of domestic capacities and the use of appropriate strategies, such as the use of the compulsory licensing, among other factors, have increased the Thai Government's bargaining power in negotiations with brand-name companies over price discounts.

Conclusion

The foregoing outlines an attempt of nations to harmonise IP regulations under the TPP in order to further liberalise trade in the Asia-Pacific region. The paper reflects that Thailand still

[46] UNAIDS, op.cit.
[47] Ibid., p. 84.

struggles to improve its capabilities needed to implement IP laws, but it has successfully developed a very strong and efficient public health system. The debate on IP protection consistently touches upon the problems that are being faced by developing countries and the impact that intellectual property implementation has on those countries. In particular, the impact and ability for local industries to use and produce new products are particularly felt in emerging economies as their growth is being slowed down because of patent protection. It is universally accepted that access to good quality essential medicines could make a vital contribution to improving health and reducing mortality and morbidity. However, those essential medicines would save lives and improve health only if they were available and affordable. However, many people in the developing world have not yet had regular access to the medicines they need. Trade globalization and the controversial TRIPS-plus issues under various FTAs, including the TPP, have made the issue of access to medicines, and especially to patented medicines such as antiretroviral agents, more acute than ever. It would be interesting to see if the TRIPS-Plus IP rules would dramatically impact future access to affordable drugs and the healthcare system in Thailand if the country decides to join the TPP.