

ABSTRACT

Recently, intellectual property rights (IPRs) has become one of the hottest, most significant issues of trade negotiations. Despite the continued claim that IPRs facilitate research activities and encourage technology transfer, the impact of IPRs on socio-economic development process of developing countries has evidently reflected in many areas, including health, agriculture and education. IPRs will no doubt continue to have a significant impact on developing countries for many years to come.

The developing countries have faced the challenge of constraint optimisation on how to implement the WTO TRIPS Agreement in such a way to minimise the socio-economic costs and maximise the national benefits. The third world states are now facing increased pressure toward higher standards of IPRs protection (i.e. the so-called TRIPS-plus). The attempts of the developed countries to evolve the TRIPS-plus regime, which appears in the form of free trade agreement (FTA), provide opportunities for those countries to negotiate rules and commitments that go beyond what was not possible on the multilateral level.

By entering into an FTA with the developed countries, the developing countries see some advantages in tariff reductions of agricultural, clothing and other products, but at the same time it closes down the opportunity for the latter to put forward the issues of their concern through the WTO including the harmonisation of TRIPS and CBD, access to medicines, and protection of genetic resources, farmers' rights and traditional knowledge.

This note explores the controversial TRIPS-plus issues under the FTAs that pose many challenges to the developing countries. Although the EU offers trade benefits under bilateralism to encourage some developing countries to provide higher level of IPR protection (for example FTAs between EU and Bangladesh and EU and Morocco), the note will only focus on FTAs signed by the US because of its leading role in this issue. The note will analyse the TRIPS-plus standard under an FTA between US and Singapore, a bilateral trade agreement (BTA) between US and Vietnam and the proposed US-Thailand FTA which might be based on recent US FTAs with other countries. It explores major TRIPS-plus issues and considers the broad implications of such rules under various headings, including patenting living organisms, effects on access to medicines, and protection of test data, trade marks, and digital technologies. Arising from the analysis outlined in the note, the final part concludes with some final remarks and key policy recommendations.

Current Developments and Trends in the Field of Intellectual Property Rights: Harmonisation through Free Trade Agreements

I. TRIPS-plus rules through FTAs

The Bush Administration has launched negotiations for an FTA with a large number of countries, including Chile, Jordan, Morocco, Singapore, Central American countries, Andean countries, Thailand, Panama, Bahrain, Southern African countries, and many others. In South East Asia, the US up till now has signed bilateral treaties with two countries (i.e. Singapore and Vietnam), and has been in negotiations with Thailand. While negotiations with Thailand are underway, the US is also looking at other three ASEAN countries (i.e. Indonesia, the Philippines, and Malaysia) as its next targets for bilateral FTAs.

The agreements that the US has signed with Singapore and Vietnam contain several IPR provisions that far exceed the obligations in the TRIPS Agreement. The countries concluding a bilateral or regional treaty with the US are required to provide more stringent IPR regimes than any other countries, in exchange with greater access for their exports to the US market.

Note that the US is conducting bilateral trade negotiations with other countries during the current round of multilateral trade negotiations. Since WTO multilateral talks have deadlocked, the rich nations have demanded for further IPR commitments from the developing countries under bilateral and regional trade deals. This strategy no doubt would benefit the US and other industrialised countries as it helps to produce the establishment of an acceptable standard for IPR protection. A successful conclusion of an FTA with one country (e.g. Singapore) will serve as a model for other FTAs (e.g. Thailand and others), and eventually for the multilateral trade negotiations.

The US unhidden agenda is reflected in the statement of objectives in the USTR's Letter of Notifications for FTA negotiations with Thailand as thus:

“The United States concerns about intellectual property protection in Thailand. The United States has worked with Thailand on intellectual property rights issues under the Trade and Investment Framework Agreement (TIFA). While some progress has been made, bringing Thailand's intellectual property regime up to the standards set in other recent FTAs that the United States has negotiated will be a high priority of these negotiations.”¹

The treaties concluded between the US and its trade partners are basically built on the provisions of the North American Free Trade Agreement (NAFTA), the World Intellectual Property Organisation (WIPO) treaties and the basic rules embodied in US legislations. Although FTAs are in principle open to negotiation, all FTAs signed by the US are quite similar to one another. While negotiation is possible on some issues, the US trade negotiators are committed to the basic structure of the model treaty and will only accept minor changes. Major TRIPS-plus issues under US FTAs can be summarised as follows.

- Greater patent protection for new subjects

¹ Letter of Notification of USTR to US Congress of Intent to Initiate Free Trade Agreement Negotiations with Thailand, 12 February 2004.

- Restricting the grounds for compulsory licensing, prohibiting revocation of patents, and restraining parallel importation
- Extending patent term
- Accession to the Patent Co-operation Treaty
- Set-term period of exclusivity for test data and relevant undisclosed information
- Higher level of protection for trade marks
- Legal protection for digital technologies

Key TRIPS-plus issues in bilateral agreements with the US

Issues	TRIPS	TRIPS-plus BTA US-Vietnam	TRIPS-plus FTA US-Singapore
Protection of plants and plant varieties	<ul style="list-style-type: none"> • Plants and plant varieties may be excluded from patentability. • Plant varieties must be protected by patents, an effective <i>sui generis</i> system, or both. 	<ul style="list-style-type: none"> • Patent protection must be available for plants. • Plant varieties may be excluded from patentability. However, the exclusion shall not apply to plant inventions that could encompass more than one variety. • Plant varieties must be protected by the <i>sui generis</i> system of UPOV 1978 or 1991 	<ul style="list-style-type: none"> • Patent protection must be available for plants and plant varieties. • Plant varieties must be protected by the <i>sui generis</i> system of UPOV 1991.
Protection of animals and animal varieties	Animal and animal varieties may be excluded from patentability.	<ul style="list-style-type: none"> • Patent protection must be available for animals. • Animal varieties may be excluded from patentability. However, the exclusion shall not apply to animal inventions that could encompass more than one variety. 	<ul style="list-style-type: none"> • Patent protection must be available for animals and animal varieties.
Compulsory licensing	Permissible subject to listed conditions. However those conditions can be flexibly interpreted as reaffirmed by the	Permissible subject to certain conditions	Forbidden except in three circumstances, plus know-how restrictions

	Doha Declaration.		
Forfeiture or revocation of patents	Permissible provided that an opportunity for judicial review of any decision to revoke or forfeit a patent is available	Permissible only on grounds that would have justified a refusal to grant the patent	Permissible on grounds that would have justified a refusal to grant the patent, or that pertain to the insufficiency of or unauthorised amendments to the patent specification, non-disclosure or misrepresentation of prescribed, material particulars, fraud, and misrepresentation
Parallel import	Permissible	Permissible	Permissible but the patentee is allowed to limit parallel import by imposing a restriction on resale of the patented article
Extension of patent term	20 years, no extension required	20 years, extension is optional in case of a delay caused by regulatory approval processes	20 years, extension is explicitly required in cases of (1) a delay in the issuance of the patent, (2) a delay caused by regulatory approval processes
Accede to the Patent Co-operation Treaty	None required	None required	Required
Protection of undisclosed test and other relevant data	Protect data relating to new chemical entities against unfair commercial use and disclosure of the data	<ul style="list-style-type: none"> • Protect data against unfair commercial use and disclosure • Provide data exclusivity to the originator company for not less than five years 	<ul style="list-style-type: none"> • Provide five-year exclusivity for test data • Prohibit registration of generics during the entire patent term • Notify the patent owner as to the identity of any third party requesting marketing approval
Protection of non-visually perceptible trade marks and well-known marks	<ul style="list-style-type: none"> • Protection of non-visually perceptible trade marks is not required. • Refuse or cancel the registration of well-known 	<ul style="list-style-type: none"> • Protection of non-visually perceptible trade marks is not required. • Refuse or cancel the registration of well-known 	<ul style="list-style-type: none"> • Give effect to the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks and the Trademark Law Treaty • No condition for trade

	marks, and prohibit the use of a mark conflicting with a well-known mark	marks, and prohibit the use of a mark conflicting with a well-known mark	mark registration that signs be visually perceptible • Make best efforts to register scent marks
Protection for digital technologies	None required	<ul style="list-style-type: none"> • Encrypted program-carrying satellite signals is included in IPR definition. • Protection for encrypted program-carrying satellite signals 	<ul style="list-style-type: none"> • Prohibit temporary reproduction, including temporary storage in electronic form • Provide term of copyright protection for not less than 70 years • Provide protection against acts of circumventing technological protection measures • Protection of rights management information • Protection for encrypted program-carrying satellite signals • Protection against use of public computers and networks for copyright infringement • Provide for effective liability for internet service providers

II. Stricter patent rules

The review of bilateral agreements that the US concluded with Vietnam and Singapore has found a number of TRIPS-plus provisions. In the field of patents, the US generally focuses on the at least four key areas: patenting of life forms, limiting access-to-medicines options, extension of patent term, and creating a world patent system.

1. Patenting of life forms

Bilateral agreements with the US maintain principally that an effective and adequate protection must be given to inventions in all technological fields. The US-Singapore FTA, for example,

provides that "each party may exclude inventions from patentability only as defined in Articles 27.2 and 27.3(a) of the TRIPS Agreement".²

This provision is designed to allow for the patentability of all categories of life-forms, including plants, animals, biological processes, genes, and gene sequences. Note that patents on biological materials and methods still have various shortcomings and flaws and are still subject to different uncertain rules. Patent law of the developed countries such as the European Patent Convention, still excludes some forms of biotechnological inventions (e.g. plant and animal varieties) from patent protection. Under FTAs, the developing countries are obligated to patent the by-products of generic engineering and other biotechnological methods without linking the patentability issues to ethical, social, economic and environmental considerations.

The patenting of life when imposed through an FTA could have a considerable socio-economic impact on the developing countries. Granting of patents on biological materials such as genes will cause a power shift in agriculture towards large biotechnology companies and will disrupt the access to essential products such as seeds or foodstuffs the same way as patents are unfairly restricting access to vital medicines for people in poor countries. Stricter protection for IPRs would increase monopoly powers of the right holders, generally multinational firms, allowing them to gain far greater control over the production chain of crops and food.

Moreover, gene patenting will have detrimental effects on the research environment and generate negative effects on downstream innovation. As pointed out by Heller and Eisenberg, patenting of biological products and processes is regarded as "anti-commons", in which "individuals put fences around the peoples' private property and destroyed the commons." This, according to the authors, could impede discovery and innovation in the fastest-growing field of technology.³

When a company is allowed to own patents on biotechnological inventions, the patents would act as a barrier to the transfer of technology to the developing countries. The third world nations always view scientific and technological advancement as the vehicle for industrialisation and economic development. Patenting such products would override technological and economic requirements of the country as it will increase the cost of modern technologies and provide innovative disincentives for local research agencies.

In regard to plant variety protection (PVP), Article 27.3 (b) of TRIPS gives signatory countries options to protect plant varieties by patents, an effective *sui generis* system, or both. The International Union for the Protection of New Varieties of Plants (UPOV) system is recognised to be one, but not the definitive means, of such *sui generis* system. The ambiguity of the term "effective *sui generis* system" under TRIPS allows the developing countries to avoid having to develop full IPR laws covering plant varieties. Some developing countries, such as Thailand and India, have flexibly implemented the TRIPS provision by incorporating the Farmers' Rights⁴ and the access and benefit sharing (ABS) system under the Convention on Biological Diversity into their national legislation.

² US-Singapore FTA, Art. 16.7.1.

³ Heller, M. and R. Eisenberg "Can Patents Deter Innovation?: The Anticommons in Biomedical Research", Science, 1998, pp.698-701.

⁴ The concept of Farmers' Rights adopted by the Food and Agriculture Organisation (FAO) has an aim of compensating farmers who have been conserving plant genetic resources for the past centuries and thereby have contributed to the development of plant varieties.

Thailand has so far resisted ratifying UPOV or adopting it as the standard for its PVP law. This is because plants are vitally important for agriculture, which is still regarded as the backbone of the Thai economy. Its current law, the Plant Variety Protection Act B.E. 2542, is notably not following the UPOV model. Unlike the UPOV, the law aims at promoting not only the creation of new varieties of plant but also the conservation and encouragement of the agricultural practices in the country. The law protects breeders' rights and recognising the rights of farmers and local communities over plant genetic resources. It also adopts legal requirements such as prior informed consent and ABS that allows individuals and communities to claim compensation for their contribution to the resources.

It seems that countries can adapt and change the PVP system to their local conditions, agriculture and farming sectors. US FTAs no doubt attempt to limit this flexibility by requiring the trade partners to join the UPOV 1991 Act. The UPOV system will leave Thailand and other FTA partners with no option regarding the scope of protection, as the 1991 Act provides the least discretion to the signatory states in choosing how to protect plant varieties.

According to Article 14 of the 1991 Act, the protection must be extended to all plant varieties. The exclusive rights must cover vegetative or reproductive propagating material, and extending to essentially derived varieties and harvested material. The rights of farmers to save, use, exchange, or sell farm-saved seeds are constrained. The full-scale monopoly right will adversely affect food and agricultural sectors, and cause adverse effects on the interest of poor farmers, in particular when their right to save seeds is removed. Moreover, the accession to UPOV 1991 will prohibit the inclusion of provision requiring the applicants to prove that the plant variety is safe and does not cause any harmful effects to environment, as currently enshrined under the PVP law of Thailand.⁵

As already mentioned, the Thai economy has been dominated by agriculture and will continue to rely on this important sector for export earnings. Ratifying a TRIPS-plus bilateral treaty, Thailand will open the door for the US biotechnology industry, the largest biotechnology industry in the world, not only to dominate its farming sector but also to exploit its abundant biological resources. Although it is endowed with plentiful amounts of biological resources, Thailand will not be able to take advantage of the resources as a source of economic growth and poverty alleviation. The UPOV system would impose the mandatory components of PVP and restrain the country's sovereign rights over its biological resources and its ability to regulate access to the biodiversity. Under the TRIPS-plus and UPOV regime, Thailand's attempts to balance the IPRs protection and to maintain the alternative rights system would be reduced accordingly.

Options

It is evident that the developing countries will gain very little from providing patents on life and/or the UPOV-type PVP. The high level of protection will not ensure a more stable framework for technology transfer and local plant breeding activities. The developing countries should take the following options into account when negotiating a TRIPS-plus treaty:

⁵ See Thailand's Plant Variety Protection Act B.E. 2542, Sec. 13.

Issues	Options
Patenting of biotechnological inventions	<ul style="list-style-type: none"> • The protection of biotechnological inventions should be based on national objectives as referred to in Articles 7 and 8 of TRIPS. • Preserve the option to exclude from patentability plants, animals, parts of plants and animals including genes and gene sequences, and biological methods as these subjects are not inventions
Protection of plant varieties	<ul style="list-style-type: none"> • Resist ratifying the UPOV Convention • The <i>sui generis</i> system should be optionally available to protect plant varieties. • FTA parties should have freedom and flexibility to interpret the term "<i>sui generis</i>" system and formulate the <i>sui generis</i> system as they see fit.
Protection of genetic resources and traditional knowledge	<ul style="list-style-type: none"> • Protection should be consistent with the international obligations that the country has assumed under the CBD. • Seek the US inclusion in its national legislation, provisions for the protection of TK and a making mandatory the disclosure of the source of genetic materials used in deriving a patented invention • Seek the US to create incentives the recognition of sovereign rights of state over genetic resources • Set up the system of information exchange, protection of ownership of genetic resources, and revoking of patents on material obtained contrary without prior informed consent • Demand the US to accede to key multilateral agreements including CBD and ITPGR • Demand for well-known marks or GI protection for the names of native animals and plants such as Jasmine/Basmati rice

2. Limiting access-to-medicines options

There has been a long debate on the balance between the costs and benefits to society from patents and other forms of IPRs. However, the view that upholds the significance of patents to generate social benefits has come under great challenge, especially when it is applied to the context of the developing countries.⁶ The contribution of patents to the poor nations is believed to

⁶ See Oddi, A.S., "The International Patent System and Third World Development: Reality or Myth?", Duke Law Journal, 1987, p.841; Anderfelt, U., International Patent-legislation and Developing Countries, Martinus Nijhoff, The Hague, 1971; and more recently CIPR, Report of the Commission on Intellectual Property Rights, UK Government's Commission on Intellectual Property Rights, London, September 2002. <http://www.iprcommission.org>

be minimal, compared to the costs that it generates on society.⁷ Due to the influence of this view, in recent years the question of how a developing nation can efficiently utilise the patent system seems to have been replaced by the question of how the profound impacts derived from patents could be effectively curtailed. Developing countries are well advised to maximise the use of all available measures (i.e. compulsory licensing, revocation of patents, and parallel import) as a remedy for abuses of IPRs such as non-working, or for the maintenance of artificially high prices for patented articles.

A. Limiting right to issue compulsory licensing

Compulsory licensing refers to a non-voluntary license issued by the State to a third party to perform acts covered by the patent exclusive rights (e.g. manufacturing, selling or importing the patented product), on the condition that the licensee pays reasonable remuneration to the patent holder in return. The multinational companies always oppose the use of this measure. They argued that the use of patents against the will of the right holder is tantamount to the free-riding of other companies, and will result in trade distortion.⁸

Nonetheless, the compulsory licensing, which the multinationals regard as trade distortion, is the very cornerstone of the patent system. The experience of many countries including the US, Canada and Brazil has shown that the compulsory licensing is an effective mechanism to limit abusive practices of the patent holder and helps to force prices down.

Countries, according to TRIPS, are free to use the compulsory licensing of patents, provided that certain conditions are fulfilled.⁹ In practice, the countries that intended to use the compulsory licensing have always been under considerable economic pressure. With the adoption of the Doha Declaration on TRIPS and Public Health, it now seems obvious that WTO member countries can legitimately employ this legal mechanism to improve access to medicines.

Limiting the right of a country to use the compulsory licensing is probably the most significant of the constraints under US FTAs. The TRIPS-plus rule attempts to make the compulsory licensing provisions difficult to apply, as it sets more stringent conditions than the TRIPS standards. The US-Singapore FTA, for example, confines circumstances under which compulsory licenses may be issued to three circumstances only, namely (1) to remedy anti-competitive practices, (2) in the case of public non-commercial use, and (3) in the case of national emergency or other circumstances of extreme urgency.¹⁰

The FTA provision prevents the country from issuing compulsory licenses in other circumstances than those mentioned above. Issuing a compulsory license on the ground of non-working or insufficient working of patents is also prohibited, despite the fact that the use of compulsory licenses for local working of patents is the cornerstone of most countries' patent law and explicitly enshrined in the Paris Convention.¹¹

⁷ See CIPR, *Ibid.*

⁸ Singham, S.A. "Competition Policy and the Stimulation of Innovation: TRIPS and the Interface between Competition and Patent Protection in the Pharmaceutical Industry", 26 *Brooklyn J. Int'l L.* 363 at 406 (2000).

⁹ TRIPS Agreement, Art. 31.

¹⁰ US-Singapore FTA, Art. 16.7.6.

¹¹ See the Paris Convention for the Protection of Industrial Property (1967), Art. 5(A). See also Penrose, E.T., *The Economics of the International Patent System*, John Hopkins Press, Baltimore, 1951; Vaitos, C.,

According to the US-Singapore FTA, a compulsory license may be issued to remedy an anti-competitive practice only after the patent holder has been adjudged by judicial or administrative process, under the competition laws, as carrying out an anti-competitive practice.¹² This requirement would render the compulsory licensing practically unworkable against the anti-competitive behaviours, as the patent holders can challenge directly sovereign conducts that injures them, through judiciary or administrative channel. When the patentee alleged abuse of patent rights can bitterly contest the proceedings and grants of the license in court or before the antitrust authority, the compulsory license system will not do much to provide an additional tool to safeguard consumer interests.

In the case of public non-commercial use or national emergency or other circumstances of extreme urgency, a compulsory license can be granted only in accordance with these conditions:

- A compulsory license can be issued only to the public sector or third parties authorised by the government.
- The patent holder shall receive full compensation with reference to the TRIPS provision for the compulsory license.
- There must be no requirement for the transfer of undisclosed information or for the disclosure of know-how without the consent of the right holder.¹³

It can be seen from the foregoing discussion that the TRIPS-plus provisions attempt to introduce language that would limit essential measure such as compulsory licensing to certain situations and make procedure for issuing a compulsory license intricate and prolonged. The constraints imposed on the developing countries will threaten to restrict the measure those countries can take to pursue affordable drugs, and will affect ability of many countries to promote access to medicines. Thailand's signing an FTA with the US will result in limited access to medicines not only in Thailand itself but also in its neighbouring countries like Vietnam, Myanmar, Cambodia and Laos, which have been relying on Thailand as an important source of drug supply.¹⁴ With the obligation to the US, Thailand will not be able to issue a compulsory license and export the compulsorily licensed drugs to those countries that have no or insufficient capacity in drug production, denying their rights as reaffirmed by the Doha Declaration on TRIPS and Public Health.

B. Prohibiting revocation of patents

The Paris Convention adopts certain conditions for the revocation of patents. By contrast, TRIPS does not set out any grounds or conditions for patent revocation. Any revocation will therefore be compatible with TRIPS.

The TRIPS-plus introduced by the US prohibits the trade partner from revoking patents on other grounds than those that would have justified a refusal to grant the patent (e.g. lack of

Patents Revisited: Their Function in Developing Countries, *Journal of Development Studies*, Vol.9 No.1, 1972, pp.71-97.

¹² US-Singapore FTA, Art. 16.7.6 (a).

¹³ *Ibid.*, Art. 16.7.6 (b).

¹⁴ Interviews with officials of Vietnam's Drug Administration, Ministry of Health, Hanoi, March 18th, 2004; officials of Myanmar's Department of Medical Sciences, the Ministry of Health, Yangon, October 16th, 2003; and officials of Cambodia's Department of Drug and Food, Ministry of Health, Phnom Penh, August 29th, 2003.

patentability, insufficiency of or unauthorised amendments to the patent specification, non-disclosure or misrepresentation of prescribed, material particulars, fraud, or misrepresentation).¹⁵ Revocation of patents is not possible in the cases where compulsory licenses were not sufficient to curb abuses of patent rights or non-working as provided by the Paris Convention.¹⁶ Limited compulsory licensing therefore becomes only one mechanism that the trade partner can use to curtail the abusive practices of the patent owners.

The TRIPS-plus treaties increase the monopolistic power of the large companies by demanding for harsh penalties, criminal enforcement for IPR violations, but imposing obstacles to the use of compulsory licensing, restricting the lever that has helped the patent-granting country to achieve practical monopoly control.

C. Restraining parallel importation

FTAs proposed by the US allow the patent holders to prevent the products that they have marketed in one country being exported to another. Under US FTAs, the party must provide a right to the patent holders to restrict parallel importing in either of these ways:

- (1) it must adopt a system of national exhaustion only, thus prohibiting the international exhaustion in which the first sale of an object embodying an IPR in a foreign country exhausts the right holder's exclusive rights, or
- (2) it must permit the right holders to take legal action against import or export of the patented product by a party who knows or has reason to know that such product is or has been distributed in breach of a contract between the right holder and a licensee, regardless of whether such breach occurs in or outside its territory.

The former is found in the FTA that the US signed with Australia, as well as the proposed draft FTAA, while the latter is constituted under the US-Singapore FTA. No such provisions are constituted under the US-Vietnam BTA.

According to Article 6 of TRIPS, countries may implement the exhaustion principle differently. Some may apply the national exhaustion principle, but other countries (notably the European Union) allow no restrictions on import when products are put on sale with the community, called regional exhaustion. Under the international exhaustion doctrine, the right owner cannot use his IPRs to prevent further distribution of the goods that has been placed into commerce anywhere by himself, or with his consent. Since the TRIPS-plus prohibits the applicability of the international exhaustion, parallel importing is regarded as IPR infringement and cannot be carried out without the authorisation of the right holders.

The FTA between the US and Singapore does not explicitly prohibit the international exhaustion rule, but provide an opportunity for the patent holders to restrain parallel importation through contractual arrangements. The FTA partners are barred from invalidating product distribution agreements that limit distributors' freedom to resell the supplied products.¹⁷ Thus, the patent owners can impose restrictions on the resale of patented goods and thus limit the possibility of exporting the product from Singapore or importing the product to Singapore when it is sold in a foreign market. Although such restrictions have an anti-competitive character, Singapore is prohibited to void the restrictions on parallel importing.

¹⁵ US-Singapore FTA, Art. 16.7.4.

¹⁶ See the Paris Convention, Art.5 (A)(3).

¹⁷ US-Singapore FTA, Art. 16.7.2.

Prohibiting parallel importation no doubt is an attempt to block the trade partners from importing cheap medicines and other goods, which will disregard the humanitarian and economic needs of the country. For a number of years, the developing countries like Thailand has been progressively promoting parallel importation through court cases and national legislation.¹⁸ This attempt will turn out to be unsuccessful when it signs the TRIPS-plus trade treaty with the US. Recent experiences of the country regarding pharmaceutical patents and access to HIV/AIDS medicines should guide Thailand into being cautious against entering any new commitments.¹⁹

Options

The accessibility to essential medicines will be increasingly hindered after 2005 when most WTO members have to fully comply with TRIPS obligations. Prices of new medicines will inevitably shoot up, far beyond the reach of the poor population of the developing countries.

Since the TRIPS-plus commitments will further strengthen and prolong the patent monopoly, and contain ineffective provisions on compulsory licensing, revocation of patents and parallel import, the developing nations will have little room to make adjustments in the law to suit their particular needs. The flexible interpretation as reaffirmed by the Doha Declaration would become meaningless, if countries cannot take advantage of the legal procedures open to them in practice. Poor countries must be aware that the TRIPS-plus, not TRIPS, is now standing in the way of addressing HIV/AIDS and other public health crises, as it will limit the tools they need for flexibility. The following options are proposed for countries dealing with a TRIPS-plus FTA.

Issues	Options
General	<ul style="list-style-type: none"> • Concern about the implication for public health and access to medicines of bilateral trade agreements and TRIPS-plus • Reaffirm the right of people to affordable healthcare and the public rights should take precedent over trade and commercial benefits • Acknowledge flexibility of the TRIPS Agreement and demand from the US a political statement of support for the compulsory licensing and parallel import options • Stand firm to the spirit and letter of the Doha Declaration and make it clear that any attempt to prevent countries from making use of the TRIPS flexibility is against the nature and spirit of the multilateral trade system • Take full advantage of the flexibilities and policy

¹⁸ See Supreme Court decision, Case No. 2817/2543. See also Patent Act B.E. 2522, Sec. 36 (7).

¹⁹ Thailand has had problems of accessibility to essential medicines, especially regarding antiretroviral drugs. It jointly proposed a draft text for a ministerial declaration on the TRIPS Agreement and Public Health in 2001. See the Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (IP/C/W/296). See Kuanpoth, J. "Patent and Access to Medicines: the Case of ddi Patents in Thailand", *International Review of Intellectual Property and Competition Law (IIC)* (forthcoming).

	<p>measures allowed in TRIPS to ensure affordable medicines</p> <ul style="list-style-type: none"> • Collaboration between the health and other government sectors such as trade and commerce to ensure that national health objectives are taken into account in trade negotiations • Exchange of experiences with other developing countries in dealing with the TRIPS agreement and FTAs, especially with regard to securing public health
Compulsory licensing	<ul style="list-style-type: none"> • Be aware that compulsory licensing can play a significant role in improving access to medicines • Use of compulsory licensing for local production and import of drugs to obtain access to pharmaceuticals • Use of compulsory licensing for exporting drugs to countries that have no manufacturing capacity • Issuing compulsory licenses must be subject to requirements of Article 31 of TRIPS only. No additional conditions shall be included. • Demand the US to take measure to promote genuine transfer of pharmaceutical technology with the aim of strengthening the use of compulsory licensing
Forfeiture or revocation of patents	<ul style="list-style-type: none"> • Avoid restrictions of the forfeiture and revocation of patents • Demand the US to establish system of information sharing and collaboration with regard to the problem of invalid and illegal patents and revocation of patents
Parallel importation	<ul style="list-style-type: none"> • Be aware that parallel import can play a significant role in improving access to medicines • Seek to use parallel imports to address the public health needs • Adopt and adhere to the principle of international exhaustion of rights and support parallel import • Seek to eliminate export prohibition arrangements in any forms, particularly exclusive distributorship agreements • Support parallel exports of drugs out of the country

3. Extension of patent term

The twenty-year patent term under TRIPS is supposed to reward the inventor for his innovative efforts. Some products, such as pharmaceuticals and agrochemicals, require official authorisation before they can enter the market, and the approval process normally takes several years. The law of the US and some other developed countries now provides for the so-called patent term restoration, in order to provide compensation for the loss of patent term due to the approval process.²⁰ The rationale behind the patent term extension is to allow the patent holders to capture

²⁰ See the Drug Price Competition and Patent Term Restoration Act of 1984, generally known as the Hatch-Waxman Act.

economic benefits that could not be obtained during the government agency (e.g. the FDA) reviews the safety and efficacy of the patented product.

Based on its law, the US demands its FTA partners to restore a portion of the patent term. Under the US-Vietnam BTA, the patent term extension is not mandatory but may be provided at the discretion of the trade partners.²¹ By contrast, the US-Singapore FTA requires patent term extension not only in cases of a delay caused by regulatory approval processes but also when there are unreasonable delays in the grant of patent.²²

The extension of the patent term will allow multinationals to monopolise the market longer than the conventional patent rule, despite the fact that those companies can utilise 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. Developing countries, which have already experienced hardship from patents on pharmaceuticals, will find the extension of a period of protection in these essential products risky to the well-being of their people.

Options

To minimise the social cost, the developing countries should grant monopoly privileges for the shortest period as possible. Any demand for such extension should be rejected right away.

Issues	Options
Patent term extension	<ul style="list-style-type: none"> • Be aware that any extension in the patent term could delay the entry of generic substitutes and thus affects accessibility to medicines • Resist any changes to patent term regime that allows for an extension of patent protection

4. Creating a world patent system

Patent granting procedures in most countries are based on the “examination system” which requires prior search and examination as to the validity of the claimed invention before a patent is granted. However, due to the growing sophisticated nature of applicable inventions, full search and examination of the application have become more and more difficult and it has led to an overloading of many patent offices.

The Patent Co-operation Treaty (PCT) was signed in June 1970 in Washington and came into effect in June 1978. It was modified twice in 1984 and 2001. The Treaty provides for a system of international filing of patent applications in different countries. It allows inventors to secure protection in several countries through a single examination procedure which significantly reduces the costs of patent application.

²¹ US-Vietnam BTA, Art.7.10.

²² US-Singapore FTA, Arts.16.7.7, 16.7.8 and 16.8.4.

A functioning system of patent protection in the developing countries is still far short of the level in the developed countries. The PCT, it is claimed, can assist the developing countries by increasing efficiency and reducing costs of patent examination. However, the system provides a lot more benefit to multinational companies as they can seek patent protection for an invention simultaneously in a large number of countries by filing a single application. The US intends to use the negotiation opportunities demanding all its trade partners to participate in the single patent filing system of the PCT 1984.²³

Joining the PCT means that the developing nations must surrender its right to conduct and implement the patent law and this will make them dependent on the patent offices of the developed countries. In fact, accession to PCT is part of the developed countries' patent agenda seeking to further harmonise patent law and to create a global patent system with an aim of transforming the trilateral patent offices (USPTO, EPO and JPTO) into the world patent office.²⁴ The patent examination carried out by those offices will most likely to serve the interests of the developed countries and their nationals. Nothing can guarantee that the foreign offices will carry out prior search and examination of patent applications to the developing countries' benefits.

Options

The international preliminary examination system under the PCT may serve requirements of the rich countries and their multinationals to achieve world-wide protection, but will not fully operate to accommodate and protect the interests of the developing countries. The following options are recommended.

Issues	Options
Accede to the Patent Co-operation Treaty	<ul style="list-style-type: none"> • Be aware that PCT accession will restrain freedom of the national patent office to assess the merits of patent applications • Oppose to joining the PCT

III. TRIPS-plus for data exclusivity

Law of most nations requires pharmaceutical and agrochemical products to be registered before they can be put on the market. The company that seeks registration must submit data relating to the products' quality, safety and efficacy, the so-called test data, with the relevant regulatory authority. Since the origination of these data involves considerable effort, international agreements demand protection for such data.

Article 39.3 of TRIPS stipulates that all member parties must protect the undisclosed data submitted for marketing approval. Legal protection must be available to protect new chemical entities against "unfair commercial use" and "disclosure" of the data. TRIPS does not require member parties to provide exclusivity protection to the first person who submits the marketing

²³ See for example US-Singapore FTA, Art. 16.1.2 (a)(v).

²⁴ GRAIN, WIPO Moves toward 'World' Patent System (<http://www.grain.org/briefings/?id=26>)

approval data with the drug regulatory authority.²⁵ This has left WTO members with considerable room to determine rules for the protection of undisclosed test data. For example, a WTO member's legislation may not prevent the third parties from using the test data, if that use does not constitute "unfair commercial use" or does not breach the "non-disclosure" obligation in the framework of unfair competition law. In addition, the regulatory authorities may rely on the data submitted by the originator company or on the evidence of a registration made in a foreign country to grant marketing approval for subsequent applications on a similar product.

Some developed countries, including the US, grant TRIPS-plus protection on the basis of data exclusivity in order to maintain technological and economic superiority of their multinationals.²⁶ Multinational drug companies have long been pushing hard for Article 39.3 of TRIPS to be interpreted as requiring data exclusivity. The US is responding to the demand by requiring all its FTA partners to enforce the data exclusivity for at least five years. A review of the bilateral agreements that the US has signed with Singapore and Vietnam has found provisions relating to data exclusivity.

According to the US-Singapore FTA, the parties are required to provide exclusivity for test data submitted to a government for the purpose of product approval, for a period of five years for pharmaceuticals and ten years in case of agricultural chemicals.²⁷ The BTA also obliges Vietnam to prohibit third parties (i.e. generic companies seeking to introduce generic versions) from relying on the test data previously submitted by the first company (i.e. an originator company) in support of an application for product approval, for at least five years.²⁸ The requirement is tantamount to granting exclusivity protection to the originator company.

Furthermore, while TRIPS requires protection only for new chemical entities, the FTA and the BTA do not contain such a limitation. Exclusivity protection must be provided for all kinds of data submitted for marketing approval, including data with respect to compositions, dosage forms and new uses of a known drug. This TRIPS-plus commitment will limit the country's ability in flexibly implementing Article 39.3 of TRIPS.

Granting data exclusivity will allow the multinationals to dominate all markets, but at the same time create a barrier to generic entry as the generic manufacturers, most of which are small companies in developing countries, will have to enter a long and costly testing process and complete the registration trials before the marketing approval of a generic drug can be obtained. Moreover, since the relevant and essential data are not available due to the exclusivity protection, the possibility for the country to issue compulsory licenses is therefore diminished. Finally, the obligation to provide data exclusivity will prohibit the regulatory authorities from relying on marketing approvals in other countries, despite the fact that most developing countries lack capacity to review data for purposes of granting marketing approval.

²⁵ Correa, C., *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre, Geneva, 2002.

²⁶ US laws adopt an absolute exclusivity regime for pharmaceuticals and a limited-exclusivity regime for pesticides. See *Ibid.* at p.8.

²⁷ US-Singapore FTA, Art. 16.8.

²⁸ US-Vietnam BTA, Art. 9.6.

Options

The TRIPS-plus data exclusivity is a means of delaying generic competition and constitutes a barrier to the use of compulsory licensing. For the countries considering entering into the TRIPS-plus world, the socio-economic implications for introducing the data exclusivity will need careful consideration. The following options should be taken into account.

Issues	Options
Protection of undisclosed test and other relevant data	<ul style="list-style-type: none"> • Be aware that data exclusivity is not an obligation under TRIPS and that the exclusivity over test data will affect the ability of the country to promote access to medicines • Reaffirm the commitment to TRIPS by protecting test data against “unfair commercial use” and “disclosure” only • Review existing regulation to ensure that generic drugs do not face entry barriers from the registration process, as well as from the data exclusivity

IV. Higher level of protection for trade marks

According to Article 15 of TRIPS, a trade mark is a sign used by any person in the course of business or trade to distinguish his goods or services from those of others. A trade mark can be personal names, letters, numerals, figurative elements, colours and any combination of these. A registrable trade mark must be distinctive (i.e. it is capable of distinguishing the goods or services of the owner from other goods or services).

Most US FTAs define trade marks in the broadest manner. According to the US-Singapore FTA, for example, the parties have to protect non-visually perceptible trade marks, including scent marks.²⁹ This obligates Singapore to change its existing law which requires that a trade mark must be a visually perceptible sign. The new trade mark regime will allow anyone to register signs identifiable by their sound, texture and smell as trade marks. No doubt, this requirement is an attempt to bring other countries' trade mark law up to the level of US legislation.

US FTAs also requires the trade partners to give effect to Articles 1 to 6 of the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks (1999), which is an international standard adopted by the Assembly of the Paris Union for the Protection of Industrial Property and the General Assembly of the WIPO, and the WIPO Trademark Law Treaty.³⁰ This requirement offers unregistered well-known marks wider protection, as a framework for determination of well-known marks under the Joint Recommendation apparently discriminates local trade marks in favour of foreign well-know marks.

²⁹ US-Singapore FTA, Art. 16.2.1.

³⁰ Ibid. Art. 16.1.b.

Strong trade mark protection will benefit trade mark owners, particularly those producing textile, perfumery and cosmetic products. Pharmaceutical companies will also benefit from the greater protection of trade marks because in this area there are many potentially conflicting trade marks. In addition, pharmaceutical is one of the industries where trade marks are employed heavily. Pharmaceutical companies generally employ brand intensive advertisement by using sophisticated techniques to build up a brand loyalty for their trade marks and brand names.

A common marketing technique widely used in the pharmaceutical industry is the launch of a product in different packaged forms and use more than one brand name for one therapeutic drug.³¹ Each drug has a single generic name, which is a generally accepted name of a drug and reflects the therapeutic class to which the drug belongs. No one can have a monopoly over the generic name. Unlike the generic name, the brand name is a proprietary name which belongs to one owner only. To the extent that a brand name is used to proclaim ownership, a drug company is able to have its brand name displace the generic name, and the drug will be known by the name that is the property of the firm.³² The brand name is then advertised to consumers, or in the case of prescription drugs to doctors, in order to build up brand loyalty. The multiplicity of brands causes confusion in consumers' minds. Consumers and doctors tend to believe that the branded drug is different from, and cannot be substituted by, another lower-priced generic. The proliferation of branded products, together with intense advertisement, enables large companies to create and sustain goodwill as well as leading market positions and can protect the market against small generic firms.

Unlike the time-limited patent rights, the trade mark rights will create indefinite commercial and marketing strength for the company through brand promotion. This is because the legal status of trade marks is different from other IPRs as it can exist forever. As there is no term of protection for trade marks, the company will continue to monopolise the market, even though their products no longer enjoy patents or other IPRs protection. A comprehensive study on drug prices carried out by Statman reveals that the prices of most patent drugs do not decline after patent expiry due to the brand loyalty built up by trade marks.³³

Options

Governments of the developing countries should be aware that the high degree of trade mark protection could also affect the accessibility of medicines for their deprived populations. The following options should be taken into consideration.

Issues	Options
Protection of non-visually perceptible trade marks and well-known marks	<ul style="list-style-type: none"> • Resist TRIPS-plus obligation of protecting non-visually perceptible trade marks • Resist pressure to implement the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks and the Trademark Law Treaty

³¹ British Medical Association, *The British National Formulary*, London, 1988.

³² Lang, R.W., *The Politics of Drugs*, Saxon House, Hants, 1974, p.31.

³³ Statman, M. "The Effect of Patent Expiration on the Market Position of Drugs", in Helms, R.B. (ed.), *Drugs and Health*, AEI, Washington, 1981, pp.140-150.

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| | <ul style="list-style-type: none">• Implement vigorously legal controls and closely monitoring on drug advertisement |
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V. TRIPS-plus for strong protection of digital technologies

The TRIPS Agreement does not incorporate minimum standards on specific IPR issues in cyberspace. In 1996 the WIPO has adopted two "internet treaties": the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. These two treaties create an entirely new body of IPR law involved with the internet. They establish important international norms related to the rights to make a work available to the public through interactive media. They also provide for the protection of rights management information and technological measures used to guard copyrighted and non-copyrighted works. Pressuring all trade partners to adopt the very dynamic digital agenda of the WIPO is one of the main objectives in current US trade policy.

The US digital agenda has focused on, *inter alia*, the following issues:

- The country entering into an FTA with the US must comply with the essential provisions of Convention Relating to the Distribution of Program-Carrying Signals Transmitted by Satellite (1974), the WIPO Copyright Treaty (1996) and the WIPO Performances and Phonograms Treaty (1996).³⁴
- The trade partner must provide longer term of protection than the TRIPS standard, i.e. the term of protection shall not be less than the life of the author and seventy years after the author's death.³⁵
- The trade partner must provide adequate protection against the decoding of encrypted program-carrying satellite signals, as well as any reception or further distribution of decoded signals, without the owner's authorisation. Again, this protection is not covered by TRIPS.³⁶
- While TRIPS is absent on obligations concerning technological protection measures (TPMs), all FTAs proposed by the US stipulate that parties must provide adequate legal protection and effective legal remedies against acts of circumventing TPMs and against devices which could be used for circumvention, regardless of the intended use of the device.³⁷ This means in effect that the US is now creating a new concept of copyright protection by extending the conventional economic rights of the author to the right to use and distribute circumventing devices.
- The TRIPS-plus commitment of "rights management information" is also imposed on the contracting parties. All US FTAs demand the trade partner to impose criminal and civil liability on anyone who provides false information, or removing or altering copyright management information.³⁸
- US FTAs provide greater protection than TRIPS for works in digital form. For example, temporary reproduction such as temporary storage in electronic form is considered copyright infringement under the bilateral trade deal between US and

³⁴ For example see US-Singapore FTA, Art. 16.1.

³⁵ *Ibid.*, Art. 16.4.4 (a).

³⁶ *Ibid.*, Art. 16.6; US-Vietnam BTA, Art. 5.

³⁷ US-Singapore FTA, Art. 16.4.7.

³⁸ *Ibid.*, Art. 16.4.8.

Singapore³⁹ (but not under the US-Vietnam BTA). This provision clearly extends the author's right over their works on the internet.

- US FTAs have gone further than TRIPS by permitting the right holders to take a legal action against the internet service provider (ISP) for the copying of works by subscribers.⁴⁰ Further, the trade partner must ensure that the owner of copyright can track every use made of digital copies and trace where each copy resides on the network and what is being done with it at any time. These two requirements will greatly affect the public right of fair use with respect to the digital works.

This new area of IPRs will no doubt allow content owners to enjoy greater protection than conventional copyright rules would afford. The provisions on prohibition of circumventing TPMs and devices, for example, will enable the owners to extend greater control over access to and distribution of works that copyright law expressly leaves unprotected in order to stimulate further creativity (i.e. works which have fallen into the public domain). The scope of fair use online will be narrowed down, as the owners can require payment for any use or excerpting of a digital work, regardless of the user's purpose. The use of the internet and digital works for educational or private non-commercial purposes, or the use by educational and library organisation will be increasingly hindered because of this prohibition.⁴¹

The worst situation arises when the temporary reproduction clause is incorporated into national law. Compared with the conventional copyright rules that no control of reading is given to the right owner, the prohibition of temporary reproduction will allow the copyright owner to control the use of the internet. This is because every use of internet browser, which requires few seconds storage in RAM, will constitute copying. While the use of conventional copyright works, such as reading a book, is not considered infringement, the browsing or using of the internet will be barred on the ground of violation of copyright.

Option

In view of the severe effects on societal, cultural and educational development, it is logical to suggest all trade partners with the US to reject the proposal on this new regime of copyright law. The following possible options are also recommended.

Issues	Options
Protection for digital technologies	<ul style="list-style-type: none"> • Consider carefully about the social and economic implications of digital technology protection, particularly implications in online uses, access to digital information and education • Be aware that temporary copying is inherent to digital technology and must not be treated as copyright infringement.

³⁹ Ibid., Art. 16.4.1.

⁴⁰ Ibid., Art. 16.9.22. This provision is basically taken from US Digital Millennium Copyright Act of 1998. There are three newly introduced copyright rules under the Act: the liability of the ISP, protection against anti-circumvention devices and protection against satellite signal theft.

⁴¹ Cohen, J.E. "Lochner in Cyberspace: The New Economic Orthodoxy of "Right Management", 97 Mich. L. Rev. 462 (1998).

	<ul style="list-style-type: none">• Not impose total ban on circumventing devices, but allow the devices to be used for legitimate non-infringing purposes such as research and study
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CONCLUSION AND POLICY RECOMMENDATIONS

In light of the considerable and long term efforts by developing countries to minimise the impact of the TRIPS Agreement, one might conclude that most developing countries oppose the high degree of IPR protection. That conclusion, however, is contradicted by widespread and enthusiastic support of many developing countries for entering into FTAs that demand for higher commitments on IPRs.

Given the fact that developing countries have often suffered from the weakening prices of raw materials, foods and semi-manufactured products, which are their main foreign exchange earners, any single developing country would have a strong incentive to sign an FTA with the US, as it is believed that such a treaty helps that country to secure access to the world's most lucrative market. However, by signing an FTA, the developing country agrees, in a binding treaty under international law, to respect any obligations contained in the agreement it has entered into. The treaty can be harmful to the country because it leads to a world in which TRIPS-plus obligations are imposed. In making decisions with respect to bilateral or regional deals, policy-makers will have to weigh the economic benefits of FTAs against the importance of protecting health and social interests of their population.

Although some sectors of the economy may gain benefits from the bilateral or regional trade deal, it should be recognised that the benefits are limited only for particular sectors and certain groups of interests. On the contrary, the long-term social and economic costs that result from IPRs commitment are significant, and should not be underestimated as they affect the majority of the population. Strengthening protection of IPRs, regardless of specific needs and social priorities of each country, may sharply reduce the developing countries' industrial and technological competitiveness and will give rise to stronger dependencies on the more powerful countries. In conclusion, we believe that increased national protection of IPRs should be made on the ground of its assistance for the promotion of national technological and economic development, rather than in exchange for the uncertain benefits under the FTA.

In addition to the options suggested earlier, the following recommendations are being made in order to reduce the impacts of the TRIPS-plus regime:

- Recognise the irreversibility nature of the FTA commitments and their long terms implications on the developing countries
- Call for a moratorium on FTA negotiations until reliable impact assessment studies have been carried out
- Any bilateral trade negotiations should be viewed as an opportunity to address a much broader range of concerns of the developing countries, including abuse of intellectual property rights, technology transfer and capacity building, protection of traditional knowledge, and controlling and regulating access to and use of genetic and biological resources