

Thai Health Sector under the New Intellectual Property Regime

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Bilateral trade and investment agreements are increasingly used in a strategic fashion by powerful countries to incorporate TRIPS-Plus commitments that have been politically difficult to achieve in multilateral settings (notably at the World Trade Organisation - WTO). Powerful developed country economies who have been dissatisfied with the multilateral forum have resorted to bilateral agreements as a way of forum shopping to better achieve their own interests in disregard of a more balanced approach to intellectual property (IP) protection. The issue at stake for developing countries is the loss of key 'policy space' in strategic areas such as health, agriculture, and the digital environment. TRIPS-Plus obligations may also deny developing countries benefits and flexibilities within trade agreements aimed at enhancing pro-innovation activities and technology transfer.

To date, the United States has signed FTAs with fourteen countries (*e.g.* Israel, Singapore, Chile, Jordan, Australia, Morocco, Central American countries and the Dominican Republic, or CAFTA-DR, and others), and is negotiating FTAs with other eleven countries (*e.g.* Colombia, South Africa, Namibia, Swaziland, Thailand, Malaysia, the Republic of Korea). The United States has been negotiating an FTA with Thailand since 2003 but the negotiation is currently on hold due to the political situation in Thailand.

The inclusion of IP chapters in US FTAs is due to the lobbying of specific industry lobby groups such as International Intellectual Property Alliance, the Biotechnology Industry Organization, and the Business Software Alliance. The Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), which plays the most important role in advising and influencing US trade policy, comprises large multinational companies like Eli Lilly, Merck, Pfizer, Anheuser-Busch, Procter & Gamble, and others. The tightening of IP laws in foreign countries through bilateral trade negotiations, together with the use of trade leverage under US trade laws, will likely help the United States establish an acceptable framework for them within the multilateral trade negotiations. This strategy was successfully employed by the United States during the Uruguay Round of trade negotiations which led to the adoption of the TRIPS Agreement.¹

¹ In the 1980s, the United States Trade Representative (USTR) requested consultations with a number of developing countries in Asia and Latin America on IP issues before and during the Uruguay Round. The United States successfully used unilateral trade sanctions against Thailand to the tune of 165 million dollars in 1989 to force the Thai government to amend and expand the coverage of patent law even before the TRIPS negotiations were concluded.

IP rules proposed by the United States are comprehensive, covering almost all areas including patents, copyright, trade marks, and others. The US draft proposal demands that the products currently excluded from patentability (*e.g.* plants, animals, biological processes, genes, gene sequences, methods of medical treatment, business methods and computer programs) must be patented.² It also requires restriction of compulsory licensing, extension of patent term, provision of data exclusivity, etc.

Although Thailand's exports to the US (currently account for a substantial US\$ 15 billion) could increase if the Thailand-US FTA is signed, it is likely a range of US agricultural goods will have an advantage over Thai products including meat, milk, dairy products, vegetable, fruit, maize and soybean. Thailand could also risk losing out its sovereign control over crucial sectors of its economy such as energy, transport, finance, education, and health.

In the pharmaceutical sector, Thailand lacks a functional technological base and this makes the country industrially and technologically dependent on foreign interests. It constantly loses trade balance in the pharmaceutical sector to its trading partners. Thailand has only acted as a host for foreign pharmaceutical companies. Those companies have entered the country to operate the final stage of medicine production solely for the purpose of penetrating the locally protected market. The perceived role of patents in Thailand's industrial and economic development should be markedly different to that portrayed in technologically advanced countries like the United States. While a stringent patent regime as enshrined under TUSFTA may be designed to foster research, the high degree of patent protection in Thailand would promote R&D and protect research results developed *elsewhere*. The inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede inflow of technology. Patents will continue to be used by foreign drug companies as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements.

On medicine prices, the TUSFTA provisions will have a tremendous impact on the health sector. The TRIPS-Plus rules that are intended to broaden the scope and prolong the period of monopoly (*i.e.* data exclusivity, extension of patent term, extending the scope of patentability, etc.) will enhance the ability of the patent holders to maintain high prices. Note that Thailand explicitly recognized its problems of access to vital medicines, when in 2001 it jointly proposed to WTO a draft text for a ministerial

² See Correa, C.M., Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organisation, Geneva, 2002; Kuanpoth, J. "Closing in on Biopiracy: Legal Dilemmas and Opportunities for the South" in Ricardo Melendez-Ortiz and Vicente Sanchez, Trading in Genes: Development Perspectives on Biotechnology, Trade and Sustainability, Earthscan, London, 2006, pp.139-152.

declaration on IP and public health.³ The collective effort of Thailand and other developing countries led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, which reinforces the importance of access to medicines and re-affirms the right of WTO Members to use the flexibilities available under TRIPS to increase the affordability of medicines.⁴ Thailand has currently switched its policy direction to bilateral trade negotiations and given very little attention to its negotiating positions in the WTO. It would be a sad irony then for Thailand to adopt the TRIPS-Plus rules that may further restrict its accessibility to essential products.

Granting exclusive rights over pharmaceutical test data will reduce generic competition. Thai generic manufacturers would have to conduct their own clinical trials, which they do not have the capacity to do. Since the trial process is too costly and time consuming, the only option for the local companies would be to wait until the exclusivity period expired, which would delay the entry of generic medicines into the market. Consumers would then be forced to pay monopoly prices for the branded drugs for an extra ten years. Data exclusivity will allow multinational pharmaceutical companies to dominate the market even if there is no patent on the medicines they sell. When a patent is granted for the medicine, Thailand would have little or no chance to grant a compulsory license or allow government use to make the patented drug available. This is because the medicine produced under the government license would still be unable to secure market approval during the exclusivity period due to the lack of the clinical test data required for registration.

The proposed TRIPS-Plus provisions require the national drug regulatory body, before approving registration for a generic version, to ensure that the manufacturing, importing and selling of the generic medicine will not infringe the original company's patent rights. The practice of linking patent status to registration is not easy to implement in view of the fact that the national drug regulatory body in Thailand has no patent expertise to determine whether the generic medicine sought for registration is the same or different from the medicine that another company has patented. This would cause considerable delays to the introduction of the generic product.

TRIPS-Plus also requires an extension of patent term which will threaten the existence of the Thai generic companies by preventing them from making use of patented technology for the duration of the extended period. This would effectively increase the patent life for a pharmaceutical, thus blocking the introduction of generic products.

³ 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 (IPR/C/W/296).

⁴ Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2.

Considering the significance of this for the well-being of society, the extended term of pharmaceutical patents proposed by the United States is too long. No matter how much investment involving drug development is claimed by the pharmaceutical companies, it would still be imprudent for Thailand and other developing countries to offer protection periods for longer than twenty years. The logic is that pharmaceuticals generate a high rate of turnover, and therefore maximum profits need to be recouped to their owners by selling drugs at high prices around the world. Due to the urgent need for technological acquisition, the developing country will be denying itself the benefits from newly developed modern technology by granting an unnecessarily lengthy protection period which will discourage competitive innovation. Modern scientific innovation has continued to yield evermore rapid technological change, and therefore new products are developed rapidly. No technology, no matter how beneficial it is, should be accorded more than a twenty-year term for protection as required by TRIPS.

The provisions that require Thailand to extend the scope of patentability to new uses and new formulations of the known drugs will allow multinational companies to claim exclusive rights over formulations that do not generate a truly new and inventive product. A great many drugs, although therapeutically effective, have other far from perfect properties and potential side-effects. Companies that hold a drug patent can come up with secondary improvements that can then also be patented.⁵ This would protect the original patent holder against generic competition, even in situations where a generic company is prepared to challenge what it perceives as bad patents. Costly and time-consuming litigation can keep the matter locked up in the courts for many years, thereby unnecessarily restraining the entry of generic medicines.

As regards technological capability, TRIPS-Plus rules will drastically curtail the ability of the Thai government to enforce transfer of technology, and inhibit the capacity of the Thai generic drugs industry to expand its market. In principle, patents are granted on condition that the holder must work the patented invention or license it within a certain period of time from the date of granting the patent. Thailand incorporates several measures into its law so as to bolster the local working of patents. The current patent law contains not only compulsory licensing but also a system of forfeiture and revocation of patents. The TRIPS-Plus provisions on compulsory licensing will limit flexibilities that Thailand can issue, such as non-voluntary licenses to enable development of local industries. It will also prevent Thailand from exporting compulsorily licensed drugs to countries that have insufficient or no medicine production capacity. The Thai government also will not be able to force the patent holder to disclose the know-how needed to manufacture the medicine.

⁵ Hutchins, M. "Extending the Monopoly — How 'Secondary Patents' can be Used to Delay or Prevent Generic Competition upon Expiry of the Basic Product Patent", *Journal of Generic Medicines*, Vol.1 No.1, 2003, pp.57-71.

The TUSFTA text prohibits Thailand from adopting pre-grant oppositions in the patent granting process. This straightforward administrative procedure is necessary for Thailand because it allows local generic companies to challenge the validity of a patent at relatively low cost, prior to an infringement action. Generic producers that work in the same field are often in a position to challenge patents before they are granted. This system reduces excessive burdens on the courts and contributes to speedy proceedings of patent invalidation. The prohibition of the pre-grant opposition will allow multinational companies to block challenges on invalid patents, increase prices and prevent local medicine manufacture.

The TRIPS-Plus provisions link IP and investment. If adopted, the rule will have an adverse impact on technology transfer and on the development of Thailand's pharmaceutical industry. According to the proposed text the patent holder can directly sue the host government in a special trade tribunal for compensation in cases of indirect expropriation of investment interest such as an issuance of compulsory licensing. The prospect of paying high compensation to the patent holder will undoubtedly discourage the Thai government from issuing compulsory licenses to protect public health, or from taking measures that facilitate transfer of technology and development of the local pharmaceutical industry.

Finally, the trade mark rule is also introduced under the TUSFTA. The new rule on trade mark protection would allow the pharmaceutical companies, to create 'brand loyalty' by using intense advertisement and sophisticated marketing techniques. The rule will create indefinite commercial and marketing strength for the company even after the expiration of the patent. It will also limit the possibility for the Thai government to control the use of trade marks for the promotion of medicines.

Pharmaceutical product patenting seems likely to generate severely negative impacts on Thailand in terms of high drug prices. A strong patent system, on the one hand, would have no relation whatsoever to the rate of R&D and foreign investment, but, on the other hand, is likely to impede the industrial development process of the country. The costs of pharmaceutical patents in Thailand will therefore outweigh the benefits. This consequently calls the Thai government for a re-examination of the TRIPS-Plus IP rules being negotiated under the current TUSFTA.