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The Proposed Europe-Thailand Free Trade Agreement: IP and Pharmaceuticals

In the next few months, the European Union (EU) is seeking to open free trade agreement (FTA) talks with Thailand. Thailand exports more goods to Europe than any other region or country in the world, with over 85% being machinery, manufactured goods, and food. In terms of imported goods into Thailand, the EU stands in third behind Japan and China, with these imports focusing heavily on machinery, transport equipment, pharmaceuticals, and medical equipment. This existing large volume of trade has the potential to grow exponentially in the future, particularly with the increasingly free movement of goods, services, capital, and people in ASEAN from 2015 onward. Given the timing, this FTA could set Thailand up to be the major import hub for European goods and investment in the ASEAN region.

Intellectual property (IP) will feature prominently in the EU's agenda. Only with a secure IP system can foreign direct investment reach its full potential. It is no secret that Thailand is one of the nations, along with China, that has not had a perfect track record when it comes to IP protection and enforcement. The Department of Intellectual Property (DIP) has shown a strong commitment to improve the situation—for example, through the forthcoming Madrid Protocol accession enabling use of the international system of trademark registration, ex officio seizure of goods by Customs, the growing number of raids by the DIP and police, and the increase in IP criminal matters being prosecuted at court. However, there remain several shortcomings in the IP system, and the EU may seek some commitments from Thailand to improve them.

Pharmaceutical Patent Registration

The main problem experienced by European pharmaceutical companies is that the patent registration process in Thailand simply takes far too long. In some cases it can take 12–14 years for applications to be granted. The DIP is well aware of this problem and has prepared draft patent examination guidelines for pharmaceutical and chemical patents, although it is not currently clear when these guidelines will come into effect.

In reviewing the draft guidelines, European industry has expressed concerns that they do not presently provide sufficient clarity or consistency in their wording or implementation. For example, when it comes to inventiveness requirements for different types of pharmaceutical patents, there is an inconsistency of terminology. For formulation patents, increased effectiveness appears to be a requirement, but then for combinations, the effectiveness requirement is dropped in favor of the "surprising effect" requirement. This is seen again when we come to polymorphs, where "obviousness" and "unexpected result" appear to be the key test, but not increased effectiveness. Then, for salts, ethers, or esters, it is not clear whether there is an effectiveness requirement; the guidelines state that if "such monomer does not have an objective to improve therapeutic effect, official(s) may request the claimer to provide related additional pharmaceutical testing results if the consideration cannot be concluded from existing documents." For isomers, again, it is not clear whether increased effectiveness is a requirement because in some examples "surprising effect" is sufficient, whereas in others "improvement in therapeutic effect" is cited as evidence of inventiveness.

NGOs and Access to Medicine

There have been some statements made by various NGOs that are attempting to alert citizens that an FTA could have a negative effect on access to medicine in Thailand. In evaluating this claim, it is crucial to distinguish between the separate issues of patentability and access to medicine. Thai citizens need to be made aware that the patentability test actually ensures that only drugs that are genuinely new and inventive are awarded a monopoly, in compliance with the TRIPS agreement, as part of a raft of IP treaties which Thailand is signed up to. This process actually improves the standard of healthcare by introducing better medicines. Generic companies, which produce generally cheaper options, are free to compete on products for which the patent has expired.

The issue of pricing of such medicines is a matter of policy that may change according to the government's position. It should be remembered that Thailand ranks 24th in the world in terms of GDP. It is therefore by no means a poor nation or one that cannot afford to offer the best medicines to its citizens. It is also worth noting that, taking AIDS as an example, incidence is at 1.3% of the population, compared to up to 25% in some African nations. Government policy therefore is the key factor in access to medicines.

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The NGOs are also fearful of the introduction of a TRIPS+ regime which they claim the EU will be seeking in this FTA. Specifically they are concerned with long data exclusivity periods and patent term extensions. It will therefore be interesting to see whether the EU does include such provisions in the FTA talks.

FTA Outlook

Overall, FTA negotiations will seek to promote trade for the benefit of both the EU and Thailand. If Thailand can strike a balance that ensures strong IP protection for its European investors, which in turn would encourage improvements in medicines, there should be no reason why Thailand cannot maintain good access to medicines for its citizens.