



# Persatuan Pengguna Pulau Pinang Consumers Association of Penang

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**Press Release**

**22 May 2017**

## **AVOID CHANGING TPP-RELATED LAWS THAT DAMAGE THE HEALTH OF MALAYSIANS**

The Consumers' Association of Penang calls on the Malaysian government not to make changes to the law relating to intellectual property rights (IPRs) to comply with the Trans-Pacific Partnership Agreement (TPPA).

Malaysia should also not join any other TPPA countries to revive the TPPA especially since the United States has confirmed it is pulling out of the agreement, as there are very damaging effects and very few benefits.

CAP is most upset and indeed disturbed to learn from news reports today quoting International Trade and Industry Minister Datuk Seri Mustapa Mohamed that Malaysia will continue to amend legislation covering several areas including IPRs, "regardless of whether or not we will be part of the TPPA," and that the laws are undergoing domestic review and are not just to comply with the TPPA.

Going ahead with the amendments to our laws on patents despite the United States calling off the TPP is completely against the public interest and welfare of consumers as it would increase the prices of life-saving medicines in Malaysia and create more barriers for Malaysians to have affordable access to medicines.

It is well known that Malaysia, like many other TPP members, had to give in to the demands of the US to grant greater monopoly to the giant drug companies in exchange for getting access to the US market for our goods.

During the TPP negotiations, Malaysia and many other countries tried to resist the push, coming mainly by the US, often supported by Japan, to have clauses that would greatly strengthen the monopoly rights to be granted to the big drug producers, and which would weaken the potential of competition from cheaper generic medicines, with patients being the ultimate losers as they would have to pay astronomical prices for many more years.

This great sacrifice is especially unnecessary now that the US is no longer in the TPPA. It is thus totally irrational and immoral to amend Malaysia's laws in ways that damage public health, in order to comply with the US-led demands in the TPPA, now that the US has pulled out and the TPPA itself may never come into force.

## **TPP CLAUSES THAT IMPOSE EXTRA IPR OBLIGATIONS**

Members of the World Trade Organisation (of which Malaysia is a party) are obliged to implement its intellectual property agreement, known as TRIPS, but they are not obliged to take on any additional obligations.

However, the TPP has many clauses that require the TPP countries to take on many extra obligations, called TRIPS-Plus, which are damaging to public health interests. We call on the government not to undertake changes in Malaysian laws that take on these TPP obligations.

The TRIPS-plus provisions in the TPP, which should be avoided in Malaysia's laws, include:

- A provision that lowers the standards a country can adopt to grant a patent. Some patent applications are not for genuine inventions but are only made to “evergreen” a patent, to enable its term to continue after it expires. Under TRIPS, a country can choose not to grant secondary patents for modifications of existing medicines.

The TPP (Article 18.37.2) requires countries to grant patents for at least one of the following modifications: new uses of a known product, new methods for using or new processes for using a known product. Examples include a drug used for treating AIDS is now granted a new patent for treating hepatitis, or a drug in injection form is given a new patent for being in capsule form.

- A provision that enables extending the patent term beyond the existing 20 years. TRIPS requires 20 years for a patent's term, and most countries count this from the date of filing. The TPP requires the patent term to be extended beyond that if there are “unreasonable” delays in issuing the patents (Article 18.46), or if the effective patent term is curtailed because of the marketing approval process.” (Article 18.48).
- A provision (Article 18.50) to create “data exclusivity” or “market exclusivity”, that prevents drug safety regulators from using existing clinical trial data to give market approval to generic drugs or biosimilar drugs and vaccines. Under TRIPS, the clinical test data of a company can be used by a country's drug regulatory authority as a basis to give safety or efficacy approval for generic drugs with similar characteristics, thus facilitating the growth and use of generic drugs.

Under the TPP, the data of the original company is “protected” and approval of similar drugs on the basis of such data is not allowed. The period of “exclusivity” is at least 5 years for products containing a new chemical entity, or 3 years for modifications (a new indication, new formulation or new method of administration) of existing medicines.

- The TPP obliges its members to undertake data protection obligations for “biologics” (Article 18.51), a category of products for treating and preventing cancer, diabetes and other conditions. These are very expensive and TPP will allow the prices to remain high for longer periods. The data protection for biologics is for at least 8 years of exclusivity or 5 years if other measures are also taken.
- A provision (Article 18.76) obliging members to allow the right holder to initiate action to detain any imported goods that are “suspected counterfeit or confusingly similar trademark”. This would open the door to blocking affordable generic medicines from entering the country. There have already been many cases where legitimate generic drugs have been detained due to actions by right holders, and later released when no infringement was found, but in the meanwhile patients were denied treatment.

## **ADVERSE EFFECTS OF THESE TPP CLAUSES**

All in all, these TPP obligations would make it more difficult for patients to obtain cheaper generics that could save their lives or alleviate their suffering. By adopting these TPP clauses into Malaysian IPR

law, it would be more difficult for Malaysia to reject patent applications that are not genuine inventions; and Malaysia may have to give extra years of monopoly for patented drugs; and generic competition would also be curbed by “data exclusivity” clauses, especially for the new drugs known as biologics.

Thus there are serious life and death implications for Malaysians. For example, there are many hundreds of thousands of people in Malaysia with Hepatitis C. They would certainly benefit from having access to the new medicines that have effective cure rates of close to 100% but the prices are reported to be over RM300,000 for a 12-week course of treatment.

In other countries like Egypt and India treatment with good-quality generic medicines is available at less than RM3,000. With the use of TRIPS flexibilities, Malaysians too can have access to these generic drugs. But if the TPP clauses are translated into domestic law, this access could be blocked.

The lives and health of millions are at stake. There is really no reason why the provisions that have adverse effects should be implemented, when there are no benefits to be obtained to offset them.

During the TPP negotiations, Malaysia did understand that the IP chapter would have negative effects, but accepted it as part of a bargain that they would benefit from the trade aspect of the TPP, namely getting better access to the markets of the other countries, especially the US.

Access to the US market is now off, and for the time being there is also no extra access to the other countries. It does not make any sense to continue with the process of changing the country’s intellectual property laws in ways that are detrimental, when the benefit of market access is no longer available.

## **CAP’S DEMANDS**

CAP therefore wants an assurance from the government that it will not introduce changes in the legislation regarding patents and intellectual property that make it comply with the extra obligations in the TPP.

In any domestic review of the patent and IPR legislation, there should be aim of fully using the flexibilities in the WTO TRIPS agreement, instead of voluntarily narrowing or giving up these flexibilities.

CAP also calls on the government not to remain in the TPP, especially now that the US has exited. Besides the adverse effects on health, the TPP will also have many other negative effects due to its chapters on investment, services, competition, state owned enterprises and government procurement.

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