TRIPS-Plus Provisions in the EU FTAs

Below is an overview of the types of TRIPS-plus provisions that have been proposed by the EU:

DATA EXCLUSIVITY

Data Exclusivity (DE) introduces barriers in the registration of generic medicines. In practice, DE prevents the registration and hence the actual sale and use of low cost generics, jeopardizing access to medicines and negatively affecting public health programmes.

Under this new style of intellectual property, medicine regulators will be prohibited from registering an equally effective generic medicine as long as the exclusivity over the clinical trial data submitted by a pharmaceutical company lasts - usually 5 to 10 years. Domestic producers will have to submit their own safety and efficacy data to register their generic medicines. This will oblige them to repeat clinical and preclinical trials - something that takes years and involves costs that the generic companies usually cannot afford. But more importantly, the repetition of clinical trials solely for registering the generic version raises serious ethical concerns.

DE would apply to all medicines, even when they do not deserve a patent or are not patented, protecting originators from price-busting generic competition. The operation of DE also means that TRIPS' public health safeguards (e.g. compulsory licensing) cannot be truly applied in practice.

INVESTMENT RULES

The EU wants to include an "investment chapter" in the FTA which will enable foreign companies to take the government to private international arbitration courts over domestic health policies like tobacco warnings and measures to reduce prices of medicines or implement TRIPS flexibilities. The EU wants what is known as an "investor-to-state" dispute mechanism to help protect the investments of EU companies. In the investment chapter, the definition of investment is extended to include intellectual property. This means that foreign investors will also be able to raise investment disputes with the government over matters related to intellectual property.

IP ENFORCEMENT MEASURES

The EU has started aggressively pushing what are known as 'IP enforcement measures.' These relate to how intellectual property rights are enforced by private companies. There are several IP enforcement provisions in the EU FTA negotiations including the following range of measures:

Injunction provisions – will undermine the independence of the judiciary to protect right to health over the multinational pharmaceutical industry's profits. When a patent holding company asks for an injunction against a generic company, it is asking the court to stop the generic company from taking some action – either launching a medicine or supplying more medicines to the market. When such a request is made, a court may refuse an injunction till the validity of the patent is checked or oblige the generic company that is infringing the patent to pay compensation to the patent-owner, rather than having to cease production or distribution of the generic medicines.

However, the IP enforcement measures demanded by the EU try to limit the ability of the courts to pay heed to public interest through tighter provisions on “injunctions” and interfere with the discretion of the courts to balance IP rights with the right to health of patients.

In practical terms could mean effective and safe medicines are stopped from being produced or are destroyed in order to protect company profits. It is also an attempt to govern the way the disputes around patents and civil trademark infringements will be managed by the courts. The EU also wants courts to have the power to freeze bank accounts of generic companies and seize their moveable and immoveable properties which would impact the production of all generic medicines by these companies.

Border measures - will hamper the import and export of generic medicines as they allow custom officials to seize generic medicines in transit from one country to another on the ground that they infringe or are suspected to infringe intellectual property rights. The impact of such measures can be seen in the case of the “seizures” at European ports that delayed the transfer of legitimate Indian generic medicines to other developing countries. If included in an FTA, such seizures could be repeated over and over again at not only European ports/airports but also at Thai ports/airports.

This can increase border searches and can interfere with cross-border transit of legitimate generic medicines as it allows IP right holders to petition customs officials to act when in-transit goods are suspected of infringing an intellectual property right, despite the fact that they do not infringe intellectual property in the country of manufacture and the country of destination.

Third Party Liability - will put third parties at risk of litigation and court orders for an alleged infringement. At present, cases of violations or infringements of intellectual property are filed against competitors. The EU wants to expand the scope of these cases and include all other parties that are connected with the competitor. This is why the phrase “third parties” is used. This could implicate, for example, suppliers of active pharmaceutical ingredients used for producing generic medicines; distributors and retailers who stock generic medicines; NGOs who provide treatment. This could act as a massive deterrent to anyone involved in the production, sale and distribution of affordable generic medicines.

PATENT TERM EXTENSION

There is no more straight-forward way to extend a company's monopoly over a medicine than to extend the life of the patent on it. TRIPS requires patents on medicines to last for 20 years from the date of filing. What the EU wants is that the life of the patent be extended by the length of time the medicine regulatory authority takes to examine an application for registration and marketing authorization, or a patent office takes to examine a patent application. The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and charge artificially high prices for the medicine, free from generic competition.

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