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Avoid patent clauses in trade treaties that can kill millions

By Martin Khor

A recent article in a prestigious journal reminds us of how the intellectual property chapter of free trade agreements can prevent the sick from getting treatment. This article also critiques the TPP clauses and warns that they should not be translated to national laws or copied into other FTAs being negotiated. This article was also published by the IPS.

Recently a very interesting article on why there are inequalities in access to health care and how medicine prices are beyond the reach of many people was published in *The Lancet*, one of the most prestigious medical journals in the world.

The authors, who are eminent experts in development and public health, pinpointed trade and investment agreements for being one of the greatest health threats.

Reading their powerful commentary leads one to think: What's the point of having wonderful medicines if most people on Earth cannot get to use them? And isn't it immoral that medicines that can save your life can't be given to you because the cost is so high?

The article picks on the Trans-Pacific Partnership (TPP), together with the Transatlantic Trade and Investment Partnership (TTIP) as the worst culprits. It says the TPP's chapter on intellectual property is "particularly intrusive to health and restricts access to the latest advances in medicines, diagnostic tools and other life-saving medical technologies."

This agreement, say the authors, contains many provisions that “strengthen patent protection that provides monopolies and inevitably leads to high prices.” They mention provisions that extend the patent terms beyond 20 years required by the WTO; lower the criteria of what can be granted patents; and “data exclusivity” provisions that put up barriers to generic manufacturers entering markets after the expiry of patents.

This viewpoint article was co-authored by Prof Desmond McNeill (University of Oslo); Dr Carolyn Deere (Oxford University); Prof Sakiko Fukuda-Parr (The New School, New York, and formerly the main author of the UNDP’s Human Development Report for many years); Anand Grover (Lawyers Collective India and formerly the Human Rights Council’s Special Rapporteur for the Right to Health); Prof Ted Schrecker (Durham University, UK); and Prof David Stuckler (Oxford University).

They said that growing evidence suggests that the agreements “will have major and largely negative consequences for health that go far beyond earlier trade agreements. This situation is particularly disturbing since the agreements have created blueprints for future trade agreements.”

The Nobel Peace Prize winning medical group, Médecins Sans Frontières (MSF), is even more scathing in its criticism. “The TPP represents the most far-reaching attempt to date to impose aggressive intellectual property standards that further tip the balance towards commercial interests and away from public health...In developing countries, high prices keep lifesaving medicines out of reach and are often a matter of life and death.”

This condemnation is just as relevant despite President Donald Trump withdrawing the United States from the TPP. There are efforts underway for the remaining 11 countries to put the TPP into effect without the US.

Moreover, these countries have prepared changes to their laws and policies to comply with the TPP’s provisions, and may implement these even if the TPP actually never comes into effect.

This would be an immense tragedy for public health, because most of these countries did understand that the chapter on intellectual property would have negative effects, but they accepted it as part of a bargain for getting better market access, especially to the US.

Since the TPP is now in suspension, it does not make any sense for the countries to change their patent laws when the benefit of market access is no longer available.

During the TPP negotiations, the other countries managed to dilute some of the very extreme demands of the US, but only to a small extent. The final intellectual rights chapter still reflects the extreme proposals of the US.

Moreover, the major developed countries can be expected to make use of the TPP's intellectual property chapter to inject into negotiations for new trade agreements, for example the RCEP, the Asian regional agreement.

Negotiators, especially from developing countries, and civil society groups should thus be vigilant that the TPP's provisions that have adverse effects on health are not reproduced in other trade agreements.

Members of the World Trade Organization are required to implement its intellectual property agreement, known as TRIPS, but they are not obliged to take on any additional obligations.

There are many provisions in TRIPS that allow a country to choose policies that are pro-health. The TPP has clauses that prevent a country from making use of many of these options because they are "TRIPS-plus", going beyond the TRIPS obligations.

First, there is a TPP 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 18.3) requires countries to grant patents for at least one of the following modifications: new uses of a known product, new methods for using a known product 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 in capsule form.

Second, there is a provision that enables extending the patent term beyond the 20 years required by TRIPS. Most countries now count this 20 years from the date of filing the patent application.

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 a delay is caused by the marketing approval process (Article 18.48). Extending the patent term means delaying affordable treatment for patients for so many more years.

Third, 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.

Fourth, a provision on Biologics (Article 18.51). For the first time in a trade agreement, the TPP obliges its members to undertake data protection obligations for “biologics”, a category of products for treating and preventing cancer, diabetes and other conditions. They are very expensive, some priced above \$100,000 for a treatment course, and the clause will enable the prices to remain high for longer periods. The exclusivity for biologics is for at least 8 years, or 5 years if other measures are also taken.

These provisions on exclusivity give drug companies extra protection, even if the product is not patented or if the patent has expired. The drugs will be out of reach except for the very wealthy for longer periods.

Fifth, a provision (Article 18.76) that requires TRIPS-plus extra enforcement of intellectual property. Countries are obliged to provide that the right holder can apply to detain any imported product that is suspected to be counterfeit or having “**confusingly** similar trademark”.

This can block legitimate generic medicines from entering the country. There have already been many cases of drugs being detained and later released when no infringement was found, thus needlessly delaying treatment to patients. The provision will increase the

incidence.

All in all, these TRIPS-Plus TPP obligations would make it more difficult for patients to obtain cheaper generics. If these clauses are widely adopted in other trade agreements and made into national laws, this would shorten the lives of millions of people who would be denied treatment.

For example, many millions of people worldwide are afflicted with Hepatitis C, which can lead to liver failure and death. They need the new medicines that have nearly 100% cure rates close but the prices are over \$80,000 for a 12-week treatment course. Even with discounts, very few can afford this.

Some developing countries, making use of TRIPS flexibilities, are able to provide treatment with generic drugs at around \$500 per patient, a very small fraction of the original drug's price. But if the TPP clauses are translated into domestic law, this access could be blocked.

People in the developing countries are the most affected by patent over-protection, but patients in developed countries are not spared. The mainstream Time magazine in October 2016 listed the need to "Reform the Patent Process" as one of the issues the US Presidential election should address.

The Time article commented that many people believe drug companies are "gaming" the system. "Instead of focusing on developing new cures, they are spending millions tweaking the way existing drugs are administered or changing their inactive ingredients. Those moves have the effect of extending a drug's patent and upping the amount of time it can be sold at monopoly prices, but they don't necessarily help consumers."

It is high time for a re-think to the system of drug patents. At the least the situation should not be allowed to worsen further, which would happen if TRIPS-Plus measures are adopted.

The lives and health of millions are at stake. Sometimes this is forgotten or put as a low priority when pitted against the promise of getting more exports in a free trade agreement.

But with the TPP in limbo and perhaps in perpetual suspension, there is really no reason

why the provisions that have adverse effects should be implemented in the countries that had negotiated the TPP, when there are no benefits to be obtained to offset them.

More generally, in all countries, policy makers and people should be on guard not to agree to TRIPS-plus clauses in the trade agreements that they negotiate or sign.

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