



## **The Need to Avoid “TRIPS-Plus” Patent Clauses in Trade Agreements**

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A very interesting article on why there are inequalities in access to health care and how medicine prices are beyond reach of many people was published in February 2017 in *The Lancet*, one of the most prestigious medical and health 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 threats to health of people worldwide. Their short but powerful commentary prompts the questions: 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) and the Transatlantic Trade and Investment Partnership (TTIP) agreements as being 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 lifesaving 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<sup>1</sup>, published in the *Lancet*’s 18 February 2017 issue, 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 are members of the Independent Panel on Global Governance for Health established by the *Lancet*-

University of Oslo Commission whose 2014 report reviewed health inequities related to global governance.

It is significant that this group of learned scholars identified trade and investment agreements as the first factor causing health inequities. They noted that the TPP and TTIP have generated a groundswell of opposition from politicians, civil society and academics. “Growing evidence suggests that they 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: a rewriting of the rules that govern the global economy, promoting corporate interests at the expense of public health priorities.”

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.”<sup>2</sup>

This condemnation by top experts and by the world’s leading medical charity may seem irrelevant now that President Donald Trump has withdrawn the United States from the TPP, thus apparently consigning it to history’s dustbin. But it is still relevant and topical. There are efforts underway, led by Australia and New Zealand, to get 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, in anticipation of the TPP coming into effect. Some of the countries may continue taking measures to implement these changes, 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, many countries resisted 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. This would weaken the potential of competition from cheaper generic medicines, with patients being the ultimate losers as they would have to face astronomical prices for many drugs for many more years.

As a result, they succeeded in diluting 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.

Thus, the authorities of the TPP countries should be alert to the need to *not* implement any changes to the laws that would increase the barriers to access to medicines.

Moreover, since the TPP is seen by its supporters as a "gold standard" of trade agreements, the major developed countries are expected to copy the TPP's intellectual property chapter to inject into negotiations for new trade agreements. For example, Japan is reported to be advocating elements of the TPP's chapter to be included in the Asian regional trade agreement known as RCEP.

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. They are known as "TRIPS flexibilities." The TPP has clauses that prevent a country from making use of many of these TRIPS flexibilities, and these clauses have been termed "TRIPS-plus", denoting that they go beyond what TRIPS obliges the WTO members to do.

The TRIPS-plus provisions in the TPP, which should be avoided in other agreements and in national laws, include the following<sup>3</sup>.

First, 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 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, a provision that enables extending the patent term beyond the normal 20 years. TRIPS requires at least 20 years for a patent's term, which is already very lengthy, as most countries had a shorter term, or no patents at all for drugs, until they joined the WTO. Most countries now count this 20-year period 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), defined as including more than 5 years after filing the application or three years after a request for examining the application has been made; or if there is an "unreasonable curtailment of the effective patent term as a result of the marketing approval process." (Article 18.48). Such extension of the patent term would mean that many people would not be able to afford treatment for 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. These are very expensive, with some cancer "biologics drugs" being priced well over \$100,000 for a treatment course. The TPP clause will enable 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.

Due to these provisions on data and market exclusivity, the big drug companies are given additional protection, even if there are no patents on the product or after the patent expires. The effect is to price the "biologics" out of reach, except for the very wealthy, for longer periods.

Fifth, a provision (Article 18.76) that requires new forms of enforcement of intellectual property that goes beyond the TRIPS obligation and may hinder the distribution and use of generic drugs. Under TRIPS (Article 51), WTO members must have procedures enabling a right

holder who has valid grounds for suspecting the importation of “counterfeit trademark” or “pirated copyright goods” to apply to the authorities to suspend the import by customs authorities at the border.

However, under the TPP, the members are obliged to provide that the right holder can apply to detain any “suspected counterfeit or *confusingly* similar trademark or pirated copyright goods that are imported.”

Allowing the right holder to apply to detain or suspend the import of generic medicines with what is alleged to be “confusingly similar trademark” will 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 there was delay in the medicines reaching the patients, and in some cases the medicines had passed the expiry date.

There are also other clauses regarding enforcement that go beyond TRIPS, including requiring that countries provide that customs authorities on their own initiative can take border measures on goods that are “imported, destined for export or in transit” (Article 18.7.6.5)

All in all, these TRIPS-Plus TPP obligations would make it more difficult for patients to obtain cheaper generics that could save their lives or alleviate their suffering. 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 because of high prices.

For example, many millions of people are afflicted with Hepatitis C, a serious ailment which can lead to liver failure, liver cancer and death. They would benefit from having access to the new medicines that have nearly 100% effective cure rates and with less side effects, but the prices are over \$80,000 for a 12-week course of treatment in the US. Even with some discounts, most governments and people in developing countries cannot afford this treatment.

Drug companies in a few developing countries, including India and Egypt, are able to produce generic versions at below \$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.

While patent over-protection especially affects people in the developing countries, patients in developed countries are also not spared the effects of high prices. The mainstream Time magazine listed the need to “Reform the Patent Process” as “one of four ways to shoot down skyrocketing drug prices” in a special feature on key issues in the US Presidential elections of 2016. According to the Time article<sup>4</sup>, 3 in 4 Americans believe that drug companies put profit before people.

In 2015, drug-makers increased brand-name drug prices in the US by an average of 16.2%, nearly 10 times the average inflation rate and the drug industry remains among the most lucrative, with annual profit margins of nearly 20%. The article says that pharmaceutical patents are supposed to reward drug companies for investing in risky R&D for new medications, and adds:

“Patents allow companies to recoup their investment by selling new drugs competition-free – and therefore at higher prices – for a number of years. But this model is increasingly under scrutiny, in part because 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.”

Thus, even in the United States, whose administrations have over the decades championed ever stronger intellectual property levels through the trade agreements, there is a growing outcry on the abuse of the patent system to enable drug companies to “skyrocket” their prices, with increasing public calls for reforming the patent system. Meanwhile, the governments of the US and other major developed countries continue to put pressure on other countries, including the poorer ones, to adopt drug-patent laws and policies similar to theirs.

It is high time for a re-think to the whole 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 by developing countries.

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.

**End notes:**

<sup>1</sup> Desmond McNeill et al, “Political origins of health inequalities: trade and investment agreements”, *The Lancet*, Vol. 389, pg 760-62, 18 Feb. 2017.

<sup>2</sup> Médecins Sans Frontières, 2016. Briefing note on Trading Away Health: The Trans-Pacific Partnership Agreement (TPP).

<sup>3</sup> In the analysis of the TPP provisions that follow, reference was made to the MSF Briefing Note (see footnote 2); Sangeeta Shashikant, “Comment on TPP Chapter 18 on Intellectual Property” (unpublished) and Carlos Correa, “Intellectual property in the TPP: Raising the barriers to affordable access to medicines”, South Centre Research Paper 62, Sept. 2015.

<sup>4</sup> Haley Sweetland Edwards, “4 ways to shoot down skyrocketing drug prices”, *Time*, 24 Oct 2016, pp 54-57.

## **Annex: Lancet Viewpoint Article**

### **Political origins of health inequities: trade and investment agreements**

*Desmond McNeill, Carolyn Deere Birkbeck, Sakiko Fukuda-Parr, Anand Grover, Ted Schrecker, David Stuckler*

*NOTE: This Viewpoint article was published in The Lancet journal of 18 Feb. 2017 (Vol 389: pg 760-62). The original article has 32 references. The article is republished here for information.*

The Trans-Pacific Partnership (TPP) agreement, signed on Feb 4, 2016, and the Transatlantic Trade and Investment Partnership (TTIP) currently under negotiation, have generated a groundswell of opposition from politicians, civil society, and academics. Growing evidence suggests that they will have major, and largely negative, consequences for health that go far beyond those of earlier trade agreements. This situation is particularly disturbing since the agreements have created blueprints for future bilateral and regional trade agreements: a rewriting of the rules that govern the global economy, promoting corporate interests at the expense of public health priorities.

Until the 1990s, multilateral negotiations under the General Agreement on Tariffs and Trade concentrated on reducing or eliminating tariffs and quotas on imports. Following the North American Free Trade Agreement (NAFTA) in 1993, and the World Trade Organization (WTO) regime in 1995, trade policy and law acquired binding dispute resolution processes, and began to have significant effects on a variety of domestic policies. Several agreements comprising the WTO regime have been identified with substantial potential effects on health. Harmonisation of intellectual property protection under TRIPS and its consequences for access to medicines are perhaps the most familiar; effects on various social determinants of health – the conditions in which people live, work, and die – are probably more important, yet indirect and harder to assess.

Nowadays, bilateral and regional trade and investment agreements (TIAs) are largely overshadowing the deadlocked WTO negotiating process. This applies most notably to so called mega regional agreements such as TPP and TTIP, as well as Economic Partnership Agreements between the European Union and African, Caribbean, and Pacific countries and regions. The TIAs intrude still further on the policy space of signatory countries: “the freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfill their aims”. Many of these agreements are more about investment than trade. They provide legal infrastructure for a global reorganisation of production in which cross-border trade of inputs and outputs takes place within the networks of affiliates, contractual partners, and suppliers of transnational corporations, which coordinate as much as 80% of world trade.

Recent agreements not only go beyond the WTO agreements in domains such as intellectual property, food safety, and trade in services, but they also extend to areas such as public procurement, disputes between corporations and states, and more. Their broad scope leads to correspondingly broad consequences for economies and societies; they are influential in shaping employment, access to technologies, environmental pollution and sustainability, and many other social determi-

nants of health. There is growing evidence that they widen inequalities in multiple ways, as the rules disproportionately affect the poorest countries and low-income, vulnerable, and marginalised populations within countries.

For example, the 1994 WTO TRIPS agreement recognised the potential conflict of intellectual property on health priorities and included provisions—so-called flexibilities—to resolve contradictions, such as to allow governments to use compulsory licensing in times of public health emergencies to oblige companies to allow generic manufacture for a suitable royalty. The 2001 WTO Doha Declaration reaffirmed these flexibilities and articulated the primacy of human health, but the new TIAs weaken this resolve and put up new barriers.

The TPP is a case in point. The 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 contains many of the provisions in previous bilateral and regional free trade agreements that strengthen patent protection that provides monopolies and inevitably leads to high prices. For example, provisions include extensions of patent terms beyond 20 years required under TRIPS; lowering patentability criteria to include modifications of existing medicines; and data exclusivity provisions that effectively put up barriers to generic manufactures entering markets after expiry of patents.

Whereas some trade agreements are between neighbouring countries at relatively equal levels of economic development (such as Argentina, Brazil, Paraguay, Uruguay, and Venezuela, which together form the Mercosur subregional bloc), trade negotiations between countries are very often asymmetrical, as are disputes about the implementation of agreements. Countries with small populations and economies might have to grant major concessions—even beyond the requirements of WTO agreements—to larger, richer trading partners to secure even modest improvements in market access.

On top of the well known asymmetry of economic and political power and capacity between states, new negotiations are skewed by asymmetry of power between corporations and states, especially small states. The situation is complicated by the fact that, at least according to some, transnational corporations can find common interest with national bureaucratic-political elites who will favour their case. Corporations clearly have the bargaining advantage over governments in their ability to shift production and investments off shore, and their capacity to lobby governments. While corporate influence has always been important in shaping trade rules, new negotiations for the TIAs build in unbalanced consultations with firms in an otherwise secretive process. During TPP negotiations in the USA, private industry and trade groups represented the majority of committee members (85% of the total).

With these power imbalances, the weakest countries and population groups have even less voice than in the WTO trade negotiations; at least in the WTO, weaker countries have opportunities to act collectively. Further, the new TIAs expose low-income and middle-income countries even more directly to the interests of corporations, such as through investment provisions.

The power asymmetries in how TIAs are negotiated and implemented—on which the *Lancet*-University of Oslo 2014

Commission report focused—are especially evident in investor state dispute settlement (ISDS) provisions. These provisions, which are included in many of the roughly 3000 bilateral investment treaties now in force, allow foreign investors, but not domestic firms or citizens, to challenge national laws and policies. ISDS reduces the risks for foreign investors by providing them with the right to seek arbitration in situations in which the actions of a host country government have deprived them of profits, usually including future or anticipated profit. Although originally established to give foreign investors protections that were not afforded by fragile host-country legal systems, such provisions now offer access to a separate, parallel channel of dispute resolution, often leading to binding awards by arbitrators that are enforceable through domestic courts even though the decisions might not be public. ISDS provisions also often take arbitration out of the hands of national institutions, in favour of tribunals such as the World Bank’s International Centre for the Settlement of Investment Disputes.

ISDS provisions have existed in international agreements since the late 1960s, but both the number of agreements incorporating them and the number of cases initiated by investors have increased rapidly in recent years. They have been used, for example, by a US tobacco company to challenge Australia’s plain packaging requirement for tobacco products, and Uruguay’s graphic health warnings. Although the Australia challenge was unsuccessful, even anticipation of such costly legal action may be sufficient to discourage regulation in areas such as alcohol control, taxes on ultra-processed foods, and environmental protection. The TTIP and TPP each propose new ISDS measures, such that the proportion of world trade and investment covered by these provisions would increase several-fold. ISDS provisions have drawn criticism from a range of actors including public health physicians, mainstream economists and UN special rapporteurs and independent experts on human rights. The UK Faculty of Public Health has argued that ISDS provisions in the TTIP threaten to compromise the National Health Service with costly threats of arbitration.

Our argument, in summary, is that TIAs, driven by corporate interests, are rewriting the rules governing trade and investments. They threaten to exacerbate the underlying political and economic drivers of health inequities in years to come. Not only do the processes of TIA negotiation routinely undermine democratic principles, their outcomes conflict with government obligations to fulfill the right to

health under human rights treaties and contradict the commitments made to implement the UN Agenda 2030, which clearly spells out health—for all—as a global priority.

To counter these trends requires a broad resistance from the health community that underlines the multiple effects on public health priorities and actively promotes alternatives. Specific agreements that regulate the global marketplace in the interests of public health can play a part but we argue that what is required is not only opposition to one agreement at a time, but also—and more importantly—a fundamentally new agenda for how TIAs are negotiated and what they should contain. In particular they need to incorporate: (1) protection of policy space for governments to treat public health as a priority, not to be compromised by trade and investment objectives; (2) transparency and accountability in the TIA negotiation process in which the health sector would have voice; and (3) rejection of new ISDS commitments and renegotiation of those in place so that they are less intrusive on national health priorities.

In short, a radical shift in policy and process is required to stop the intrusive provisions of these agreements and enable states to fulfil their human rights obligations to their citizens and pursue public health priorities.

#### Contributors

The authors are members of the Independent Panel on Global Governance for Health, established by the *Lancet*-University of Oslo Commission. The Commission’s 2014 report, published in *The Lancet*, reviewed health inequities related to global governance in several areas. The issue of trade and investment was selected as the first one for follow-up review by the Panel. A full-length article detailing the Panel’s findings is forthcoming in *Journal of World Trade*. This Viewpoint highlights some of the key messages for the health community: the challenges to health posed by the new landscape of trade and investment agreements.

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