



**2014**

**The Trans-Pacific  
Partnership Agreement:  
Implications for Access to  
Medicines and Public Health**

**EXECUTIVE SUMMARY**

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## FOREWORD

In recent years, the number of bilateral and regional trade negotiations has been increasing. Many of these negotiations involve both developed and developing countries, and the ensuing free trade agreements often contain extensive provisions on the protection of intellectual property rights. These provisions usually impose a higher level of protection for intellectual property rights than is required under the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement. These so-called “TRIPS-plus” provisions delay generic market entry and competition. As such, they run counter to UNITAID’s efforts to increase the affordability of, and access to, medicines and other medical products.

TRIPS-plus provisions also limit or undermine developing countries’ policy options for legislating and using TRIPS flexibilities, even though safeguards and flexibilities were included in the TRIPS Agreement to enable governments to protect public interests, including access to medicines. This has led to concerns that TRIPS-plus provisions in free trade agreements will undermine public health safeguards and objectives—notably access to medicines. These concerns are particularly pertinent with regard to the negotiation of a Trans-Pacific Partnership Agreement, which has been positioned as a “model” for the 21<sup>st</sup> century—implying that the same or similar provisions are likely to appear in future trade agreements, including those involving developing countries.

Through this analysis of provisions that are proposed in the context of the Trans-Pacific Partnership Agreement negotiations, UNITAID seeks to better understand current and future issues in trade negotiations and their impact on access to medicines.

The present analysis is largely based on the text of the proposals of the USA that were leaked and made available in the public domain in 2011 and 2012. In November 2013, a more recent text became available (through Wikileaks). This more recent text shows not only the position and proposals of the USA but also the proposals of other countries participating in the Trans-Pacific Partnership Agreement negotiations. This text indicates that several countries involved in the negotiations have not agreed to many of the USA’s demands; the alternative language they propose is certainly preferable from the perspective of access to medicines. It also indicates that the USA appears to be reconsidering some of its problematic proposals, such as the prohibition of opposition prior to the granting of patents (pre-grant opposition).

Nevertheless, many other proposals remain substantially the same, and have the potential seriously to hamper access to medicines. Moreover, even those proposals that appear to be under reconsideration may resurface, whether in the Trans-Pacific Partnership Agreement or in future negotiations and agreements. Therefore UNITAID feels that it is worthwhile to publish and share this analysis, including the review of some provisions that may, for now, have been dropped or amended.

## EXECUTIVE SUMMARY

### Introduction

The proposed Trans-Pacific Partnership Agreement (TPPA) has complex origins. It was originally a free trade agreement (FTA) between Chile, New Zealand and Singapore and, later, Brunei Darussalam, known as the “Trans-Pacific Strategic Economic Partnership Agreement”. The negotiations were, however, later expanded to become the TPPA and included other negotiating partners—Australia, Malaysia, Peru, the United States of America (USA) and Viet Nam. More recently, Canada, Japan and Mexico joined. To date, there have been 19 formal rounds of negotiations, the most recent being held in Brunei in August 2013, as well as a number of inter-sessional meetings.

The proposed TPPA goes well beyond traditional trade concerns and includes, among other elements, extensive obligations related to intellectual property and investor protection. The intellectual property obligations proposed for the TPPA exceed the minimum standards of the multilateral World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Public interest and public health groups, as well as a number of United Nations agencies, have voiced concern over such “TRIPS-plus” provisions. A dramatic illustration of the direct impact of TRIPS-plus rules captured global attention when, in 2007 and 2008, shipments of generic medicines from India to other developing countries were detained at European ports on allegations of intellectual property infringement. One of the shipments included an HIV medicine, *abacavir sulfate*, the purchase of which had been funded by UNITAID and which was destined for a project implemented by the Clinton Foundation in Nigeria. As cautioned by UNITAID in its statement following the seizure of the *abacavir sulfate* shipment:

“... Interruption in HIV therapy is extremely dangerous and can cause resistance to the medicines. We therefore strongly urge the Dutch government to release the medicines so that they can reach patients as soon as possible. UNITAID is worried more generally about the trend that seems to have taken hold in recent months where generic medicines are stopped or confiscated while transiting through the Netherlands. Generic medicines are not counterfeit medicines.”

The ongoing TPPA negotiations have attracted significant controversy and debate. Aside from the proposed scope and potential impact, the secrecy under which the TPPA negotiations have been conducted has attracted criticism. Negotiating texts that have been leaked to the public domain have caused disquiet regarding the scope and content of the provisions under negotiation.

In addition to TRIPS-plus intellectual property provisions being negotiated as part of the TPPA, there are also serious concerns that proposed provisions related to financing and/or reimbursement of medicines, as well as to investment, will have adverse implications for access to medicines and the protection of public health in general.

In light of these concerns, UNITAID commissioned this report to identify proposed TPPA provisions that are likely to have implications for public health and access to pharmaceutical products.

UNITAID’s mission is to contribute to the scale-up of access to treatment of HIV/AIDS, malaria and tuberculosis in developing countries. Through the use of innovative and global market-based approaches, UNITAID seeks to introduce interventions that decrease prices and improve the quality and acceptability of products so that greater access to treatment can be achieved at less cost. A vital component of this strategic approach is the promotion of competition in the pharmaceutical market via generic production of pharmaceutical products, including through the use of the flexibilities available in the TRIPS Agreement and affirmed by the Doha Declaration. TRIPS-plus provisions that can restrict or prevent the use of TRIPS flexibilities will thus have implications for UNITAID’s ability to fulfill its mission and mandate.

## Objective and methodology

The objective of this report is to provide an analysis of the provisions in the proposed TPPA in order to obtain a clearer understanding of their implications. It is hoped that the report will also be a useful resource for other stakeholders in the public health field.

The report analyses the key negotiating issues in the USA's proposals (widely considered to be the basic negotiation text for the TPPA) which are likely to have an impact on access to medicines and public health.

Analysis in this report is based on negotiation texts that were leaked and made available in the public domain in 2011 and 2012. The main texts include the USA's proposals for chapters on intellectual property, on the regulation of pharmaceutical reimbursement programmes and on investment. It should be borne in mind that it may not be possible to provide a comprehensive examination of all relevant provisions or to assess fully how these provisions will impact and interact with other parts of the TPPA (which are not currently in the public domain). Moreover, as long as the negotiations are ongoing, the text may evolve and change.

## Patents

Several articles of the intellectual property chapter proposed by the USA relate to patents. Overall, the USA's TPPA proposal appears to weigh heavily in favour of patent applicants by requiring lower levels of disclosure, lower standards of patentability, no pre-grant opposition proceedings, and multiple opportunities to amend patent applications. The overall impact of these measures is likely to be the granting of a greater number of patents on medicines and medical technologies, including a greater number of weak or "poor-quality" patents.

### Proliferation of patents on medicines

#### *The lowering of patentability standards may lead to more patents on medicines*

The TRIPS Agreement requires WTO members to make patent protection available for inventions—including inventions related to medicines—that satisfy the criteria of being new (or novel), inventive and industrially applicable. The TRIPS Agreement does not define these terms and allows countries flexibility in determining the standards for patentability. The USA's proposal, however, would require TPPA parties to adopt low standards of patentability, which may result in a greater number of patents being granted, including on medicines and medical technologies. It is of note that specific recommendations for higher standards of patentability to be adopted in developing countries have come from a number of United Nations agencies, the United Kingdom's Commission on Intellectual Property Rights and WHO's Commission on Intellectual Property, Innovation and Public Health.

#### *Exclusion of bars on "evergreening" may lead to more patents on new uses and new forms of old medicines*

Developing countries are increasingly adopting, through laws or patent examination guidelines, higher standards of patentability than those applied in the USA and other developed countries. The USA's TPPA proposal appears specifically to target provisions that set strict patentability criteria in the case of new uses and new forms of existing medicines, or that exclude new uses/new forms from patentable subject matter. Such provisions are considered to remove uncertainty from patent examinations and to provide patent examiners with clear guidance on patentability standards related to pharmaceutical products. Adopted in countries such as Argentina, India, Philippines and Zanzibar, such provisions have featured in the rejection and withdrawal of patent applications, particularly with regard to patent applications on antiretroviral (ARV) medicines.

By explicitly requiring that new uses, new forms and new methods of use are patentable, the proposal of the USA removes the option for TPPA parties to adopt patentability standards similar to those adopted by Argentina and India.<sup>1</sup> This is of particular concern as research over the past decade has shown that the overwhelming majority of patents relating to medicines today are for new uses, new forms or new formulations/dosages/combinations of existing medicines. Often referred to as “evergreening”, such patents effectively allow patent holders, through successive and overlapping patents on new forms of old medicines, to enjoy longer periods of exclusivity on a medicine than the 20-year minimum period prescribed by TRIPS.

### **Expanding the scope of what can be patented (limiting exclusions from patenting)**

The USA’s TPPA proposal also requires TPPA parties to grant patents on plants and animals. Plants may provide the raw materials used in allopathic and traditional systems of medicine. The requirement of patents on plants and animals may also raise concerns over the patenting of gene sequences. In addition, the USA’s proposal requires that patents be granted on surgical and diagnostic methods—which could seriously hamper the provision of treatment by health-care providers and could lead to a situation where doctors may be prevented from using a method of diagnosing a disease or where payment of a royalty is required for use of a surgical or diagnostic method. The TRIPS Agreement explicitly allows countries to make these exclusions from patenting, but the TPPA proposal of the USA would remove this flexibility.

### **Lowering and weakening disclosure standards**

Disclosure standards in applying for and obtaining intellectual property protection can impact access to medicines in several ways. For instance, higher standards of disclosure can aid local manufacturers, researchers and others in adopting and learning from patented technologies. However, several provisions of the USA’s TPPA proposal appear to weaken the disclosure standards in patent applications. The USA’s proposal waters down the requirement for disclosing the best mode of working (or practising) a patented invention. As a result, where a patent barrier no longer exists, a generic company may not know the best mode of producing a medicine. This could lead to later entry into the market or production through inferior and more expensive means.

### **Tilting patent examination procedures in favour of patent applicants: removal of pre-grant oppositions**

A number of countries allow competitors and/or public interest groups to oppose patent applications. Pre-grant opposition proceedings are particularly important because of the difficulty of opposing or revoking a patent once it is granted. In several developing countries—such as Brazil and India—public interest and health groups have successfully used pre-grant opposition proceedings to ensure that only good-quality patents are granted on medicines. The USA’s TPPA proposal, however, would prohibit countries from providing for pre-grant opposition proceedings in national legislation, thus eliminating a crucial health safeguard in patent laws.<sup>2</sup>

### **Tilting patent office filing procedures to favour patent applicants: amendment of patent claims**

In addition to lower patentability and disclosure standards and the removal of pre-grant opposition, the USA’s TPPA proposal also requires patent offices to provide patent applicants with extensive opportunities to amend their claims (before they receive any communication from the patent office).

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1 The previous US TPPA proposal was explicit in stating “In addition, the Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.” In the more recent text the US proposal has been amended; it now states: “The Parties confirm that: (a) patents shall be available for any new uses or methods of using a known product, (b) a Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.”

2 According to the text that became available in November 2013, the US appears to have withdrawn its proposal for the removal of pre-grant oppositions. The text states, however, that this is “pending confirmation from capital.”

### **Patent term extensions**

Extending the term of a patent is a straightforward way of delaying generic entry. The negotiating history of the TRIPS Agreement shows that the demand for longer patent periods to compensate for delays by drug regulatory agencies in granting marketing approval or by patent offices in granting patents was made at that time and was rejected by developing countries. Further, the adoption of a 20-year term—three years longer than the previous term in the USA—was grounded on the reality of patenting and regulatory delays. Under the USA’s TPPA proposal, patent terms may be extended up to five additional years in the case of delays by drug regulatory authorities, while in the case of delays at the patent office there appears to be no explicit limitation on the period of extension, although state practice, including in the USA, does limit such extensions.

The impact of generic entry on the prices of medicines can be significant. This has been most dramatically demonstrated in the case of HIV medicines. In 2001, the price available from originator companies for the first-line triple combination of ARVs was \$10 439 per person per year, while generic companies were able to offer a price of \$350 per person per year. Impact assessments of patent term extensions in various countries indicate significant increases in health spending.

### **Weakening of the Bolar provision**

The Bolar provision allows generic manufacturers to obtain provisional regulatory marketing approval or “registration” in order to be ready to enter the market as soon as the patent barrier no longer exists. However, while recognizing the validity of this exception, the USA’s TPPA proposal also seeks to enforce and extend patent rights beyond what is required. Specifically, the proposal appears to prevent the use of the Bolar provision for marketing approval in other countries. Effectively this means that a generic company would have to manufacture the medicine locally in every country where it wishes to seek early marketing approval. This is highly unlikely to happen since it would not be economically feasible for generic companies to establish quality-assured manufacturing sites in all developing countries. Alternatively, compulsory licences for import and export would have to be issued even for regulatory approval and in the case of every medicine. This would create significant barriers to the rapid entry of generic medicines into export markets.

### **Data exclusivity and patent linkage**

The proposed intellectual property chapter also includes requirements regarding data exclusivity and patent linkage (formally referred to as “Submission of information or evidence concerning the safety or efficacy of a new pharmaceutical product”). A placeholder remains for data exclusivity for biologicals.

#### **Data exclusivity**

In many countries, drug regulators do not require generic manufactures to conduct clinical trials in order to obtain marketing approval for their (generic) versions of medicines which are already on the market. Duplicate clinical trials on human populations for a medicine of which the safety and efficacy is already proven are considered unethical. Such trials would also add considerably to the cost of generic production. Instead, under the regulatory framework of many developing countries, generic manufacturers have to prove that their generic versions are “bio-equivalent” to the medicine already approved and on the market. Data exclusivity as demanded in the USA’s TPPA proposal would require generic manufacturers to conduct their own clinical trials to obtain marketing approval or to wait until a specified exclusivity period is over (five years plus any relevant three-year extension for small-molecule chemical medicines) before a generic product could be approved.

This measure creates exclusivity over medicines that is distinct from patent protection and even applies to medicines that are off-patent. Data exclusivity can, potentially, interfere with the implementation of compulsory licences. Data exclusivity is widely considered to be a TRIPS-plus measure that has a negative

impact on access to medicines. Assessments in Guatemala and Jordan of the impact of data exclusivity have found significant increases in the prices of medicines.

The few developing countries that apply data exclusivity have evolved a number of ways to limit its impact on access to medicines. The USA's TPPA proposals, however, restrict the use of several of these safeguards. For instance, countries such as Peru (which is obliged to implement data exclusivity under a previous FTA with the USA) require that the period of data exclusivity on a medicine should commence from its first registration in the USA. The TPPA proposal instead requires that the period of exclusivity should start from the point at which the medicine is registered in the country concerned.

In many respects the USA's TPPA proposals on data exclusivity are not only TRIPS-plus but they also require data exclusivity in excess of previous FTAs concluded by the USA by substantially restricting the ability of governments to limit the anticipated negative impacts of data exclusivity. From a public health perspective, the recommendations of United Nations agencies and human rights institutions have been unanimous in warning developing countries against adopting data exclusivity in the first place.

### Patent linkage

Patent linkage systems in countries such as Canada and the USA allow originator companies to trigger a stay of generic entry through the drug regulatory authorities rather than the patent system. The USA's proposal would require such a system of patent linkage to be adopted by the TPPA countries.

Patent linkage is of particular concern in developing countries. Through the system of patent linkage, pharmaceutical companies effectively have another avenue for preventing the launch of generic medicines, with the drug regulator providing an early warning system while also implementing what is effectively an injunction on the generic version if the patent holder commences infringement proceedings. Patent linkage offers patent holders in the pharmaceutical sector an advantage that patent holders in other areas of technology do not have—i.e. the use of the health and regulatory mechanism to facilitate the enforcement of their patents. Patent linkage furthermore can create an additional burden on medicines regulators. It is notable that patent linkage is not implemented in the European Union. The impact of the patent linkage system in delaying generic entry is well documented. The United Nations Special Rapporteur on the Right to Health has accordingly cautioned developing countries against adopting a system of patent linkage.

### Trademarks

Alongside the provisions on patents and data exclusivity, the proposed intellectual property chapter of the TPPA also includes TRIPS-plus provisions related to the protection of trademarks. Trademark protection is typically provided for distinctive signs—including symbols, letters or names—which enable consumers to identify easily specific producers of goods and services with an established reputation. The provisions in the USA's TPPA proposal suggest a shift away from this consumer-oriented justification for trademarks towards the protection of the producer's investment in advertising and promotion. Such a shift can have implications for access to medicines and protection of public health.

### Broad-ranging trademark protection

As well as increasing the term of trademark protection, the USA's proposals appear to expand significantly the scope of trademark protection and may require TPPA countries to provide protection that includes colours *per se*, in addition to sounds, scent and other non-visual marks. Broad-ranging trademark protection could potentially be a means of obtaining intellectual property protection for products that are currently not eligible for patent protection. In the pharmaceutical context, a concern would be whether the expanded trademark protection could be used to prevent generic producers from using colours or shapes identical or similar to those of the originator pharmaceutical product. Differences in the appearance of generic and originator products may cause confusion, reduce adherence and increase prescription/dispensing errors, with adverse consequences for patients. Nevertheless, current jurisprudence suggests that



trademarks for tablet colour or shape are not registrable since the colour and/or shape of a tablet has an important function because patients often rely on the colour, size and shape of medication for reassurance that they are taking the right pill.

### **Use of generic names and trademark infringement**

The USA proposal requires TPPA countries to ensure that the requirements for the use of the “common name” for a good or product do not impair the use or effectiveness of the trademark. It remains to be seen how this provision would operate, but the text raises questions about the implications for domestic regulations which are in force in a number of countries that require the international nonproprietary name (INN) or generic name of the pharmaceutical product to be prominently displayed.

## **Copyright**

The proposed intellectual property chapter sets out the provisions proposed for copyright and related rights in the TPPA. As with other intellectual property protection in the USA’s TPPA proposals, copyright protection is also significantly expanded. The overall effect of the proposed copyright provisions would be an extension of international obligations relating to the length and scope of copyright protection. While the implications of these provisions for access to medicines and public health are unclear, it would be prudent to explore whether such expanded copyright protection could be interpreted in ways that hamper or prevent the production and sale of generic medicines.

### **Restrictions on parallel importation**

The proposed TPPA provisions on copyright seek to create a new international legal requirement that would limit the ability of countries to apply their chosen regime of exhaustion of intellectual property rights. This is in contrast to Article 6 of the TRIPS Agreement which preserves the freedom of countries to choose their regime of exhaustion in order to allow for parallel importation.

The USA’s TPPA proposal, in preventing the parallel importation of copyrighted works, raises the additional possibility that it could be used to prevent the import of medicines, even when patents have expired, on the grounds that a component of the product contains copyrighted material, such as parts of the packaging or the packaging insert. This relates to claims by some originator pharmaceutical companies regarding copyright infringement of their product information documents or product labelling. Such claims have caused confusion because in some countries, such as Australia and the USA, generic producers, when applying for marketing approval, are required by the drug regulatory authorities to use the same product information and labelling as the originator. In a number of jurisdictions, the courts have refused thus far to hold generic producers liable for copyright infringement in such cases on the grounds that regulatory requirements preclude an infringement action by the originators. In Australia, the government clarified the situation by amending the Australian Copyright Act 1968. The amendment, which came into force in 2011, enables generic producers legally to use product information or labels that have been previously approved by the drug regulatory authority. The question is whether the USA’s TPPA proposal seeks to change this situation.

### **Access to scientific publications and journals**

In the public health context, the expansive copyright protection sought under the TPPA could also have an effect on the research and development process in developing countries. Research on new medicines and other innovations in health care may be hampered if access to scientific publications and journals is restricted or curtailed. Incorporation of appropriate copyright exceptions and limitations would facilitate access to scientific publications and journals, as well as other educational material, and is justifiable on the grounds of protecting the public interest in promoting both research and education.

## **Enforcement of intellectual property rights**

Several articles of the proposed intellectual property chapter relate to the enforcement of intellectual property rights.

### **Presumptions of validity increase the difficulty in challenging patents and increase the likelihood of poor-quality patents remaining in force**

The presumption of validity of patents and trademarks is likely to make it considerably more difficult to challenge intellectual property rights on medicines, while also increasing the risk to generic competitors of infringement proceedings. The presumption of validity of patents or trademarks may be premised on the expectation that patent and trademark offices are sufficiently successful in ensuring the quality of registrations. However, even the quality of patents granted in developed countries with extensive patent offices, staff and budgets is increasingly being questioned. Patent offices in developing countries are highly reliant on the findings of the United States Patent and Trademark Office and the European Patent Office in relation to the granting or rejection of patents, so concerns over patent quality can accordingly be surmised to extend to most developing countries as well.

Several developing countries are attempting through legislation or patent examination guidelines to improve the quality of patents granted, particularly in the field of pharmaceuticals. These measures, coupled with expanded patent opposition provisions, have resulted in low-quality patents on several key medicines being denied or revoked in countries such as India. However, not only would the substantive provisions of the USA proposals limit these options for TPPA signatories but the general obligations on enforcement also require a presumption of validity. When read with the further expanded enforcement provisions discussed below, this presumption is likely to make both patent challenges and defence in infringement proceedings more difficult—and to deter generic competition. The presumption of validity will also increase the likelihood that provisional measures such as interim injunctions will be imposed; this in turn would result in generics not being available to patients. In the case of trademarks, the USA's proposal specifies that the presumption would also apply in criminal proceedings, thus increasing the likelihood that a criminal penalty of a fine or even imprisonment could be imposed on a generic competitor.

### **Limits on the ability of governments to balance intellectual property enforcement with the public interest**

The proposal that civil judicial procedures should be available for any intellectual property right is likely to reduce the flexibility of TPPA countries to determine what forms of enforcement should be available for different types of intellectual property rights. TPPA parties will be confronted with a significantly expanded range of enforceable intellectual property rights available to patent and trademark holders (compared to the TRIPS requirements). For example, patents on surgical methods are not enforceable in the USA against medical practitioners in the course of their practice. If the USA's TPPA proposals require that every aspect of the intellectual property right must be enforceable, TPPA countries may be unable to balance the enforcement of intellectual property rights in pharmaceuticals with the rights of patients to access affordable generic medicines or to ensure that certain forms of intellectual property rights, even if granted, do not impede the provision of medical care.

### **Chilling effect on generic producers**

Several of the provisions proposed by the USA are likely to have a chilling effect on generic producers. The proposals would empower patent-holding companies to seek information in infringement proceedings regarding the entire supply and distribution chain of a generic company. This information could then be used to harass or intimidate other players in the supply and distribution chain—such as transporters, distributors etc. In addition, the USA is proposing harsh enforcement measures, high damages for infringement and criminal penalties for trademark cases in excess of what is required in the TRIPS Agreement.

The USA's proposal would allow the seizure of generic medicines that are subject to trademark disputes while the case is still pending in court. In addition, materials and implements used for generic manufacture—which could include machines, active pharmaceutical ingredients, packaging etc.—could also be seized. Where trademark counterfeiting is proven, the medicines as well as the materials and implements used in their manufacture may be destroyed. If such materials and implements are destroyed, or even disposed of outside commercial channels, the ability of the generic company to continue manufacturing could be significantly hampered.

The USA's proposal would also authorize judicial authorities to impose debilitating financial damages on generic companies if the latter are unsuccessful in an infringement case. Just one case of infringement under the USA's proposals could potentially bankrupt a generic competitor.

### **Border measures on trademarks likely to hamper import and export of generic medicines and increase the risk of seizure of generic medicines in transit**

Concerns over border measures in relation to the enforcement of intellectual property rights have become acute in recent years with the detention at various ports in the European Union of generic medicines exported from India to Africa and Latin America. The primary grounds for the detention of these medicines were alleged violations of intellectual property rights—i.e. patents and trademarks—in the European Union.

The TRIPS Agreement requires border measures only in cases of import and in cases of trademark counterfeiting. The USA's TPPA proposal on border measures applies to “confusingly similar” trademarks. This is a different and much lower standard than that of trademark counterfeiting. Trademark disputes between pharmaceutical companies are commonplace. One of the primary reasons is the use of a medicine's international nonproprietary name (INN) by both sets of companies. The INN is allotted by the World Health Organization which has long recommended that governments ensure that the whole or part of an INN is not used in brand names. It is noteworthy that among the seizures in the European Union was a shipment of the generic antibiotic amoxicillin on its way to Vanuatu. The seizure took place as customs officials suspected trademark infringement of GlaxoSmithKline's brand name “Amoxil”<sup>3</sup>.

The case illustrates the concern that customs officials may not be in the best position to judge whether a trademark is infringed in the context of import, export or transit. Under the USA's TPPA proposal, the application of border measures for the import, export and transit of confusingly similar trademarks means that such seizures of generic medicines are likely to continue.

In addition, the USA's proposal requires that the main course of action in relation to infringing goods affected by border measures should be their destruction. In the case of medicines this is of great concern as, instead of being destroyed, generic medicines that are legitimate, safe and effective should be capable of being donated or even returned to the manufacturer. The destruction of life-saving or life-prolonging medicines should be an exception rather than the rule.

## **Investment**

The proposal of the USA on investment demonstrates a high degree of similarity to the investment chapter in the North American Free Trade Agreement (NAFTA), which has been criticized for restrictions on the regulation of corporations and the grant of broad-ranging rights which, *inter alia*, permit investors to seek compensation for domestic rules that they claim undermine their investments. In terms of the proposed TPPA investment chapter's potential impact on public health, three main areas of concern are highlighted for consideration.

First, the provisions of the proposed investment chapter of the TPPA provide expansive rights and privileges to foreign investors, with the obligation on governments to provide protection of such rights. The

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<sup>3</sup> The shipment was released several weeks later, after confirmation that the medicines did not infringe the brand name “Amoxil”.

limitation on “performance requirements” can prevent governments from imposing conditions on the conduct of foreign companies, even when those conditions are imposed in the interest of protecting public health and promoting access to medicines. For example, it may be a contravention of the proposed TPPA provisions if a government were to require that a foreign pharmaceutical company should ensure a domestic supply (whether through import or production) of a minimum quantity of active pharmaceutical ingredients.

Secondly, the proposed investment chapter combines strong investors’ rights and a broad scope of protection with an investor-state dispute settlement mechanism, which provides the “teeth” for enforcement of obligations. Under the WTO dispute settlement system, only WTO members (i.e. governments) may challenge each other for non-compliance with TRIPS or any other WTO agreements. The investor-state dispute settlement, however, would allow for the possibility that investors could sue a government with respect to intellectual property and regulatory issues pertaining to medicines.

Finally, it is important to note that the jurisdiction of arbitration tribunals is defined by the provisions of the relevant investment treaty. Typically, these provisions do not impose obligations on the arbitrators to take into account in their decision-making the constitutional obligations of governments or even human rights considerations.

The implications of investment provisions and investor-state disputes in the context of public health and access to medicines are being played out in the current dispute between the pharmaceutical company Eli Lilly and the Government of Canada in the context of NAFTA. In Canada, Eli Lilly’s patents related to two pharmaceutical products—Strattera and Zyprexa—were revoked on grounds of failure to prove the “utility” of the patented drug, as required under Canada’s patent law. Eli Lilly claims that the patent revocations violated the minimum standard of treatment guaranteed to foreign investors under NAFTA, which obliged signatories to accord to another party “treatment in accordance with international law, including fair and equitable treatment and full protection and security”. The text of NAFTA’s Article 1105 is similar to that of Article 12.6 of the TPPA draft. Eli Lilly further claims that the patent revocations discriminated against Eli Lilly in favour of generic firms. Eli Lilly also alleges that the patent revocations amounted to an expropriation of property rights. For these alleged violations, Eli Lilly is demanding compensation of CDN\$ 500 million.

### **Pharmaceutical pricing, financing and reimbursement of medicines**

One of the leaked TPPA texts is the annex on “Transparency and procedural fairness for healthcare technologies”. The text proposed by the USA in the annex would require TPPA signatories to comply with obligations relating to pharmaceutical pricing and reimbursement schemes.

The probable effect of these proposals would be to limit countries’ policy space to adopt and enforce therapeutic formularies, reimbursement policies and other price-moderating mechanisms within public health systems. While many developing countries have yet to establish pharmaceutical reimbursement schemes, adoption of the provisions proposed in this annex would have the effect of prescribing the type of system that governments would be permitted to establish, instead of allowing them to choose or design the system that is most suited to the specific national context and priorities. The proposal would also have the effect of imposing obligations in an area of domestic regulation that is well beyond the protection of intellectual property rights; it would affect health policy-making itself.

### **Conclusion and recommendations**

Commentators from across a broad spectrum have expressed concerns about the potentially adverse impacts of the TPPA. The analysis in this report supports the view that the TPPA, if adopted, will have major implications for public health and access to medicines. The primary concern is that the implementation of the provisions proposed in the USA’s TPPA proposal, as they currently stand, will restrict the adoption

of policy options for developing countries to ensure that trade or commercial interests do not hinder the protection of health and human development.

While the promotion of trade and economic growth is certainly important, it must be balanced against the need to ensure both a population's access to needed medicines and its long-term health and well-being. Policy-makers should be wary of the effect of the USA's TPPA proposal on the gains achieved in global public health. For example, the massive investment of effort and funds in the global battle against HIV/AIDS has resulted in tremendous gains in meeting treatment goals in developing countries, but the implementation of the USA's TPPA proposal may well undermine these gains and prevent further progress toward meeting public health targets in TPPA signatories. The strategies and tools that have been so successfully employed to reduce the prices of antiretroviral medicines may no longer be available. At a time when financing is threatened by funding cuts, the need for the widest range of options to reduce costs is paramount. Without effective approaches to reduce costs, medicine prices will stand in the way of access. This scenario will be applicable not only to HIV/AIDS but also to other diseases and medicines.

### **A positive agenda for intellectual property and access to medicines**

As an alternative to signing the TPPA and adopting TRIPS-plus provisions that can threaten treatment access for many in developing countries, the negotiating parties may wish to consider the types of measures that would strengthen and further expand the gains made in the effort to increase treatment access. Governments may wish to adopt coherent approaches in which trade and intellectual property policies are formulated in a manner that preserves the ability to provide long-term, affordable and sustainable access to medicines. As an interested stakeholder, UNITAID supports the adoption of a "positive agenda", wherein governments actively identify and implement policies that can help achieve the goals of trade and economic growth alongside the objectives of ensuring access to needed medicines and the protection of public health. Such a positive agenda might include some of the approaches outlined below.

### **Public health impact assessments of FTAs**

Given the increasing numbers of bilateral and regional trade agreements, there should be a corresponding level of analysis of such FTAs from the economic and public health perspectives. While considerable effort has been expended on economic modelling to demonstrate the benefits of trade liberalization, there has been limited analysis aimed at measuring the costs and benefits of introducing intellectual property rights in developing countries, and even less analysis of the impact of specific changes in intellectual property policy in each country. The economic impacts of stronger intellectual property protection can be multifarious; because there may be variable effects on a range of sectors in each country, it will be important to assess and measure these varied implications properly. Since some FTAs have been in force for several years, it may now be possible to examine and assess the public health impact of those FTAs that incorporate a number of TRIPS-plus provisions, including measuring the effects of data exclusivity or patent term extensions on access to affordable medicines.

The availability of credible empirical information can serve a variety of purposes. First and foremost, it provides a basis of evidence to inform policy-makers and strengthen their position in trade negotiations. The information can help to identify those areas in which greater flexibility in the negotiation of new intellectual property protection standards may be warranted, or can make the case that new standards may not be desirable at all. Further, in countries that have already adopted TRIPS-plus standards, the evidence can provide an important basis from which to identify complementary policies that can remedy or alleviate the negative impacts of implementation.

### **Balancing intellectual property rights and competition for public health outcomes**

The introduction of generic HIV medicines into the global market created the competition that led to massive price reductions in HIV medicines. Generic competition, particularly from India, persists in reducing prices today, with the prices of first-generation HIV medicines at less than 1% of their 2001 prices. In

carrying out its mandate, UNITAID relies on the ability to leverage the effects of competition to reduce prices of pharmaceuticals and to increase access to treatment.

The importance of the relationship between intellectual property rights and competition law should not be understated. While intellectual property protection effectively vests exclusive control of the production and supply of a protected invention in the rights holder, competition law seeks to encourage a multiplicity of suppliers in order to ensure effective competition in the market place. In most developed countries, higher standards of intellectual property protection have evolved alongside the development of norms providing effective defence against anti-competitive practices related to the acquisition and exercise of intellectual property rights. The policy objective is therefore to achieve a balance between intellectual property rights and competition that is appropriate to the domestic context. This still represents a complex challenge in developing countries since most lack competition laws or effective mechanisms for their implementation. Nevertheless, in most of these countries, intellectual property rights have been expanded and strengthened.

Thus, for a start, competition laws should be established or strengthened to control abuses related to the acquisition and exercise of intellectual property rights, including through the application of the “essential facilities” doctrine to address situations of control of essential technologies and products. In the context of pharmaceutical products and access to medicines, it would also be important to consider the competition implications of various policies and regimes determining market entry, such as regulations on marketing approval of pharmaceutical and agrochemical products. The pro-competition approach to intellectual property rights should, however, go beyond issues of market entry; the process of examining and granting patents may well have implications for competition. Frivolous or low-quality patents may restrain legitimate competition and hinder innovation; therefore it is important to ensure that the applicable standards of patentability and the patent examination process are such that they prevent the grant of poor-quality patents. Moreover, while much of the literature on intellectual property rights and competition law focuses on patents, anti-competitive behaviour may be based on or facilitated by other types of intellectual property rights, such as copyright and trademarks, as well as enforcement and border measures. This issue should be explored further.

### **Public-health-sensitive examination of pharmaceutical patents**

There is increasing evidence that low standards of patentability and shortcomings in patent examination can lead to the grant of poor-quality patents. As indicated above, this can have implications for competition as well as innovation. Although a small number of new chemical entities are approved annually, the number of pharmaceutical patents applied for and granted is disproportionately large. There is a need to monitor and analyse trends in pharmaceutical patenting in order to respond to growing concerns about the increase in patents that protect relatively minor variants of existing drugs or processes while the number of new molecular entities is small. In these circumstances, the criteria applied to examine and grant pharmaceutical patents are a matter of concern.

A paper by WHO, the International Centre for Trade and Sustainable Development, and the United Nations Conference on Trade and Development<sup>4</sup> reviews the various categories of patent claims for pharmaceutical products from a public health perspective. It proposes a set of general guidelines for the assessment of some common pharmaceutical patent claims, and suggests elements for the development of public-health-sensitive guidelines for the evaluation and review of pharmaceutical patents at national level in developing countries. The use of such guidelines should be encouraged, particularly in developing countries, to prevent the grant of poor-quality patents on pharmaceutical products.

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<sup>4</sup> Guidelines for the examination of pharmaceutical patents: developing a public health perspective. Geneva: International Centre for Trade and Sustainable Development, United Nations Conference on Trade and Development, World Health Organization; 2007 (<http://ictsd.org/i/publications/11393/>, accessed 18 January 2014).