2014

The Trans-Pacific Partnership Agreement:

Implications for Access to Medicines and Public Health

MARCH 2014

UNITAID Secretariat
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27
Switzerland
T +41 22 791 55 03
F +41 22 791 48 90
unitaid@who.int
www.unitaid.eu

UNITAID is hosted and administered by the World Health Organization

This report was prepared by Kajal Bhardwaj and Cecilia Oh, with support from UNITAID.

World Health Organization

CONTENTS

LIST OF ABBREVIATIONS

ACTA	Anti-Counterfeiting Trade Agreement
ARV	Anti-retroviral
AUSFTA	Australia-United States FTA
BIT	Bilateral investment treaty
DRA	Drug Regulatory Authority
EPO	European Patent Office
FDA	Food and Drug Administration (United States of America)
FET	Fair and equitable treatment
FTA	Free trade agreement
FTC	Federal Trade Commission (United States of America)
GATT	General Agreement on Tariffs and Trade
INN	International non-proprietary name
ICTSD	International Centre for Trade and Sustainable Development
ISDS	Investor–state dispute settlement
KORUS FTA	Korea-United States Free Trade Agreement
NAFTA	North American Free Trade Agreement
TPPA	Trans-Pacific Partnership Agreement
TRIPS	(Agreement on) Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
WTO	World Trade Organization

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 21st 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.[1] 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

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."

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.[2]

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).

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.

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."

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 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"[3].

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

3 The shipment was released several weeks later, after confirmation that the medicines did not infringe the brand name "Amoxil".

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 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[4] 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.

4 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).

CHAPTER 1. Introduction

The proposed Trans-Pacific Partnership Agreement (TPPA) has complex origins. Originally a free trade agreement (FTA) between Chile, New Zealand and Singapore and, later, Brunei Darussalam, the "Trans-Pacific Strategic Economic Partnership Agreement"—also known as the P4 Agreement—came into force in 2006[5]. In 2008, the United States of America (USA) began negotiations with the four parties to include investment and financial services provisions, later extending the negotiations to a full FTA as well as including three new negotiating partners—Australia, Peru and Viet Nam. Malaysia was accepted as the ninth negotiating partner in 2010.

The broad outlines of the proposed TPPA were thus initially announced by the nine negotiating partners—Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the USA and Viet Nam—at the Asia-Pacific Economic Cooperation Forum (APEC) in November 2011, at which time the parties also declared their intention to complete negotiations by the end of 2012.

In October 2012, Canada and Mexico announced that they had formally joined the TPPA negotiations, attending their first session in December 2012. Japan announced in March 2013 that it had formally applied to join the TPPA negotiations, and actually joined in August 2013. News reports suggest that Thailand is also considering joining the TPPA negotiations.

To date, there have been 19 formal rounds of negotiations, the most recent being held in Brunei Darussalam in August 2013. In addition, there have been a number of inter-sessional meetings.

Described by its advocates as a "new generation agreement for the 21st century", the TPPA seeks to promote greater trade through the elimination of over 11 000 tariff lines. The proposed agreement, however, goes well beyond traditional trade concerns. The TPPA is viewed by some of the negotiating parties as a potential building block for an even larger free trade area; the USA and certain other parties regard the TPPA as the vehicle for trans-Pacific economic integration. They have thus expressed interest in incorporating a broad array of new areas into the negotiations so that the TPPA becomes the "gold standard" for future FTAs. With 29 chapters incorporating the various new areas, the TPPA has the potential to limit national decision-making and restrict national policy space more than any previous FTA.

The intellectual property obligations in FTAs typically go beyond those currently existing in multilateral agreements, such as the minimum standards under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement. These "TRIPS-plus" provisions have the effect of negating the spirit and intention of the 2001 Doha Declaration on the TRIPS Agreement and Public Health. FTA provisions that have the potential to hinder access to generic medicines are those that: (a) limit the cir-

5 The P4 (which stands for the Pacific 4) Agreement represents the first multiparty FTA linking Asia, the Pacific and the Americas. Aside from comprehensive tariff elimination among the four countries, P4 also includes measures to open up trade in services and government procurement. The agreement seeks to promote cooperation on customs procedures, intellectual property and competition policy. For further details see, for instance, the website of New Zealand's Ministry of Foreign Affairs and Trade at: http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/2-P4.php.

cumstances under which compulsory licences may be issued; (b) lower the standards of patentability and extend the minimum period of patent protection beyond the 20 years required by TRIPS; (c) require drug regulatory authorities (DRAs), most of whom have limited expertise with regard to patents, to consider the patent status of drugs before granting marketing authorization to generic manufacturers; (d) restrict the use of clinical trial data submitted to DRAs, which traditionally rely on such data to establish the safety and efficacy of generic products, to hasten the registration process; (e) restrict parallel importation; or (f) require greater intellectual property enforcement.

Public interest and public health groups, as well as a number of United Nations agencies, have voiced concern over such TRIPS-plus provisions in FTAs, urging a careful assessment of the impact of both concluded FTAs and ongoing negotiations. For instance, the FTA negotiations between the European Union and India have caused considerable disquiet due to concerns that the concluded agreement could hinder the essential role played by Indian generic producers in supplying HIV medicines to developing countries. UNITAID has cautioned that "if the Free Trade Agreement introduces TRIPS Plus measures many of the people on medicines today will not be able to access vital second-line treatment when they become resistant to the medicines they are taking now". [1]

Noting the trend in increasing numbers of bilateral and regional FTAs, WHO Member States adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which called on countries to "take into account … the impact on public health when considering adopting or implementing more extensive intellectual property protection than [required by the TRIPS Agreement]". [2] Similarly, a policy brief, issued in 2012 by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the United Nations Development Programme (UNDP), states that "there is growing evidence that TRIPS-plus provisions may adversely impact medicine prices and, consequently, access to treatment". The policy brief recommends that "to retain the benefits of TRIPS Agreement flexibilities, countries at a minimum should avoid entering into FTAs that contain TRIPS-plus obligations that can impact on pharmaceuticals price or availability". [3] In its 2012 report, the Global Commission on HIV and the Law went further, recommending a total ban on TRIPS-plus FTAs and a temporary moratorium on the enforcement of intellectual property rights in low- and middle-income countries, at least with respect to pharmaceuticals. [4]

A dramatic illustration of the direct impact of TRIPS-plus rules on intellectual property enforcement 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. Enforcement provisions similar to those under European Union legislation that allowed these seizures to take place are being exported to developing countries through FTA obligations. The obvious concern is that such enforcement provisions may lead to an increase in similar detentions of medicine shipments, with dire consequences for access to medicines in developing countries. As cautioned by UNITAID 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."* [5]

The lack of transparency in the TPPA negotiating process has given rise to calls for greater openness and for the TPPA negotiating texts to be made public, and over 130 members of the United States House of Representatives have petitioned the country's trade representative to make the TPPA draft texts available to the United States Congress.[6] [6] The TPPA negotiating texts that have been leaked to the public domain

6 The House of Representatives Oversight Committee chairman took the unprecedented step of posting on the Internet a copy of a previously-leaked United States proposal for the chapter on intellectual property provisions, in the hope of pressuring the administration to make a public disclosure of the negotiating texts. See, for instance: http://www.huffingtonpost.com/2012/05/16/darrell-issa-trans-pacific-partnership-trade-deal_n_1521035.html (accessed 29 January 2014).

have caused disquiet. Of particular concern to public health groups is the intellectual property chapter proposed by the USA.[7]

In June 2011, based on a petition by public interest advocacy groups and academics, the Special Rapporteur for the United Nations on the right of everyone to the enjoyment of the highest attainable standard of health requested a response from the nine negotiating parties on, among other complaints, the allegation that some of the TPPA's intellectual property provisions "would strengthen monopolies for life-saving medicines and create barriers for access to medicines", as well as "negatively impact the ability of developing countries to take positive steps towards ensuring the enjoyment of the right to health of their citizens". [8] Three of the nine parties—Australia, Chile and New Zealand—responded stating that they would not agree to provisions that would constrain their ability to regulate effectively to protect public health.[8]

Concerns about the potential impact of the TPPA on access to medicines have also been raised in other fora, including at the WTO TRIPS Council. [9, 10]

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 (and other health commodities).

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.[9] 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.

7 The chapter has also drawn criticism from USA-based public health advocates and members of the Congress as it demonstrates an obvious backtracking on the commitments made under the New Trade Policy of 2007 related to TRIPS-plus provisions in FTA negotiations. [7]

8 A copy of the Special Rapporteur's communique to the negotiating parties can be found here https://spdb.ohchr.org/hrdb/19th/AL_USA_19.07.2011_(13.2011).pdf (accessed 29 January 2014). For more details and responses from the negotiating parties, see the Knowledge Ecology International (KEI) website (http://keionline.org/node/1554).

9 For more details, see the UNITAID website at: http://www.unitaid.eu/how/market-approach.

CHAPTER 2. Objective and Methodology

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

This report analyses the key negotiating issues presented 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. Chapters 3, 4, 5 and 6 examine the proposals related to intellectual property—namely patents, data exclusivity and patent linkage, copyright and trademarks, and enforcement of intellectual property rights. Chapter 7 analyses the provisions related to investment insofar as they may affect access to medicines and the protection of public health, while Chapter 8 examines the impact of the proposed provisions on pharmaceutical pricing and on the financing and reimbursement of medicines. The chapters are organized in a similar manner: the relevant portions of the negotiating text are reproduced, followed by an analysis of the text in terms of the objective(s) and effect(s) of the provision, and an explanation of the potential implications for access to medicines and public health, particularly in developing and least-developed countries. Where relevant, the evolution of the negotiating text is described, including proposals from other negotiating partners.

This report was prepared by Kajal Bhardwaj and Cecilia Oh. Input, suggestions and comments on all or part of the document were provided by the following reviewers: William Aldis, Brook Baker, Michelle Childs, Carlos Correa, Krista Cox, Sean Flynn, Sangeeta Shashikant, Sanya Reid Smith and Karin Timmermans.

The analysis in the report is based on negotiating texts that were leaked and made available in the public domain in 2011 and 2012. The main texts include the USA's proposals for an intellectual property rights chapter and a chapter regulating pharmaceutical reimbursement programmes, as well as an investment chapter.

These proposals and negotiating texts, which were in the public domain at the time of writing this report, are listed in Table 1. Relevant portions of the texts are reproduced in this report to facilitate ease of reference. The TPPA texts have been made available in the public domain by civil society organizations, such as Knowledge Ecology International, Public Citizen and Public Knowledge, and by various academics, which upload the texts on the Internet and maintain dedicated web pages on the TPPA.[10]

As noted above, the TPPA negotiations are being conducted without the public having access to the negotiating texts. It should be borne in mind that it may not be possible to provide a comprehensive examination of all relevant provisions or to fully assess how these provisions will impact and interact with other parts of

10 See, for instance, Knowledge Ecology International at http://keionline.org/tpp; Public Information at http://tppinfo.org/; and Public Citizen at http://www.citizen.org/TPP. The website http://infojustice.org/ is a collaborative project between academics in Brazil and the USA on issues related to access to knowledge goods and the free flow of innovation, with a comprehensive resource of TPPA documents and references.

the TPPA (which are not currently in the public domain). Moreover, as long as the negotiations are ongoing, the text may evolve and change.

Table 1. Leaked TPPA texts available in the public domain (as of October 2013)

Title	Provenance	Date
TPP Regulatory Coherence	Text proposed by USA	4 March 2010 (Date text made available in public domain)
US Introduction to Proposed TBT Annexes on Medical Devices, Pharmaceutical Products and Cosmetic Products	Text proposed by USA	4 March 2010 (Date text made available in public domain)
TPP: Intellectual Property Chapter: Horizontal Issues/Overall Structure, General Provisions and Cooperation	Paper submitted by New Zealand	4 December 2010 (Date text made available in public domain)
TPP Intellectual Property Rights Chapter	Text proposed by USA	10 February 2011 (Date of text)
Chapter "X", Intellectual Property	Text submitted by New Zealand	23 February 2011 (Date text made available in public domain)
Preliminary Considerations for TPP Intellectual Property Chapter	Text submitted by Chile	23 February 2011 (Date text made available in public domain)
TPP Transparency Chapter – Annex on Transparency and Procedural Fairness for Healthcare Technologies	Text proposed by USA	22 June 2011 (Date of text)
TPP Intellectual Property Rights Chapter (Selected Provisions)	Text proposed by USA	September 2011 (Date of text)
TPP Investment Chapter	Text proposed by USA	13 June 2012 (Date text made available in public domain)

CHAPTER 3. Patents

Several articles of the intellectual property chapter proposed by the USA relate to patents. While Article 8 is the primary provision in the USA's proposal covering patents, other articles in the chapter relating to enforcement also deal with patents. This chapter analyses Article 8 of the USA's proposal. The February 2011 version of the USA's negotiating text had placeholders for the Bolar and patent term extension provisions. The proposals on these provisions were included in the September 2011 leaked text.

This chapter analyses the provisions in the intellectual property chapter on patents and their likely impact on access to medicines and the protection of health. The key provisions are analysed in turn. For ease of reference, the relevant provisions are reproduced in Box 1.

Box 1. Proposed text on patents

USA proposal, draft dated 10 Feb. 2011;
Articles 8.5 & 8.6 from draft Sept. 2011

ARTICLE 8: PATENTS

1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.[15] 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.

2. Each Party shall make patents available for inventions for the following:
   (a) plants and animals, and
   (b) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.

3. Each Party may only exclude from patentability inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.

4. Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

5. [*Placeholder for "Bolar" provision* – from the September draft]
Consistent with paragraph [4] (patent exceptions and limitations), each Party shall permit third persons to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product in that Party, and shall further provide that any product produced under such

authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an application for meeting marketing approval requirements of that Party. If the Party permits exportation of such a product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.

6. [*Placeholder for provisions concerning patent term restoration/adjustment* - from the September draft]
   (a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable or unnecessary delays.
   (b) Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in the granting of the patent. For purposes of this subparagraph, an unreasonable delay at least shall include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application has been made, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.
   (c) Each Party, at the request of the patent owner, shall make available an adjustment of the patent term of a patent which covers a new pharmaceutical product[1] or a patent that covers a method of making or using a pharmaceutical product, to compensate that patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
   (d) In implementing subparagraph 6(c), a Party may:
      (i) limit the applicability of subparagraph 6(c) to a single patent term adjustment for each new pharmaceutical product that is being reviewed for marketing approval;
      (ii) require the basis for the adjustment to be the first marketing approval granted to the new pharmaceutical product in that Party; and
      (iii) limit the period of the adjustment to no more than 5 years.
   (e) In implementing subparagraph 6(c), and as a condition for providing the adjustment set forth in subparagraph 6(c) for a new pharmaceutical product approved consistent with Article 9.2(b) or Article 9.2(d), a Party may require an applicant that has submitted an application for marketing approval consistent with Article 9.2(b) or Article 9.2(d) to commence the process of obtaining marketing approval for that new pharmaceutical product in the Party within [X] years of the date of first marketing approval of the same pharmaceutical product in another Party.[2]
   (f) Any patent term adjustment under subparagraph 6(b) or subparagraph 6(c) shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions that would otherwise apply to the patent absent any adjustment of the patent term.

7. Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking a patent or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.

8. Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure:
   (a) was made or authorized by, or derived from, the patent applicant; and
   (b) occurred within 12 months prior to the date of filing of the application in the territory of the Party.

9. Each Party shall provide patent applicants with at least one opportunity to make amendments, corrections, and observations in connection with their applications. Each Party shall permit applicants to make amendments to their patent claims prior to receipt of a first patent office action or communication on the merits.

10. Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.

11. Each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date.

12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.

13. For published patent applications and issued patents, each Party shall make available to the public the following information connected to the patent prosecution of such patent applications and patents:

(a) search and examination results, including any relevant prior art search histories;
(b) communications from applicants; and
(c) patent and non-patent related literature citations submitted by applicants, other patent offices, and relevant third parties.

[15] For the purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as being synonymous with the terms "non-obvious" and "useful," respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been obvious to a skilled artisan (or a person having ordinary skill in the art) at the priority date of the claimed invention.

[1] For greater certainty, new pharmaceutical product in subparagraphs 6 (c)-(e) means a product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product in the territory of the Party.

[2] [Negotiators Note: For purposes of paragraph 6(e) of Article 8 and paragraphs 4 and 6 of Article 9, the length of the [X]-year period should: enhance certainty regarding access to innovative and generic pharmaceutical products for all; provide incentives for innovation; provide incentives for the diffusion of pharmaceutical products within the TPP region; respect commercial considerations; and account for special challenges in developing and commercializing such products throughout the region (e.g., challenges faced by smaller or less experienced applicants, or the time that an applicant may need to assess additional safety or efficacy implications of marketing a product, such as to assess such implications in jurisdictions where risks may differ from those faced in markets where the product has previously been approved)].

3.1 Analysis of provisions

Articles 8.1, 8.8 and 8.12, when read together, deal with the patentability criteria and standards to be applied by TPPA parties. **Article 8.1** lists the patentability criteria to be mandatorily applied by all parties to the TPPA in determining the grant of a patent, i.e. for products and processes that are new, involve an inventive step and are capable of industrial application. These criteria are further clarified in footnote 15 to Article 8.1 (see Box 1). The first sentence of the footnote is taken directly from the footnote to Article 27 of the TRIPS Agreement and states that a party may treat the term "inventive step" as being the same as the standard of "non-obviousness" and the term "industrial applicability" as being the same as "useful". It should be noted that "useful" is considered a lower standard than industrial applicability, as "useful" allows for the patenting of a product or process simply by satisfying the examining authority that the invention would be of use regardless of whether it could actually be applied in an industry. [11]

The second sentence of footnote 15 is not taken from TRIPS. It specifies the standard to be applied by TPPA parties in determining "inventive step" or "non-obviousness". This criterion is assessed on the basis of whether a person skilled in the art would find the invention obvious or not. However, the TRIPS Agreement does not specify that the standard to be applied for a person skilled in the art should be that of a person who has "ordinary skill". Under TRIPS, countries are free to adopt a higher standard. Parties to the TPPA would, however, be restricted to the "ordinary skill" standard.

The second sentence of Article 8.1 places further limits on how TPPA members may apply the patentability criteria. While the Doha Declaration reiterated the right of all WTO members to determine the interpretation and manner of implementation of the TRIPS Agreement, which would include patentability criteria, [12] this provision limits the rights of TPPA parties in this regard. This second sentence provides, firstly, that TPPA parties must make available patents for new uses, new forms and methods of use of known products. It states further that such forms, uses and methods should be allowed to meet patentability criteria even if the new form or use shows no improvement in efficacy. As discussed below, this provision is in direct contrast to increasingly higher standards of patentability being adopted in several developing countries to deal with the problem of "evergreening" of patents including through the adoption of strict patentability criteria or patentable subject matter exclusions.

Article 8.8 limits the public information that TPPA parties may rely on when applying the novelty or inventive step criteria to a patent application. Any information put in the public domain in the 12 months prior to the date of filing the patent application that is made, authorized by or derived from the patent applicant cannot be considered to be part of the "prior art".[11] At present, under the laws of most countries, disclosures made after the priority date are not included in the prior art; under this proposed provision, however, disclosures made even before the priority date could be excluded from being considered as prior art.

Article 8.12 relates to the third patentability criterion of "industrial applicability" and states that this criterion would be met if the invention is specific, substantial and has credible utility. While the footnote to Article 8.1 provides flexibility for TPPA countries as to whether they want to use the utility standard, Article 8.12 takes this flexibility away. Article 8.12 imposes a lower standard than industrial applicability by requiring that the applicant show only the utility of an invention. This provision strengthens both the second part of Article 8.1, which requires that patents be made available for new uses, and Article 8.2 which requires patents to be granted for methods of treatment. Under the more rigorous "industrial applicability" standard, new uses can be excluded from patentability because the new use cannot be applied in an industry as such; it is simply an older medicine that has an alternative purpose/use. [11]

Article 8.2 requires that TPPA parties make patents available for plants and animals and for diagnostic, therapeutic and surgical methods for the treatment of humans and animals. Article 27.3 of the TRIPS Agreement, on the other hand, explicitly allows countries to exclude these from patenting. Several countries have adopted these exclusions and they have also been featured in previous United States FTAs, such as the Australia-USA FTA. [13] The exclusion of "methods of treatment of humans" would provide textual support for the exclusion of patents on new uses or methods of use of existing medicines. [11] However, Article 8.2 would require TPPA parties to remove this exclusion.

Article 8.3 builds on the limits placed by Articles 8.1 and 8.2 on the ability of TPPA parties to interpret patentability criteria and apply exclusions to patentability. This article makes it clear that members can exclude from patentability only those inventions the prevention of the commercial exploitation of which is necessary to protect public order or morality, including for the protection of human, animal or plant life or health or to avoid serious prejudice to the environment. While the provision closely mirrors Article 27.2 of the TRIPS Agreement, the addition of the word "only" in the first sentence may require closer scrutiny to determine if it restricts the flexibility of countries by limiting exclusions only to the situations mentioned in Article 8.3. The implications of such a scenario may call into question the routine practice of several countries, including developed countries, to specify several exclusions other than those specifically mentioned in Article 27.2 and 27.3 of TRIPS.

Article 8.4 is an exact reproduction of Article 30 of the TRIPS Agreement. This provision in TRIPS on exceptions to patent rights is considered to be the basis for well-known and now widely-used exceptions such as the Bolar exception (also known as the "early working exception" or "regulatory review exception"), the research exception and exceptions for noncommercial uses, teaching, testing, etc.

However, the following provision, **Article 8.5**, places restrictions on the Bolar exception in relation to pharmaceutical products by limiting the flexibility originally available to TPPA parties under TRIPS. Under the Bolar exception, a patent on a medicine cannot be used to prevent third parties from taking steps towards the registration of generic versions of the medicine in order to market the medicine. This includes, for instance, using the medicine to generate data required for such approvals. While Article 8.5 recognizes this exception, it places limits on it by requiring a TPPA party to ensure that, although preparation for registration may take place, the medicine cannot be made, sold or used in its territory and, if it is

11 Prior art refers to the body of knowledge taken to exist prior to a patent application and is the basis for determining whether an alleged invention is really "new" or "non-obvious". What constitutes prior art, and when and how it can be used varies across jurisdictions. Some countries, like the USA, test newness or novelty of an invention based on whether it is disclosed in a single document (also known as a single prior art document) to defeat newness. Countries also differ on whether publication anywhere in the world or within the country would constitute prior art. For inventive step, several countries require that all documents and knowledge are taken into account to see if a person skilled in the art and deemed to have had access to, or to have known everything in the prior art, would consider the invention obvious (have an inventive step). On the issue of what information should be included in prior art, there seems to be some amount of consensus that information put in the public domain after the priority date should not be considered prior art. For information before the priority date, the time varies according to whether countries adopt the so-called grace periods that Article 8.8 would mandate for all TPPA parties.

exported, even that export must be for the purpose of generating information for a marketing approval in that TPPA party. Accordingly, a generic producer could not export Bolar-permitted medicines in order to register them in other countries. In addition, this provision recognizes the Bolar exception only in relation to pharmaceutical products while in some countries, including the USA, the exception is considered broad enough to cover medical devices. [14]

Article 8.6 details provisions for the extension of patent terms (or the restoration or adjustment of the patent term). By contrast, the TRIPS Agreement provides only for 20-year patent terms. ***Article 8.6(a)*** requires parties to the TPPA to make best efforts to process patent and marketing approval applications expeditiously. While patent applications are processed by patent offices, marketing approvals refer to approvals from a drug regulatory authority for putting medicines on the market. This article states that there should be no unreasonable or unnecessary delays in these approvals.

Article 8.6(b) provides that an unreasonable delay in the granting of a patent would be a delay of more than four years from the date of filing of the application or two years after a request for examination is made, whichever is later. Delays that can be attributed to the actions of the patent applicant can be deducted in calculating the time period for the extension. This provision appears to apply to all product and process patents.

Article 8.6(c) requires the grant of patent term extensions for delays in marketing approval. However, what the "unreasonable" period would be for a marketing approval delay is not specified. The extension of the patent term for marketing approval delays is required for a patent covering a new pharmaceutical product, as well as for patents covering methods for making or using any pharmaceutical product. The new pharmaceutical product is defined in the relevant footnote as a product that contains at least one new chemical entity (NCE) not previously approved in the TPPA country. This definition removes the option for TPPA countries to limit this provision only to those products for which the NCE has not been previously approved anywhere in the world. In addition, unlike the provision relating to delays in the granting of patents, it appears that delays by the applicant for marketing authorization cannot be deducted in determining whether or not there has been an unreasonable delay.

Article 8.6(d) appears to allow TPPA countries to place some limitations on the requests for patent term extensions in cases of marketing approval delays, namely: (1) to base the extension on only the first marketing approval of the new pharmaceutical product in that country; (2) to limit the period of extension for marketing delays to five years; and (3) to allow only one single patent term extension for each new pharmaceutical product. As noted above, the definition of the new pharmaceutical product is restrictive. TPPA parties cannot apply any of these limitations where the patent term extension is required due to the delay in the grant of the patent.

Article 8.6(e) allows TPPA parties to impose an additional limitation on patent term extensions for the delay in marketing approval in cases of medicines that are covered both by patents and by data exclusivity. This provision has to be read along with Article 9.2(b) and Article 9.2(d) (see below) and applies only in situations where these two articles are satisfied. In such cases, countries may also require that the marketing approval process commence within a certain number of years of the date of first marketing approval of the same medicine in another TPPA country. The negotiator's note to this article specifies that, in determining the number of years within which marketing approval should commence, incentives for innovation, difficulties that may be faced by applicants and commercial considerations should be taken into account, among other things. Although the term of the proposed marketing application window has not yet been specified, a leading association of originator companies in the USA, PhRMA, has reportedly proposed that the window should be six years long. [15]

Article 8.6(f) makes it clear that an extended patent will confer the same rights and be subject to the same limitations as would the patent before extension. This removes any scope for additional limitations that the parties to the TPPA may wish to impose on the patent holder during the period of extension.

Article 8.7 limits the grounds for the revocation of a patent to only those grounds that would have led to a refusal of the patent in the first place. As noted above several provisions of this article significantly limit the

grounds on which patents can be refused. The only additional grounds for revocation that a TPPA country may add are fraud, misrepresentation or inequitable conduct. These additional grounds may be used either to revoke a patent or to hold it unenforceable. In contrast, Article 32 of the TRIPS Agreement provides only one condition for the revocation of patents—i.e. that the decision must be subject to judicial review. TRIPS specifies no restrictions on the grounds for revocation of patents. The last sentence of Article 8.7 requires that TPPA parties allow only post-grant opposition proceedings and not pre-grant opposition.

Article 8.9 requires parties to the TPPA to provide patent applicants with at least one opportunity to make amendments, corrections and observations in relation to their applications. The subsequent sentence requires that patent applicants be allowed to make as many amendments as they wish to their patent claims before the first action of the patent office or a communication on the merits of the application. This implies that unlimited amendments can be made at the initial stage of examination and, after this, there will be at least one opportunity to make amendments, corrections and observations in connection with the application. These opportunities to amend patent applications are not required by the TRIPS Agreement and may encourage the filing of over-broad and otherwise deficient first applications. [16]

Articles 8.10 and **8.11** relate to the standard of disclosure that a party to the TPPA can require from patent applicants. Disclosure of the invention and the mode of working it are considered essential for ensuring that the invention is available to the public. ***Article 8.10*** limits the level of disclosure that can be required to such information as allows the invention to be made and used by a person with ordinary skill in the art without undue experimentation. Article 29 of the TRIPS Agreement specifically allows countries to require patent applicants to disclose the best method of working an invention. This is in fact a specific requirement in the law of the USA[12] under which, although the patent may not be invalidated if the best mode is not disclosed,[13] nondisclosure may lead to a rejection of the patent application when it is being examined [17] or potentially to claims of fraud or inequitable conduct. [18] The relationship between the USA's TPPA proposal and the law of the USA on disclosure requirements appears to be unclear. ***Article 8.11*** further limits the disclosure requirement to one that reasonably conveys to a person skilled in the art that the applicant had possession of the claimed invention.

Article 8.13 imposes requirements on TPPA parties to make available in the public domain information and documents related to published patent applications and patents.

3.2 Implications for public health and access to medicines

3.2.1 Proliferation of patents on medicines

3.2.1.1 The lowering of patentability standards may lead to more patents on pharmaceutical products

The TRIPS Agreement requires that WTO member countries make patent protection available for inventions—including inventions related to medicines—that satisfy the criteria of novelty (or new), inventive step and industrial applicability. TRIPS does not, however, define these terms and allows countries flexibility in determining the standards they will apply to patentability. On the other hand, Articles 8.1, 8.8 and 8.12 require parties to the TPPA to adopt lower standards of patentability. 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,[14] the United Kingdom's Commission on Intellectual Property Rights (CIPR) and WHO's Commission on Intellectual Property, Innovation and Public Health (CIPIH). [20, 21] Lower standards of patentability mean that a greater number of patents could be granted, including on medicines and medical technologies. For each of the three criteria of novelty (new), inventive step (or non-obviousness) and industrial applicability, the USA's TPPA proposal prescribes relatively low standards.

12 "The specification … shall set forth the best mode contemplated by the inventor … of carrying out his invention." 35 USC 112.
13 Section 15, Leahy – Smith America Invents Act, H.R. 1249.
14 See, for instance, UNDP [19]

In judging novelty and inventive step, the USA's TPPA proposal requires countries to ignore any disclosure made/authorized by, or derived from, the patent applicant 12 months before the filing of a patent application (Article 8.8). This is sometimes referred to as a "grace period"[15] for patent applicants and is a feature of USA patent law. The grace period is different from the priority period under the Paris Convention for the Protection of Industrial Property.[16] The grace period can act as an additional period of time over and above the priority date for which disclosures made by the applicant will not be considered to be part of prior art. For countries following priority dates only, any disclosure made before the priority date can result in the patent application being considered not novel or not inventive and thus liable for rejection. With a grace period, a disclosure—even if made before the priority date but within 12 months before the filing of the patent application—would not be considered as part of prior art. The additional grace period would also mean that, for others working in the same area of medicines or medical technology, there would be additional uncertainty as to whether they can work on or produce a particular medicine or medical technology disclosed by any person for fear that a patent application may be filed 12 months later. [24]

In judging inventive step, the USA's TPPA proposal mandates that the person skilled in the art must have "ordinary" skill. Nothing in the TRIPS Agreement prevents developing countries from requiring a higher level of skills in judging whether a claimed invention is obvious and, in discussions on the Substantive Patent Law Treaty, developing countries have noted their concerns that the use of the term "ordinary" may lower the standard for judging inventive step.[17]

In judging "industrial application" the USA's TPPA proposal restricts the standard to that of "specific, substantial and credible" utility. This standard is considered by some authors to be an improvement on the previous standard of utility applied in the USA, particularly as a response to the concerns around the patenting of genes. [26] However, the standard remains lower than that of industrial applicability. This means that TPPA countries would not be able to require that the claimed invention should be shown capable of being applied in industry. If a patent applicant has to demonstrate that its invention can be applied in industry, a surgical method, such as making an incision during eye surgery in a particular manner, which may not be capable of being used or applied in an industry, could fail this standard. [27] Under the USA's re-definition of industrial application, however, it would have utility. The lower standard thus helps strengthen the case for patent applications on new uses, and in particular on methods of treatment, to be granted. In addition, the implications of adopting the utility standard, combined with mandatory patenting of plants and animals and the recognition of new use patents, have also raised concerns in the field of biotechnology. [28]

The lowering of patentability standards, or preventing countries from adopting higher standards, could lead to an increase in the number of patent applications being granted. The standards to be applied in determining patentability are constantly evolving, even in developed countries.[18] [29] For instance, the United States Supreme Court has interpreted the "obviousness" requirement more strictly than was previously being employed by the United States Patents and Trademark Office (USPTO). [30, 31] It has also held that that "genes and the information they encode are not patent eligible ... simply because they have been isolated from the surrounding genetic material." [32] Canadian courts are also considered to employ a stricter standard in interpreting the "utility" requirement than that employed in the USA.[19]

15 "Some countries, however, allow for a grace period, which provides a safeguard for applicants who disclosed their inventions before filing a patent application, and the novelty criteria may be interpreted differently depending on the applicable law." [22]

16 "The Paris Convention for the Protection of Industrial Property provides that once you file an application in one country party to the Convention, you are entitled to claim priority for a period of twelve months and the filing date of that first application is considered the 'priority date.' Therefore, when you apply for protection in other member countries (of the Paris Convention) during those twelve months, the filing date of your first application is considered to have 'priority' over other applications filed after that date. In such a case, you still succeed in being the first-to-file in other member countries, even if there are other applications filed before the filing date of your application in those countries." [23]

17 "The delegation of Argentina, supported by the delegation of India, suggested that the use of the terms 'general knowledge' and 'ordinary skill' could result in a level of inventive step that was too low." [25]

18 See for instance changes to Australia's intellectual property system that came into effect in 2013 through the Intellectual Property Laws Amendment (Raising the Bar) Act 2012, No. 35, 2012 (Australia).

19 See, for instance: Eli Lilly Canada Inc., Eli Lilly and Company, Eli Lilly and Company Limited and Eli Lilly SA v.Novopharm Limited, [2012] 1 F.C.R. 349 invalidating Lilly's patent on olanzapine on the basis that Eli Lilly's patent application did not meet Canada's utility standard.

Developing countries, as discussed below, are also adopting higher patentability standards. The USA's TPPA proposal however, considerably limits the flexibility of TPPA parties to adopt and maintain higher standards of patentability.

3.2.1.2 Patents on new forms and new uses of known products will hamper efforts to restrict or prevent "evergreening"

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 ensure higher standards of patentability that developing countries are increasingly adopting—i.e. provisions that set strict patentability criteria in the case of new uses and new forms of existing medicines, or that exclude new uses and new forms from patentable subject matter. Such explicit provisions remove uncertainty from patent examinations and provide patent examiners with better guidance on patentability standards related to pharmaceutical products. In India, section 3(d) of the Patents Act 1970 (amended in 2005) restricts patents on new forms of existing substances unless the new form has significantly increased efficacy. In addition, new uses are absolutely excluded from patenting.[20] Similar standards have been adopted in the Philippines through the Cheaper Medicines Law of 2008 [33], by Zanzibar in its amended Industrial Property Bill of 2008 and through patent examination regulations in Argentina. [34] They are also being considered in other countries such as Brazil and South Africa.

Section 3(d) of India's patent law has featured in rejections and withdrawals of patent applications on key anti-retroviral (ARV) medicines, including for a combination of lamivudine and zidovudine, a syrup form of nevirapine, a salt form of tenofovir, and a combination of lopinavir and ritonavir (see Table 2 below). In April 2013, the Supreme Court of India upheld the strict interpretation and application of section 3(d) (and in particular of the efficacy requirements of the provision) in a widely publicized litigation between Novartis AG and the Indian government, stating that the provision leaves "the door open for true and genuine inventions but, at the same time …" checks "any attempt at repetitive patenting or extension of the patent term on spurious grounds." [35]

In May 2012, the Ministry of Industry, Ministry of Health and the National Institute for Intellectual Property of Argentina jointly issued new guidelines for the examination of chemical-pharmaceutical patent applications. [34] The guidelines provide explicit reasons why new forms and new uses of existing medicines fail to fulfil patentability criteria. For instance, in the case of patents for new uses, the guidelines state, "Patent applications for second medical indications (or other medical uses) are equivalent to therapeutic treatment methods and have no industrial application." It may be noted that a specific provision was included in the European Patent Convention to allow for the patenting of new uses.[21]

By requiring that patents be available for new forms, new uses and new methods of use, the USA's proposal prevents TPPA parties from adopting provisions similar to those being implemented in Argentina's guidelines. By removing the filter of efficacy, it prevents TPPA parties from adopting the Indian-style restriction on "evergreening" which allows new forms to be patented provided they show significantly enhanced therapeutic efficacy.[22]

---

20 Indian Patents Act, 1970, Section 3(d): "The following are not inventions within the meaning of this Act, ... (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy"

21 See Articles 54 (4) and (5), Convention on the Grant of European Patents (European Patent Convention), 5 October 1973 (revised 1991, 2000).

22 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." For analysis of the potential impact of the new text, see Baker. [36]

The requirement for granting patents on new uses and new forms of existing medicines 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 forms, new uses or new formulations/dosages/combinations of existing medicines. The 1999 Human Development Report noted that, between 1981 and 1991, less than 5% of drugs introduced by the top 25 companies in the USA were therapeutic advances. [37] In 2001, WHO noted that, "the difference between the number of new drugs ('new chemical entities') that are developed globally each year, and the number of patents awarded for new uses of a drug, processes, dosage forms, formulations and different forms of the same molecule, including patents on genes and genomic sequences, is enormous. The latter is influenced by national legislation and practices. Yet because 'new' and 'inventive' are not defined, countries must establish their own criteria for these terms. They should recognize that patentability standards which are too broad can contribute to 'evergreening'." [38] Evergreening effectively allows patent holders to enjoy longer periods of exclusivity on a pharmaceutical product than the 20-year minimum period prescribed by TRIPS through successive and overlapping patents on new forms of existing medicines. Patents on new forms and new uses by competitors, universities and other institutions may also maintain a monopoly on existing pharmaceutical products. [39]

A 2002 study by the National Institute for Health Care Management Foundation (NIHCM) of 1035 new medicines approved by the United States Food and Drug Administration (FDA) between 1989 and 2000 showed that 65% of the medicines that were approved contained active ingredients already on the market and that, of these, the overwhelming majority (558 medicines) differed from earlier medicines only in dosage form, route of administration or combination with another active ingredient, while the remaining other medicines were identical to products already on the market. [40] A study of patent claims on all new molecular entities approved in the U.S. between 1988 and 2005 presented evidence that secondary claims were common, that "independent secondary patents tend to be filed and issued later than chemical compound patents, and are also more likely to be filed after the drug is approved" and that "late-filed independent secondary patents are more common for higher sales drugs." The study also found that "independent formulation patents add an average of 6.5 years of patent life … independent method of use patents add 7.4 years … and independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years …". [41] Analysis of patents and patent applications presenting evidence of evergreening strategies is also emerging from Australia, Canada, India and Thailand.[23]

This practice also creates what are known as "patent thickets", making it extremely difficult for generic competitors to ascertain whether there is an existing valid patent on a medicine. Evergreening and the creation of patent thickets can delay the entry of generic competitors into enter the market. As an example, the European Competition Authority found 1300 patent applications and patents on a single medicine. [46] In 2011, the World Intellectual Property Organization (WIPO) released its patent landscape report for ritonavir which is considered a critical part of HIV treatment and which acts as a booster in combination with key ARVs. The report found that since the first specific patent filing on this essential medicine in 1994, around 800 patent families have been filed (with Abbott Laboratories as the primary assignee). [47] A further study of over a 100 patents and patent applications by Abbott Laboratories on ritonavir and lopinavir/ritonavir found that the final patent covering lopinavir/ritonavir that was in force at the time of the study would expire in 2028, "twelve years after the expiration of the patents on the underlying base compounds." [48]

Evergreening is also drawing concern because of its impact on innovation, with a recent expression of concern coming from the Canadian Medical Association Journal whose editorial in June 2013 arguing for restrictions on evergreening of patents stated: "As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits." [49]

Patent evergreening strategies are likely to prevent or restrict generic entry on the expiration of the original patents on several key medicines. The impact of generic entry on prices, affordability and availability of

23 A study in Canada estimated an average of 40 patents per medicine. [42] In Thailand, over 80% of patent applications related to "evergreening". The top three countries from where patent applications originated (57.1%) were the USA, Germany and Switzerland; applications originating in Thailand accounted for 0.5%. [43] Studies have also been conducted in Australia [44] and India [45].

medicines is well documented. The USA's TPPA proposal in so far as it limits the ability of governments to address patent evergreening and the attendant creation of patent thickets should also be read with the harsher intellectual property enforcement measures proposed in the TPPA negotiations (See Chapter 6).

3.2.2 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. This is in contrast to the laws of several developing countries that do not consider plants and animals to be eligible for patenting. [50] Patents on plants and animals raise a plethora of ethical and legal issues. In relation to health, plants can be a source of raw materials used in allopathic and traditional systems of medicine. [51] Attempts, in developed countries, to patent medicinal plants whose healing properties are well known or that have traditionally been used in developing countries have led to considerable controversy. [52] Animals such as mice used in pharmaceutical R&D, particularly if they are transgenic, may be subject to patents in TPPA parties. Such patents in developed countries have reportedly created barriers for the research and academic community.[24]

In addition, the USA's proposal appears to be ambiguous on the ability of governments to specify further exclusions from patenting. For instance, patents on genes is an area of considerable debate and controversy [54, 55] as evidenced in the case of patents on the BRCA1 and BRCA2 genes and the resultant barriers to more affordable diagnostics and screening for mutations in these genes that are associated with significantly increased risks of breast and ovarian cancer as well as other forms of cancer. [56] In addition, patents on these genes have been considered to have created barriers to further research into confirmatory tests, improved tests or other gene variants (polymorphisms) associated with familial breast cancers. [57] The patent battles on the BRCA1 and BRCA2 genes also demonstrate the wide range of patentability standards in different countries. In 2013, while the Federal Court of Australia ruled that isolated genes could be patented,[25] the US Supreme Court held that "genes and the information they encode are not patent eligible … simply because they have been isolated from the surrounding genetic material." [58]

Patents on gene sequences have had other unintended consequences, as demonstrated by the controversy over the patenting of the H5N1 virus sequence. The virus sequences were submitted by the government of Indonesia to WHO to allow for research into vaccines and treatment. However patents on the sequences and subsequent lack of access to affordable vaccines for the country that originally deposited the sequences led to the decision of the Indonesian government to withhold further specimens. [59, 60] Subsequently it took nearly four years for governments at the WHO to reach an agreement on virus sharing. [61]

In addition, the USA's proposal requires patents to be granted on surgical and diagnostic methods. This sort of claim is typically considered invalid because a surgical or diagnostic method cannot be shown to have industrial applicability. [11] Allowing patents on such methods 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 particular method of diagnosing a disease or where payment of a royalty is required for using of a surgical or diagnostic method. TRIPS explicitly allows countries to make these exclusions from patenting, but the USA's TPPA proposal would remove this flexibility that the vast majority of countries have taken advantage of to exclude or limit patents on surgical and diagnostic methods. [62] It should also be noted that patents on surgical methods are not enforceable under United States law.[26]

24 A well-known example of this is the Harvard "oncomouse" which was patented in the US. Harvard gave an exclusive licence to DuPont on the oncomouse. "The company set a high price per mouse although researchers had long-standing norms about freely trading mice. They placed restrictions on breeding programs, although this was considered a scientist's prerogative. They demanded publication oversight, although scientists were loath to share such information with outsiders. Finally, DuPont insisted upon a share of any commercial breakthroughs made using the Oncomouse. In response to this encroachment on their daily practices, many in the mouse genetics community were outraged, raising questions about previously taken-for-granted assumptions underpinning the institution of academic science." [53]

25 Cancer Voices Australia v Myriad Genetics Inc, (2013) 99 IPR 567. Federal Court of Australia (Date of Decision: 15 February 2013). The decision is currently in appeal before the full Federal Court of Australia. See: Federal Court appeal begins as human gene patent challenged. Australia Broadcasting Corporation. 7 August 2013.

26 Section 287, United States Code Title 35 – Patents.

3.2.3 Lowering and weakening disclosure standards

Disclosure standards for patent applications, particularly for developing countries, may be considered key to ensuring that the balance between public interest and private rights is maintained. The key argument supporting the exclusivity awarded by the patent system is that society benefits from the disclosure of the invention both during the period of exclusivity (in order to allow further experimentation and innovation) and thereafter through unrestricted copying and adaptation/diffusion. This is sometimes referred to as the "patent bargain".[27] Over time governments have imposed stricter standards of disclosure. Indeed some of these stricter standards emanate from the TRIPS Agreement itself which allows countries to demand that patent applicants disclose the best mode known to them of working the invention. Laws in some countries also require patent applicants to report to the patent office on the status of their applications and to provide any other relevant information on the application in other jurisdictions.[28] In addition, some countries are requiring patent applicants to declare genetic sources or traditional knowledge sources.[29] There is also discussion on requiring patent applicants to include the international nonproprietary name (INN) of a medicine in their applications. [64] Courts in some developed countries are also applying stricter standards of disclosure to patent specifications, and pharmaceutical patents in Canada, for instance, have been overturned for insufficiency of disclosure.[30]

Disclosure standards can affect access to medicines in several ways. At the patent office, higher levels of disclosure can ensure that good-quality patents are granted. The quality of patents is considered important in the pharmaceutical sector in order to ensure that only genuine inventions are patented and to prevent the granting of multiple overlapping patents related to a single medicine. [65] For society, higher standards of disclosure can aid local manufacturers, researchers and others in adopting and learning from patented technologies. This is particularly important for developing countries with lower technological development.

However, several provisions (see Article 8.10 and Article 8.11) of the USA's TPPA proposal weaken the disclosure standards that TPPA parties may require of patent applicants. The USA's proposal waters down the requirement for disclosing the best mode of working. As a result, on the expiry or revocation of a patent or when a compulsory licence is granted, a generic company may not know the best method of producing a medicine. This could lead to later entry of the generic medicine into the market or production through inferior or costlier means. The impact of the USA's proposal on the ability of governments to limit overbroad claims in patents also requires greater analysis. Higher levels of disclosure, particularly with respect to claims, are also important for ensuring that very broad patents are not granted since these may allow patent holders to monopolize research in a particular area. An area of particular concern in this regard is that relating to Markush-style claims (i.e. "claims that include a general formulae with multiple options that allow for the protection, under a single patent, of up to several millions of molecules patents" [66]), which "raise issues concerning sufficiency of disclosure, since normally the patent applicant has empirically obtained only a few of the multiple claimed compounds. In addition, it is virtually impossible to make prior art searches for thousands or millions of compounds. They also pose a transparency problem, since it is very difficult for third parties to identify patent applications that would merit a pre or post-grant opposition." [66]

Article 8.13 of the USA's TPPA proposal requires governments to provide considerable information, including prior art search histories and information from other patent offices, to the public. However, the apparent lowering of disclosure standards in the two immediately preceding articles should not be read as limiting the ability of patent offices to require that this information be furnished by patent applicants who are the ones most likely to have access to this information. Several countries do require that patent applicants produce this information. By lowering disclosure standards, the USA's proposal not only creates barriers

27 "The patent system is based on a 'bargain': the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. Sufficiency of disclosure lies at the very heart of the patent system, so adequate disclosure in the specification is a precondition for the granting of a patent." [63]

28 See for instance Section 8, Patents Act, 1970 (India). See also Section 18, Patent Law 5727-1967 (Israel).

29 See for instance Decision 486 – Common Regime of Industrial Property, 2000 (Andean Community); Article 31, Provisional Act No.2.186-18, 2001 (Brazil); Section 104, Patents Act 1970 (India); Section 8b, Patent Law, 1967 (Norway).

30 See for instance Teva Canada Ltd v. Pfizer Inc. [63]

in technology transfer and learning, but also contributes to increasing the cost and administrative burden of examining patents in developing countries.

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

When patent applications are filed in their patent offices, several countries allow competitors and/or public interest groups to oppose these applications. Opposition proceedings before (pre-grant oppositions) and after (post-grant oppositions) the grant of a patent are aimed at assisting the patent office to obtain and assess all available information about the product or process for which the patent is sought. While it is the responsibility of the patent office to ensure that patents are granted only where patent applications meet patentability standards, where there are thousands applications to examine, the role of oppositions is critical in bringing frivolous or tendentious applications to light. This is particularly important in developing countries where patent offices often find their financial and human resources insufficient to deal with the volume of patent applications. [67] Some countries allow both pre- and post-grant opposition proceedings and from a public health perspective both sets of proceedings are considered important. According to UNDP, UNAIDS and WHO, "providing for public health sensitive guidelines … as well as pre and post grant opposition procedures can help to prevent the patenting of products and processes that lack innovation." [68]

Pre-grant opposition proceedings are particularly important because of the difficulty of opposing or revoking a patent once it is granted. Even if a patent is challenged after it is granted, it remains in force during the period of the challenge, thereby prohibiting generic entry during this period. In several developing countries, public interest and health groups are using pre-grant opposition proceedings to ensure that only good-quality patents are granted on medicines. For instance, in 2006, PLHIV networks in India announced that they had filed a pre-grant opposition to a patent application filed by GSK on a combination of two existing ARVs i.e. lamivudine and zidovudine. [69] In August 2006, protests against the patent application took place simultaneously in India and Thailand. [70] On 9 August 2006, GSK announced that it was withdrawing its patent applications on the combination. [71] In Brazil, a pre-grant opposition filed by health groups against Gilead Science's patent application on tenofovir disoproxil fumarate (TDF) saw the rejection of the application. [72, 73] Brazilian and Indian groups were also successful in a joint challenge to one Gilead's patent application on TDF in India. [74] An illustrative list of pre-grant patent oppositions by public interest groups in India is contained in Table 2. The list of public interest patent oppositions is not comprehensive and also does not include patent oppositions filed by generic companies.

Table 2. Examples of pre-grant oppositions to patent applications in India

Medicine	Patent applicant	Opponent (public interest groups that have opposed the patent application)	Status of the patent application
Abacavir sulfate *ARV*	GSK	Indian Network for People Living with HIV/AIDS	Patent application withdrawn
amprenavir *ARV*	GSK	Uttar Pradesh Network of Positive People and Indian Network for People living with HIV/AIDS	Patent application abandoned
atazanavir *ARV*	Novartis	Karnataka Network for People Living with HIV and AIDS and Indian Network for People living with HIV/AIDS	Patent application abandoned
imatinib mesylate Cancer medicine	Novartis	Cancer Patients Aid Association	Patent application rejected
lamivudine/ zidovudine *ARV*	GSK	Manipur Network of People Living with HIV/AIDS, Indian Network for People Living with HIV/AIDS	Patent application withdrawn
lopinavir *ARV*	Abbott Laboratories	Delhi Network of Positive People, Network of Maharashtra by People Living with HIV/AIDS and Indian Network for People Living with HIV/AIDS	Patent application rejected
lopinavir/ritonavir (soft gel) *ARV*	Abbott Laboratories	Delhi Network of Positive People and Indian Network for People Living with HIV/AIDS	Patent application abandoned
lopinavir/ritonavir (tablet) *ARV*	Abbott Laboratories	Initiative for Medicines, Access & Knowledge	Patent application rejected
ritonavir ARV	Abbott Laboratories	Delhi Network of Positive People and Indian Network for People Living with HIV/AIDS	Patent application abandoned
Tenofovir disoproxil (TD) ARV	Gilead Sciences	Delhi Network of Positive People and Indian Network for People Living with HIV/AIDS; Brazilian Interdisciplinary AIDS Association (ABIA) and Sahara (Centre for Residential Care and Rehabilitation)	Patent application rejected
Tenofovir Disoproxil Fumarate ARV	Gilead Sciences	Delhi Network of Positive People and Indian Network for People living with HIV/AIDS	Patent application rejected

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.[31]

3.2.5 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 the claims in their patent applications before they receive any communication from the patent office. In addition, at least one opportunity to amend the application must be given though it is unclear at what stage of the proceedings before the patent office this opportunity must be given.

31 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."

Overall, the USA's TPPA proposal appears to weigh heavily in favour of patent applicants since it requires 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. This is likely to be achieved not only by lowering substantive standards but also by limiting patent office procedures that ensure higher patent quality and the highest standard of patent examination.

3.2.6 Patent term extensions

Extending the term of a patent is a straightforward way of delaying generic entry. The demand for an extended patent term is not new, nor is the reasoning behind it. The negotiating history of the TRIPS Agreement shows that the demand for longer patent periods to compensate for regulatory or patent office delays was made at that time and rejected by developing countries. [27] Further, the adoption of a 20-year term—a period longer than patent terms in most countries, including developed countries, at the time—was adopted in substantial part to compensate for patenting and regulatory delays. [75] Requirements for patent term extensions can also create direct or indirect pressure on the patent office or on the drug regulator to rush the examination of the applications. No direct or indirect pressure on drug regulatory authorities should result in the penalization of patients as a result of rushed marketing approvals. Drug regulatory authorities are required to be thorough in their analysis of the safety and efficacy of a medicine and they require time to assess information provided by applicants. Under the USA's TPPA proposal, in the case of delays by drug regulatory authorities, patent terms may be extended up to five additional years, 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. For instance, the European Commission's Competition Directorate-General has calculated that prices of generic medicines were on average 25% lower than their patented versions on entry into the market, and within two years generic prices were 40% lower. [46] A study of how the pharmaceutical market in the US evolves from monopoly pricing to competitive pricing found that prices decreased as more producers enter the market and "begin to approach long-run marginal cost when there are 8 or more competitors." According to the study, "the negative effect of increased competition on prices continues until at least the fifth, and perhaps even the sixth or seventh firm enters." [76] The impact of generic entry has been most dramatically demonstrated in the case of HIV medicines. In 2001, the price available from originator companies for what was then considered to be the first-line triple combination of ARVs was approximately US$ 10 000 per person per year, while generic companies were able to offer a price of US$ 350 per person per year. As the number of generic competitors increased, the prices continued falling; the price of that combination of ARVs is now close to US$ 100 per person per year. The lowest available price for the current WHO recommended first line combination is approximately US$ 113 per person per year. [77]

By delaying generic entry, patent term extensions prevent patients and government treatment programmes from accessing these lower generic prices for a longer period of time. Impact assessments of these longer periods of exclusivity have been conducted in some countries.

Provisions proposed for extending patent terms in the FTA between the Republic of Korea and the USA were estimated by the Korean National Health Insurance Corporation to cost approximately US$ 529 million for an extension of three years and US$ 757 million for an extension of four years. [78] An assessment in 2009 of the impact of TRIPS-plus patent term extensions of four years in Peru, as proposed in the European Union's FTA negotiations with the Andean Community, estimated that there could be an increase in pharmaceutical expenditure of US$ 159 million by 2025. The methodology used in this study was developed by a consortium of organizations, including WHO, the Pan American Health Organization (PAHO), the World Bank Institute and the International Centre for Trade and Sustainable Development. [79]

3.2.7 Limiting the early working or regulatory review exception (Bolar provision)

The TRIPS compliance of the early working exception or regulatory review exception, (also known as the Bolar exception or Bolar provision[32]) was affirmed by the WTO Dispute Settlement Body in 2000 in a case brought by the European Union against Canada. [80] The Bolar exception 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. [81] (A patent barrier may be removed on the expiry of a patent, or if it is revoked or if a compulsory licence is issued on that patent.)

The Bolar exception is considered to be a key TRIPS flexibility that developing countries are encouraged to include in their national laws. [82, 83] While Article 8.5 recognizes this exception, it also seeks to enforce and extend patent rights beyond what is required by TRIPS. Specifically, it places limits on the Bolar exception by requiring TPPA countries to ensure that, although preparation for registration may take place, the medicine cannot be made, sold or used on its territory and, if it is exported, even that export must be solely for the purpose of generating information for a marketing approval in that country (i.e. the country of production).

By way of example, Company A may make and test batches of a medicine in country X, only for the purposes of regulatory approval in country X. If Company A exports the batches, the exports must be for the purposes of regulatory approval only in country X. This would possibly cover situations where regulatory approval is sought in country X based on multicountry clinical data, or where tests are conducted in other countries to save costs. This means that Company A cannot manufacture batches in country X to apply for marketing approval in country Y.[33]

Thus the proposal appears to prevent the use of the Bolar provision for marketing approval in other countries. Effectively this means a generic company would have to manufacture the medicine locally in every country where it wishes to seek early marketing approval.[34] This is highly unlikely to happen as generic companies will not establish quality assured manufacturing sites in all developing countries and it would not be economically feasible for them to do so; in effect this would adversely impact access to generic medicines in countries that have small markets. 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 for generic medicines to enter export markets quickly. Where markets are small and offer lower remuneration for generic companies, additional barriers created in the registration of their medicines may act as deterrents to the widespread availability of their medicines, particularly in poorer countries. Since the Bolar exception is a well-recognized limited exception under Article 30 of TRIPS, there is no reason why its scope should be restricted to early-working/provisional-registration in one country only.

In addition, the USA's proposal limits the use of the Bolar exception to pharmaceutical products. Even in the USA, the Bolar provision extends to medical devices. [84, 85] It has application across the pharmaceutical sector and even beyond pharmaceuticals in other countries too.[34]

32 The name refers to a court case in the USA: Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc 733 F.2d 858, 863, United States Federal Circuit (1984). See also: 35 U.S.C. Section 271(e)(1) introduced by the Drug Price Competition and Patent Term Restoration Act, 1984, P.L. 98-417 (United States).

33 A similar requirement in Article 14.8.5 of the US-Bahrain FTA (which entered into force in 2006) is reflected in Bahrain's patent law as: "Use of the Patent subject for purposes of supporting an approval to market a pharmaceutical product provided that the products is not manufactured, used or sold in the Kingdom unless it is for the sole purpose of meeting the terms of the approval to market the product upon elapse of the Patent protection period. In this case it is prohibited to export the product outside the Kingdom unless for the purpose of meeting the terms of approving the marketing of the product in the Kingdom." Article 13, Law No. (14) for the year 2006 Amending some Provisions of Law Number (1) of the Year 2004 In respect of Patents and Utility Models (Kingdom of Bahrain).

34 By contrast, the relevant articles in the laws of several countries allow for the production of information, data and test results for the purpose of either national registration or registration in other countries. See for instance: Article 43, Law No. 9279 of 14th May 1996 (Brazil); Section 55,2(1), Patent Act, R.S.C., 1985, c. P-4 (Canada) and Section 107A Patents Act 1970 (India). Bolar provisions in these countries furthermore do not specify that this provision applies only in the pharmaceutical context.

CHAPTER 4. Data Exclusivity and Patent Linkage

Article 9 of the intellectual property chapter of the USA's proposal covers data exclusivity and patent linkage. A placeholder in the February 2011 text, the USA's proposal on data exclusivity as it relates to pharmaceutical products was included in the September 2011 negotiating text. A placeholder remains for data exclusivity for biologicals. Article 9 appears to contain the most comprehensive data exclusivity proposal ever put forward by the USA in FTA negotiations. The detailed proposal outlines multiple scenarios where data exclusivity must be awarded. In addition, the proposal prevents the adoption of key safeguards in the application of data exclusivity that developing countries have utilized in the past.

While the rest of the provisions of Article 9 provide for data exclusivity, Article 9.5 and Article 9.6 outline how a TPPA party should deal with the marketing approval of a generic version of a patented medicine. Thus, in addition to the provisions on data exclusivity, Articles 9.5 and 9.6 require TPPA countries to introduce the system of "patent linkage" or "drug regulation-patent linkage".

This chapter analyses the intellectual property chapter provisions on data exclusivity and patent linkage and their impact on access to medicines and the protection of public health. The key provisions are analysed in turn. For ease of reference the relevant provisions are reproduced in Box 2.

Box 2. Proposed text on provisional measures on certain regulated products

USA proposal, draft dated Sept. 2011

ARTICLE 9: MEASURES RELATING TO CERTAIN REGULATED PRODUCTS

…

Pharmaceutical Products

Submission of Information of Evidence Concerning the Safety or Efficacy of a New Pharmaceutical Product

2.

(a) If a Party requires or permits, as a condition for granting marketing approval for a new pharmaceutical product, the submission of information concerning the safety or efficacy of the product, the origination of which involves a considerable effort, the Party shall not, without the consent of a person previously submitting such safety or efficacy information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on:

(i) the safety or efficacy information previously submitted in support of the marketing approval; or

(ii) evidence of the existence of the marketing approval

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

(b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person previously submitting the safety or efficacy information to obtain marketing approval in the other territory, authorize a third person to market a same or similar product based on:
(i) the safety or efficacy information submitted in support of a prior marketing approval in the other territory; or
(ii) evidence of the existence of a prior marketing approval in the other territory,
for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

Submission of New Clinical Information or Evidence relating to a Pharmaceutical Product that Includes a Chemical Entity that has been Previously Approved for Marketing in Another Pharmaceutical Product

(c) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on:
(i) the new clinical information previously submitted in support of the marketing approval; or
(ii) evidence of the existence of the marketing approval that was based on the new clinical information,
for at least three years form the date of marketing approval based on the new clinical information in the territory of the Party.

(d) If a Party requires or permits, in connection with granting marketing approval for a pharmaceutical product of the type specified in subparagraph (c), the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory, other than evidence of information related to bioequivalency, such as evidence of prior marketing approval based on new clinical information, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the other territory, authorize a third person to market a same or a similar product based on:
(i) the new clinical information submitted in support of a prior marketing approval in the other territory; or
(ii) evidence of the existence of a prior marketing approval that was based on the new clinical information in the territory of the Party.
for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.

Additional Provisions relating to Pharmaceutical Products

3. Notwithstanding paragraph 2 above, a Party may take measures to protect public health in accordance with:
(a) the Declaration of the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");
(b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
(c) amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.

4. A Party that requires or permits an applicant to obtain approval for marketing a new pharmaceutical product in its territory by relying, in whole or in part, on the prior approval of the pharmaceutical product by the regulatory authority in another territory may, as a condition for providing the period of data protection specified in subparagraph 2(b) or 2(d), require an applicant that has submitted an application for marketing approval consistent with said subparagraphs to commence the process of obtaining marketing

approval for that pharmaceutical product within [X] years of the date of first marketing approval of the same pharmaceutical product in another Party….

5. Where a Party requires or permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence concerning safety or efficacy information for a product that was previously approved, such as evidence of prior marketing approval in another territory, each Party shall:[3]
   (a) provide a transparent and effective system to:
      (i) identify a patent or patents covering an approved pharmaceutical product or its approved method of use; and
      (ii) provide notice to a patent holder of the identity of another person who intends to market, during the term of the identified patent or patents, a product that is the same as, or similar to, the approved pharmaceutical product referenced in subparagraph 5(a)(i).

   (b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by providing:
      (i) an automatic delay of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate[4] disputes concerning the validity or infringement of allegedly infringed patents; and
      (ii) judicial or administrative procedures, including effective provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent.

   (c) if such other person's product has been found to infringe a valid patent identified pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent.
   (d) when a Party delays the grant of marketing approval consistent with subparagraph 5(b)(i), provide an effective reward, consistent with the provisions of this Agreement, for the successful challenge of the validity or applicability of the patent.[5]

6. In implementing subparagraph 5(b)(i), and as a condition for providing the automatic delay of the grant of marketing approval specified in subparagraph 5(b)(i) for a new pharmaceutical product approved consistent with subparagraph 2(b) or 2(d), a Party may require that an applicant that has submitted an application for marketing approval consistent with subparagraph 2(b) or 2(d) to commence the process of obtaining marketing approval for that new pharmaceutical in the Party within [X] years of the date of first marketing approval of the pharmaceutical product in another Party.

7. Where a Party provides for a period of data protection for a pharmaceutical product of more than [5+Y] years pursuant to subparagraph 2(a) or 2(b) of this Article, that Party is not required to implement for that pharmaceutical product subparagraphs 2(c), 2(d) (3-year data protection in connection with submission of new clinical information), 5(b)(i) (automatic delay of marketing approval) or 5(d) of this Article (reward for the successful challenge of the validity or applicability of a patent).

8. Where a Party chooses to apply subparagraph 6(e) of Article 8 and paragraphs 4 and 6 of this Article, the following provisions shall apply:
   (a) a Party shall permit an applicant to commence the process of obtaining marketing approval by providing the regulatory authority of the Party information supporting approval of the new pharmaceutical product in the Party that is available to the person at the time the request is made, such as evidence of the prior approval of the product in another Party. It is understood that, while a Party may impose reasonable additional requirements or deadlines as a condition of authorizing the person to market the pharmaceutical product in its territory, satisfaction of those additional requirements or deadlines or the granting of approval shall be recognized by the Party as necessarily occurring after the commencement of the marketing approval process within the meaning of subparagraph 6(e) of Article 8 and paragraphs 4 and 6 of this Article; and
   (b) a Party may not refuse to grant approval of a new pharmaceutical product on the basis of a failure of

an applicant for marketing approval to satisfy the requirements of subparagraph 6(e) of Article 8, or paragraphs 4 and 6 of this Article.

9. [Placeholder for specific provision applying to biologics].

General Provisions relating to Pharmaceutical Products and Agricultural Chemical Products

10. For purposes of this Article, a new pharmaceutical product means a product that does not contain a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product.[6] For purposes of this Article, a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product.

11. Subject to paragraph 3 (protection of public health), when a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1 or 2 and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1 or 2.

[2] [Negotiators Note: For purposes of paragraph 6(e) of Article 8 and paragraphs 4 and 6 of Article 9, the length of the [X]-year period should: enhance certainty regarding access to innovative and generic pharmaceutical products for all; provide incentives for innovation; provide incentives for the diffusion of pharmaceutical products within the TPP region; respect commercial considerations; and account for special challenges in developing and commercializing such products throughout the region (e.g., challenges faced by smaller or less experienced applicants, or the time that an applicant may need to assess additional safety or efficacy implications of marketing a product, such as to assess such implications in jurisdictions where risks may differ from those faced in markets where the product has previously been approved)].

[3] For greater certainty, the Parties recognize that this paragraph does not imply that the marketing approval authority should make patent validity or infringement determinations.

[4] [Negotiator's Note: As used in Article 9.5(b)(i), "adjudicate" does not mean final adjudication].

[5] A Party may comply with paragraph 5(d) by providing a period of marketing exclusivity in appropriate circumstances to the first such other person or persons to challenge a patent.

[6] For greater certainty, the Parties understand that the term "pharmaceutical product" as used in this Chapter includes biologic products.

4.1 Analysis of provisions

Article 9.2 is the key provision related to data exclusivity in the intellectual property chapter of the USA's proposal. It outlines four situations in which data exclusivity must be granted. ***Article 9.2(a)*** mandates a minimum period of five years of data exclusivity where a country requires or permits the submission of information concerning the safety or efficacy of a new pharmaceutical product for marketing approval. ***Article 9.2(b)*** specifies that the minimum five-year data exclusivity requirement also covers situations in which a government, in connection with granting marketing approval, requires or permits the submission of evidence concerning the safety or efficacy of a product approved in another territory, including evidence of prior marketing approval in another country. ***Article 9.2(c)*** expands the scope of data exclusivity beyond new chemical entities to include new clinical information potentially covering new uses, new forms or combinations of old medicines and requires a minimum period of three years of data exclusivity in such cases. As in Article 9.2(b), ***Article 9.2(d)*** expands the minimum three-year data exclusivity requirement for new clinical information to include situations where a government requires or permits the submission of evidence based on marketing approval in another territory.

The provisions of Article 9.2 are considered to be TRIPS-plus provisions. Although developed countries propose a disputed interpretation of Article 39.3 of the TRIPS Agreement and often argue that it requires the imposition of a period of data exclusivity,[35] WHO and other United Nations agencies have advised developing countries that data exclusivity would be TRIPS-plus and have cautioned against its adoption. [3, 68, 87] This is discussed in greater detail in the next section which highlights the potential impact of

35 See for instance USTR. [86] (http://www.ustr.gov/archive/assets/Document_Library/Reports_Publications/2004/2004_Special_301/asset_upload_file16_5995.pdf, accessed 22 February 2014).

these provisions on access to medicines. Apart from the requirement of the grant of exclusivity, several other elements of Article 9.2 are also TRIPS-plus. While Article 39.3 of the TRIPS Agreement only requires data protection—and not data exclusivity—it is further limited to undisclosed data. However, in all four situations under the proposed TPPA Article 9.2, the requirement appears not to be limited to undisclosed data; whether the data are disclosed or undisclosed appears to be irrelevant to the requirement of providing data exclusivity. While TRIPS refers to test or other data, the USA's proposal appears to use a broader formulation by referring only to "information." In addition, the obligation under TRIPS is limited to new chemical entities while Article 9.2 also appears to provide for exclusivity for new uses and new forms of known medicines.

Article 9.3 recognizes that, notwithstanding the provisions of Article 9.2, a party may take measures to protect public health in accordance with the Doha Declaration. Article 9.3(a) refers to the Doha Declaration on the TRIPS Agreement and Public Health. The Doha Declaration, agreed by all WTO members in 2001, specifically recognizes the right of WTO members to interpret and implement the TRIPS Agreement in a manner supportive of the right to health and the fulfilment of access to medicines for all. However, as noted below, the provisions of the intellectual property chapter in the USA's proposal impose TRIPS-plus requirements on TPPA parties, and the actual protection offered by this provision is likely to be restricted. It is unclear how this provision can be used by the TPPA parties as the Doha Declaration enshrines the right of countries to use TRIPS flexibilities which are antithetical to the TRIPS-plus provisions in the USA's proposal. Articles 9.3(b) and (c) appear to refer to the August 30th decision of the TRIPS Council [88]—also known as the "Paragraph 6 solution"—waiving the requirement that compulsory licences issued under Article 31 of the TRIPS Agreement be limited to the domestic market, provided that certain procedural requirements are met.

Article 9.4 is to be read with Articles 9.2(b) and 9.2(d) and allows TPPA parties to impose one condition in the grant of data exclusivity where, in considering marketing approval, a country requires or permits the submission of information based on marketing approval in another country. In such cases, a TPPA party may require a company seeking to take advantage of the data exclusivity period to commence the process of obtaining marketing approval within a certain (undefined) number of years of the first marketing approval in another country. This provision is also to be read with Article 9.8 below.

Article 9.5 outlines the measures to be taken by a TPPA party in the approval of a generic version of a medicine when one or more patents related to that medicine may exist. Footnote 3 to Article 9.5 makes clear that, in implementing these measures, the drug regulatory authorities of TPPA countries are not required to determine if a patent is valid or if the generic version infringes it. This clarification appears to be in response to criticisms that the patent linkage system can require drug regulatory authorities to divert already limited human and financial resources towards patent determinations that they are not qualified to make. [89]

When an application for the registration of a generic version of a patented medicine is made, ***Article 9.5(a)*** requires that parties to the TPPA put in place a system that identifies any patent covering the medicine or its approved use, and that notifies the patent holder of the identity of the person who intends to market the same or similar medicine. If the generic company does not agree to postpone marketing the generic version until after the patent expires, ***Article 9.5(b)*** requires the TPPA party to ensure that the patent holder has the opportunity to seek remedies such as a suit for infringement. This opportunity is to be provided by automatically delaying the registration of the generic company. The length of the delay is not specified; the provision requires only that it should be sufficient for the adjudication of a patent dispute. The negotiator's note, in footnote 4 to this provision, clarifies that this does not mean a final adjudication. In addition, the TPPA party must provide judicial or administrative procedures, including provisional measures, to enable the patent holder to pursue an infringement suit or for the initiation of proceedings to determine the validity of the patent. As the USA's proposal also includes provisions for expanded patent enforcement remedies, this Article should be read with the enforcement provisions including the requirements on provisional measures.

If the patent is held to be valid, ***Article 9.5(c)*** would require the TPPA party to prohibit the unauthorized marketing of the generic medicine until the patent expires. If the patent is found to be invalid, ***Article 9.5(d)*** requires the TPPA party to provide a reward to the generic company. The footnote to this provision states that a party may comply with this clause by providing a period of exclusivity to the company that first challenges the patent.

Article 9.6, like Article 9.4, allows TPPA parties to impose one condition on patent holders who seek marketing approval for their medicine on the basis of approval in another country (under Article 9.2(b) and 9.2(d)) and who are seeking the benefit of the automatic delay of the registration of a generic version under Article 9.5(b). The patent holder may be required to commence the process of registration of the medicine for which it desires this benefit within a certain number of (as yet unspecified) years of the approval in the other country. This condition can only be imposed in the case of a new pharmaceutical product—i.e. one that contains a new chemical entity not previously registered in the TPPA country concerned. The provisions of Article 9.5, however, apply to all pharmaceutical products, thus, this condition may be applicable to relatively few medicines. This provision is to be read with Article 9.8 below.

Article 9.7 provides an incentive for governments to provide more than five years of data exclusivity for new chemical entities. The number of additional years in excess of five is yet to be specified. If a government provides this higher number of years of data exclusivity, it would not have to provide the additional three-year data exclusivity for new clinical information of existing chemical entities. Nor would it have to implement certain elements of the patent linkage system mandated in Article 9.5, i.e. the requirement of providing an automatic delay on the marketing approval application of a generic company or providing a reward to a company that successfully challenges a patent.

Article 9.8 covers the three situations in Articles 8 and 9 that would allow TPPA parties to require applicants to register their medicines within a certain number of years of the first registration with another TPPA party—i.e. in relation to patent term extensions in Article 8.6(e), data exclusivity in Article 9.4 and patent linkage in Article 9.6. In all these situations ***Article 9.8(a)*** specifies that the only condition a TPPA party may impose is that the registration process should commence. Commencement must be allowed based on the information available to the person applying for approval at the time such as evidence of marketing approval in another Party. Although a TPPA party may impose other conditions, meeting those conditions is to be understood to occur after the commencement. Thus, TPPA parties may be restricted from requiring, for instance, that a complete registration dossier should be submitted to the regulatory authorities within a certain number of years of first registration. ***Article 9.8(b)*** further specifies that, if the applicant cannot commence the process for marketing approval within the specified years, this would not be a reason to deny marketing approval. In addition it may be noted that the requirements for patent term extension due to marketing delays discussed in Chapter 3 do not allow the exclusion of delays by applicants in determining the period of extension. For instance, if an originator company commences the process of registering a medicine but fails to provide all information necessary to complete the registration, thus delaying the grant of marketing approval, this delay, even though caused by the applicant, would result in a patent term extension being granted.

Article 9.9 has a placeholder for specifying the period of time of data exclusivity for biologicals. During a video-recorded hearing of the United States Senate, an official of the USPTO stated that this period was likely to be 12 years [90] (which is in line with current practice in the USA). However, it appears that there are ongoing discussions in the USA to revise this period to seven years [91] and the USPTO official subsequently retracted that statement. [92]

Article 9.10 defines a new pharmaceutical product as one that contains a chemical entity that has not been registered with the TPPA party applying the provisions of Article 9. As in the case of Article 8 discussed in the previous chapter, this definition prevents TPPA parties from restricting the application of data exclusivity or patent linkage to a new chemical entity that has no prior registration anywhere in the world. Footnote 6 to this article further clarifies that the term "pharmaceutical product" used in the intellectual property chapter includes biologic products. The implications of including biologicals within the

obligations of TPPA parties, including in relation to proposed provisions on patent term extensions, data exclusivity and patent linkage, may require closer scrutiny.

Article 9.11 removes the ability of TPPA parties to specify that the data exclusivity term and the patent term of a medicine should run concurrently. This practice is considered a safeguard to ensure that exclusivity over a medicine does not extend beyond the patent period because of the data exclusivity period. [93] However, Article 9.11 prevents the adoption of this safeguard by a TPPA party.

4.2 Implications for public health and access to medicines

4.2.1 Data exclusivity

In many countries, generic manufacturers are not required to conduct full scale clinical trials to demonstrate the safety and efficacy of already approved medicines. Duplicate clinical trials on human populations for a medicine of which the safety and efficacy are already proven are considered unethical. They would also add considerably to the cost of generic manufacturing. Instead, under the regulatory laws of many countries, generic manufacturers have to show that the generic medicines for which they seek marketing approval 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 full scale clinical trials in order to obtain marketing approval or to wait until a specified exclusivity period is over (a minimum of five years for new chemical entities plus a minimum of three years for new clinical information related to existing molecules, and potentially 12 years for biologicals) before a generic product can be approved. This measure creates an exclusivity over medicines distinct from patent protection and applies even to medicines that are off-patent (because the patent was not granted, has expired or has been revoked) and, potentially, even in cases when a compulsory licence is issued. The USA's TPPA proposal on data exclusivity is TRIPS-plus. It also restricts the little flexibility that the few developing countries imposing data exclusivity have evolved to limit its potential negative impact on access to medicines.

TRIPS and data exclusivity: Data exclusivity is now widely considered to be a TRIPS-plus measure that negatively affects access to medicines. [68] However, some developed countries argue that data exclusivity is required by the TRIPS Agreement [86] and cite Article 39.3, which states: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The question of whether or not Article 39.3 of TRIPS requires data exclusivity relates to the interpretation of "unfair commercial use". Some developed countries argue that when a drug regulator relies on information on the safety and efficacy of a medicine, submitted by originator companies, to approve the generic version of a medicine, this amounts to unfair commercial use. Whether these actions of a regulator amount to unfair commercial use was best articulated in a 1990 House of Lords (United Kingdom) decision where it was held that, "it is the right and duty of the licensing authority to make use of all the information supplied by any applicant for a product licence which assists the licensing authority in considering whether to grant or reject any other application, or which assists the licensing authority in performing any of its other functions under the Act of 1968. The use of such information should not harm the appellants and even were it to do so, this is the price which the appellants must pay for cooperating in the regime designed by Parliament for the protection of the public and for the protection of the appellants and all manufacturers of medicinal products from the dangers inherent in the introduction and reproduction of modern drugs." [94]

In addition, the negotiating history of Article 39.3 of TRIPS shows that the original proposal for data exclusivity moved by the USA was rejected in favour of the present provision quoted above that requires only data protection. [27]

Impact of data exclusivity on prices and availability of generic medicines: Data exclusivity has been implemented in some developing countries (usually because they have signed an FTA that imposes it), and evidence of the impact of data exclusivity is now emerging from those countries. In Guatemala, a study found wide variations in the prices of medicines in the same therapeutic class because of data exclusivity. [95] In Jordan, a 2006 study by Oxfam showed that, of the 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79% had no competition from a generic equivalent as a consequence of data exclusivity.[36] [96] A more recent analysis funded by the Medicines Transparency Alliance (MeTA) estimates that delayed market entry of generics resulting from the TRIPS-plus requirements in the USA-Jordan FTA cost consumers in Jordan's retail market US$ 18 million in 2004. [98] Both Guatemala and Jordan impose data exclusivity as a result of their FTAs with the USA. A study on the anticipated impact of data exclusivity in Thailand (conducted with reference to the USA-Thailand FTA negotiations) found that the economic effect of data exclusivity over five years could be as high as US$ 2400 million. [99]

Data exclusivity applies regardless of the patentability of a medicine. As noted in the Report of the CIPIH:

> *"If the patent period has expired, or there is no patent on the product, this sui generis data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent, where required. The only alternative for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues since it would involve replicating tests in humans to demonstrate what is already known to be effective. These sui generis regimes, which provide for data exclusivity need to be clearly differentiated from the TRIPS agreement's requirement for data protection."* [21]

Where countries adopt provisions to ensure high standards of patentability, through the strict application of patentability criteria or patentable subject matter exclusions, and fewer patents are granted, data exclusivity would create additional exclusive rights. The USA's proposal of providing exclusivity even for new clinical information about an existing chemical entity thwarts provisions in countries that do not allow patents on new uses or that restrict patents on new forms of existing medicines. In essence the minimum three-year periods of data exclusivity for new clinical information may result in evergreening of data monopolies, just as patenting of variations of existing medicines may result in evergreening of patent monopolies.

Where patents exist on a medicine, data exclusivity is likely to undermine key TRIPS flexibilities available to developing countries, such as the Bolar exception which allows generic competitors to have all the regulatory data filed and regulatory approval ready so they are ready to launch the generic medicine as soon as the patent is no longer blocking them. This could happen when the patent expires, or is revoked or when a compulsory licence is issued. Where the data exclusivity period extends beyond the patent period, generic entry is delayed even though the patent may have expired. Arguably, the laws of TPPA parties may provide for a waiver of data exclusivity in cases where compulsory licences are issued under the recognition of the Doha Declaration in the proposed Article 9.3 of the TPPA. If the implementation of data exclusivity prevents drug regulators from accepting or processing marketing approval applications of generic competitors, then even if it is waived in the case of a compulsory licence, generics may not be able to enter the market immediately as their marketing applications would be processed only after the waiver takes effect. It is unclear if Article 9.3, which refers to the Doha Declaration on TRIPS and Public Health, can be used to provide public interest provisions to override data exclusivity when there is no patent (and hence no compulsory licence).

Data exclusivity and traditional medicines: Another area in which data exclusivity could have implications is in relation to traditional medicines. Patent laws in many developing countries do not permit the

36 It has also been noted that: "Data exclusivity is attractive to originator companies because unlike a patent, data exclusivity is automatic (rather like copyright). No fees are incurred for application or maintenance of the right, and there is more limited scope than exists in patent law for legal challenges, which are expensive to mount and to defend. For these reasons pharmaceutical companies are strong proponents of data exclusivity regimes. Whatever the benefits, which depend on exclusivity extending beyond the patent term, the costs to these companies are very low." [97]

patenting of products based on traditional knowledge, or patent offices do not grant patents on traditional medicines as they fail the novelty test. However, as noted earlier, data exclusivity applies even for an off-patent medicine. In the case of traditional medicines, data exclusivity may allow companies that generate information regarding the safety or efficacy of a traditional medicine to prevent competitors from registering their versions of traditional medicines.

The impact of market exclusivity on the availability of traditional medicines can be seen through the analogous example of *colchicine* in the USA, where orphan drug exclusivity worked in a similar manner to data exclusivity. Like other traditional medicines, *colchicine* cannot be patented as it has been in use and known for 3000 years. It has been available in generic form in the USA since the 19th century. Under United States law, exclusivity over a medicine can be granted if it is for a rare disease. One company provided one-week trial data of the medicine to show its use in debilitating fevers and abdominal pain (which was already known) and received exclusivity over this traditional medicine. As a result, other manufacturers of the medicine were forced to leave the market and the price of the medicine rose 50-fold from US$ 0.09 to US$ 4.85. [100] Data exclusivity on traditional medicines may have a similar impact.

Restricting policy options for limiting the impact of data exclusivity: The few developing countries that apply data exclusivity have evolved a number of ways to limit its impact on access to medicines. One of these ways is to limit data exclusivity strictly to new chemical entities and to undisclosed information. However the TPPA proposal appears to cover all information submitted, regardless of whether it is disclosed or not, and requires three years of data exclusivity for new clinical information related to existing chemical entities. The proposal also defines a "new pharmaceutical product" as one that contains at least one new chemical entity that is not registered in the country where registration is being sought. TPPA countries are therefore prevented from defining new chemical entities as those that have not been registered anywhere in the world.

In addition, 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 specified countries with well-established regulatory systems (e.g. Canada, the EU, the USA). The TPPA proposal instead requires that the period of exclusivity should start from the point at which the medicine is registered within the country concerned, removing yet another flexibility. Some countries also provide that the period of data exclusivity would run concurrently with the patent term (if there is one) on that medicine. This safeguard is also removed in the TPPA proposal.

The USA's proposal allows only those TPPA countries that permit registration by reference to impose conditions requiring a company that seeks to avail itself of a patent term extension, patent linkage or data exclusivity provisions to commence registration within a certain number of years (which remains undefined). Such a condition may prove more effective if the company would be required to complete its registration within a certain number of years and not just commence the process within that time. The requirement that data exclusivity be provided in case of registration by reference in itself limits the scope for TPPA parties to restrict data exclusivity, as in such cases it could be argued that there is no reliance on any information submitted by an originator company.[37]

The USA's proposal offers TPPA countries the possibility of not having to impose three years of data exclusivity for new clinical information only if they provide data exclusivity periods of longer than the minimum five years for new chemical entities. However the additional number of years for data exclusivity on new chemical entities is not specified.

37 A key argument used by proponents of data exclusivity is that the reliance by drug regulators on data submitted by originators to approve generic medicines amounts to unfair commercial use. However drug regulators in several countries do not actually require such data to be submitted and several countries simply rely on the fact of registration in another country or on the WHO pre-qualification system to determine the registration of drugs. [101] The meaning of direct or indirect reliance on the originator's data arose in Canada in Bayer Inc. v. Canada (Attorney General). T-1154-97. Muldoon J. 2/12/98 (Canada) where the Court held that to trigger data exclusivity required a direct reliance on the innovator's drug submission. According to Health Canada: "In most cases, Health Canada does not consult the information in the innovator's drug submission and, therefore, does not rely directly on the innovator's information." [102] However, in 2006 Canada amended its data exclusivity rules to provide that the trigger for data exclusivity would be is there was a "direct or indirect comparison" between the originator and the generic drug. [103] The USA's TPPA proposal bypasses this possible limitation on data exclusivity by providing for data exclusivity regardless of whether or not there is actual reliance on originator data by a drug regulator.

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, a number of United Nations agencies and human rights institutions have recognized the adverse impact of data exclusivity on access to medicines, and WHO, for instance, has cautioned developing countries against adopting data exclusivity. [87]

More recently, the Report of the Consultative Expert Working Group on Research and Development: Financing and Co-ordination, released in April 2012, supported a proposal for the removal of data exclusivity where it exists. According to the report, "(W)e considered that there was no evidence that data exclusivity materially contributes to innovation related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases, and therefore we concluded that its removal where it existed would not adversely affect innovation incentives for these diseases and also would contribute to reduced prices of affected medicines. While recognizing that removal of data exclusivity would not constitute a significant contribution to increased innovation, we noted that it might enable generic companies to innovate incrementally on products which otherwise would have been under exclusivity." [104]

4.2.2 Patent linkage (Article 9.5, Article 9.6, Article 9.7 and Article 9.8)

According to the TRIPS Agreement, patents are private rights. This means that patent holders must use their own resources to protect and enforce their patents. If a generic company launches a medicine that a patent holder believes violates its patent or patents, it can file an infringement suit against the generic company. In the USA, however, the Drug Price Competition and Patent Term Restoration Act 1984 provides for the use of the government's human and financial resources to assist patent holders substantially in enforcing their patents. The USA's system creates a link between the drug regulatory mechanism and the patent system. In most countries, both systems are separate and have different functions. The drug regulator is concerned with assessing the safety, efficacy and quality of a medicine among other things. The patent office administers the patent system. However, under the USA's patent linkage system, the drug regulator is also involved in the enforcement of patent rights. As reflected in the USA's TPPA proposal, patent linkage is a form of TRIPS-plus patent enforcement.

Impact of patent linkage in the USA: Under United States law, patent holders are required to list the patents related to medicines for which they have marketing approval in a register at the FDA. If a generic company submits a request for marketing authorization, notice is given to the patent holder. If the patent holder launches an infringement action within 45 days of the notice, a 30-month delay on the generic company's application for marketing authorization is triggered. If the generic company is successful in its challenge to the patent, it is granted 180 days of exclusivity. This means that no other generic medicine will receive marketing approval for six months even though there is no patent barrier.

The USA's TPPA proposal, however, contains only the broad outline of the patent linkage system and leaves TPPA parties to decide how they will implement the system. The USA's proposal does not detail the amendments that have been made to the original system in the USA as a result of abusive practices by first registrants. An investigation by the USA's competition authority, the Federal Trade Commission (FTC), in 2002 found that patent holders were exploiting multiple loopholes in the law to delay generic entry beyond the original 30-month period. [105] These included filing multiple patent applications and triggering back-to-back 30-month automatic delays. As a result, the law was amended in 2003, nearly 20 years after it was first enacted, so that patent holders may have only one 30-month stay on a medicine. The FTC also found that, in 73% of the cases in which a decision was reached on the merits, the generic company was successful in invalidating the patent. But the FTC also found that, in several cases, the issue of patent validity was never determined as the patent holder and the generic company concluded settlements that in some cases delayed generic market entry. Patent settlements are now the subject of further FTC scrutiny as they keep more affordable generic versions off the US market.

In June 2005, a report of the United States House of Representatives Committee on Government Reform – Minority Staff, [89] highlighted the impact of patent linkage on access to generic medicines and noted in

particular that "even the FDA does not have adequate expertise or resources to review the applicability of patents, and it has been unable to prevent abuses of the system by patent holders that have led to delays in the availability of generic drugs". The report cites the FDA's own statement in this regard:

> *"FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."* [106]

The footnote to Article 9.5, which states that the drug regulator does not have to make findings on the validity of a patent, may have been included in response to these concerns. However, other concerns related to enforcing or assisting in the enforcement of patents through the drug regulatory mechanism may require further analysis.

Patent linkage in other developed countries: In Canada the implementation of patent linkage [107] has similarly given rise to concerns regarding generic entry. The Canadian Competition Commission, in an investigation in 2007, highlighted some of these concerns, and noted that "legal costs for the first generic to challenge were said to be commonly in excess of $1 million and potentially much higher in complicated cases". [108] In Canada a department under the Ministry of Health maintains a register of patents and vets the list of patents on approved medicines, which is considered to be a safeguard in addressing potential abuses of the linkage system. It is, however, a burden on the health ministry. Canada also amended its regulations in 2006 providing stricter criteria for the listing of patents on the register and freezing the list so that generic competitors do not have to address patents listed after the date of submission of the generic application. [109] In Australia, the implementation of patent linkage because of requirements in the Australia-USA FTA generated significant debate and resulted in legal provisions that require, among other things, a patent holder who wishes to sue a generic company to certify that the proceedings are in good faith with a reasonable expectation of success; if found to be false, the statement can attract a fine of up to 10 million Australian dollars.[38]

The CIPIH noted that "in both Canada and the United States, there remain provisions whereby a brand-name company can trigger a stay of generic entry, irrespective of the merits of the claim of the generic company to be non-infringing. Thus these types of rules provide, in effect, for additional periods of exclusivity, offered by the regulatory authority, rather than the patent system." [21]

It is notable that patent linkage is not implemented in the European Union. Recent attempts by Italy to introduce a system of patent linkage resulted in a notice from the European Commission asking for the removal of these provisions from Italian law. [111] The report on the pharmaceutical sector inquiry of the European Union's Competition Directorate General found that, despite patent linkage being unavailable in the European Union, patent holders have launched multiple actions against drug regulators in European Union countries that approve generic versions of medicines they hold patents on. [46]

Impact of patent linkage in developing countries: The impact of delayed generic entry can be high both for patients purchasing their own medicines and for government health systems supplying or reimbursing the cost of medicines. In developing countries, patent linkage is introduced either through FTAs with the USA, through litigation by patent holders or in some cases reportedly by pressure on drug regulatory authorities. In 2006, Pfizer Ltd. sued the Philippine government-owned company Philippine International Trading Corporation (PITC), the Bureau of Food and Drugs (BFAD) and two BFAD officials in their personal capacity. PITC had begun the process of registering more affordable generic versions of amlodipine besylate with the BFAD by submitting imported samples in order for them to be registered; this would enable the generic versions to promptly enter the market when Pfizer's Philippines patent on amlodipine besylate expired in June 2007. [112, 113, 114] In 2005, BFAD issued clear guidelines stating that the drug regulator's mandate under the constitution was to check medicines for their safety, efficacy and quality and it would not get involved in any matters of intellectual property.[39] In 2008, the Philippines Cheaper Medicines Act specifically rejected patent linkage.

38 See Sections 26C and 26 D of the Therapeutic Goods Act, 1989 (Australia). See also Faunce and Lexchin. [110]

39 See: Administrative Order, A.O. No. 2005-0001. Department of Health, Republic of Philippines, 3 January 2005 (http://www.fda.gov.ph/attachments/article/15853/ao 1 s 2005.pdf, accessed 8 March 2014) requiring BFAD to accept and process applications for marketing approval without verifying whether

In India, the German multinational company Bayer sued the Indian drug regulator in 2008 asking Indian courts to direct the Indian regulator to adopt a system of patent linkage. The attempts by Bayer were ultimately rejected by the Indian Supreme Court in 2010. [115]

Patent linkage is of particular concern in developing countries, especially those with limited drug regulatory capacity and infrastructure. In 2004, Médecins Sans Frontières (MSF) reported that a country in Africa refused to register a generic version of fluconazole, a drug used to treat opportunistic infections associated with HIV, on the grounds that the originator had claimed that there was a patent. According to MSF:

> *"The drug regulator had no legal obligation to refuse registration on such grounds, but it had been pressured to do so by the drug company. Under further investigation, it was revealed that the originator company's claim was false and that the patent had expired more than a year earlier."* [116]

The negative impact of a patent linkage system in developing countries on access to medicines has been highlighted in the USA by Senator Henry A. Waxman, who co-authored the United States law on patent linkage. Commenting on attempts to introduce patent linkage through FTAs, he stated:

> *"As we are all painfully aware, devastating epidemics in the developing world, including AIDS, TB, and malaria are killing millions of people and crippling whole societies. Even in middle-income countries, leading killers like heart disease, diabetes, cancer and other conditions are going untreated because essential medications are unaffordable in these countries, costing many times the average citizen's annual income. While the pharmaceutical industry's approach is to cure this problem with a dose of Hatch-Waxman, this would have the lethal effect of keeping drug prices in these countries unaffordable for many years longer than is the case now.*
>
> *I think it goes without saying that the U.S. faced nothing like these kinds of problems when Hatch-Waxman was enacted here. We did not face a situation where only a tiny percentage of the population was receiving the medicines that they needed to survive. We did not face a situation where a very large percentage of the young people in our society had already contracted diseases that would swiftly and almost certainly kill them if they did not receive such medicines.*
>
> *If we had, the solution would certainly not have looked like Hatch-Waxman, which delays market entry of low-cost generic drugs for years after a life-saving drug becomes available. That system works in this country because most people in the U.S. have health insurance that pays for essential drugs and because we have a health care safety net to assure that the poorest in our society are not left without medical care and treatment. But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical. In developing countries, we must do everything in our power to make affordable drugs for life-threatening diseases available now."* [117]

A key component of the USA's TPPA proposal (discussed in Chapter 6) is that TPPA parties are required to adopt TRIPS-plus mechanisms of intellectual property enforcement, including the grant of injunctions or interlocutory orders against generic manufacturers, preventing their version of a medicine from entering the market during the pendency of litigation. However, courts in some countries (including in the USA) have been reviewing the grant of interim and final injunctions in infringement cases where there is public interest at stake. Indeed, even in the USA, courts have declined to issue injunctions and instead have granted royalties as a remedy [118]—in essence issuing a judicially-authorized compulsory licence as authorized by TRIPS Article 44.2. Similarly, in India, courts have refused to grant temporary injunctions in infringement cases involving life-saving or life-extending drugs. [119] Patent linkage provisions, by requiring automatic delays of generic registration, could be considered to be injunctions enforced by the drug

or not the pharmaceutical submitted for registration is under patent protection.

regulator that do not take into consideration issues related to the public interest or the evolution in jurisprudence related to the enforcement of patents that is even taking place within the USA's judicial system.

Patent linkage also undermines the ability of generic companies to consider at-risk launches of generic products. Generic companies may consider putting their products on the market even if patents are claimed to be in force. Generic companies may do this if they feel the patent is so weak that the patent holder may not even try to defend it, or if they feel that the market is too small for the patent holder to be interested in an infringement suit, or because they can launch revocation proceedings through these suits. Or they may anticipate that courts, considering public interest needs, may decide against issuing a permanent injunction and direct only the payment of royalties. The ability of generic companies to launch an infringing generic product does not run counter to the TRIPS Agreement since the generic risk-taker is not legally exempt from infringement proceedings.

Through the system of patent linkage, originator pharmaceutical companies effectively have another avenue to prevent 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. According to public interest groups, this is of considerable advantage to the patent holder. Patent linkage offers patent holders in the pharmaceutical sector an advantage that patent holders in other areas of technology do not have—the use of the health and regulatory mechanism to facilitate the enforcement of their patents.

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. [82]

CHAPTER 5. Trademarks and Copyright

As well as the provisions on patents and data exclusivity (see Chapters 3 and 4), the proposed intellectual property chapter of the TPPA also includes provisions related to the protection of trademarks and copyright (Box 3 and Box 4). As with the patents and data exclusivity provisions, the provisions on trademarks and copyright have attracted controversy because the standards of protection exceed the minimum protection standards required by the TRIPS Agreement. The provisions that would potentially affect access to medicines in the proposed text on trademarks and copyright appear to be based on, but also go beyond, the provisions found in the Korea–USA FTA (KORUS FTA).

While it is not within the scope of this paper to examine all the proposed trademark and copyright provisions in the intellectual property chapter of the TPPA, this chapter seeks to address the concern that the provisions may also have implications, whether intended or otherwise, on access to medicines and the protection of public health. The chapter therefore analyses the proposed provisions that are likely to have such impact.

Box 3. Proposed text on trademarks

USA proposal, draft dated 10 Feb. 2011

ARTICLE 2: TRADEMARKS, INCLUDING GEOGRAPHICAL INDICATIONS

Trademarks

1. No Party may require, as a condition of registration, that a sign be visually perceptible, nor may a Party deny registration of a trademark solely on the grounds that the sign of which it is composed is a sound or a scent.

2. Each Party shall provide that trademarks shall include certification marks. Each Party shall also provide that geographical indications are eligible for protection as trademarks.[4]

3. Each Party shall ensure that its measures mandating the use of the term customary in common language as the common name for a good or service ("common name") including, *interalia*, requirements concerning the relative size, placement or style of use of the trademark in relation to the common name, do not impair the use or effectiveness of trademarks used in relation to such good or service.

4. Each Party shall provide that the owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs, including geographical indications, for goods or services that are related to those goods or services in respect of which the owner's trademark is registered, where such use would result in a likelihood of confusion. In the case of the use of an identical sign, including a geographical indication, for identical goods or services, a likelihood of confusion shall be presumed.

5. Each Party may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interest of the owner of the trademark and of third parties.

6. No Party may require as a condition for determining that a mark is a well-known mark that the mark has been registered in the Party or in another jurisdiction. Additionally, no Party may deny remedies or relief with respect to well-known marks based solely on the lack of:

(a) a registration;
(b) inclusion on a list of well-known marks; or
(c) prior recognition of the mark as well-known.

7. Article 6*bis* of the *Paris Convention for the Protection of Industrial Property* (1967) shall apply, *mutatis mutandis*, to goods or services that are not identical or similar to those identified by a well-known trademark,[5] whether registered or not, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or service and the owner of the trademark, and provided that the interests of the owner of the trademark are likely to be damaged by such use.

8. Each Party shall provide for appropriate measures to refuse or cancel the registration and prohibit the use of a trademark or geographical indication that is identical or similar to a well-known trademark, for related goods or services, if the use of that trademark or geographical indication is likely to cause confusion, or to cause mistake, or to deceive or risk associating the trademark or geographical indication with the owner of the well-known trademark, or constitutes unfair exploitation of the reputation of the well-known trademark.

…

12. Each Party shall provide that initial registration and each renewal of registration of a trademark shall be for a term of no less than ten years.

….

[5] For purposes of determining whether a mark is well-known, no Party shall require that the reputation of the trademark extend beyond the sector of the public that normally deals with the relevant goods or services.

5.1 Analysis of trademark provisions: implications for public health and access to medicines

Article 2 of the intellectual property chapter of the TPPA sets out the proposed provisions on trademarks and geographical indications. As already noted, these provisions are TRIPS-plus in that they require the protection of trademarks beyond the minimum standards prescribed by the TRIPS Agreement, or limit the flexibility permitted therein. 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 TPPA proposal suggest a shift away from this consumer-oriented justification for trademarks towards that of protection of the producer's investment in advertising and promotion. Such a shift can have implications for access to medicines and the protection of public health.

Article 2.1 of the intellectual property chapter provides that signatory parties of the TPPA may not require "as a condition of registration, that a sign be visually perceptible", and that no party may deny "registration of a trademark solely on the grounds that the sign of which it is composed is a sound or a scent". This amounts to an expansion of the scope of trademark protection beyond the current international legal minimum that is set by the TRIPS Agreement. While Article 15(1) of the TRIPS Agreement provides a broad definition of "signs"—which does not exclude those such as sounds, scents, tastes or textures—it does however permit WTO members the discretion to require that signs have to be visually perceptible to be eligible for registration as a trademark. Further, TRIPS allows members to make registrability of marks depend on distinctiveness acquired through use. The proposed expansion of scope follows the approach

taken, for example, in the USA where the absence of the limitation to visual signs has been broadly interpreted to include colours per se, sounds, scent and other nonvisual marks. [16]

Article 2.3 requires parties to the TPPA to take measures to ensure that requirements for the use of the "common name" of a particular good or service do not impair the use or effectiveness of trademarks. Although it is unclear how this provision would operate, it may have possible implications in relation to the use of common pharmaceutical terms, such as the International Non-Proprietary Names (INNs) or the generic names of pharmaceuticals. The issue is whether the generic names of pharmaceuticals or chemical compounds may be considered "common names".

Article 2.4 further expands the scope of trademark protection by prohibiting the use of similar signs "for goods and services that are related to those goods or services in respect of which the owner's trademark is registered". This formulation is broader than that in Article 16.1 of the TRIPS Agreement, which prohibits the use of identical or similar signs "for identical or similar goods or services". The use of the terms "related to" instead of "identical or similar" suggests a broader scope of protection that could be used to prevent the use of similar signs for a broader range of goods and services.

While the TRIPS Agreement provides for a seven-year minimum term of protection for trademarks at registration and each renewal, **Article 2.12** of the intellectual property chapter extends the term of protection to 10 years for the initial registration and for each renewal of registration.

These proposed TPPA provisions signal an attempt to expand the scope of trademark protection by importing into the TPPA text the standard of protection found in United States law, which has also been adopted in KORUS FTA. The effect of Article 2.1 is to remove the ability of countries to subject trademark protection to certain conditions that may be useful in providing consumer protection. For instance, the conventional justification for trademarks is the benefit derived from consumers being able to make purchasing decisions by associating signs with known qualities or characteristics of goods and services. It would be difficult to justify a trademark on the grounds of consumer protection when the mark is not easily identifiable—for instance, if it was based on solely on a sound or scent.

While the actual impact of these changes remains to be seen, the concern is that the expansion of scope may make trademarks a form of monopoly protection rather than a means of consumer protection. [16] Furthermore, registration of trademarks may be renewed indefinitely; hence, trademark protection could in theory subsist in perpetuity. Although **Article 2.5** restates Article 17 of the TRIPS Agreement to the effect that parties may provide for "limited exceptions" to the rights conferred by a trademark, including the fair use of descriptive terms, this provision may offer little defence in the face of the broad-ranging protection already carved out by Articles 2.1 and 2.4.

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, the question is whether trademark protection could be used to prevent generic producers from using the colours, shapes, tastes and/or scents 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. [120] It is possible that the broad scope of protection could be interpreted to include the non-visual aspects of a product, such as taste or scent, in which case it may be yet another factor that could affect generic pharmaceutical production.

Current jurisprudence[40] suggests, however, that trademarks for tablet colour or shape may not be registered on the grounds that trademark protection relates to the identification of the product but not its function. The colour and shape of tablets have an important functional characteristic. Since consumers and patients often rely on the colour, size and shape of medication for assurance that they are taking the

40 For cases in the USA, see for instance: Engelberg A. The case for standardizing the appearance of bioequivalent medications. J Manag Care Pharm. 2011;17(4) (http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9996, accessed 29 January 2014. For cases in South Africa, see: Wimpey B. South Africa. In: Pharmaceutical trademarks 2012: a global guide. London: World Trademark Review; 2012 (http://www.nortonrose.com/files/za-world-trademark-reviews-global-guide-64017.pdf, accessed 29 January 2014).

right pill, problems can arise when patients are not able to identify a medication if the generic versions are different in colour and/or shape. The justification for using the same colour and/or shape of equivalent drugs can thus be made on two grounds. First, the colour does not serve a trademark function because it is functional; and second, the use of the colour is a limited exception to the rights of the trademark owner as a fair use in the public interest. [27] The same argument of "functionality" may be made for trademarks for scent or taste of medication; furthermore, depending on the ingredients or chemical compounds used in a pharmaceutical product, the scent or taste of the product may not be easily manipulated or controlled.

Another related concern is raised by the text of **Article 2.3** which would oblige 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. In the context of access to medicines, this provision could lend itself to an interpretation that may impact on the use of the INN on the labels or packaging of pharmaceutical products. 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 INN or generic name of the pharmaceutical product to be prominently displayed. The use of INNs in labelling, product information and advertising is typically required by national regulations in many countries, which may define the minimum size of characters in which INNs must be printed under the trademark label and advertising. Such use of INNs is encouraged to facilitate the use of the often more affordable generic versions of originator pharmaceutical products. If use of an INN in this manner were to be restricted, on the grounds that it would affect the effectiveness of a trademark, this may have an effect on the use of generics and may increase the risk of confusion and errors in the prescription and use of medicines.

The case of the seizure by German customs officials of a shipment of 76 000 courses of generic antibiotic Amoxicillin[41] illustrates the problems that can arise out of confusion over the use of INNs and trademark infringement. Customs officials detained the shipment, which was in transit at Frankfurt en route to the Republic of Vanuatu, on the grounds of alleged trademark infringement of a brand-name antibiotic, Amoxil, produced by GSK. In fact there was no trademark or other intellectual property infringement in either the country of export or the country of import. The shipment was released only four weeks later when GSK confirmed that no trademark had been infringed. [121, 122]

Box 4. Proposed text on copyright and related rights

USA proposal, draft dated 10 Feb. 2011

ARTICLE 4: COPYRIGHT AND RELATED RIGHTS

1. Each Party shall provide that authors, performers, and producers of phonograms[8] have the right[9] to authorize or prohibit all reproductions of their works, performances, and phonograms,[10] in any manner or form, permanent or temporary (including temporary storage in electronic form).

2. Each Party shall provide to authors, performers, and producers of phonograms the right to authorize or prohibit the importation into that Party's territory of copies of the work, performance, or phonogram made without authorization, or made outside that Party's territory with the authorization of the author, performer, or producer of the phonogram.[11]

…

5. Each Party shall provide that, where the term of protection of a work (including a photographic work), performance, or phonogram is to be calculated:
   (a) on the basis of the life of a natural person, the term shall be not less than the life of the author and 70 years after the author's death; and
   (b) on a basis other than the life of a natural person, the term shall be:
      (i) not less than 95 years from the end of the calendar year of the first authorized publication of the work, performance, or phonogram, or

41 Amoxicillin is the INN of an essential medicine used to treat a wide range of bacterial infections.

(ii) failing such authorized publication within 25 years from the creation of the work, performance, or phonogram, not less than 120 years from the end of the calendar year of the creation of the work, performance, or phonogram.

…

7. Each Party shall provide that for copyright and related rights, any person acquiring or holding any economic right in a work, performance, or phonogram:

(a) may freely and separately transfer that right by contract; and

(b) by virtue of a contract, including contracts of employment underlying the creation of works, performances, and phonograms, shall be able to exercise that right in that person's own name and enjoy fully the benefits derived from that right.

[11] With respect to copies of works and phonograms that have been placed on the market by the relevant right holder, the obligations described in Article [4.2] apply only to books, journals, sheet music, sound recordings, computer programs, and audio and visual works (i.e., categories of products in which the value of the copyrighted material represents substantially all of the value of the product). Notwithstanding the foregoing, each Party may provide the protection described in Article [4.2] to a broader range of goods.

5.2 Analysis of copyright provisions: implications for public health and access to medicines

Article 4 of the intellectual property chapter sets out the provisions proposed for copyright and related rights in the TPPA (Box 4). The analysis below seeks to highlight those provisions that are relevant to, or may potentially impact, access to medicines and the protection of public health.

Article 4.1 of the intellectual property chapter grants intellectual property rights holders the exclusive right to "prohibit all reproduction … in any manner or form, permanent or temporary (including temporary storage in electronic form)". As with the trademarks provisions, this text is similar to that adopted in KORUS FTA. This would appear to go even further than the protection offered under the USA's Copyright Act which prohibits reproduction of the "copyrighted works in copies or phonorecords", rather than "in any manner or form".[42] Article 4.1 also goes further than current United States law in extending protection to "temporary storage in electronic form"; copyright protection in the USA requires that a copy be "fixed", which means "sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration". [16, 123]

Article 4.2 provides copyright owners an exclusive right to prevent "parallel imports" of copyrighted works. This provision seeks to create a new international legal requirement that would limit the ability of countries to apply their chosen regime of exhaustion. This is in contrast to Article 6 of the TRIPS Agreement which preserves the freedom of countries to choose their regime of exhaustion of intellectual property rights in order to allow for parallel importation. Article 4.2 effectively seeks to prevent the parallel importation of lower-priced foreign-produced copyrighted goods. The limitation on parallel importation would also appear to be in conflict with the current legal position in the USA where the Supreme Court, in its decision on Kirtsaeng v. John Wiley & Sons Inc. published in March 2013, held that the doctrine of first sale applied not only to domestically produced goods but also to those manufactured abroad. In deciding that international exhaustion principles applied in the USA, this decision resolved the previously unsettled legal situation.[43]

Parallel trade allows distributors to seek supplies of the legitimate copyrighted work in another market where it is available at a cheaper price. The text and footnote 11 of Article 4.2 suggest a focus on preventing the operation of parallel importation of a range of copyright-protected goods such as books, movies and music—namely, those products in which the value of the copyrighted material represents substan-

42 Section 106(1) of the USA Copyright Act.

43 The decision of Kirtsaeng v. John Wiley & Sons, Inc. is available at: http://www.supremecourt.gov/opinions/12pdf/11-697_d1o2.pdf (accessed 29 January 2014). See also analysis of the case, for instance by Cox. [124]

tially all of the value of the product. In reserving the right of TPPA parties to extend the protection afforded by Article 4.2 to a broader range of goods, footnote 11 raises the question of whether the provision may be used to prevent or hamper the parallel importation of medicines. In terms of determining whether parallel importation of patented originator medicines or pharmaceutical products can take place, the key question is whether the patent rights have been exhausted. If the patent rights subsisting in a product are exhausted by the importing country's exhaustion regime, then the product can be parallel imported. Article 4.2, in preventing the parallel importation of copyrighted works, however, raises the additional possibility that it could be interpreted to prevent imports of originator medicines, even when patents have expired, on grounds that a component of the product contains copyrighted material, such as parts of the packaging, or the packaging insert.

This concern should be seen in the light of 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 labelling and product information 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 the regulatory requirements preclude an infringement action by the originators.[44] 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 Australia's drug regulatory authority. [125] According to the Australian government, the amendments were necessary to combat the emerging trend of originator companies claiming copyright infringement in an attempt to delay market entry of competing generics.[125] The question is whether the text of Article 4.2 would affect such situations.

Article 4.5 provides that the term of copyright protection should be the "life of the author plus 70 years", or "not less than 95 years from the first publication or 120 years from creation". The length of protection (i.e. the life of the author plus 70 years) is consistent with the Copyright Act of the USA but the TPPA provision proposes to set this specified period as the minimum term of protection, whereas under current United States law it represents the ceiling of the term of protection. The proposed terms of protection are well beyond the requirements of the TRIPS Agreement which specifies the life of author and 50 years after the author's death for individual authorship, and 50 years from publication or creation for corporate authorship.[45]

The overall effect of the TRIPS-plus copyright provisions above is an extension of the international obligations relating to the length and scope of copyright protection. Although the implications of these provisions for access to medicines and public health are unclear at this stage, it is only prudent to explore the ways in which such expanded copyright protection could lend itself to interpretations that hamper or prevent the production and sale of generic medicines. As pointed out above, the prohibition against parallel imports of copyrighted materials in Article 4.2 highlights the particular concern that expanded copyright protection could be used to prevent parallel importation of originator medicines by virtue of copyrighted material within its packaging.

The 14th round of TPPA negotiations which took place in September 2012 reportedly focused on the issue of copyright exceptions, considering whether or not the TPPA would incorporate provisions expressly to permit certain limitations and exceptions, as well as to reserve the policy space for the creation of new ones. This is the approach adopted in the TRIPS Agreement, which contains provisions that limit the scope of copyright protection in a number of ways—such as by preventing copyright protection from extending to mere ideas as opposed to the expression of those ideas, or to facts, or limiting the scope of the performance right to public performances so that private performances are an unprotected area. Exceptions and limitations to copyrights, such as fair use or private copying exceptions, allow for access to goods and information.

44 See, for instance: SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc., 211 F.3d 21 (2nd Cir. 2000).
45 See Article 12 of the TRIPS Agreement and Article 7 of the Berne Convention for the Protection of Literary and Artistic Works.

Facilitating and preserving access to knowledge is an important justification for copyright limitations and exceptions, since these permit students and teachers to make copies of excerpts from various publications. This is of particular concern in developing countries where the cost of educational material often would be prohibitively high without the ability to make copies. 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 by subscription prices.

CHAPTER 6. Enforcement of Intellectual Property Rights

Articles 10 to 16 of the intellectual property chapter of the USA's TPPA proposal relate to the enforcement of intellectual property.

The key provisions are analysed in turn, followed by a discussion of their potential impact on access to pharmaceutical products. For ease of reference, the relevant provisions are reproduced in text boxes. Unlike in previous chapters, due to the length and complexity of the enforcement provisions, each set of enforcement provisions is analysed separately.

6.1 Enforcement provisions

6.1.1 General obligations

The USA's proposed text on general obligations is contained in Box 5.

Box 5. Proposed text on general obligations on enforcement of intellectual property rights

USA proposal, draft dated 10 Feb. 2011

ARTICLE 10: GENERAL OBLIGATIONS RELATING TO THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

1. The Parties understand that a decision that a Party makes on the distribution of enforcement resources shall not excuse that Party from complying with this Chapter.

2. In civil, administrative, and criminal proceedings involving copyright or related rights, each Party shall provide for a presumption that, in the absence of proof to the contrary, the person whose name is indicated in the usual manner as the author, producer, performer, or publisher of the work, performance, or phonogram is the designated right holder in such work, performance, or phonogram. Each Party shall also provide for a presumption that, in the absence of proof to the contrary, the copyright or related right subsists in such subject matter. In civil, administrative, and criminal proceedings involving trademarks, each Party shall provide for a rebuttable presumption that a registered trademark is valid. In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.

6.1.1.1 Analysis of provisions

Article 10.1 specifies that decisions made by TPPA parties on the allocation of resources for enforcement cannot excuse them from complying with the provisions of this chapter. By contrast, Article 41.5 of TRIPS[46], which was introduced by developing countries during the WTO negotiations, [27] recognizes that countries may include the enforcement of intellectual property within general law enforcement without additional or different resource allocation. In 2009, the WTO Dispute Panel found that Article 41.5 "is an important provision in the overall balance of rights and obligations in Part III of the TRIPS Agreement". [126] With several provisions of the USA's TPPA proposal requiring a greater role of government agencies in the enforcement of intellectual property, this expanded role would de facto require a greater allocation of public resources (human, financial and institutional) regardless of government priorities. Developing countries may be compelled to divert already limited resources to intellectual property enforcement and away from other development or health priorities.

The last two sentences of **Article 10.2** relate to trademarks and patents and require that TPPA parties provide a rebuttable presumption of the validity of these intellectual property rights in civil and administrative proceedings and, in the case of trademarks, in criminal proceedings as well. Providing a rebuttable presumption shifts the burden of proof onto the person against whom infringement is alleged. The TRIPS Agreement does not require any such presumption to be created and in several jurisdictions no such presumption of validity exists.[47] In criminal proceedings (which may lead to imprisonment as well as fines) relating to trademarks, the impact of a rebuttable presumption may need closer scrutiny to determine if it effectively reverses or weakens the presumption of innocence that usually forms the basis of criminal cases. Although the presumption is "rebuttable", this would require the leading of evidence before the presumption can be rebutted. Until such time, courts or tribunals before whom enforcement proceedings are initiated will be required to presume that the intellectual property in question is valid; this may potentially provide a stronger basis for an intellectual property holder to request the imposition of provisional measures such as injunctions or, in the case of criminal proceedings, the seizure of goods.

6.1.2 Enforcement practices

Box 6 contains the USA's proposed text on enforcement practices.

Box 6. Proposed text on enforcement practices relating to intellectual property rights

USA proposal, draft dated 10 Feb. 2011

ARTICLE 11: ENFORCEMENT PRACTICES WITH RESPECT TO INTELLECTUAL PROPERTY RIGHTS

1. Each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights shall be in writing and shall state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based. Each Party shall also provide that such decisions and rulings shall be published[16] or, where publication is not practicable, otherwise made available to the public, in its national language in such a manner as to enable governments and right holders to become acquainted with them.

2. Each Party shall promote the collection and analysis of statistical data and other relevant information concerning intellectual property rights infringements as well as the collection of information on best practices to prevent and combat infringements.

3. Each Party shall publicize information on its efforts to provide effective enforcement of intellectual property rights in its civil, administrative and criminal systems, including statistical information that the Party collects for such purposes.

46 Article 41.5 of the TRIPS Agreement: "Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general".

47 For instance, Viet Nam does not have a presumption of the validity of a patent. [127] India also does not have a presumption of validity of patents.

4. Nothing in this Chapter shall require a Party to disclose confidential information the disclosure of which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

[16] A Party may satisfy the requirement for publication by making the decision or ruling available to the public on the Internet.

6.1.2.1 Analysis of provisions

Article 11.1 makes it mandatory for final judicial decisions or administrative rules relating to the enforcement of intellectual property to be made in writing and to be published (which may be via the Internet as provided in footnote 16) or otherwise made available to the public. The TRIPS Agreement requires only that decisions are "preferably" in writing and reasoned, and makes it mandatory that the decisions be available to the parties (and not to the public). The final phrase of the article reveals the primary purpose of this requirement which is to enable "governments and rights holders" to become acquainted with those decisions.

Article 11.2 requires TPPA countries to gather and analyse data related to intellectual property infringements, as well as information on best practices to combat infringements. **Article 11.3** further requires countries to publicize information on their efforts to enforce intellectual property. **Article 11.4** exempts TPPA countries from disclosing confidential information that may hamper law enforcement or that may be contrary to the public interest or the commercial interests of enterprises. The requirements of this article are likely to have expanded budgetary implications for TPPA parties and are only indirectly related to the enforcement of intellectual property. The USA's proposal makes the collection and publicising of only some aspects of intellectual property mandatory (i.e. related to infringement and enforcement). The implementation of this provision may result in skewed data and information on the intellectual property environment in the country as it does not require that the analysis covers other aspects of intellectual property infringement (including, for instance, difficulties faced by defendants, number and impact of settlements resulting from litigation, percentage of cases won by defendants) or that efforts of TPPA parties to balance intellectual property rights and public interest should also be publicized.

6.1.3 Civil and administrative procedures

The proposed text on civil and administrative procedures is contained in Box 7.

Box 7. Proposed text on civil and administrative procedures.

USA proposal, draft dated 10 Feb. 2011

ARTICLE 12: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

1. Each Party shall make available to right holders[17] civil judicial procedures concerning the enforcement of any intellectual property right.

2. Each Party shall provide for injunctive relief consistent with Article 44 of the TRIPS Agreement, and shall also make injunctions available to prevent the exportation of infringing goods.

3. Each Party shall provide that:
   (a) in civil judicial proceedings, its judicial authorities shall have the authority to order the infringer to pay the right holder:
      (i) damages adequate to compensate for the injury the right holder has suffered as a result of the infringement,[18] and
      (ii) at least in the case of copyright or related rights infringement and trademark counterfeiting, the profits of the infringer that are attributable to the infringement and that are not taken into account in computing the amount of the damages referred to in clause (i).

(b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder.

4. In civil judicial proceedings, each Party shall, at least with respect to works, phonograms, and performances protected by copyright or related rights, and in cases of trademark counterfeiting, establish or maintain a system that provides for pre-established damages, which shall be available upon the election of the right holder. Pre-established damages shall be in an amount sufficiently high to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by the infringement. In civil judicial proceedings concerning patent infringement, each Party shall provide that its judicial authorities shall have the authority to increase damages to an amount that is up to three times the amount of the injury found or assessed.[19]

5. Each Party shall provide that its judicial authorities, except in exceptional circumstances, have the authority to order, at the conclusion of civil judicial proceedings concerning copyright or related rights infringement, trademark infringement, or patent infringement, that the prevailing party shall be awarded payment by the losing party of court costs or fees and, at least in proceedings concerning copyright or related rights infringement or willful trademark counterfeiting, reasonable attorney's fees. Further, each Party shall provide that its judicial authorities, at least in exceptional circumstances, shall have the authority to order, at the conclusion of civil judicial proceedings concerning patent infringement, that the prevailing party shall be awarded payment by the losing party of reasonable attorneys' fees.

6. In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities shall have the authority to order the seizure of allegedly infringing goods, materials and implements relevant to the infringement, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement.

7. Each Party shall provide that in civil judicial proceedings:
   (a) at the right holder's request, goods that have been found to be pirated or counterfeit shall be destroyed, except in exceptional circumstances;
   (b) its judicial authorities shall have the authority to order that materials and implements that have been used in the manufacture or creation of such pirated or counterfeit goods be, without compensation of any sort, promptly destroyed or, in exceptional circumstances, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements; and
   (c) in regard to counterfeit trademarked goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce.

8. Each Party shall provide that in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities shall have the authority to order the infringer to provide any information that the infringer possesses or controls regarding any persons or entities involved in any aspect of the infringement and regarding the means of production or distribution channel of such goods or services, including the identification of third persons involved in the production and distribution of the infringing goods or services or in their channels of distribution, and to provide this information to the right holder.

9. Each Party shall provide that its judicial authorities have the authority to:
   (a) fine or imprison, in appropriate cases, a party to a civil judicial proceeding who fails to abide by valid orders issued by such authorities; and
   (b) impose sanctions on parties to a civil judicial proceeding their counsel, experts, or other persons subject to the court's jurisdiction, for violation of judicial orders regarding the protection of confidential information produced or exchanged in a proceeding.

10. To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that such procedures conform to principles equivalent in substance to those set out in this Chapter.

11. In the event that a Party's judicial or other authorities appoint technical or other experts in civil proceedings concerning the enforcement of intellectual property rights and require that the parties to the litigation bear the costs of such experts, that Party should seek to ensure that such costs are closely related, *inter alia*, to the quantity and nature of work to be performed and do not unreasonably deter recourse to such proceedings.

…

[17] For the purposes of this Article, the term "right holder" shall include exclusive licensees as well as federations and associations having the legal standing and authority to assert such rights; the term "exclusive licensee" shall include the exclusive licensee of any one or more of the exclusive intellectual property rights encompassed in a given intellectual property.

[18] In the case of patent infringement, damages adequate to compensate for the infringement shall not be less than a reasonable royalty.

[19] No Party shall be required to apply this paragraph to actions for infringement against a Party or a third party acting with the authorization or consent of a Party.

6.1.3.1 Analysis of provisions

Article 12.1 requires that civil judicial procedures for the enforcement of any intellectual property right should be made available. While Article 42 of the TRIPS Agreement restricts this requirement only to those rights covered by TRIPS, TPPA parties will be confronted with a significantly expanded range of intellectual property rights. In addition, in defining "rights holders", the USA's proposal, in footnote 17, expands the list of rights holders to include not only federations and associations who have the legal authority to assert these rights (as already provided in TRIPS) but also exclusive licensees. It may be noted that the proposed TPPA text does not expand or strengthen several of the other requirements which relate to the rights of defendants, vis-à-vis Article 42 of TRIPS. This is of particular note given the increasing concern over so called "patent trolls" that act as intellectual property rights holders in enforcing intellectual property that the original intellectual property holder is often not interested in enforcing or aggressively pursuing. Legal and regulatory measures to address the problems of patent trolls are being considered in several jurisdictions, including the USA. [128]

Article 12.2 requires that injunctions be available consistent with Article 44 of the TRIPS Agreement but also requires that this relief should be available to prevent exports of infringing goods. Article 44 of TRIPS requires only that judicial authorities have the authority to issue injunctions in cases of imports and does not mandatorily require that these injunctions are awarded. In this respect, the language of Article 12.2 is ambiguous as to whether it requires only compliance with TRIPS Article 44 or requires that injunctions should be made available when requested. Article 44.2 of TRIPS also provides for limitations on remedies available for enforcement and recognizes the sovereignty of national laws in providing for situations where the only remedies available would be declaratory judgements and adequate compensation.

Articles 12.3, 12.4 and **12.5** of the USA's proposal relate to the remedy of damages for infringement and legal costs. These matters are dealt with under Article 45 of the TRIPS Agreement.

While Article 45 of TRIPS requires that judicial authorities have the authority to order the payment of damages, the USA's TPPA proposal could significantly expand the amount of damages. Where judicial authorities decide to award damages, **Article 12.3** of the USA's proposal mandates the manner in which those damages must be calculated. Footnote 18 specifies that "adequate" damages in the case of patent infringements would not be less than a reasonable royalty. In the case of trademark counterfeiting, the damages that must be paid to the rights holder would have to be greater than the profits accrued by the infringer. In addition, in the case of all intellectual property infringements including patent infringements, the USA's proposal mandatorily requires the court to consider the value of the infringed product or service in determining damages. The provision further specifies that this value is to be based on the retail price suggested by the intellectual property holder, or any other measure of value, again suggested by the intellectual property holder. In effect, the calculation of the value of the goods would be determined largely by the intellectual property holder and is likely to be relatively high. The suggested retail price for a medicine, for instance, is higher than the amount that the intellectual property holder would earn since the retail

price accounts for the costs and profits of several intermediaries in the supply chain, such as distributors and pharmacies. [129] Such a measure of value is likely to result in high damages. As these considerations are mandatory, they severely restrict the flexibility that judicial authorities currently have under the TRIPS provisions in how damages are calculated or awarded. In addition, the USA's proposal does not refer to the safeguards in the TRIPS Agreement which provides that damages are not required "unless the infringer knowingly, or with reasonable grounds to know, engaged in infringing activity". Where this is not the case, TRIPS states that countries may provide damages in such situations only in "appropriate cases".

Article 12.4 mandates that pre-established damages (or statutory damages) in cases of trademark counterfeiting are to be awarded at the request of the trademark holder. The amount of damages is required to be high enough to constitute a deterrent, while at the same time compensating the rights holder fully. In cases of patent infringement, the provision requires that judicial authorities have the power to increase the damages to three times the amount of injury assessed (treble damages). As noted above, the last line of Article 12.3 requires that this assessment is to be made on the basis of figures provided by the rights holder. This provision removes the flexibility that countries have under Article 45 of TRIPS regarding whether to provide pre-established damages at all. It may be noted that, during the negotiations of a possible intellectual property enforcement treaty (ACTA) primarily among developed countries, there was no agreement to include a similar requirement. Article 12.4 also seems to apply regardless of whether the infringement was committed wilfully or otherwise. It is interesting that footnote 19 to Article 12.4 states that it is not mandatory for TPPA parties to apply the provision for pre-established damages where the alleged infringer is a TPPA party itself or a third party acting on its authorization. The specific exception for TPPA parties only from this particular provision in the enforcement chapter raises the question whether other provisions of the enforcement chapter would have to be available when a TPPA party, or a third party acting on its authorization, is the alleged infringer. This may need to be clarified.

Article 12.5 requires that judicial authorities have the power to award legal costs to the prevailing party and, in cases of wilful trademark counterfeiting and exceptional cases of patent infringement, the attorney's fees as well. It may be noted that the costs of litigation as well as of attorney's fees in litigation relating to intellectual property can be considerably high, and in the USA are reported to run into millions of dollars.[48] Anecdotal information from developing countries also suggests that the costs originator companies are willing to incur in litigation in these countries (including the production of foreign experts in courts) would be high in these countries as well.[49]

Articles 12.6 and **12.7** provide for the remedies of seizure and destruction in infringement cases. Article 46 of the TRIPS Agreement also provides for seizure and destruction of infringing goods as well as of "materials and implements" but includes safeguards and mandatorily requires proportionality. TRIPS further requires that the interests of third parties should be taken into account. These safeguards are absent in the USA's proposals.

It should be noted that the USA's proposals on seizure and destruction apply only in cases of copyright infringement and trademark counterfeiting.

While the TRIPS provision for seizures applies to situations where infringement is proven, **Article 12.6** provides for the seizure of "allegedly" infringing goods. In relation to materials and implements, the TRIPS Agreement allows for their seizure only when their "predominant use" has been creating the infringing goods. The USA's proposal, however, allows for the seizure of materials and implements "relevant" to the infringement, which could cover a broader range of materials and implements that could be seized. Again in the case of materials and implements TRIPS allows their seizure only after the infringement is proven. In addition, the USA's proposal requires that, in cases of trademark counterfeiting, judicial authorities also have the power to direct the seizure of documentary evidence.

48 "Highmark was awarded approximately $5 million in attorneys' fees and expenses in this case. Highmark … Bard was awarded … $19 million in attorneys' fees and costs …" [130]

49 WIPO's Arbitration and Mediation Centre estimates that IP litigation in the first instance in China can cost US$ 150 000 and an additional US$ 50 000 on appeal. [131] A partner at an Indian law firm estimates that "the average cost of patent litigation in India can range from INR 1.2 million to INR 2.5 million ($22,000 to $47,000), subject to further uncertainty depending on the engagement of senior counsel to argue the matter." [132]

Article 12.7 provides for the destruction of infringing goods as well as materials and implements used in the manufacture or creation of those goods after there is a finding of infringement, although the provision is ambiguous as to the stage of proceedings at which destruction can be ordered. A lower court finding of infringement may be overturned at the stage of appeal. While Article 46 of the TRIPS Agreement only requires that judicial authorities have the power to order destruction, the USA's proposal makes this mandatory where the rights holder requests it, except in exceptional circumstances. While TRIPS provides that the destruction cannot take place if it conflicts with constitutional requirements, this crucial safeguard is missing from the USA's proposal. Article 46 of TRIPS only requires that judges have the authority to order the disposal, outside the channels of commerce, of materials and implements the"predominant use" of which was in creating the infringing goods. The USA's proposal not only requires that authorities have the power to order their prompt destruction, but also appears to cover a broader category of materials and implements "used" to manufacture or create pirated or counterfeit goods. Only in exceptional circumstances does the proposed Article 12.7 allow the disposal of such materials and implements outside channels of commerce. In 2009, the WTO Dispute Panel confirmed the flexibility available under TRIPS and found that auctions of infringing goods, voluntary sales to the rights holder and donations to welfare organizations are among the options available under Article 46, which it notes is in any case not exhaustive. [126] As noted above, the USA's proposal casts a much wider net for materials and implements than the TRIPS Agreement does.

The last line of **Article 12.7** also removes another crucial safeguard that is present in Article 47 of TRIPS in relation to counterfeit trademark goods. While both provide that the simple removal of the trademark unlawfully affixed is insufficient to allow the re-entry of the goods into channels of commerce, TRIPS does allow this to take place in exceptional circumstances. Under the USA's proposal there is no such allowance. For instance, it could be argued that patients' need for life-saving or life-prolonging generic medicines in an importing country may be an exceptional circumstance in which the removal of an infringing trademark would be sufficient to allow those generic medicines to be exported. However, the USA's proposal would not allow such a circumstance, notwithstanding the need or urgent situation of patients.

Article 12.8 requires TPPA parties to empower their judicial authorities to order an infringer to provide information to the rights holder regarding third parties involved in any aspect of the infringement of the infringing goods. Article 47 of the TRIPS Agreement on the other hand does not make it mandatory for this power to be accorded to judicial authorities and, even where this power is provided, TRIPS provides for it to be exercised only when the request for this information is in proportion to the seriousness of the infringement. The TRIPS requirement additionally applies more restrictively to those involved in production and distribution while the USA's TPP proposal broadens this to cover "any aspect of the infringement". In addition, while TRIPS limits the information to be provided only to the identity of third persons and their channels of distribution, this article expands this requirement to providing "any information."

Article 12.9 requires parties to the TPPA to empower their judicial authorities to take action, under certain circumstances, against parties involved in a civil judicial proceeding. The first relates to a case in which a party does not abide by valid orders issued by the judicial authority. In appropriate cases, the authorities are to be empowered to fine or imprison such a party. The second circumstance relates to a case in which the parties, their counsels, experts or other persons violate judicial orders regarding confidential information that is produced or exchanged during the proceedings. In such cases Article 12.9 requires judicial authorities to have the power to impose sanctions on such persons. The broad scope of the second circumstance means it could extend even to persons reporting on the trial.

Article 12.10 extends the provisions related to the powers and obligations of judicial authorities provided in Article 12 to administrative authorities as well. In effect, where the civil remedies of injunction, damages, seizure, destruction and so on can be ordered by an administrative body in a TPPA country, the provisions of Article 12 should apply. Accordingly, an administrative body that can order an injunction should also be able to order the injunction against exports, as provided in Article 12.1 above. Further, if an administrative body can order damages on findings of infringement the provisions of Article 12.3 and 12.4 should apply as well. While Article 49 of TRIPS has similar requirements, it may be noted that the

enforcement provisions of the USA's TPPA proposal are significantly stronger than those provided in TRIPS and do not contain several of the safeguards contained in TRIPS.

Article 12.11 appears to place restrictions on the costs of the appointment of experts or technical persons by judicial and other authorities where such costs have to be borne by the parties to the litigation. In such situations the USA's proposal mandates that the TPPA parties should ensure that these costs are related to the quantity and nature of the work and should not unreasonably deter the initiation of such proceedings. The USA's proposal specifies that such costs should not unreasonably deter recourse to enforcement measures. In effect, the proposals appear to favour intellectual property rights holders in pursuing enforcement cases.

Box 8. Proposed text on provisional measures

USA proposal, draft dated 10 Feb. 2011

ARTICLE 13: PROVISIONAL MEASURES

1. Each Party shall act on requests for provisional relief *inaudita altera parte* expeditiously, and shall, except in exceptional cases, generally execute such requests within ten days.

2. Each Party shall provide that its judicial authorities have the authority to require the applicant, with respect to provisional measures, to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a reasonable security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse, and so as not to unreasonably deter recourse to such procedures.

6.1.3.2 Analysis of provisions

Article 13 provides for provisional measures for the enforcement of intellectual property to be applied by TPPA countries before or during the pendency of judicial proceedings.

Article 13.1 mandates that TPPA parties should act on requests for provisional relief without hearing the person against whom such measure is demanded (ex parte) and should execute these requests within 10 days other than in exceptional cases. The period of 10 days can be relaxed only in exceptional cases. This is in contrast to the provisional measures detailed in Article 50 of the TRIPS Agreement. In particular, Article 50.2 of TRIPS leaves it to the discretion of judicial authorities to provide such *ex parte* provisional measures and does not prescribe any time limit for their execution. No such discretion appears to be allowed under the TPPA proposal.

Article 50.3 of the TRIPS Agreement requires WTO members to provide judicial authorities with the power to require some evidence before awarding provisional measures. **Article 13.2** of the USA's TPPA proposal similarly requires such power to be given to judicial authorities but with one key difference: it excludes from the evidence that may be required by judicial authorities, evidence that the applicant is in fact the rights holder. In addition, TRIPS allows judicial authorities to ask for a security or assurance from the person applying for the provisional measures in order to protect the defendant and prevent abuse of provisional measures. However, the USA's proposal restricts the scope of such assurances by requiring that the security or assurance should not be of a level that would deter recourse to provisional measures by rights holders.

6.1.4 Border measures

Box 9. Proposed text on requirements for border enforcement

USA proposal, draft dated 10 Feb. 2011

ARTICLE 14: SPECIAL REQUIREMENTS RELATED TO BORDER ENFORCEMENT

1. Each Party shall provide that any right holder initiating procedures for its competent authorities to suspend release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods[20] into free circulation is required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable by its competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to these procedures. Each Party shall provide that the application to suspend the release of goods apply to all points of entry to its territory and remain in force for a period of not less than one year from the date of application, or the period that the good is protected by copyright or the relevant trademark registration is valid, whichever is shorter.

2. Each Party shall provide that its competent authorities shall have the authority to require a right holder initiating procedures to suspend the release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods, to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance shall not unreasonably deter recourse to these procedures. A Party may provide that such security may be in the form of a bond conditioned to hold the importer or owner of the imported merchandise harmless from any loss or damage resulting from any suspension of the release of goods in the event the competent authorities determine that the article is not an infringing good.

3. Where its competent authorities have seized goods that are counterfeit or pirated, a Party shall provide that its competent authorities have the authority to inform the right holder within 30-days[21] of the seizure of the names and addresses of the consignor, exporter, consignee, or importer, a description of the merchandise, quantity of the merchandise, and, if known, the country of origin of the merchandise.

4. Each Party shall provide that its competent authorities may initiate border measures *ex officio*[22] with respect to imported, exported, or in-transit merchandise,[23] or merchandise in free trade zones, that is suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.

5. Each Party shall adopt or maintain a procedure by which its competent authorities shall determine, within a reasonable period of time after the initiation of the procedures described under Article 14.1 whether the suspect goods infringe an intellectual property right. Where a Party provides administrative procedures for the determination of an infringement, it shall also provide its authorities with the authority to impose administrative penalties following a determination that the goods are infringing.

6. Each Party shall provide that goods that have been determined by its competent authorities to be pirated or counterfeit shall be destroyed, except in exceptional circumstances. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized, except in exceptional circumstances, to permit the exportation of counterfeit or pirated goods or to permit such goods to be subject to other customs procedures.

7. Where an application fee, merchandise storage fee, or destruction fee is assessed in connection with border measures to enforce an intellectual property right, each Party shall provide that such fee shall not be set at an amount that unreasonably deters recourse to these measures.

8. A Party may exclude from the application of this Article (border measures), small quantities of goods of a non-commercial nature contained in traveler's personal luggage.

---

[20] For purposes of Article 14:
(a) **counterfeit trademark goods** means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the country of importation; and
(b) **pirated copyright goods** means any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and that are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

[21] For purposes of this Article, "days" shall mean "business days".

[22] For greater certainty, the parties understand that *ex officio* action does not require a formal complaint from a private party or right holder.

[23] For purposes of Article 14.4, **in-transit merchandise** means goods under "Customs transit" and goods "transhipped," as defined in the *International Convention on the Simplification and Harmonization of Customs Procedures* (Kyoto Convention).

6.1.4.1 Analysis of provisions

Article 14 of the USA's TPPA proposal outlines border measures that can be invoked at border points, often through customs authorities and therefore at public expense, for the enforcement of intellectual property. It may be noted that border measures are unlike civil measures that require intellectual property holders to approach courts for the enforcement of their intellectual property at their own expense. To some extent this is considered to be an inbuilt check as the intellectual property holder would weigh the financial and other considerations of initiating judicial proceedings before starting them. This check is particularly important where the intellectual property right involved may be weak and unlikely to be upheld at the end of enforcement proceedings. However, the use of public money, resources and personnel for enforcement decreases the risks to intellectual property holders and could lead to an increase in enforcement actions. Customs authorities, unlike judicial authorities, are also less likely to be trained or have the requisite resources to make appropriate decisions in relation to intellectual property enforcement actions and are likely to rely excessively on the information and inputs of the intellectual property holder making the request for the imposition of a border measure. In addition, when read with Article 10 above, this would require governments to increase the resources allocated to intellectual property enforcement and divert them away from other priorities, including priorities in health care such as initiatives to provide universal access to health care which is an increasingly important priority for developing countries.

Article 14.1 provides for border measures as part of the enforcement of intellectual property. While the TRIPS Agreement requires these border measures for counterfeit trademark goods and pirated copyright goods, the USA's TPPA proposal expands the scope to include confusingly similar trademark goods. The provision also provides for an application to seize goods to remain in force for a period of one year or until the end of the period the trademark or copyright is in force (whichever is less). The person applying for the border measures must provide sufficient information that the trademarks will be infringed under the law of the country of importation. While Article 14.1 may apply to imports, Article 14.4 appears to expand this to exports and goods in transit. In such cases it is unclear how authorities in one country can judge whether a trademark in another country is being infringed. Footnote 20 to Article 14 defines counterfeit trademark goods and pirated copyright goods. These definitions are taken from footnote 14 of the TRIPS Agreement.

Article 14.2 modifies the provisions of Article 53 of the TRIPS Agreement with regard to the power to require the applicant for a border measure to provide a security or assurance to protect the defendant or the competent authorities and to prevent abuse of these provisions. While TRIPS requires a security, the USA's TPPA proposal limits this to a reasonable security and further provides that a bond to hold the importer or owner of the imports harmless from loss or damage would be sufficient. Under TRIPS, countries have the flexibility to require a security that is sufficiently high so as to deter frivolous or weak requests.

Article 14.3 goes beyond the provisions of Article 57 of the TRIPS Agreement with regard to information about the seized goods that the authorities may provide to the rights holder. While TRIPS leaves it to the discretion of WTO members to mandate authorities to inform the rights holder of the names and addresses of the consignor, the importer and the consignee and the quantity of goods, the USA's TPPA proposal requires this. The USA's proposal further expands the information to be given to the rights holder to include the name of the exporter and the country of origin of the merchandise. Under TRIPS this authority can be given only after there is a positive determination on the merits of the case—i.e. a finding that the goods are indeed infringing. There is no such restriction in the USA's TPPA proposal and it appears this information can be given even before a decision on merits has been made. Finally, the TRIPS Agreement does not specify any time period within which this information is to be given, while the USA's proposal requires the information to be given to the rights holder within 30 business days of the seizure of the goods.

Article 14.4 modifies several of the TRIPS provisions regarding the power of competent authorities in relation to border measures. Under the TRIPS Agreement, WTO members are required to take these measures only on a written request by an alleged rights holder, while the USA's TPPA proposal mandates that TPPA parties authorise ex officio actions, i.e.—as specified in footnote 22—to be exercised by the competent authorities on their own initiative, without requirement for a formal complaint by the rights holder or other private party. Under TRIPS, WTO members have the flexibility to determine whether or not to allow authorities to initiate action without a complaint from the rights holder, where they have acquired prima facie evidence that an intellectual property right is being infringed. If WTO members allow ex officio actions, TRIPS requires that the importer and the rights holder are informed immediately and that public officials taking these actions are not exempt from liability unless they are taken or intended in good faith. Such safeguards are essential to ensure accountability for ex officio actions and to prevent the overzealous enforcement of intellectual property, particularly in the case of pharmaceutical products. As noted below with regard to seizures of medicines by customs officials in Europe, one particular case where suspected trademark infringement formed the basis for the seizure was the result of an ex officio action.

While TRIPS mandates these measures only in cases of imports, the USA's TPPA proposal requires them to be taken in cases of exports, goods in transit[50] or merchandise in free trade zones. The proposal also expands the application of border measures to "confusingly similar" trademark goods.

Article 14.5 relates to the time frame within which proceedings on the merits of the case must commence. Under Article 55 of TRIPS (read with Article 50.6) this must be done within 10 days with provision for an extension by another 10 days, and where the suspension takes place as a result of judicial provisional measures, the proceedings on the merits must commence within a reasonable period of time as determined by that judicial authority, without which they must commence within 20 working days or 31 calendar days. The USA's TPPA proposal does not specify a timeframe for these actions. In addition it requires that administrative authorities that are given the power to determine if there has been an infringement should also be given the power to impose administrative penalties if they find infringement. This could add an additional set of penalties over and above the remedies already available to the patent holder.

Article 14.6 specifies the remedies available if the goods are found to be infringing. Article 59 of the TRIPS Agreement (read with Article 46) requires competent authorities to have the power to order either the destruction of the goods or their disposal outside the channels of commerce. However, the USA's TPPA proposal mandatorily requires destruction of pirated or counterfeit goods, except in exceptional circumstances. These exceptional circumstances are not defined. With regard to counterfeit trademark goods, unlike TRIPS which allows the removal of the trademark to be sufficient for the release of the goods in exceptional circumstances, this article makes no such allowance. The proposed provision further specifies that only in

50 Footnote 23 to the proposed TPPA Article 14.4 refers to the International Convention on the Simplification and Harmonization of Customs Procedures (Kyoto Convention) for definitions of "customs transit" and goods "transhipped", which are included within the understanding of "in-transit merchandise." This Convention defines "Customs transit" as "the Customs procedure under which goods are transported under Customs control from one Customs office to another", and "transhipped" as "the Customs procedure under which goods are transferred under Customs control from the importing means of transport to the exporting means of transport within the area of one Customs office which is the office of both importation and exportation." See: Specific Annex E, International Convention on the Simplification and Harmonization of Customs Procedures (Kyoto Convention).

exceptional circumstances can any other customs procedure (re-export, import) take place with infringing goods.

Article 14.7 provides that any fee related to storing or destruction of infringing goods should not be so high as to discourage the use of these measures.

Article 14.8 specifies exclusions from border measures. While Article 60 of TRIPS allows small quantities of goods of a noncommercial nature in a traveller's personal luggage or sent in small consignments to be exempt from border measures, the USA's TPPA proposal limits the exemption only to the traveller's personal luggage. Small consignments would not be exempt from border measures under the USA's proposal. This also increases the resource commitment required from TPPA countries as the requirement of applying border measures to small consignments would greatly increase the number of shipments that customs officials would be required to check.

6.1.5 Criminal enforcement

Box 10. Proposed text on criminal enforcement

USA proposal, draft dated 10 Feb. 2011

ARTICLE 15: CRIMINAL ENFORCEMENT

1. Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. Willful copyright or related rights piracy on a commercial scale includes:
   (a) significant willful copyright or related rights infringements that have no direct or indirect motivation of financial gain; and
   (b) willful infringements for purposes of commercial advantage or private financial gain.[24]

Each Party shall treat willful importation or exportation of counterfeit or pirated goods as unlawful activities subject to criminal penalties.[25]

2. Each Party shall also provide for criminal procedures and penalties to be applied, even absent willful trademark counterfeiting or copyright or related rights piracy, at least in cases of knowing trafficking in:
   (a) labels or packaging, of any type or nature, to which a counterfeit trademark[26] has been applied, the use of which is likely to cause confusion, to cause mistake, or to deceive;

…

4. With respect to the offenses for which this Article requires the Parties to provide for criminal procedures and penalties, Parties shall ensure that criminal liability for aiding and abetting is available under its law.

5. With respect to the offences described in Article 15.[1]-[4] above, each Party shall provide:
   (a) penalties that include sentences of imprisonment as well as monetary fines sufficiently high to provide a deterrent to future infringements, consistent with a policy of removing the infringer's monetary incentive. Each Party shall further establish policies or guidelines that encourage judicial authorities to impose those penalties at levels sufficient to provide a deterrent to future infringements, including the imposition of actual terms of imprisonment when criminal infringement is undertaken for commercial advantage or private financial gain;
   (b) that its judicial authorities shall have the authority to order the seizure of suspected counterfeit or pirated goods, any related materials and implements used in the commission of the offense, any assets traceable to the infringing activity, and any documentary evidence relevant to the offense. Each Party shall provide that items that are subject to seizure pursuant to any such judicial order need not be individually identified so long as they fall within general categories specified in the order;
   (c) that its judicial authorities shall have the authority to order, among other measures, the forfeiture of any assets traceable to the infringing activity, and shall order such forfeiture at least in cases of trademark counterfeiting;

(d) that its judicial authorities shall, except in exceptional cases, order
  (i) the forfeiture and destruction of all counterfeit or pirated goods, and any articles consisting of a counterfeit mark; and
  (ii) the forfeiture or destruction of materials and implements that have been used in the creation of pirated or counterfeit goods.
  Each Party shall further provide that forfeiture and destruction under this subparagraph and subparagraph (c) shall occur without compensation of any kind to the defendant;
(e) that its judicial authorities have the authority to order the seizure or forfeiture of assets the value of which corresponds to that of the assets derived from, or obtained directly or indirectly through, the infringing activity.
(f) that, in criminal cases, its judicial or other competent authorities shall keep an inventory of goods and other material proposed to be destroyed, and shall have the authority temporarily to exempt such materials from the destruction order to facilitate the preservation of evidence upon notice by the right holder that it wishes to bring a civil or administrative case for damages[28]; and
(g) that its authorities may initiate legal action *ex officio* with respect to the offenses described in this Chapter, without the need for a formal complaint by a private party or right holder.

24 For greater certainty, "financial gain" for purposes of this Article includes the receipt or expectation of anything of value.

25 A Party may comply with this obligation in relation to exportation of pirated goods through its measures concerning distribution.

26 Negotiator's Note: For greater certainty, the definition of "counterfeit trademark goods" in footnote [12] shall be used as context for this Article.

28 For greater certainty, a notice from the right holder that it wishes to bring a civil or administrative case for damages is not the sole basis for the authority to exempt materials from the destruction order.

6.1.5.1 Analysis of Provisions

Although the provisions of the USA's proposal discussed above relate largely to civil enforcement proceedings, **Article 15** additionally provides for criminal enforcement measures. Insofar as these measures relate to trademarks and copyright and may impact public health, they are analysed below. It is important to note that civil judicial proceedings are carried out at the expense of the intellectual property rights holder while criminal proceedings are carried out at the expense of the government. Expanding the scope of criminal enforcement is therefore likely to create a greater burden on government resources—human, financial and institutional.

Article 15.1 requires that TPPA countries provide for criminal procedures and penalties for wilful trademark counterfeiting and copyright or related rights piracy on a commercial scale. This provision extends obligations beyond the scope of Article 61 of the TRIPS Agreement by including copyright "related rights". The USA's proposal further requires that TPPA parties provide criminal penalties for the wilful import and export of counterfeit and pirated goods. Footnote 25 allows TPPA parties to fulfil their obligations related to the export of pirated goods through measures concerning distribution.

In addition, while Article 61 of TRIPS does not specify what may be considered to be "commercial scale", Article 15.1 of the TPPA proposal provides a definition in the case of wilful copyright or related rights piracy. This includes significant infringement with no direct or indirect motivation of financial gain, and wilful infringement for commercial advantage or private financial gain. Footnote 24 to Article 15.1 further specifies that financial gain includes receipt or expectation of anything of value.

It may be noted that in its 2009 report on a case brought by the USA against China, the WTO Dispute Panel found that the use of the phrase "commercial scale" indicated that the TRIPS negotiators had not intended to require criminal penalties for all activity for financial gain or profit but that "the word 'scale' was a deliberate choice" and "reflects the intention of the negotiators that the limitation on the obligation" to provide criminal penalties "depended on the *size* of acts of counterfeiting and piracy." It further held that "counterfeiting or piracy 'on a commercial scale' refers to counterfeiting or piracy carried on at the magnitude or extent of typical or usual commercial activity with respect to a given product in a given

market ... It follows that what constitutes a commercial scale for counterfeiting or piracy of a particular product in a particular market will depend on the magnitude or extent that is typical or usual with respect to such a product in such a market, which may be small or large. The magnitude or extent of typical or usual commercial activity relates, in the longer term, to profitability." [126]

The USA's TPPA proposal therefore appears to remove the flexibility that countries have under the TRIPS Agreement in terms of defining commercial scale and in particular appears to provide less emphasis on the aspects of "scale" in determining criminal penalties for wilful copyright or related rights piracy.[51]

Article 15.2 requires TPPA parties to further apply criminal sanctions even where there is no wilful trademark counterfeiting or copyright or related rights piracy. This is in contrast to Article 61 of TRIPS, which mandates criminal remedies only in cases of "wilful" trademark counterfeiting or copyright piracy. In particular, Article 15.2(a) of the TPPA proposal requires criminal remedies to be applied in cases of knowing trafficking of labels and packaging to which a counterfeit trademark[52] is applied that is likely to cause confusion, mistake or deceive. The broad scope of this provision may make it applicable to labels and packaging of medicines and raises concerns over its impact on parallel imports.[53] Civil trademark disputes over brand names of medicines are common due to the use of (parts of) the INN in the names of medicines, and the impact of this provision on access to generic medicines may require further critical analysis.

Article **15.4** requires TPPA parties to include criminal liability for aiding and abetting for offences covered in Article 15. This provision extends criminal liability to third parties and is not a requirement under TRIPS.

Article 15.5 expands the range of actions and extent of punishment that judicial authorities can impose in criminal matters. ***Article 15.5(a)*** requires that TPPA parties provide for prison terms and monetary fines that are high enough to act as deterrents and which would remove the infringer's monetary incentive. By contrast, Article 61 of TRIPS requires imprisonment and/or fines, leaving it to the discretion of countries as to whether to provide for one or both criminal remedies. Indeed, in several jurisdictions, courts have the option of deciding between imprisonment or fines depending on the circumstances of the case. In addition, the requirement in Article 61 of TRIPS regarding criminal remedies is that these must be consistent with the level of penalties applied for crimes of corresponding gravity. The USA's TPPA proposal on the other hand requires that the criminal remedies be consistent with a policy of removing the infringer's monetary incentive. The USA's proposal further requires policies or guidelines that would reduce the flexibility that judicial authorities would have in determining the punishment imposed and would encourage them to impose higher penalties to ensure deterrence. In particular, the USA's proposal requires policies or guidelines to be established that should encourage judges to impose prison terms where commercial advantage or private financial gain is the purpose of the infringement. As noted above, footnote 24 to this article defines financial gain as including the receipt or expectation of anything of value, which significantly lowers the bar for the imposition of a prison term.

Article 15.5(b) mandates that judicial authorities have a broad authority for ordering seizures of suspected counterfeit or pirated goods and related materials and implements in the case of all offences identified in Article 15. By contrast, Article 61 of TRIPS requires the availability of remedies of seizures only in (i) appropriate cases and (ii) for infringing goods and for materials and implements used predominantly in the commission of the offence. In addition, the authority for seizures under the USA's TPPA proposal also extends to assets traceable to the infringing activity as well as any documentary evidence. This article pre-

51 Commentators have also observed that this provision in the USA's proposal does not reflect US law. "This provision does not track the details of current U.S. domestic law. U.S. Law does not contain this definition of 'private financial gain.' And U.S. law contains what might be seen as a floor on the term 'significant,' limiting criminal infringement to willful infringement of at least $1,000 worth of material in a 180-day period." [16]

52 While footnote 26 states that the definition of "counterfeit trademark goods" in footnote 12 would apply in the context of this Article, footnote 12 does not specify any such definition.

53 Article 15.2 appears to be based on US law, specifically 18 USC § 2320, Trafficking in Counterfeit Goods or Services. It is considered to go beyond a similar provision (Article 23.2) of the Anti-Counterfeit Trade Agreement (ACTA). [16] The provision in ACTA has been critiqued as presenting a barrier to parallel imports. "Art. 23.2 ACTA prescribes criminal procedures and penalties on the wilful importation and domestic use on a commercial scale of goods infringing trademark rights. The vague language of the article could seem to cover importation and domestic use of products which, although lawfully marketed in the exporting country, have not been authorized in the importing country. Such interpretation would hinder parallel import ...". Opinion of European academics on anti-counterfeiting trade agreement, January 2011. See also Flynn and Madhani. [133]

vents TPPA parties from requiring that items seized are individually identified, thus restricting a common safeguard in legal proceedings that would otherwise ensure some measure of restraint in the use of the powers of seizure. This may be particularly important in the case of pharmaceutical manufacturers whose materials and implements are used to manufacture a wide variety of medicines.

Article 15.5(c) mandates that judicial authorities have the power to order the forfeiture of assets traceable to the infringing activity. It further requires that judges must mandatorily order such forfeiture in cases of trademark counterfeiting. This removes any flexibility that judicial authorities would have and could potentially use to ensure that such orders, for instance in the case of pharmaceutical manufacturers, would not impact manufacture and production of other medicines. The TRIPS Agreement does not require this.

Article 15.5(d) mandates that judicial authorities are required, except in "exceptional cases", to order the forfeiture and destruction of all counterfeit goods and any articles consisting of a counterfeit mark. While Article 61 of TRIPS requires that such remedies be available for infringing goods, it restricts these to "appropriate cases" and does not mandate that these orders be given. While under TRIPS such orders should be the exception, under the USA's TPPA proposal they would be the norm. As noted above for similar remedies in the case of civil cases, the destruction of pharmaceutical products that may otherwise be safe and effective should not be the norm for the sake of intellectual property enforcement, and a range of other options, including donations, could be considered as more appropriate remedies. Similarly, the USA's proposal mandates the forfeiture or destruction of materials and implements used in the creation of pirated or counterfeit goods. The proposal expands the scope of materials and implements covered by enforcement measures which under TRIPS are limited to those that have been predominantly used in the commission of the offence. As noted previously, such orders are of particular concern in the case of pharmaceutical manufacturers whose materials and implements are used to manufacture a wide variety of medicines.

The TPPA proposal further requires that the forfeiture or destruction should be without any compensation to the defendant. Given the broad range of powers and scope of assets, materials and implements that may fall under these provisions, TPPA countries may have to determine if these provisions would conflict with domestic laws and constitutional requirements related to limits on state power in relation to private property, as well as constitutional limits on the reach of criminal remedies.[54]

Article 15.5(e) further expands the power of judicial authorities with regard to the forfeiture of assets. While Article 15.5(c) provides for forfeiture of assets traceable to the infringing activity, this provision allows forfeiture even where there is no link but where the value of a defendant's asset corresponds to those assets derived from or obtained directly or indirectly through infringing activity. This provision has also been proposed in the ACTA text. The broadening of the scope of assets to those that appear not to be linked to the infringing activity may again require an assessment by TPPA countries of the impact of such provisions on constitutional and other domestic restrictions on state power.[55]

Article 15.5(f) requires judicial or other authorities to maintain an inventory of goods and materials proposed for destruction and allows for a temporary delay in the destruction if the rights holder gives notice that it plans to bring a civil or administrative case for damages. Thus defendants could face both criminal action with harsh penalties and destruction of goods as well as civil actions. Footnote 28 provides that the notice from the rights holder would not be the sole reason for the delay in destruction. The delay even if granted is, however, temporary in nature.

Article 15.5(g) requires TPPA parties to allow ex officio legal actions related to offences. This means that authorities may commence legal action without a formal complaint by a private party or a rights holder.

54 For instance, Flynn et al argue that certain provisions of the USA's TPP proposal may implicate the Fourth Amendment to the US Constitution which "requires that search and seizure warrants 'particularly' describe places to be searched and items to be seized." [16]
55 See also Kaminski. [134]

6.2 Implications for public health and access to medicines

TRIPS-plus intellectual property enforcement measures emerging at different fora [135] have been critiqued as being part of an intellectual property enforcement "agenda" that has the effect of undermining the flexibility that developing countries have under TRIPS to balance rights and obligations. In this context, the World Intellectual Property Organisation's (WIPO) Development Agenda, which was adopted to ensure that development concerns are incorporated in WIPO's work, has called for approaching intellectual property enforcement "in the context of broader societal interests and especially development-oriented concerns". [136]

Enforcement measures implemented in developed countries can have a direct impact in developing countries, as evidenced in the case by the seizures of in-transit generic medicines at various European ports. Attempts at introducing anti-counterfeit legislation in developing countries have also been critiqued as promoting intellectual property enforcement in the guise of protecting public health. [137] These concerns and critiques have coalesced around the negotiations of the Anti-Counterfeit Trade Agreement (ACTA), which witnessed considerable resistance, including in developed countries. [138] The USA's TPPA proposals are considered by some to be "enacting ACTA provisions through the back door." [139]

6.2.1 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, including in criminal proceedings in the case of the latter, is likely to make it considerably more difficult to challenge patents on medicines while increasing the risk for generic competitors in 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 patents or trademarks granted. However, even the quality of patents granted in developed countries with extensive patent offices, staff and budgets has come under some scrutiny. [140, 141]

It is noteworthy that a 2003 report of the Federal Trade Commission of the USA found that generic competitors prevailed in 72% of patent challenges that were finally determined by a court. [105] In 2009, the European Union Competition Directorate General similarly found that, even though the majority of patent-related litigation was initiated by originator companies, generic companies prevailed in 62% of cases where courts rendered final decisions. [46] In a significant number of these cases either the patents were revoked or the generic version was found to be non-infringing. In 2011, the OECD Science, Technology and Industry Scoreboard concluded that patent quality between the 1990s and 2000s had declined by 20%. According to the OECD, "the quality of patent filings has fallen dramatically over the past two decades. The rush to protect even minor improvements in products or services is overburdening patent offices. This slows the time to market for true innovations and reduces the potential for breakthrough inventions ...". [142] The report found that "sectors generally believed to be highly innovative and known to rely more on basic science, e.g. biotechnology and pharmaceuticals, show on average relatively lower patent quality". [143]

Patent offices in developing countries are highly reliant on the findings of the USPTO and the EPO in relation to the grant or rejection of patents, and the concerns over patent quality can accordingly be surmised to extend to most developing countries as well.[56]

Several developing countries are attempting through legislation or patent examination guidelines to improve the quality of patents granted, particularly in the field of pharmaceuticals. As noted in Chapter 3, these measures coupled with expanded patent opposition provisions, have resulted in low-quality patents on several key medicines being denied or revoked. However, not only would the substantive provisions in the USA's proposals remove or restrict these options for TPPA countries but the general obligations on enforcement would require a presumption of validity. When read with the expanded enforcement provi-

56 For an overview of how patent offices in developing countries rely on developed country patent offices in determining acceptance or rejection of patent applications, see Drahos. [67]

sions discussed below, this presumption of validity is likely to have a chilling effect on generic competition by making patent challenges more difficult and making defences in infringement proceedings harder.

The presumption of validity may also increase the likelihood that provisional measures such as interim injunctions will be imposed; this would result in generic medicines not being available to patients. With evidence increasing that generic competitors or public interest groups can succeed in invalidating patents, the ultimate revocation of the patent will not compensate those patients who are unable to access more affordable medicines during the pendency of the litigation. This also highlights the importance of pre-grant opposition which, as noted in Chapter 3, is prohibited under the USA's TPPA proposal. In a significant decision in India, a court refused to grant an interim injunction on a generic version of a cancer medicine citing, among other things, the need for caution from courts in not always presuming the validity of a patent and the need to consider public interest in the granting of such injunctions in case of pharmaceutical products, particularly life-saving medicines. [119]

As noted in Chapter 5, trademarks in relation to pharmaceuticals are likely to continue to be the subject of civil and criminal disputes due to the use of (part of) the INN by both originator and generic companies in branding their respective versions of the same medicine. In the case of trademarks, the USA's TPPA 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 as well as third parties.

6.2.2 Limiting the ability of government to balance intellectual property enforcement with public interest and development priorities.

Several provisions in the USA's TPPA proposal limit the flexibility enjoyed by TPPA parties under the TRIPS Agreement in terms of the enforcement of intellectual property rights. The requirement that civil judicial procedures be available to any intellectual property right is likely to reduce the flexibility of TPPA countries to determine what type of enforcement should be available for different forms of intellectual property. An example of this would be the case of patents on surgical methods, which are not enforceable in the USA against medical practitioners in the course of practising medical activity. [144]

The USA's proposals also limit the ability of judicial and other authorities to balance public interest with intellectual property enforcement. Proposals related to the presumption of the validity of patents, trademarks and copyright and related rights, the prescriptive provisions on the calculation of damages, the requirement for policies or guidelines encouraging judges to pass orders of imprisonment, mandatory requirements for the destruction of goods, and the prescriptive requirements for ex parte orders are among those likely to heavily favour rights-holders in enforcement proceedings.

Over-broad intellectual property and enforcement provisions are coming under increasing scrutiny of courts in developing countries. For instance in 2012, the High Court of Kenya found in favour of people living with HIV who had challenged Kenya's *Anti-Counterfeit Act, 2008* as violating their Constitutional rights. Among the issues raised by the petitioners were the ambiguous definition of counterfeit goods that appeared to include legitimate generics, provisions allowing rights-holders to file complaints against goods suspected of infringing their intellectual property and the power of customs officials to seize those goods based on such a complaint. The Court found that "the tenor and object of the Act is to protect the intellectual property rights of individuals" as opposed to the government position that the "intention of the Act is to safeguard the petitioners and others against the use of counterfeit medicines." The Court held, "while such intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life of others, I take the view that they must give way to the fundamental rights of citizens in the position of the petitioners." [145] Courts in India have also rejected attempts by rights-holders to institute TRIPS-plus enforcement such as patent linkage [115] through litigation and have carved out public interest principles in the grant of injunctions in cases where medicines are involved. [119]

Concerns over increased public enforcement of intellectual property, particularly through the criminalisation of IP infringements, have been recognised by the Commission on Intellectual Property Rights (CIPR). The CIPR notes:

> *"the 'private' nature of IP rights suggests the importance of resolution of disputes between parties either out of court or under civil law. Indeed, as state enforcement of IPRs is a resource-intensive activity, there is a strong case for developing countries to adopt IPR legislation that emphasises enforcement through a civil rather than a criminal justice system. This would reduce the enforcement burden on the government in the case of counterfeiting on a large scale, although the state enforcement agencies would still be required to intervene. That said, we note that developing countries have come under pressure from industry which advocates enforcement regimes based on state initiatives for the prosecution of infringements. Such pressures should be resisted, and right owners assume the initiative and costs of enforcing their private rights."* [20]

In contrast, the TPPA proposals significantly expand the intellectual property enforcement obligations of TPPA parties, including the collection, analysis and publicising of information relating to enforcement, a greater burden on the judicial system, increased obligations for customs authorities at borders and on law enforcement through the expansion of criminal remedies and so on. At the same time, the USA's proposals limit the ability of TPPA parties to determine the allocation of national resources and requirements related to intellectual property enforcement are likely to prevail over the development priorities of developing countries. Developing countries are estimated to have faced significant costs in complying with the TRIPS Agreement.[57] In some respects, the USA's TPPA proposals on enforcement may be considered to be an expansion of the substantive rights of holders of intellectual property and developing countries may therefore consider conducting an impact assessment of the likely cost of the implementation of these proposals on "(1) the cost of enforcement, which equals the value of additional resources required to implement new obligations and (2) the impact or effects of enforcement on the economy and on society, defining impact as effects on public goods, prices, consumption, production, innovation, etc., and ultimately on welfare." [148]

6.2.3 A chilling effect on generic producers; risks for governments and treatment providers

Several of the provisions proposed by the USA are likely to have a chilling effect on generic production and supply. Apart from the presumption of validity discussed above, several provisions of the USA's proposal are likely to tilt judicial and administrative proceedings relating to infringement allegations in favour of holders of patents, trademarks and copyrights, while limiting judicial flexibility to balance public interest in such proceedings. In effect, holders of intellectual property will find it easier to launch infringement proceedings and have lower costs in pursuing litigation (with requirements that costs of experts etc. be kept low).

Even as proceedings continue, patent and trademark holders would be able to seek ex-parte injunctions against generic companies that must be implemented within 10 days. Such preliminary injunctions prevent generic medicines from coming into the market and are usually easier to obtain where the judge does not hear the other side in the case. In the case of medicines, such injunctions ultimately impact patients. As noted by an Indian court, "the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensatable." [119] In the US as well, in a case involving stents, public interest was considered to be a valid concern in refusing a preliminary injunction as, "a strong

57 The costs for developing countries complying with TRIPS, SPS and Customs obligations under the WTO were estimated at $150 million. [146] The World Bank also estimated that developed countries were likely to see a significant increase in net payments as a result of the full implementation of the TRIPS Agreement with six countries (United States, Germany, Japan, France, United Kingdom, and Switzerland) estimated to see a total of $40 billion per year of increased payments. [147]

public interest supports a broad choice of drug-eluting stents," "the accused product had the possibility of eliminating safety risks present in other products" and "the public would be harmed by an injunction because some physicians prefer the defendant's product." [149] Courts are also upholding public interest in denying permanent injunctions where infringement is proven. However, the USA's proposals are likely to restrict the ability of courts to explore public interest and public health considerations and by requiring injunctions for exports as well, may ultimately adversely impact patients in other countries.

The USA's proposal also empowers rights holders with a broad scope to seek information from an infringer regarding the entire supply and distribution chain of a generic company, and this information may be used to harass or intimidate smaller operators in this chain, such as transporters, stockists, distributors etc. Such third parties could also be affected by enforcement measures and may find themselves at the receiving end of ex-parte provisional measure orders. The impact of extending criminal remedies to "aiding and abetting" and its impact on third parties may also require careful scrutiny. According to Médecins Sans Frontières a broad scope of enforcement measures against third parties can also, "implicate, for example, suppliers of active pharmaceutical ingredients (API) used for producing generic medicines; distributors and retailers who stock generic medicines; NGOs, such as MSF, who provide treatment; funders who support health programs; and drug regulatory authorities who examine medicines." [150]

The USA's proposal would authorize judicial authorities to impose potentially debilitating financial damages including, for instance, treble damages in patent infringement cases and pre-established damages in trademark counterfeiting cases on generic companies. The USA's proposal seeks to introduce parameters for the calculation of damages similar to those that apply in the US and other developed countries. A survey of damages awarded in recent patent infringement cases may raise concerns for governments and generic companies in developing countries of the impact of such parameters.[58]

The impact of high damages in patent infringement cases is compounded by the problem of patent thickets whereby originator companies have multiple patents on the same medicine. In the European Union, the Competition Directorate General found a case of 1300 patents and patent applications on one medicine alone. [46] Patent thickets create difficulties for competitors to determine whether there are any patents that their products or processes may infringe. With the threat of high damages, generic competitors are unlikely to even attempt to enter the market.

Both the United States FTC and the European Union Competition Directorate General have noted that patent litigation is a strategy employed by originators to prevent generic competition. [105] Their reports also document the high rate of success of generic competitors if these cases go to court. Yet nothing in the USA's proposal addresses situations where patents have been wrongly claimed, frivolous patents filed and where patents or trademarks are used in litigation either to prevent generic competition or to secure a settlement with generic competitors that will delay their entry on the market. The USA's proposals are likely to increase the costs and uncertainty for generic competitors in infringement litigation and could lead to increased settlements between originators and generics. According to the FTC and the EU Competition DG, such settlements ultimately harm patients and governments who end up paying more for medicines. [153, 154] Expanded enforcement measures may also make the pursuit of litigation and settlements easier for "patent trolls" (entities typically not involved in research or manufacturing but that hold or acquire patents primarily for the purposes of securing damages and pursuing litigation).[59]

In addition, in the case of copyright piracy and trademark counterfeiting, depending on the nature of the infringement, the USA proposes harsher enforcement measures and criminal penalties far in excess of what is required by TRIPS.

58 In 2011, Canadian company Apotex was ordered to pay $442.2 million in damages to Bristol Myers Squibb and Sanofi over its at-risk launch of clopidogrel. Apotex was also ordered to pay $1.26 million in interest and $900 000 in legal costs. [151] In 2013, the Federal Court in Canada awarded $119 million plus interest to Merck against Apotex for the infringement of Merck's patent on lovastatin. Of this amount, $114 million was for lost profits for Merck Canada's lost sales in Canada and Merck US's lost sales to Merck Canada and $5 million was calculated as a reasonable royalty on all other infringing sales. Merck was also awarded interest which is likely to amount to several millions of dollars as the litigation originated from Apotex's sales of lovastatin in 1997. [152]

59 Efforts to control patent trolls through improvement of patent quality and restriction of enforcement measures may have a potential positive spin-off effect on aggressive enforcement actions by other institutions (such as universities). [155]

In cases of trademark counterfeiting, even as trademark disputes are being determined by courts, the USA's proposal would allow the seizure of generic medicines. In addition, materials and implements used for their manufacture—which could include machines used in generic factories, active pharmaceutical ingredients, packaging, etc.—could be seized. The proposed provisions also allow for the seizure of documentary evidence related to the infringement, which could include information about the distribution and supply system of the generic competitor. If criminal remedies are being pursued (where trademark counterfeiting is on a commercial scale) courts are required to order the seizure of assets traced to the infringing activity. The seizure of generic medicines on grounds of alleged trademark counterfeiting would mean that these medicines would stay out of the hands of patients. The seizure of machines or other implements would be likely to hamper the production of other medicines by the generic company. These are significant measures that trademark holders can pursue against generic companies without even proving that trademark counterfeiting has actually taken place. The impact of criminal remedies as they relate to exports and imports (including in relation to parallel imports) may require further analysis.

Where trademark counterfeiting is proven, these medicines as well as the materials and implements used in their manufacture may be destroyed and assets derived directly or indirectly from the infringing activity may be forfeited. Generic competitors may face extraordinary fines and imprisonment sentences. Where safe and effective medicines are destroyed (it may be noted that trademark disputes are not about the safety, efficacy or quality of a medicine), access to medicines for patients is restricted. If the implements and materials are destroyed, or even disposed outside the channels of commerce, the ability of the generic company to continue manufacturing could be significantly hampered. Unlike TRIPS which provides flexibility for governments to determine how to dispose of infringing goods outside the channels of commerce, the USA's TPPA proposal lays great emphasis on the destruction of these goods.

The enforcement provisions of the TRIPS Agreement provide several safeguards that WTO members can make use of in exceptional circumstances. Medicines differ from other goods since they can be life-saving or life-prolonging; thus they may qualify for exceptional treatment such as the mere removal of an unlawful trademark and re-entry into channels of commerce. The consideration of proportionality, as required by the TRIPS Agreement, between seizure and destruction and trademark counterfeiting, as well as of the interests of third parties such as patients, could prevent the seizure or destruction of medicines or the materials or implements used to make them. However, the USA's TPPA proposal leaves less room for the exercise of discretion by the judicial authorities.

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

In relation to the impact on health and medicines, the analysis in this section focuses primarily on border measures as they relate to trademarks.

Concerns over border measures in relation to the enforcement of intellectual property rights have become acute in recent years with the detention of generic medicines made in India while in transit in the European Union in 2008 and 2009. These generic medicines were being exported to Africa and Latin America. The primary basis for the detention of those medicines was that they violated intellectual property, i.e. patents and/or trademarks in the European Union. [156] It may be noted that these medicines were legal in both the country of import and the country of export. The Brazilian government estimated that approximately 300 000 patients could have been treated by medicines made from the quantity of the active pharmaceutical ingredient of a key blood pressure medicine (lossartam potassium) that was seized at European ports and eventually sent back to India. [157] In 2009, UNITAID issued a press release asking for the immediate release of a shipment of abacavir sulfate stating that it was, "gravely concerned for the patients who are waiting for these urgently needed medicines, which were destined for a programme implemented by the William J. Clinton Foundation on behalf of UNITAID in Nigeria. Interruption in HIV therapy is extremely dangerous and can cause resistance to the medicines." [158] The seizures resulted in Brazil and India filing a WTO dispute against the EU. [159] In 2011, the Indian government announced that it had reached

an "understanding" with the EU that border measures would apply for in-transit goods, patented in the EU, only if there is a credible belief that the goods would enter the market in the European Union. [160]

The USA's TPPA proposal on border measures requires TPPA parties to empower customs officials to seize not only medicines that are being imported but also those that are being exported or are in transit. The TRIPS Agreement, on the other hand, requires border measures only in cases of import and only in cases of trademark counterfeiting and pirated copyright goods. In terms of procedure, the TRIPS provisions have several safeguards related to border measures, including who can apply for border measures and when, and how long they would remain in effect. TRIPS also provides for safeguards for those whose goods have been seized. Not only are these safeguards missing from the USA's TPPA proposal but they are specifically overridden. For instance, providing detailed information about importers when infringement is not even proven may lead to generic producers being subject to unnecessary harassment.

The USA's proposal does not cover patents, which is positive, but it does apply to "confusingly similar" trademarks. This is a lower and different standard from trademark counterfeiting. The term "counterfeit" is defined in the TRIPS Agreement in the context of trademarks. A WTO Panel has noted that "trademark counterfeiting" is different from "trademark infringement" [126] and that this distinction must be acknowledged in measures to fight counterfeiting.

Trademark disputes between pharmaceutical companies are commonplace. One of the primary reasons is the use of a medicine's international non-proprietary 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 by companies in their brand names. It is noteworthy that among the seizures in the European Union was a shipment of the antibiotic amoxicillin (equivalent to 76 000 courses of treatment), on its way from India to Vanuatu, one of the least-developed countries. The detention took place as one of the customs officials suspected trademark infringement of GSK's brand name "Amoxil." [161]

This 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. One concern is that this may lead to the misuse of these provisions. Any hold-up at ports and customs can result in delays in the delivery of life-saving medicines, and while delays represent a commercial setback for generic companies they also put lives at risk. Médecins Sans Frontières, reacting to proposals by the European Commission to impose border measures on in-transit goods for trademark infringement has stated, "MSF has multiple supply centres in Europe that buy and store these generic medicines in-transit before they are shipped for use in the field. The Commission's proposal as it stands creates barriers that could have an impact on MSF suppliers, MSF Supply Centers and MSF operations". [162] In addition, as mentioned in Chapter 5, other provisions of the USA's TPPA proposal raise the question of whether the expanded scope of trademark protection may be used to prevent generic manufacturers from using colours and shapes of pills identical or similar to those of the originator pharmaceutical products, thereby increasing the likelihood of trademark disputes.

Under the USA's TPPA proposal, the application of border measures for the import, export and transit of confusingly similar trademarks makes it likely that generic medicines will continue to face detentions both from exporting countries and transit countries. A key feature of intellectual property rights, including trademarks, is that they are recognized under national laws and are registered in national trademark registries. Trademarks are therefore territorial in nature and what is trademarked in one country may not be in another. Given that there are no international trademarks, the issue of seizures of medicines for confusingly similar trademarks, particularly in transit, becomes complex. It is unclear how a customs official in the USA, for instance, would be able to determine whether a consignment of medicines in transit in the USA may violate trademarks registered in another country. In effect, USA trademarks will be enforced beyond the borders of the USA if such seizures are permitted.

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 legitimate, safe and effective generic medicines, rather than being destroyed, should be capable of

being donated or returned to the manufacturer. The destruction of life-saving or life-prolonging medicines should be an exception rather than the rule. The border measures under the USA's proposal also apply to small consignments. Thus, patients will be unable to import, even in small consignments, generic medicines that customs officials judge to have confusingly similar trademarks. The USA's proposal would require patients to personally travel to another country to purchase their medicines to be exempt from border measures.

Box 11. Proposed Article [X] in intellectual property chapter: summary analysis of implications of the understandings regarding certain public health measures

USA proposal, draft dated Sept. 2011

ARTICLE [X]: UNDERSTANDINGS REGARDING CERTAIN PUBLIC HEALTH MEASURES

1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).

2. The Parties have reached the following understandings regarding this Chapter:
   (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.
   (b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively, the "TRIPS/health solution"), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.
   (c) With respect to the aforementioned matters, if an amendment of the TRIPS Agreement enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the amendment.

Article X was included in the September 2011 text and contains provisions applicable to the whole proposed intellectual property chapter (i.e. patents, data exclusivity and patent linkage, trademarks and copyright, and intellectual property enforcement). The proposed Article [X] ostensibly reflects the understandings of TPPA parties on public health measures. While Article [X] borrows some of the language from the Doha Declaration on the TRIPS Agreement and Public Health, the specific formulation of the provision appears to have the effect of narrowing the scope for public health protection.

First, it should be noted that while **Article [X]** applies to the entire intellectual property chapter of the TPPA, it does not apply to other chapters of the TPPA that may raise concerns about their

impact on public health. Although **Article [X].1** affirms the commitment of TPPA parties to the Doha Declaration, a number of the TRIPS flexibilities (higher patentability standards, data protection instead of data exclusivity) are in fact overridden by the USA's proposals, while TRIPS-plus obligations are specified. Accordingly, the effect of the reaffirmation of the commitment of TPPA parties to the Doha Declaration is unclear.

Secondly, **Article [X].2(a)** uses language similar to the Doha Declaration with regard to the interpretation and application of the obligations of the intellectual property chapter in the TPPA, with some crucial differences. The first sentence, in conflating public health measures with promoting access to medicines, appears to limit the type of measures that may be taken. It appears to equate the promotion of public health only to access to medicines, whereas a much wider range of measures can be envisaged, including preventative measures (such as those related to tobacco use, for instance). The language in the Doha Declaration is broader in using the words "in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." While the second sentence of Article [X].2(a) uses the broader formulation found in the Doha Declaration, whether it is qualified by the preceding sentence may require closer scrutiny.

Thirdly, the Doha Declaration uses HIV/AIDS, TB and malaria and other epidemics as illustrative examples. Measures taken by WTO Members to promote public health reflect this interpretation which does not limit the use of TRIPS flexibilities to epidemics or specific disease areas. Thus, countries are for example applying strict patentability criteria to products in all disease areas, and some countries have issued compulsory licences for cancer and heart disease medicines. The formulation of Article [X].2(a) however raises the question whether it may limit TPPA parties to taking action only in the cases of HIV, TB, malaria or other epidemics. The first sentence is also ambiguous in terms of whether it would limit TPPA parties—when taking measures to protect public health—to situations of national emergency and extreme urgency; thus leaving out other grounds, for instance public non-commercial use that forms the basis of compulsory licenses in many developing countries. The analysis in the previous chapters also indicates that safeguards currently used by countries that are already implementing some TRIPS-plus provisions may be restricted by the USA's proposals and raises questions regarding the extent to which the understandings reflected in this Article could be used by TPPA parties to protect public health.

Moreover, the use of the phrase "do not" in the first sentence raises concerns as to whether this would be an implicit agreement by TPPA parties that TRIPS-plus provisions contained in the intellectual property chapter do not create barriers to promoting health and access to medicines, despite evidence and analysis to the contrary. It furthermore raises concerns as to whether this may have implications for the interpretation of the Doha Declaration itself. [16]

Article [X].2(b) and (c) relate to the Paragraph 6 solution. [88] Similar concerns however arise as to whether it would be possible to effectively use this solution, given the TRIPS-plus provisions in the intellectual property chapter and the narrow scope of this understanding. It may be noted that the Paragraph 6 solution itself has been seldom used and there is ongoing discussion over whether it may need modification. It is also unclear how Article [X].2(c), which talks of "adapting" the TPPA's intellectual property chapter, in view of the possible amendment to the TRIPS Agreement, would operate.

CHAPTER 7. Investment

The text proposed by the USA for the investment chapter of the TPPA was leaked and made available on the Internet in June 2012. The 52-page text is divided into two main sections: section A of the chapter spells out the definitions and obligations of the parties, while section B outlines an investor–state dispute settlement system that would provide arbitration in the event of a dispute between a party and an investor. The text demonstrates a high degree of similarity to the investment chapter in NAFTA, which has been criticized for restrictions on the regulation of corporations and for the grant of broad-ranging rights which, inter alia, permit investors to seek compensation for domestic rules that they claim undermine their investments. The text also has a number of annexes; including Annex 12-C in which the parties confirm their understanding of the rules related to expropriation.

This chapter analyses the most relevant investment provisions insofar as they impact on access to medicines and the protection of public health. The key provisions are analysed in turn, and for ease of reference the relevant provisions are reproduced in Box 12.

Box 12. Proposed text on investment

USA proposal, draft, made public on 13 June 2012

INVESTMENT

Article 12.2: Definitions

For purposes of this Chapter:

…

covered investment means, with respect to a Party, an investment in its territory of an investor of another Party in existence as of the date of entry into force of this Agreement or established, acquired, or expanded thereafter [which has been legally constituted in accordance with its laws and regulations, provided that such formalities do not materially impair the protections afforded by the Party to the investors of another Party or covered investments under this Chapter];

…

investment means every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. Forms that an investment may take include:

(a) an enterprise;
(b) shares, stock, and other forms of equity participation in an enterprise;
[

(c) bonds, debentures, [other debt instruments,] and loans [1] [but does not include a debt instrument of a Party or of a state enterprise] ;]
[
(c) debt securities and loans, as follows:
(i) a debt security of an enterprise:
(A) where the enterprise is an affiliate of the investor, or
(B) where the original maturity of the debt security is at least three years,
(ii) a loan to an enterprise[2]:
(A) where the enterprise is an affiliate of the investor, or
(B) where the original maturity of the debt security is at least three years;]
(d) futures, options and other derivatives;
(e) turnkey, construction, management, production, concession, revenue-sharing and other similar contracts;
(g) intellectual property rights [which are conferred pursuant to domestic laws of each Party];
(h) licenses, authorizations, permits and similar rights conferred pursuant to domestic law,:[3] and
(i) other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens and pledges; but investment does not mean
[
(a) claims to money that arise solely from
(i) commercial contracts for the sale of goods or services by a national enterprise in the territory of a Party to an enterprise in the territory of the other Party, or
(ii) the extension of a credit in connection with a commercial transaction, such as trade financing, other than a loan covered by subparagraph (c); and
(b)] an order or judgment entered in a judicial or administrative action.

…

investor of a non-Party means, with respect to a Party, an investor that attempts to make[7], is making, or has made an investment in the territory of that Party, that is not an investor of a Party;

investor of a Party means a Party, or a national or an enterprise of a Party, that attempts to make[8], is making, or has made an investment in the territory of another Party; [provided, however, that a natural person] who is a dual national shall be deemed to be exclusively a national of the State of his or her dominant and effective nationality;] [provided, however, that a natural person who is a national of more than one Party shall be deemed to be exclusively a national of the State of his or her dominant and effective nationality]

…

Article 12.3: Scope and Coverage [9]

1. This Chapter applies to measures adopted or maintained by a Party relating to:
   (a) investors of another Party;
   (b) covered investments; and
   (c) [with respect to Articles 12.7 (Performance Requirements) [and 12.15 (Investment and Environment)] , all investments in the territory of the Party.]

2. A Party's obligations under this [Chapter] [Section] shall apply to measures adopted or maintained by:
   (a) the central, regional, or local governments and authorities of that Party; and
   (b) [a state enterprise or other person when it exercises any regulatory, administrative, or other governmental authority delegated to it by that Party such as the authority to expropriate, grant licenses, approve commercial transactions, or impose quotas, fees, or other charges. 10][non-governmental bodies in the exercise of powers delegated by central, regional, or local governments or authorities;]

3. For greater certainty, the provisions of this Chapter do not bind any Party in relation to any act or fact that took place or any situation that ceased to exist before the date of entry into force of this Agreement.

Article *12.3bis:* Relation to Other Chapters

1. In the event of any inconsistency between this Chapter and another Chapter, the other Chapter shall prevail to the extent of the inconsistency.
2. A requirement by a Party that a service supplier of another Party post a bond or other form of financial security as a condition of the cross-border supply of a service does not of itself make this Chapter applicable to measures adopted or maintained by the Party relating to such cross-border supply of the service. This Chapter applies to measures adopted or maintained by the Party relating to the posted bond or financial security, to the extent that such bond or financial security is a covered investment.
3. This Chapter does not apply to measures adopted or maintained by a Party to the extent that they are covered by Chapter 14 (Financial Services).

Article 12.4: National Treatment

1. Each Party shall accord to investors of another Party treatment no less favourable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in its territory.
2. Each Party shall accord to covered investments treatment no less favourable than that it accords, in like circumstances, to investments in its territory of its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.
   [
   The treatment to be accorded by a Party under paragraphs 1 and 2 means, with respect to a regional level of government, treatment no less favourable than the most favourable treatment accorded, in like circumstances, by that regional level of government to investors, and to investments of investors, of the Party of which it forms a part.]

Article 12.5: Most-Favoured Nation Treatment

1. Each Party shall accord to investors of another Party treatment no less favourable than that it accords, in like circumstances, to investors of any other Party or of any non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in its territory.

2. Each Party shall accord to covered investments treatment no less favourable than that it accords, in like circumstances, to investments in its territory of investors of any other Party or of any non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.
3. For greater certainty, the treatment referred to in this Article does not encompass international dispute resolution procedures or mechanisms such as those included in Section B.

Article 12.6: Minimum Standard of Treatment[11]

I. Each Party shall accord to covered investments treatment in accordance with customary international law, including fair and equitable treatment and full protection and security.

2. For greater certainty, paragraph 1 prescribes the [applicable rules of] customary international law [minimum] standard of treatment of aliens as the [minimum] [general] standard of treatment to be afforded to covered investments. The concepts of "fair and equitable treatment" and "full protection and security" do not require treatment in addition to or beyond that which is required by that standard, and do not create additional substantive rights. The obligations in paragraph 1 to provide:
   (a) "Fair and equitable treatment" includes the obligation not to deny justice in criminal, civil, or administrative adjudicatory proceedings in accordance with the principle of due process embodied in the principal legal systems of the world; and
   (b) "Full protection and security" requires each Party to provide the level of police protection required

under customary international law.

3. A determination that there has been a breach of another provision of this Agreement, or of a separate international agreement, does not establish that there has been a breach of this Article.

…

Article 12.7: Performance Requirements

1. No Party may, in connection with the establishment, acquisition, expansion, management, conduct, operation, or sale or other disposition of an investment of an investor of a Party [or of a non-Party] in its territory, impose or enforce any requirement or enforce any commitment or undertaking:[12]
   (a) to export a given level or percentage of goods [or services];
   (b) to achieve a given level or percentage of domestic content;
   (c) to purchase, use or accord a preference to goods produced in its territory, or to purchase goods from persons in its territory;
   (d) to relate in any way the volume or value of imports to the volume or value of exports or to the amount of foreign exchange inflows associated with such investment;
   (e) to restrict sales of goods [or services] in its territory that such investment produces [or supplies] by relating such sales in any way to the volume or value of its exports or foreign exchange earnings; [
   (f) to transfer a particular technology, a production process or other proprietary knowledge to a person in its territory;] [or]
   (g) to supply exclusively from the territory of the Party the goods that such investment procedures [or the services that it supplies] to a specific regional market or to the world market [; or
   (h) (i) to purchase, use, or accord a preference to, in its territory, technology of the Party or persons of the Party[13]; or
   (ii) that prevents the purchase or use of, or the according of a preference to, in its territory, particular technology, so as to afford protection on the basis of nationality to its own investors or investments or to technology of the Party or of persons of the Party] .

2. No Party may condition the receipt or continued receipt of an advantage, in connection with the establishment, acquisition, expansion, management, conduct, operation , or sale or other disposition of an investment in its territory of an investor of a Party [or of a non-Party,] on compliance with any requirement:
   (a) to achieve a given level or percentage of domestic content;
   (b) to purchase, use, or accord a preference to goods produced in its territory, or to purchase goods from persons in its territory;
   (c) to relate in any way the volume or value of imports to the volume or value of exports or to the amount of foreign exchange inflows associated with such investment; or
   (d) to restrict sales of goods [or services] in its territory that such investment produces [or supplies] by relating such sales in any way to the volume or value of its exports or foreign exchange earnings.

3. (a) Nothing in paragraph 2 shall be construed to prevent a Party from conditioning the receipt or continued receipt of an advantage, in connection with an investment in its territory of an investor of a Party [or of a non-Party,] on compliance with a requirement to locate production, supply a service, train or employ workers, construct or expand particular facilities, or carry out research and development, in its territory.

   [
   (b) Paragraph l(f) does not apply:]
   [(b) Paragraphs l(f) and (h) do not apply:]
   (i) when a Party authorizes use of an intellectual property right in accordance with [Article 31 14 of the TRIPS Agreement] [Article __ (Intellectual Property Rights Chapter; Patents Article; Paragraph on use of the subject matter of a patent without the authorization of the right holder)] , or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement; or
   (ii) when the requirement is imposed or the commitment or undertaking is enforced by a court, administrative tribunal, or competition authority to remedy a practice determined after judicial or

administrative process to be anticompetitive under the Party's competition laws. [15]

(c) Provided that such measures are not applied in an arbitrary or unjustifiable manner, or do not constitute a disguised restriction on international trade or investment, paragraphs l(b), (c), [and] [(f)], [and (h),] and 2(a) and (b), shall not be construed to prevent a Party from adopting or maintaining environmental measures:
(i) necessary to secure compliance with laws and regulations that are not inconsistent with this Agreement;
(ii) necessary to protect human, animal, or plant life or health; or
(iii) related to the conservation of living or non-living exhaustible natural resources.]

(d) Paragraphs l(a), (b), and (c), and 2(a) and (b), do not apply to qualification requirements for goods [or services] with respect to export promotion and foreign aid programs.

[

(e) Paragraphs l(b), (c), (f), [and] (g), [and (h),] and 2(a) and (b), do not apply to government procurement.]

(f) Paragraphs 2(a) and (b) do not apply to requirements imposed by an importing Party relating to the content of the goods necessary to qualify for preferential tariffs or preferential quotas.

3bis For greater certainty, nothing in paragraph I shall be construed to prevent a Party in connection with the establishment, acquisition, expansion, management, conduct, operation or sale or other disposition of an investment of an investor of a Party [or of a non-Party] in its territory from imposing or enforcing a requirement or enforcing a commitment or undertaking to employ or train workers in its territory [provided that such employment or training does not require the transfer of a particular technology, production process, or other proprietary knowledge to a person in its territory.]

4. For greater certainty, paragraphs 1 and 2 do not apply to any commitment, undertaking, or requirement other than those set out in those paragraphs.

5. This Article does not preclude enforcement of any commitment, undertaking, or requirement between private parties, where a Party did not impose or require the commitment, undertaking, or requirement.

…

Article 12.11: Transfers [16] [17]

1. Each Party shall permit all transfers relating to a covered investment to be made freely and without delay into and out of its territory. Such transfers include:
(a) contributions to capital Footnote;
(b) profits, dividends, interest, capital gains, royalty payments, management fees, and technical assistance and other fees;
(c) proceeds from the sale of all or any part of the covered investment or from the partial or complete liquidation of the covered investment;
(d) payments made under a contract [entered into by the investor, or the covered investment] , including a loan agreement;
(e) payments made pursuant to Article 12.x (Treatment in case of Armed Conflict or Civil Strife) and Article 12.12 (Expropriation and Compensation); and
(f) payments arising out of a dispute

2. Each Party shall permit transfers relating to a covered investment to be made in a freely usable currency at the market rate of exchange prevailing and the time of transfer.
[

3. No party may require its investors to transfer, or penalize its investors that fail to transfer, the income, earnings, profits, or other amounts derived from, or attributable to, investments in the territory of another Party.]
[3bis. Each Party shall permit returns in kind relating to a covered investment to be made as authorised or specified in a written agreement between the Party and a covered investment or an investor of another Party.]

4. Notwithstanding paragraphs 1 [,] [and] 2 [and *3bis],* a Party may prevent or delay a transfer through the equitable, non-discriminatory, and good faith application of its laws relating to:
   (a) bankruptcy, insolvency, or the protection of the rights of creditors;
   (b) issuing, trading, or dealing in securities, futures , options, or derivatives;
   (c) criminal or penal offenses;
   (d) financial reporting or record keeping of transfers when necessary to assist law enforcement or financial regulatory authorities; or
   (e) ensuring compliance with orders or judgments in judicial or administrative proceedings. [
   (f) social security, public retirement, or compulsory savings schemes.
   [

5. Notwithstanding paragraph 1, a Party may restrict transfers of returns in kind in circumstances where it could otherwise restrict such transfers under this Agreement, including as set out in paragraph 4.]

Article 12.12: Expropriation and Compensation

1. No Party may expropriate or nationalize a covered investment either directly or indirectly through measures equivalent to expropriation or nationalization ("expropriation"), except:
   (a) for a public purpose [19] ;
   (b) in a non-discriminatory manner;
   (c) on payment of prompt, adequate, and effective compensation in accordance with paragraphs 2 through 4 ; and
   (d) in accordance with due process of law.

2. Compensation shall:
   (a) be paid without delay
   (b) be equivalent to the fair market value of the expropriated investment immediately before the expropriation took place ("the date of expropriation");
   (c) not reflect any change in value occurring because the intended expropriation had become known earlier; and
   (d) be fully realizable and freely transferable.

3. If the fair market value is denominated in a freely usable currency, the compensation paid shall be no less than the fair market value on the date of expropriation, plus interest at a commercially reasonable rate for that currency, accrued from the date of exposition until the date of payment.

4. If the fair market value is denominated in a currency that is not freely usable, the compensation paid-converted into the currency of payment at the market rate of exchange prevailing on the date of payment-shall be no less than:
   (a) the fair market value on the date of expropriation, converted into a freely usable currency at the market rate of exchange prevailing on that date, plus
   (b) interest, at a commercially reasonable rate for that freely usable currency, accrued from the date of expropriation until the date of payment.

5. This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement [,or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter _ (Intellectual Property Rights] .

…

Article 12.14: Denial of Benefits

1. A Party may deny the benefits of this Chapter to an investor of another Party that is an enterprise of such other Party and to investments of that investor if the enterprise:
   (a) is owned or controlled either by persons of a non-Party or of the denying Party; and
   (b) has no [substantive business operations] [substantial business activities] in the territory of any Party

other than the denying Party. [

2. A party may deny the benefits of this Chapter to an investor of another party that is an enterprise of such other Party and to investments of that investor if persons of a non-Party own or control the enterprise and the denying Party:
   (a) does not maintain diplomatic relations with the non-Party; or
   (b) adopts or maintains measures with respect to the non-Party or a person of the non-Party that prohibit transactions with the enterprise or that would be violated or circumvented if the benefits of this Chapter were accorded to the enterprise or to its investments.]

Article 12.15: Investment and Environment] [,Health Safety and Labour] [Article 12.15: Health Safety and Environmental Measures][

1. Nothing in this Chapter shall be construed to prevent a Party from adopting, maintaining or enforcing any measure otherwise consistent with this Chapter that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental [,health, safety, or labour] [,health or safety] concerns.]
   [

2. The Parties recognise that it is inappropriate to encourage investment by relaxing its health safety or environmental measures. Accordingly, a Party should not waive or otherwise derogate from or offer to waive or otherwise derogate from, such measures as an encouragement for the establishment, acquisition, expansion, or retention in its territory of an investment of an investor.]

Section B: Investor-State Dispute Settlement [20]

[Article *12.16bis:* Scope

Section B applies where there is a dispute between a Party and an investor of another Party related to a covered investment made in the territory of a Party in accordance with its laws, regulations and investment policies.]

[Section B does not apply where there is a dispute between a Party and an investor of a Party related to government procurement or the provision of a subsidy or grant.]

Article 12.17: Consultation and Negotiation

1. In the event of an investment dispute, [[between a Party and an investor of another Party concerning an alleged breach of an obligation of the former under Section A of this Chapter [which causes loss or damage to the investor or its investment]] the claimant and the respondent [shall] [should] initially seek to resolve the dispute through consultation and negotiation, which may include the use of non-binding, third-party procedures, such as good offices, conciliation and mediation. [Such consultations shall be initiated by written request for consultations delivered by the claimant to the respondent [, and shall state the nature of the dispute].

   [

2. Upon the receipt of a notice referred to in paragraph 1, the state Party may require the investor concerned to pursue any applicable domestic administrative review procedures specified by the laws and regulations of the state party, which may not exceed three months, before the submission of the claim to arbitration under Article 12.18 (Submission of a Claim to Arbitration).]

…

Article 12.18: Submission of a Claim to Arbitration

1. If an investment dispute has not been resolved within 6 months of the [receipt by the respondent of the written request for consultations:] [events giving rise to the claim:]
   (a) the claimant, on its own behalf, may submit to arbitration under this Section a claim
      (i) that the respondent has breached

(A) an obligation under section A, [
(B) an investment authorization, or
(C) an investment agreement;] and

(ii) that the claimant has incurred loss or damage by reason of, or arising out of, that breach; [and

(b) the claimant, on behalf of an enterprise of the respondent that is a juridical person that the claimant owns or controls directly or indirectly, may submit to arbitration under this Section a claim

(i) that the respondent has breached
(A) an obligation under section A,] [
(B) an investment authorization, or
(C) an investment agreement;]

[and

(ii) that the enterprise has incurred loss or damage by reason of, or arising out of, that breach,]

[provided that a claimant may submit pursuant to subparagraph (a)(i)(C) or (b)(i)(C) a claim for breach of an investment agreement only if the subject matter of the claim and the claimed damages directly relate to the covered investment that was established or acquired, or sought to be established or acquired, in reliance on the relevant investment agreement] .

…

Article 12.28: Awards

1. Where a tribunal makes a final award against a respondent, the tribunal may award, separately or in combination; only:
   (a) monetary damages and any applicable interest; and
   (b) restitution of property, in which case the award shall provide that the respondent may pay monetary damages and any applicable interest in lieu of restitution.

   A tribunal may also award costs and [attorney's] fees in accordance with this Section and the applicable arbitration rules.

2. Subject to paragraph 1, where a claim is submitted to an arbitration under Article 12.18(1)(b):
   (a) an award of restitution of property shall provide that restitution be made to the enterprise;
   (b) an award of monetary damages and any applicable interest shall provide that the sum be paid to the enterprise; and
   (c) the award shall provide that it is made without prejudice to any right that any person may have {under applicable domestic law} in the relief {provided in the award}.]

3. A tribunal may not award punitive damages.

4. An award made by a tribunal shall have no binding force except between the disputing parties and in respect of the particular case.

5. Subject to paragraph 6 and the applicable review procedure for an interim award, a disputing party shall abide by and comply with an award without delay.

6. A disputing party may not seek enforcement of a final award until:
   (a) in the case of a final award made under the ICSID Convention,
      (i) 120 days have elapsed from the date the award was rendered and no disputing party has requested revision or annulment of the award; or
      (ii) revision or annulment proceedings have been completed; and
   (b) in the case of a final award under the ICSID Additional Facility Rules, the UNCITRAL Arbitration Rules, or the rules selected pursuant to Article 12.18(3)(d),
      (i) 90 days have elapsed from the date the award was rendered and no disputing party has commenced a proceeding to revise, set aside, or annul the award; or
      (ii) a court has dismissed or allowed an application to revise, set aside, or annul the award and there is no further appeal.

7. Each Party shall provide for the enforcement of an award in its territory.

8. If the respondent fails to abide by or comply with a final award, on delivery of a request by the Party of the claimant, a panel shall be established under Article_ (Dispute Settlement Chapter; Establishment of an Arbitral Tribunal Article).] [The requesting Party may seek in such proceedings:
   (a) a determination that the failure to abide by or comply with the final award is inconsistent with the obligations of this Agreement; and
   (b) in accordance with Article _ (Dispute Settlement Chapter; Initial Report Article), a recommendation that the respondent abide by or comply with the final award.]

9. A disputing party may seek enforcement of an arbitration award under the [ICSID Convention], the New York Convention [,or the Inter-American Convention] [regardless of whether proceedings have been taken under paragraph 8.]

10. A claim that is submitted to arbitration under this section shall be considered to arise out of a commercial relationship or transaction for purposes of Article I of the New York Convention [and Article I of the Inter-American Convention].

11. The assumption of expenses incurred by the disputing parties in the arbitration shall be established:
   (a) by the arbitration institution to which the dispute has been submitted, in accordance with its rules of procedure for arbitration proceedings; or
   (b) in accordance with the rules of procedure for arbitration proceedings agreed by the disputing parties, where applicable.]

[11. Subject to paragraph 12:
   (a) the costs of arbitration shall be borne equally by the disputing parties unless the tribunal decides otherwise; and
   (b) the prevailing ICSID rate for arbitrators shall apply.

12. The disputing parties may establish rules relating to expenses incurred by the tribunal, including arbitrator's remuneration.]

---

[7] For greater certainty, the Parties understand that an investor "attempts to make" an investment when that investor has taken concrete action or actions to make an investment, such as channeling resources or capital in order to set up a business, or applying for permits or licenses.

[8] For greater certainty, the Parties understand that an investor "attempts to make" an investment when that investor has taken concrete action or actions to make an investment, such as channeling resources or capital in order to set up a business, or applying for permits or licenses.

[[9] For greater certainty this chapter is subject to and shall be interpreted in accordance with Annexes 12-A through 12-XX.]

[[10] For greater certainty, government authority that has been delegated includes a legislative grant, and a government order, directive or other action transferring to the state enterprise or other person, or authorizing the exercise by the state enterprise or other person of, governmental authority.]

[12] For greater certainty, a condition for the receipt or continued receipt of an advantage referred to in paragraph 2 does not constitute a "requirement" or a "commitment or undertaking" for the purposes of paragraph 1.

[[13] For the purposes of this Article, the term "technology of the Party or of persons of the Party" includes technology that is owned by the Party or persons of the Part, and technology for which the Party holds, or persons of the Party hold, an executive license.]

[[14] The reference to "Article 31" includes footnote 7 to article 31.]

[[15] The Parties recognize that a patent does not necessarily confer market power.]

[[16]For greater certainty, Article 12.11 is subject to Annex 12-1.)

[[17]For greater certainty, Annex 12-A (Temporary Safeguard Measures) applies to this Article.]

For greater certainty, contributions to capital for the purposes of this Article, include the initial contribution

[[20] Section B does not apply to Australia or an investor of Australia. Notwithstanding any provision of this Agreement, Australia does not consent to the submission of a claim to arbitration under this Section.]

7.1 Analysis of provisions

The investment chapter starts with **Article 12.2** which defines the terms used in the chapter. Key terms include "investment", "investor" and "covered investment". "Investment" is defined broadly, going well beyond the "bricks and mortar" definition of property and covering any asset owned or controlled directly or indirectly by an investor, whose characteristics include a "commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk". The definition also includes a non-exhaustive list of the forms such investments may take, including intellectual property rights, licences and permits, as well as debt securities and loans, futures, options and other derivatives. The effect of such a broad definition of "investment" would be that parties will be required to protect all such forms of investment within their territories; failure to do so would lay them open to the risk of a dispute by the affected investor (see the discussion below of section B on the investor–state dispute settlement mechanism). Intellectual property rights are specified as a form of investment under Article 12.2(g), and this covers all forms of intellectual property rights. Article 12.2(g) also includes, in brackets, the words "which are conferred pursuant to domestic laws of each Party". It is unclear whether the text in brackets would significantly affect the definition, since intellectual property rights are in fact conferred under domestic laws.

The definition of "investor" is similarly expansive—merely "attempting" to make an investment by a concrete action suffices to qualify one as an investor. Thus, as clarified in footnotes 7 and 8 in **Article 12.2,** the mere act of "channeling resources or capital in order to set up a business" or "applying for permits and licenses" would be sufficient to make one an investor. The definition of "covered investment" further suggests that the rights conferred on investors would extend to investments that already existed before the TPPA would go into legal effect, given that the definition covers "an investment in its territory of an investor of another Party in existence as of the date of entry into force of this Agreement".

Article 12.4 and **Article 12.5** incorporate the principles of national treatment and most-favoured nation treatment with regard the provisions in the investment chapter. These provisions require that domestic policies and laws must apply equally to foreign investors as they would to domestic firms. The potential effect of the application of national treatment and most-favoured nation treatment is that investors may claim that government policies and laws are in violation of the "national treatment" and "most-favoured nation treatment" rules—for instance, where the investor experiences a higher burden in complying with such policies and law, despite the fact that this was an unintended consequence of the application of the policy or law. [163]

Article 12.6 requires TPPA signatories to provide investments with the minimum standard of treatment that is in accordance with customary international law, including fair and equitable treatment (FET). Article 12.6(2) further explains that the FET standard includes the obligation not to deny justice in criminal, civil or administrative adjudicatory proceedings. This standard, however, has been variously interpreted by arbitration tribunals. Although the text links FET with "denials of justice", tribunals have also found that government policy-making or law-making that merely differed from what investors' argued were their "reasonable expectations" amounted, in fact, to FET violations. In the pharmaceutical context, it has been argued that companies may well claim reasonable expectations about future profits arising from intellectual property filings, and thus changes to intellectual property laws or standards that impact their expectations of profits could be interpreted as a FET violation. [164] In this context, the use of TRIPS flexibilities could also be interpreted as contradicting the minimum standards of treatment. The provisions of Article 12.12 on expropriation specifically exempt the use of compulsory licences from being considered an expropriation, but this does raise the question of whether the use of compulsory licences and the other TRIPS flexibilities could run afoul of the FET and minimum treatment standards in Article 12.6. It remains to be seen how these provisions will be interpreted if they are adopted, in which case the negotiating history of the TPPA could be an important factor.

Although the heading of **Article 12.7** is "Performance Requirements", the provision is, in effect, a restriction on the TPPA parties from imposing or enforcing certain requirements on foreign investors. Governments would not be permitted to require that foreign investors carrying out business in their territories comply with certain requirements related to the level or volume of imports and exports, or to the percentage

of domestic content in the goods they manufacture. In addition, Article 12.17 also provides that governments may not require investors to transfer or to purchase a specific technology. This is important, since performance requirements are often used by both developed and developing countries as a means of channelling or directing investment in priority sectors and increasing the gains from foreign direct investment.

Article 12.11 of the investment chapter requires that governments "shall permit all transfers relating to a covered investment to be made freely and without delay into and out of its territory". This would have the effect of restricting governments' ability to regulate the flow of capital, and would prevent the use of capital controls or financial transaction taxes. [163]

Article 12.12 addresses the issues of expropriation and compensation. The provision prohibits parties to the TPPA from expropriating or nationalizing a covered investment, except in cases where the expropriation is for a public purpose, is carried out in a non-discriminatory manner, is in accordance with due process of law and on payment of prompt, adequate and effective compensation. While governments' obligation to compensate for expropriation typically applies to the taking physical property (e.g. expropriation of land or buildings to enable road construction), the provision in Article 12.12 would appear to extend to investors the right to demand compensation for "indirect" expropriation, which has been interpreted to mean reduction in the value of a foreign investment due to regulations and other government actions. [163] The provision essentially requires governments to pay compensation equivalent to a fair market value, plus interest, for any government actions that have been found to reduce the value of an investment.

It is noted above that the definition of investment also covers intellectual property rights. The use of compulsory licensing to limit the exclusive rights of a patent or other intellectual property could be seen as an expropriation, but Article 12.12(5) appears to provide an exemption for the use of compulsory licensing—by providing that the provisions related to expropriation and compensation do "not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement". Article 12.12(5) goes on to state that the provisions on expropriation and compensation also do not apply to the revocation, limitation or creation of intellectual property rights, provided they are consistent with the provisions of the intellectual property chapter. While this appears to afford some safeguard against claims of expropriation by investors, the broad scope of protection afforded by the provisions of the intellectual property chapter (discussed in Chapter 3 above) would limit the scope of this safeguard. Moreover, this part of the provision remains in brackets, indicating that there is as yet no agreement on its inclusion as part of the negotiating text.

Article 12.14 addresses the issue of denial of benefit whereby a party to the TPPA may deny an investor the benefits of the chapter where "the enterprise is owned or controlled by persons of a non-Party". The aim of this provision is to discourage "free-riding" and "treaty shopping" by multinational firms to derive benefits from the TPPA. [163] This safeguard against investors manipulating their nationalities would be important since the provisions in the investment chapter seem to allow companies from non-TPPA countries that have been incorporated in a TPPA signatory country to also benefit from the TPPA provisions. The usefulness of this denial of benefit safeguard may well be undermined by the text of Article 12.14(1)(b) that appears to require only that a company has "substantial business activities" in a TPPA country—a phrase which could be interpreted to mean a significantly reduced presence rather than having actual business activities or making significant commitment of capital in the host country.

Article 12.15 on issues relating to environment, health and safety (the title of the article remains bracketed with different options) appears to limit the ability of governments to exempt themselves from the rules of the TPPA in order to safeguard environmental, health and consumer protection policies. Such general exceptions have typically been included in trade agreements, including WTO agreements, where Article XX of the General Agreement on Tariffs and Trade (GATT 1994) allows WTO members to deviate from substantive obligations in pursuit of environmental and natural resource protection and social and cultural policies. GATT Article XX(b), for example, permits WTO members to adopt policy measures that are inconsistent with GATT disciplines but which are necessary to protect human, animal or plant life or health. The provision in Article 12.15 of the USA's TPPA proposal suggests that parties may take appropriate measures to ensure that investment activity is undertaken in a manner sensitive to environmental,

health and/or safety concerns, yet stipulates that such measures have to be consistent with the provisions in the investment chapter. Such a formulation may effectively limit the effect of the safeguards and raises the obvious concern that Parties would be prevented from taking the necessary action to address environmental, health or safety issues.

Section B of the text sets out the proposed Investor-State Dispute Settlement (ISDS) procedure under the TPPA. While the provisions in Section A define the rights of investors and the protection they can expect under the TPPA, the provisions in Section B spell out the recourse available to investors where they allege a breach of their rights. The ISDS procedure in Section B provides investors the right to submit a claim for arbitration under the International Centre for Settlement of Investment Disputes (ICSID), or the United Nations Commission on International Trade Law (UNCITRAL) or any other arbitration institution. This right to arbitration effectively allows foreign investors to pursue claims against the host country outside of the country's judicial system. This is potentially the most controversial section of the investment chapter, because the ISDS system would enable foreign investors and corporations to sue governments directly for non-compliance with the provisions in the investment chapter.

Section B thus lays down the procedure for initiating an arbitration process, including specifying the time frames for submission of claims and the rules relating to the selection of arbitrators. Prior to initiation of the arbitration process, **Article 12.17** provides for a period of consultation and negotiation during which the parties to an investment dispute are required to seek to resolve the dispute through the use of "non-binding, third party procedures such as good offices, conciliation and mediation". While host governments can require the investor to pursue administrative review procedures under its national laws, Article 12.17 allows only three months for the completion of such a process. Where a period of six months has elapsed without resolution of the investment dispute, **Article 12.18** permits the claimant in the dispute to submit a claim for arbitration. **Article 12.28** provides that the arbitration tribunal may make awards both in the form of monetary damages, including applicable interest, and/or in the form of property restitution.

Negotiations on the text of the investment chapter are believed to be still ongoing, but Australia has already objected to the provisions contained in Section B. A footnote in Section B (footnote 20) notes Australia's objection to the effect that Australia will not be subject to the provisions related to the ISDS.

7.2 Implications for public health and access to medicines

In terms of the investment chapter's potential impact on public health, three main areas of concern are highlighted for consideration.

First, the provisions in section A 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. These obligations will have the probable effect of significantly restricting a government's ability to regulate how companies operate within its national borders, which may then have an impact on the promotion of access to medicines and the protection of public health in general. A number of illustrations can be provided to demonstrate these potential effects.

The limitation on "performance requirements" can prevent governments from imposing conditions on the conduct of business of foreign investors, even when the conditions are imposed in the interests of protecting public health and promoting access to medicines. For instance, it may be a contravention of the provisions of Article 12.7 if a government were to require that a foreign pharmaceutical company provide (whether through import or production) a minimum quantity of active pharmaceutical ingredients, even if this was in the interests of guaranteeing an adequate supply of such ingredients for the continued production of essential medicines in the country. This restriction on performance requirements raises concerns, particularly in light of the trend of acquisitions of domestic pharmaceutical companies by multinational pharmaceutical companies. The host government may be prevented from requiring the domestic producer, once acquired by a foreign investor, to continue to produce the essential medicine products locally. India, for example, has recently adopted such a requirement for brown-field investments in its pharmaceutical sector.

The series of current disputes in tobacco regulation also demonstrates the implications of broad definitions of "investment" and the obligation to protect investors and their investments. Attempts by various countries, both developed and developing, to regulate tobacco packaging have met with aggressive legal action. The legal suits launched by the tobacco company Philip Morris International against Uruguay and more recently Australia have been based on the provisions in investment treaties that contain broad definitions of investment and permit the use of investor-state dispute settlement mechanisms. In the tobacco cases, Philip Morris has claimed that rules requiring health warnings or plain packaging for tobacco products amount to an infringement of its trademarks and that, since intellectual property rights are included in the definition of "investment", such rules have adversely affected the company's investments and/or its rights as investor. [165]

Secondly, the proposed investment chapter combines strong investors' rights and a broad scope of protection with an ISDS mechanism, which provides the "teeth" for enforcement of obligations. The ISDS mechanism thus allows corporations to challenge government measures if they deem that these measures are likely to cause harm to their rights as investors, and their investments or profits—even if the measures were put in place to protect the public's interests and welfare.

As already noted above, intellectual property rights are defined as investments within the investment chapter of the TPPA, thus implying that a government measure that affects the intellectual property holdings of investors may be considered an "expropriation" or a withholding of "fair and equitable treatment". The disputes over tobacco packaging regulations focus on the investor's claim that its trademarks have been infringed. In the context of access to medicines, defining investment as including intellectual property rights would raise concerns about the ability of governments to implement and use the range of TRIPS flexibilities, many of which could be seen as limitations or restrictions of the exclusive rights granted under a patent. Although Article 12.12(5) states that the use of compulsory licensing does not constitute an expropriation where the compulsory licence is granted "in accordance with the TRIPS Agreement", this may still leave room for investor corporations to challenge the compulsory licence using the ISDS on the grounds that it does not comply with TRIPS. [164] Article 12.12(5) also has text, in brackets, specifying that "the revocation, limitation, or creation of intellectual property rights" would not be considered expropriation when consistent with the intellectual property chapter of the TPPA. Even if this text were to be accepted, this exemption might be of only limited effect since the proposed text of the intellectual property chapter of the TPPA leaves little room for revocation or limitation of intellectual property rights (see the discussion in Chapters 3, 4 and 5 of this report).

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. However, the ISDS would allow for the possibility that an investor could sue a government on the grounds that the use of compulsory licensing (or another TRIPS flexibility) is in violation of both the provisions of the investment chapter (because of adverse effects on investment) and the provisions of the TRIPS Agreement. [164] Such a course of action would effectively create a TRIPS-plus or WTO-plus forum in which corporations could challenge governments on the implementation of the TRIPS Agreement on the grounds of its effect on investors' rights.

As noted above, Australia has formally stated that it objects to the ISDS provisions, as indicated in a footnote to section B of the investment chapter. This is consistent with Australia's position in its negotiations on the Australia-USA FTA (AUSFTA) where the final agreement also excluded the ISDS mechanism. This decision might be seen as prescient, given the current challenge under an Australia-Hong Kong bilateral investment treaty by Philip Morris International against the plain packaging tobacco laws in Australia. It is still unclear if the other negotiating parties have agreed to the ISDS mechanism in the TPPA, but a final agreement that excludes only Australia from ISDS would result in differential treatment for the parties to the TPPA.

It is also difficult to justify allowing foreign investors the right to pursue claims against a government outside of its judicial system—particularly where many of the TPPA negotiating partners have strong domestic legal systems. Australia, Singapore and New Zealand are highly ranked by the World Bank with regard to anti-corruption measures, transparency and adherence to rule of law. [163] In contrast, it is not

clear whether private arbitration tribunals would meet the standards of transparency, consistency or due process common to countries' domestic legal systems. The key objective of such tribunals is economic expediency rather than the appropriate balancing of rights and interests.

The cumulative effect of the provisions in the investment chapter may be to prevent or restrict not just the promulgation of pro-health policies and regulations, but also regulatory or legal reform for a broad range of social and environmental aims. As discussed already, the extensive rights extended to investors and the accompanying ISDS provide a legal framework by which corporations may challenge any government measure that may have an impact on their business operations, profits or even expectations of profits.

Yet another concern is that the ISDS mechanism can result in multiple cases of investment arbitration. The increasing trend towards FTAs and bilateral investment treaties with an ISDS mechanism can give rise to the problem of treaty-shopping, wherein investors may choose the options that provide them with the most strategic advantage. Thus, an investor can choose to litigate in the domestic courts under one agreement, whereas another investor may choose to use investment arbitration under another FTA. Australia, for example, currently faces that situation with Philip Morris International suing under the Australia-Hong Kong bilateral investment treaty and British American Tobacco suing in Australia's domestic courts. [166, 167]

A key lesson that can be learned from the rising numbers of investor-state disputes with exorbitant compensation awards is that they may have a "chilling effect" on government regulations. Regardless of the robustness of the legal basis of investor challenges, the risk of legal suits on the interpretations of strong investor rights, coupled with the ability of private international arbitration tribunals to award large compensation amounts, may now cause governments to be cautious when making policy or law that affects investor rights. This situation can expose governments to vast liabilities, since investor-state tribunals can have enormous discretion in awarding compensation amounts, which is a serious concern for developing countries with limited resources, particularly where this may mean the diversion of budgetary resources from meeting public interest and public health needs in the country. There is a trend towards increased compensation amounts in investor-state disputes. In a case under NAFTA, the investor sued for US$ 14 billion in compensation. Under a bilateral investment treaty, an investor claimed the amount of US$ 33 billion in compensation. [168] Even where outcomes are in their favour, such legal challenges would amount to a significant drain on the governments' resources. For example, the average legal costs incurred by governments are between US$ 1 and 2 million; the Government of the Czech Republic reportedly spent US$ 10 million defending two claims. [169]

Finally, private arbitration panels are not obliged to take into account the constitutional obligations of governments or even human rights considerations in their decision-making.

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 under NAFTA. In Canada, Eli Lilly's patent on a drug for attention deficit hyperactivity disorder—Strattera—had been revoked on grounds of failure to prove the "utility" of the patented drug, as required under Canada's patent law. The revocation paved the way for generic manufacturers in Canada to produce generic equivalents of Strattra.[60] Opting not to appeal in Canada, Eli Lilly instead initiated formal proceedings under NAFTA in November 2012.

Eli Lilly claims that the patent revocation 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 revocation discriminated against Eli Lilly in favour of generic firms, in violation of Canada's national treatment obligations under NAFTA. Under NAFTA, foreign investors are to be accorded treatment that is "no less favourable" than that afforded to domestic corporations "in like circumstances". According to Eli Lilly, "(T)he measures in issue de facto discriminate against Lilly, a U.S. investor, when

60 The patent was due to expire in 2016.

compared to domestic investors, by requiring the Strattera patent (which was filed on the basis of an international application) to meet elevated and additional standards for utility and disclosure that are not required by the laws of the United States of America, the European Union, or the harmonized PCT [Patent Cooperation Treaty] rules". Third, Eli Lilly alleges that the patent revocation amounted to an expropriation of property rights. The company argues that "the judicial decisions invalidating the Strattera patent are illegal from the perspective of international law", alleging violation of the WTO TRIPS Agreement, NAFTA's intellectual property rules, the Patent Cooperation Treaty and the Paris Convention for the Protection of Intellectual Property. [170]

In September 2013, Eli Lilly submitted a Notice of Arbitration against Canada alleging that Canada violated its NAFTA intellectual property obligations. Along with its claims related to the Strattera patent, Eli Lilly has added a further similar claim related to the patent of another product, Zypreza. 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". For these alleged violations, Eli Lilly is demanding compensation of 500 million Canadian dollars. [171]

It remains to be seen whether and how this dispute will proceed. While it is not within the scope of this paper to analyse the merits of Eli Lilly's claims, the dispute demonstrates the risks of providing extensive protection of investor rights and of using investor-state dispute systems.

CHAPTER 8. Pharmaceutical Pricing, and Financing & Reimbursement of Medicines

One of the TPPA texts is the Annex on "Transparency and procedural fairness for healthcare technologies" (healthcare transparency annex). This document is reportedly annexed to the transparency chapter of the TPPA (which is not currently in the public domain).

The text proposed by the USA in the healthcare transparency annex would require TPPA signatories' to comply with obligations relating to pharmaceutical pricing and reimbursement schemes. Provisions related to the operation of pharmaceutical pricing and reimbursement schemes were, thus far, found only in the KORUS FTA and the AUSFTA. Analysis of the text indicates that the healthcare transparency annex of the TPPA is modelled on text in these FTAs. The inclusion of this issue in the TPPA negotiations breaks new ground because, if it is adopted, the TPPA would be the first FTA in which a standard governing the operation of domestic pharmaceutical price policies in developing countries is established.

This chapter analyses the provisions in the healthcare transparency annex in terms of their impact on access to medicines and the protection of public health. Relevant provisions are reproduced in Box 13.

Box 13. Proposed text on transparency and procedural fairness

USA proposal, draft dated 22 June 2011

TRANSPARENCY AND PROCEDURAL FAIRNESS FOR HEALTHCARE TECHNOLOGIES

PARAGRAPH X.1: AGREED PRINCIPLES

The Parties share a commitment to promoting the development of and facilitating access to high quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their nationals. In pursuing these objectives, the Parties affirm the importance of:

(a) adequate access to high-quality pharmaceutical products and medical devices in providing high-quality health care;

(b) high-quality patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;

(c) sound economic incentives and the operation of competitive markets, or the adoption or maintenance by a Party of procedures that appropriately value objectively demonstrated therapeutic significance of high quality patented and generic pharmaceutical products and medical devices, for the efficient development of and access to such products and devices;

(d) promoting innovation and timely and affordable access to safe and effective pharmaceutical products and medical devices through transparent, expeditious and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy;
(e) ethical practices by manufacturers and suppliers of pharmaceutical products and medical devices and by health care providers on a global basis in order to achieve open, transparent, accountable, and reasonable health care decision-making; and
(f) cooperation among the Parties to improve the availability of safe, effective, high-quality pharmaceutical products and medical devices through transparent, expeditious and accountable procedures, without regard to the origin of the products or devices.

PARAGRAPH X.2: TRANSPARENCY RELATED TO HEALTHCARE TECHNOLOGIES

1. Each Party shall comply with Articles [XX.2.] (Transparency-Publication) with respect to any matter related to the reimbursement for pharmaceutical products or medical devices.

2. To the extent possible, each Party shall allow reasonable time between publication of final regulations of general application at the central level of government respecting any matter related to the reimbursement for pharmaceutical products or medical devices and the effective date of such regulations.

3. Each Party shall ensure that all measures of general application at the central level of government respecting any matter related to reimbursement for pharmaceutical products or medical devices are administered in a reasonable, objective, consistent, non-discriminatory, and impartial manner.

PARAGRAPH X.3: PROCEDURAL FAIRNESS RELATED TO HEALTHCARE TECHNOLOGIES

To the extent that health care authorities of a Party's central level of government maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government[1], a Party shall:

(a) ensure that consideration of all formal applications for the approval of pharmaceutical products or medical devices for reimbursement or for setting the amount of reimbursement for such products is completed within a reasonable, specified period;
(b) disclose to applicants within a reasonable, specified period all procedural rules, methodologies, principles, criteria (including those used, if any, to determine comparator products), and guidelines used to determine the eligibility for, and amount of, reimbursement for pharmaceutical products or medical devices;
(c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the decision-making process related to reimbursement for pharmaceutical products or medical devices;
(d) ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market-derived prices in the Party's territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue;
(e) where a Party provides for a determination of the reimbursement amount on a basis other than competitive market-derived prices in that territory, that Party shall permit a manufacturer of the pharmaceutical product or medical device in question, before or after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product or device based on evidence the manufacturer provides on the product's superior safety, efficacy or quality as compared with comparator products;
(f) establish procedures that allow a manufacturer of a pharmaceutical product or medical device to apply for reimbursement for additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy;
(g) within a reasonable, specified period, provide detailed written information to applicants regarding the basis for recommendation or determination relating to their applications for reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic

studies upon which the Party has relied;

(h) make available to the public written information regarding its recommendations and determinations relating to the reimbursement of pharmaceutical products or medical devices, subject to any requirements under the Party's law to protect information considered to be confidential;

(i) make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices; and

(k) make publicly available the membership list of all committees involved in determinations related to the reimbursement of pharmaceutical products or medical devices.

PARAGRAPH X.4: DISSEMINATION OF INFORMATION TO HEALTH PROFESSIONALS AND CONSUMERS

Each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, information that is truthful and not misleading regarding its pharmaceutical products that are approved for sale in the Party's territory, provided that the information includes a balance of risks and benefits and is limited to indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceutical products.

…

PARAGRAPH X.7: DEFINTIONS

For purpose of this Chapter:

health care authorities of a Party's central level of government means entities that are part of or have been established by a Party's central level of government to operate or administer its health care programs;

health care programs operated by a Party's central level of government means health care programs in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies;[2] and

pharmaceutical product or medical device means a pharmaceutical, biologic, medical device, or diagnostic product.

[2] [Negotiator's Note: Clarifying footnote regarding scope of application, such as with respect to central versus regional level of government healthcare programs.]

8.1 Analysis of provisions

The text of the healthcare transparency annex is short; it is only five pages long, with a total of seven paragraphs. The text begins with a statement of **Agreed Principles** in Paragraph X.1, which are a re-statement of the principles found in the KORUS FTA. The principles espouse a commitment to promoting the development of, and facilitating access to, high-quality patented and generic pharmaceutical products and medical devices. Although both patented and generic pharmaceuticals are mentioned, the principles refer chiefly to the promotion of "access" and "availability". The concept of affordability is referred to only once in the principles. [16] In the context of pharmaceutical reimbursement schemes, one would expect that a key concern would be the promotion of affordable access to pharmaceuticals and not merely the availability of the products themselves.

In Paragraph X.2 on **Transparency related to healthcare technologies**, TPPA parties are required to comply with a number of obligations on any matter related to pharmaceutical reimbursement schemes, including the requirement to allow for "reasonable time" between the publication of regulations and the effective date of the regulations. Another requirement is that "all measures" related to pharmaceutical reimbursement should be administered in a "reasonable, objective, consistent, non-discriminatory and impartial" manner. There is, however, no definition of these concepts in the text (although there is a placeholder in Paragraph X.7 for additional definitions). What is meant in this context thus remains unclear, giving rise

to the concern that this uncertainty will invite the use of costly and time-consuming legal challenges to define them. In the context of the operation of pharmaceutical reimbursement schemes, it also raises the question of whether the typical method of choosing medicines for a national formulary based on multiple factors, including price and availability, would in fact pass the test set out in the provision. [16]

During the AUSFTA negotiations—in the face of Australia's refusal to dismantle its Pharmaceutical Benefits Scheme (PBS)—Australia and the USA eventually agreed to a series of consultation and transparency obligations to be incorporated into the PBS which was designed to afford pharmaceutical manufacturers an opportunity to make their case for inclusion of their products in the PBS formulary. [172] The USA has also expressed concern that the practices and procedures of New Zealand's Pharmaceutical Management Agency (PHARMAC), which maintains the national formulary for medicines that the government purchases for its national health service, put "innovative pharmaceutical products" (often made in the USA) at a disadvantage to older generic products. New Zealand has reportedly signalled its opposition to changes to the PHARMAC system in the absence of "reciprocal" concessions by the USA in relation to its drug pricing or reimbursement programmes, such as Medicaid. [172]

Addressing **Procedural Fairness**, Paragraph X.3 sets out a number of procedural requirements in relation to the operation of pharmaceutical reimbursement schemes. The requirements aim ostensibly to promote procedural transparency—for example, that consideration of applications for approval of pharmaceutical products shall be completed within a "reasonable, specified period", or that all methodologies used to negotiate drug prices shall be disclosed within a similar "reasonable, specified period". There is concern, however, that the provisions can be used to regulate the processes by which governments determine pharmaceutical reimbursement prices, thus restricting the role of governments to regulators rather than as actors or negotiators within the market. The requirement, in Paragraph X.3(c), to provide notice and allow opportunities for comment during the reimbursement decision-making process may also prevent health authorities from effectively using negotiation rather than regulation to set drug prices. [16]

Paragraph X.3(d) relates to the means of determining the reimbursement amount for pharmaceuticals. The paragraph requires that parties to the TPPA ensure that there is a transparent and verifiable basis for such determination consisting of either "competitive market-driven prices in the Party's territory" or other benchmarks that "appropriately recognize the value" of the products. In the first part of the provision, it is unclear how the "competitive market-driven prices" should be determined since this is not defined. [173] It also bears pointing out that this approach is not followed in the USA's Medicaid programmes, which are able to obtain discounts of up to 50% off the list price for pharmaceuticals by virtue of their increased purchasing power. [16] The Medicaid programmes are, in fact, specifically carved out under the KORUS FTA. The risk is that the provision could be interpreted as discouraging or preventing the use of benefits from economies of scale, such as from pooled procurement. In addition, the phrase "in the Party's territory", which has not been included in previous FTAs, could also be interpreted as restricting use of the common practice of using international reference prices to determine reasonable reimbursement rates, with the effect of locking in high prices and raising low prices. [174] Limiting the use of reference pricing is likely to restrict the ability of governments to establish effective price determination systems and to use cost-effectiveness assessments to set prices to enable affordable access to new health technologies.

The second part of Article X.3(d) suggests that, where countries do not set reimbursement prices at "competitive market-derived prices", they must then provide for alternative methods that "appropriately recognize the value of the patented or generic pharmaceutical products". It is difficult to see how this provision would be implemented—difficulties would lie in determining the competitive market-derived prices or the value of the patented product, since in the case of a patented product there would likely be a monopoly situation. Within a monopoly market for an essential good, particularly in countries with high income inequality, the market price would be excessively high. There would also be no objective measure of the "value" of a patented product. [174]

The provisions in Paragraph X.3(g), (h) and (i) require that governments provide written reasons for every decision [(g) and (h)] and then allow for an "independent appeal" of any reimbursement decision (i), presumably based on the substantive restrictions on reimbursement programmes defined in Paragraph

X.2(d). These provisions are likely to increase pharmaceutical company negotiating power to exact higher prices from governments through threats of litigation. It has also been noted that the requirement under Paragraph X.3(k) to make public the membership list of the committees involved in reimbursement decisions might invite the possibility of pressure or other forms of inducement being put on the individual members. [174]

In Paragraph X.4, the provisions on **Dissemination of information to health professionals and consumers** would appear to require countries to permit direct-to-consumer and direct-to-physician marketing efforts over the Internet. This is an issue currently subject to regulatory investigations in the USA, which is one of only two countries in the world (the other is New Zealand) that allows for direct-to-consumer advertising of prescription medicines. Attempts to relax restrictions on such advertising in Canada and the European Union, for example, have been unsuccessful due to concerns over the reliability of information provided by pharmaceutical companies, as well as the implications for pharmaceutical consumption and pharmaceutical expenditure. [174, 175]

Paragraph X.5 on **Ethical business practices** contains no text at present. It remains to be seen whether text proposed for the paragraph will provide a level of consumer protection that is sufficient to counter the current emphasis on the promotion of corporate concerns.

The definition section in Paragraph X.7 includes definitions of health authorities and health-care programmes operated by a TPPA party's central level of government, to which the provisions of the annex apply. A bracketed footnote in Paragraph X.7 indicates that a clarification will be made to the effect that the provisions in the healthcare transparency annex will apply to central-level government programmes as opposed to regional ones. In previous United States FTAs that have included provisions related to pharmaceutical reimbursement, the USA has claimed that those provisions do not apply to programmes in the USA on the grounds that the largest federal drug reimbursement programme in the country—included in the Medicaid programme—is administered by state governments (although it was created by federal statute). [16] The provisions in the AUSFTA and KORUS FTA were applicable to the "central" level of government; the KORUS FTA also included a footnote (footnote 3) which states: "(F)or greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program". [176] It would appear, therefore, that in a country without a similarly distinct federal-state dichotomy as applies in the USA, all government programmes may be subject to the provisions of the healthcare transparency annex.

8.2 Implications for public health and access to medicines

Public health advocates have criticized the text of the healthcare transparency annex. They allege that the text represents an attempt by multinational pharmaceutical companies to counter pharmaceutical cost-containment efforts and that the real intention is to limit the efficacy of price controls in public health programmes rather than to promote transparency within them.[61] The text seems to be based on pharmaceutical pricing-related chapters in United States FTAs with Australia (the AUSFTA) and the Republic of Korea (the KORUS FTA).

In Australia, critics have expressed the view that the AUSFTA provisions would "potentially aggregate to create a regulatory environment more attuned to encouraging private investment and profit-making". [177] Their concern is that the provisions in the AUSFTA are more than mere procedural adjustments and that their implementation may lead to a move away from scientific cost-effectiveness evaluation of pharmaceuticals by Australia's Pharmaceutical Benefits Advisory Committee (PBAC). [177] The AUSFTA requires that "Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list". While there is no appeal provided under the AUSFTA for a medicine that is listed at a lower-than-desired price, the KORUS FTA goes further by including a process for appeal against pricing decisions. The impact of the KORUS FTA remains to be seen but in the USA there is increasing concern that the proposed restrictions on pharmaceuti-

61 See, for instance, Public Citizen [173].

cal reimbursement programmes will prevent real reform of the USA's system that lacks the more effective medicine pricing controls such as those of Australia, Canada and New Zealand which are aimed at increasing both affordability and access. [176] The concern is that such market-derived pricing rules will lock in high pharmaceutical prices in the USA, where prices are already among the highest in the world. [174] Despite the "carve outs" for existing programmes in the USA, during the Chicago Round of TPPA negotiations members of the United States Congress urged that the TPPA should not "undermine either US or other member countries' current or prospective, non-discriminatory drug reimbursement policies and programs (e.g. Medicare, Medicaid, the VA, and other programs)." [178]

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 the healthcare transparency annex would have the effect of prescribing the type of system that governments would be permitted to establish, instead 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.

CHAPTER 9. Conclusion

As the negotiating parties prepare for the next round of negotiations, the stakes are high—not only for the negotiating parties but also for the populations in the countries represented by the negotiating governments.

For the negotiating governments, the TPPA represents an attempt to conclude a broad-ranging trade agreement between some of the world's most robust economies in the hope of injecting growth within the current uncertain economic climate. The Office of the United States Trade Representative (USTR), for example, has described the TPPA as a means to "boost US economic growth and support the creation and retention of high-quality jobs by increasing American exports". [179] The TPPA negotiations are also seen as potentially defining trade policy for the Obama administration. [172] Similarly, the Australian government hopes that the TPPA will increase market access for its goods and services, as well as allowing Australian exporters to take advantage of regional rules of origin "to tap into global supply chains".[62] A completed TPPA is also seen as a valuable conduit towards greater Asia-Pacific regional economic integration; thus, countries regard it to be in their economic and political interests to participate in shaping it.

The USTR describes the TPPA as "a high-standard agreement that addresses new and emerging trade issues and 21st-century challenges". [179] The TPPA negotiating parties have stated their intention for the TPPA to be a "living agreement" that will remain relevant to emerging issues as well as allowing its membership to expand. Thus, even after the completion of negotiations, the TPPA will remain open for other countries to join. This feature of the TPPA architecture could very well represent the end of the current generation of trade agreements as there may no longer be any need for new ones. In future, rather than negotiating new agreements bilaterally, countries would possibly simply be asked to join the TPPA. This provides the justification for the negotiating parties to aspire to the highest standard in the breadth and scope of the agreement.

These highest-standard ambitions are also the reason why the stakes are high for the populations in the TPPA countries and beyond. Learning from the experience of addressing the impact of the TRIPS Agreement, as well as the various other international and regional agreements that have sought to impose TRIPS-plus obligations, civil society and health advocates have raised vociferous criticism of the proposed TPPA provisions. Although in the WTO developing countries succeeded in pressing for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health—which confirmed the right of countries to adopt public-health-friendly and access-sensitive provisions in complying with the TRIPS Agreement's obligations—the TRIPS-plus provisions in subsequent FTAs limited the effectiveness of the Doha Declaration and undermined flexibilities in TRIPS. The concern is that TRIPS-plus requirements will prevent countries from formulating and implementing an intellectual property regime that can calibrate between two intertwined challenges: ensuring affordable access to health products and technologies on the one hand and, on the other, facilitating continued research and development, technology transfer and innovation to meet the public health needs, particularly of developing countries. The inability to design

62 See the website of Australia's Department of Foreign Affairs and Trade at: http://www.dfat.gov.au/fta/tpp/ (accessed 30 January 2014).

such a regime is likely to have adverse implications for public health and access to medicines (and other health commodities).

Summary of analysis

In the preceding chapters of this report, an attempt has been made to analyse some of the intellectual property provisions that reportedly are proposed in the context of the TPPA negotiations, as well as some non-intellectual property proposals that are likely to have an impact on access to medicines and public health. The key points and findings are summarized below.

In Chapter 3, analysis of the TPPA proposals of the USA relating to patent protection points to a number of concerns. Through substantive provisions that seek to lower the standards of patentability, to limit exclusions from patentability and weaken disclosure requirements, as well as procedural requirements that remove the important safeguard of pre-grant opposition proceedings, the TPPA proposals may have the general effect of permitting the grant of a greater number of patents on medicines and medical technologies. This will in turn create more barriers to generic production. Moreover, the lower standards may also lead to an increase in the number of patents that are considered weak, but the presumption of validity, proposed in the context of enforcement measures (discussed in Chapter 6), would make it harder to challenge such patents. The result could well be that weaker patents become stronger barriers to competition.

In addition, the proposed TPPA proposals would require an extension of the minimum 20-year patent term to compensate for delays in the drug regulatory approval and patent granting processes, which would further delay generic entry. The TPPA proposals furthermore seem to place limits on the use of the Bolar provision, with the possible effect of requiring generic manufacturers to manufacture their medicines locally in every country for which they seek early marketing approval.

The issue of marketing approval is discussed further in Chapter 4, which analyses the proposals requiring data exclusivity and patent linkage. Data exclusivity creates exclusive rights on medicines that function separately from patents (and would also apply to medicines that are not under patent) but have the same impact in terms of delaying generic entry, leading to higher prices for governments and patients. Now widely accepted as a TRIPS-plus measure, data exclusivity can limit the effectiveness of key TRIPS-flexibilities. The proposals go further by limiting the policy space available to countries to alleviate the adverse effects of data exclusivity on access to medicines. For example, some countries limit the scope of data exclusivity to new chemical entities, to undisclosed information, or require that the exclusivity period starts from first registration in a developed country. These options would not be available for TPPA parties. Chapter 4 also raises concerns over patent linkage provisions which link marketing approval to the patent status of medicines, providing patent holders with a TRIPS-plus avenue for the enforcement of their patents.

Chapter 5 examines the potential implications of the TPPA proposals related to copyright and trademarks. The analysis cautions that the proposed broad-ranging trademark protection may have implications in the pharmaceutical context. The concern would be whether this broad protection would prevent generic producers from using names, colours, shapes and/or scents similar to those of the originator pharmaceutical product. Such a broad scope of trademark protection could prevent or hamper the manufacture and sale of generic versions of medicines. Although the implications of TRIPS-plus copyright provisions for access to medicines and public health is unclear at this stage, it is only prudent to examine the ways in which such expanded copyright protection could lend itself to hampering or preventing the production and sale of generic medicines, including the potential impact of the prohibition against parallel imports of copyrighted materials on the parallel importation of patented medicines containing copyrighted material in the packaging.

Chapter 6 analyses the USA's proposals related to intellectual property enforcement in courts and through law enforcement and customs authorities. While enforcement is an area where WTO members enjoy considerable flexibility under the TRIPS Agreement, the USA's proposals are far more restrictive. Rebuttable presumptions for patent validity in civil proceedings and for trademarks in civil and criminal proceedings

may make patent and trademark challenges as well as defences in infringement proceedings more difficult. The analysis reveals an expansion in the range of orders that can be requested from courts including ex-parte orders and provisional measures (such as injunctions and even the seizure of medicines) and the potential of heightened financial damages. It also raises concerns for governments, treatment providers and third parties in the production and supply chain. The ability of the judiciary to balance public interest with enforcement measures is likely to be restricted. In addition, the USA proposes expanded border measures in the case of copyright and trademarks, i.e., the granting of authority to customs officials to seize not only medicines intended for import but also medicines that are exported or are in transit. This is not only an expansion of the TRIPS Agreement requirements, which merely oblige enforcement of border measures in relation to imports, but it also goes against the basic tenet of territoriality of intellectual property rights. The expansion of border measures to confusingly similar trademarks is likely to mean that generic medicines may continue to be seized both by exporting countries and transit countries. This, coupled with the broad scope of proposed trademark provisions that may seek protection of various non-functional aspects of medicines such as pill colour and shape, as discussed in Chapter 4, is likely to increase the disputes on these issues and in consequence hinder access to affordable generic medicines. [180] Furthermore, the TPPA proposals appear to favour the destruction of infringing goods affected by border measures as well as those involved in civil and criminal proceedings. In the case of legitimate, safe and effective generic medicines, this raises ethical questions.

Apart from the intellectual property-related issues, the TPPA texts also cover areas that will impact on access to medicines and the protection of public health in general. Thus, Chapter 7 examines the potential impact on public health of the proposed TPPA provisions on investment, highlighting three areas of concern. First, the expansive rights and privileges accorded foreign investors, with the corresponding obligation on governments to provide protection of such rights is likely to have the effect of significantly restricting governments' ability to regulate how companies operate within their national borders. Current disputes in tobacco regulation demonstrate the potential public health implications that may arise from broad definitions of "investment" and the obligation to protect investors and their investments. Second, the investment provisions combine strong investors' rights and high protection standards with a dispute settlement mechanism (the ISDS), which would provide the "teeth" for enforcement of those obligations. It is also noted that intellectual property rights are included in the definition of "investment", which would mean that a government measure affecting the intellectual property holdings of investors may be considered an "expropriation" or the withholding of "fair and equitable treatment". This raises concern about the ability of governments to implement and use the range of TRIPS flexibilities, many of which could be seen as limitations or restrictions of the exclusive rights granted under a patent. Although the proposals provide that compulsory licensing does not constitute an expropriation where such a licence is granted "in accordance with the TRIPS Agreement", this still leaves room for investor corporations to challenge the compulsory licence using the ISDS on the grounds that it does not comply with TRIPS. A third concern is that the extensive investor rights and the accompanying ISDS provide a legal framework by which corporations may challenge any government measure, thus engendering a "chilling effect" on government regulation and action. It is notable that Australia has already explicitly stated its objection within the investment chapter to the arbitration under the ISDS.

Finally, Chapter 8 analyses the impact of the proposed text of the healthcare transparency annex that requires compliance of TPPA signatories with obligations relating to pharmaceutical pricing and reimbursement schemes. This text breaks new ground; the TPPA would be the first FTA to include rules for the operation of domestic pharmaceutical price policies in developing countries. The 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, agreement to the provisions in the healthcare transparency annex would have the effect of prescribing the type of system that governments would be permitted to establish, limiting a government's options for choosing or designing the system that is most suitable in the national context.

The analysis of the TPPA negotiating texts in the preceding chapters illustrates that TRIPS-plus provisions in previous FTAs have been used as the basis for the TPPA negotiating texts but it is also clear that the TPPA proposals go beyond the previous FTAs and require significantly higher standards of protection for intellectual property rights. It is also worth emphasizing that the TPPA proposals that give cause for concern are not confined only to the provisions relating to intellectual property rights protection and enforcement; the proposals related to investment and to pharmaceutical pricing and reimbursement will also have an impact on the ability of governments to regulate and design systems that focus on promoting affordable access to medicines and the protection of public health in general. In many ways, these proposals would reinforce the effect of the TRIPS-plus provisions through limitations on governments' ability to regulate. This particular feature would make the TPPA a new generation of trade agreement in that it would not only impose TRIPS-plus provisions but would also incorporate provisions and measures not previously found in trade agreements; these would further restrict and limit policy space to the detriment of access to medicines.

Commentators from across a broad spectrum have already 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 many provisions in the USA's TPPA proposal will result in a policy environment where trade and commercial interests will take precedence over the protection of health and human development.

In this regard, policy-makers and negotiators should also bear in mind the obligations and responsibilities of governments. While the promotion of trade and economic growth is certainly important, it must be balanced against the need to ensure 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 towards meeting treatment goals in developing countries, but the implementation of proposed TPPA provisions may well undermine these gains and prevent further progress. The strategies and tools that have been so successfully employed to enhance competition and reduce the prices of ARV medicines—to the extent that universal access to such medicines is finally a reachable aim—may no longer be available. At a time when financing needs are 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 multifari-

ous; 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.

A number of efforts have been made to develop tools and methodologies for conducting such impact assessments. Among these is a methodology jointly developed by WHO, the World Bank Institute and the International Centre for Trade and Sustainable Development (ICTSD). [181] Designed to estimate the impact of policy interventions on the basis of the extent to which they alter the period of market exclusivity of pharmaceutical products, the methodology attempts to quantify the possible costs of TRIPS-plus standards that are commonly introduced in FTAs in terms of increased prices of pharmaceuticals and the consequent increase in public expenditure for health programmes or in out-of-pocket costs for patients. This or similar methodologies could be used for empirical analysis to strengthen capacity in developing countries for evaluating the public health impact of TRIPS-plus provisions and to enable informed decision-making. The adoption of an effective and credible methodological framework to provide an evidence base for decision-making should thus be a priority for governments involved in or contemplating an FTA.

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.

Except for the limited coverage of competition issues within the TRIPS Agreement—wherein Article 40 permits WTO members to adopt measures to prevent anti-competitive practices in intellectual property licensing agreements and Article 31 permits the grant of compulsory licences to remedy anti-competitive behaviour[63]—there are no international rules governing the ability of countries to regulate anti-competitive effects arising from intellectual property rights protection. Countries therefore have considerable leeway in designing and adopting a broad pro-competition approach to balance intellectual property rights. [182]

63 See also Article 8(2) of the TRIPS Agreement.

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 is disproportionately large. There is a need to monitor and analyse trends in pharmaceutical patenting in order to respond to growing concerns[64] 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 ICTSD, and the United Nations Conference on Trade and Development (UNCTAD) [185] 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.

64 See, for instance, Jaffe and Lerner [183] and FTC [184].

REFERENCES

1. UNITAID concerned over future of medicines access after EU-INDIA FTA. Geneva: UNITAID; 3 March 2011 (http://www.unitaid.eu/resources/news/320-unitaid-concerned-over-future-of-medicines-access-after-eu-india-fta, accessed 29 January 2014).

2. Global strategy and plan of action on public health, innovation and intellectual property, Article 5.2(b). Sixty-first World Health Assembly, May 2008, Resolution WHA61.21 (http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, accessed 29 January 2014).

3. The potential impact of free trade agreements on public health. UNDP, UNAIDS Issue Brief, May 2012. Geneva: Joint United Nations Programme on HIV/AIDS; 2012 (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2349_Issue_Brief_Free-Trade-Agreements_en.pdf, accessed 29 January 2014).

4. Global Commission on HIV and the Law, Risks, Rights, and Health. New York, NY: United Nations Development Programme; 2012 (http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf, accessed 29 January 2014).

5. UNITAID Statement on Dutch Confiscation of Medicines Shipment. Geneva: UNITAID; 2009 (http://www.unitaid.eu/Resources/News/156-Unitaid-Statement-On-Dutch-Confiscation-Of-Medicines-Shipment, accessed 29 January 2014).

6. Letter from over 130 members of the House of Representatives to USTR seeking for greater transparency in the TPP, 27 June 2012 (http://infojustice.org/archives/26456, accessed 29 January 2014).

7. A New Trade Policy for America, 2007 (http://infojustice.org/wp-content/uploads/2012/03/New-Trade-policy-house-version.pdf, accessed 29 January 2014). The New Trade Policy provisions were thereafter codified into revised United States FTAs with Colombia and Peru.

8. Basis for request that the Special Rapporteur of the United Nations on the right of everyone to the enjoyment of the highest attainable standard of health issue an urgent appeal with regard to the Trans-Pacific Partnership Agreement Negotiation, 22 March 2011. Washington DC: Knowledge Ecology International 2011 (http://keionline.org/sites/default/files/r2h_anand_grover_tpp_22march2011.pdf, accessed 29 January 2014).

9. Minutes of meeting. Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/M/67. Geneva: World Trade Organization; 2011.

10. Minutes of meeting. Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/M/69. Geneva: World Trade Organization; 2012.

11. Correa CM. Integrating public health concerns into patent legislation in developing countries. Geneva: South Centre; 2000 (http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf, accessed 29 January 2014).

12. WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Doha, November 14, 2001. Geneva: World Trade Organization; 2001 (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, accessed 29 January 2014).

13. Australia-US Free Trade Agreement, 2004, Article 17.9. Barton, ACT: Department of Foreign Affairs and Trade (http://www.dfat.gov.au/fta/ausfta/final-text/chapter_17.html, accessed 29 January 2014).

14. Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605, (U.S.1990).

15. IPR remains toughest TPP area. Key pieces of U.S. proposal still missing. Inside U.S. Trade, 31 August 2012 (http://insidetrade.com/Inside-Trade-General/Public-Content-World-Trade-Online/ipr-remains-toughest-tpp-area-key-pieces-of-us-proposal-still-missing/menu-id-896.html, accessed 29 January 2014).

16. Flynn S, Kaminski M, Baker B, Koo J. Public interest analysis of the US TPP proposal for an IP chapter. Washington, DC: Program on Information Justice and Intellectual Property (PIJIP), American University Washington College of Law; 2011 (http://infojustice.org/wp-content/uploads/2011/12/TPP-Analysis-12062011.pdf, accessed 29 January 2014).

17. 2165: The Best Mode Requirement (R-9). Alexandria, VA: United States Patent and Trademark Office (http://www.uspto.gov/web/offices/pac/mpep/s2165.html, accessed 29 January 2014).

18. Gunderman R, Hammond J. The America Invents Act—Best Mode Requirement. The Rochester Engineer, August 2012:14-15 (http://www.patenteducation.com/images/AIA_Best_Mode_LM_website.pdf, accessed 29 January 2014).

19. Good practice guide: improving access to treatment by utilizing public health flexibilities in the WTO TRIPS Agreement. New York, NY: United Nations Development Programme; 2010 (http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf, accessed 29 January 2014).

20. Integrating intellectual property rights and development policy. Report of the Commission on Intellectual Property Rights. London: Commission on Intellectual Property Rights; 2002 (http://www.iprcommission.org/papers/text/final_report/reporthtmfinal.htm, accessed 8 March 2014).

21. Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva: World Health Organization; 2006 (http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, accessed 29 January 2014).

22. Frequently Asked Questions. Geneva: World Intellectual Property Organization (http://www.wipo.int/patentscope/en/patents_faq.html, accessed 29 January 2014).

23. What is Meant by Priority Date. Geneva. World Intellectual Property Organization (http://www.wipo.int/sme/en/faq/pat_faqs_q9.html, accessed 29 January 2014).

24. Analysis of the responses to the UK consultation on grace periods for patents. London: The Patent Office; 2002 (http://www.ipo.gov.uk/response-grace.pdf, accessed 29 January 2014).

25. World Intellectual Property Organization. Standing committee on the law of patents. Ninth session. Report. Geneva: World Intellectual Property Organization, 12-16 May 2003.

26. Norrgard K. Diagnostic testing and the ethics of patenting DNA. Nature Education 2008;1(1):84 (http://www.nature.com/scitable/topicpage/diagnostic-testing-and-the-ethics-of-patenting-709, accessed 8 March 2014).

27. United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development. Resource book on TRIPS and development: an authoritative and practical guide to the TRIPS Agreement. New York, NY: Cambridge University Press; 2005 (http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm, accessed 29 January 2014).

28. Musungu SF, Oh C. The use of TRIPS flexibilities by developing countries: can they promote access to medicines? Commission on Intellectual Property Rights, Innovation and Public Health, Study 4C, p. 66 (http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf, accessed 29 January 2014).

29. Correa CM, ed. A guide to pharmaceutical patents, Volume I. Geneva: South Centre; 2008.

30. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

31. Mojibi A. An empirical study of the effect of Ksr V. Teleflex on the federal circuit's patent validity jurisprudence. Albany Law J Sci Technol. 20(3):559 (http://www.albanylawjournal.org/Documents/Articles/20.3.559-Mojibi.pdf, accessed 3 February 2014).

32. Association for Molecular Pathology et al. *v.* Myriad Genetics, Inc., et al. Supreme Court of the United States, No. 12–398. Decided June 13, 2013, (http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf, accessed 22 February 2014).

33. An Act Providing For Cheaper And Quality Medicines, Amending For The Purpose Republic Act No. 8293 Or The Intellectual Property Code, Republic Act No. 6675 Or The Generics Act Of 1988, And Republic Act No. 5921 Or The Pharmacy Law, And For Other Purposes, Republic Act 9502, 2008.

34. Joint Resolution 118/2012, 546/2012 and 107/2012 (Ministry of Industry, Ministry of Health and National Industrial Property Institute). Adoption of guidelines for patentability examination of patent applications for chemical and pharmaceutical inventions, Buenos Aires, 5/2/2012. Argentine Official Gazette, 8 May 2012 (Unofficial translation, on file with the authors).

35. Novartis AG v. Union of India and others. Civil Appeal Nos. 2706-2716 OF 2013, Supreme Court of India, 1 April 2013 (http://supremecourtofindia.nic.in/outtoday/patent.pdf, accessed 29 January 2014).

36. Baker B. US's "new" proposed TPP intellectual property chapter still requires patents on medicinal forms with "distinguishing features". Infojustice, 7 February 2014 (http://infojustice.org/archives/32152, accessed 22 February 2014).

37. United Nations Development Programme. Human development report 1999. New York, NY: Oxford University Press; 1999.

38. Globalization, TRIPS and access to pharmaceuticals. WHO Policy Perspectives on Medicines, No. 003. Geneva: World Health Organization; 2001 (http://apps.who.int/medicinedocs/en/d/Js2240e/3.html, accessed 29 January 2014).

39. Christie AF, Dent C, McIntyre P, Wilson L, Studdert DM. Patents Associated with High-Cost Drugs in Australia. PLoS ONE 2013;8(4). doi:10.1371/journal.pone.0060812.

40. Changing patterns of pharmaceutical innovation. Washington, DC: National Institute for Health Care Management Foundation; 2002 (http://www.nihcm.org/pdf/innovations.pdf, accessed 29 January 2014).

41. Kapczynski A, Park C, Sampat B. Polymorphs and prodrugs and salts (Oh My!): an empirical analysis of "secondary" pharmaceutical patents. PLOS One 2012;7(12) (http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470, accessed 22 February 2014).

42. Bouchard RA, Hawkins RW, Clark R, Hagtvedt R, Sawani J. Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals. 8 Nw. J. Tech. & Intell.Prop. 174 (2010) (http://scholarlycommons.law.northwestern.edu/njtip/vol8/iss2/2, accessed 8 March 2014).

43. Maleewong U, Kessomboon N, Kijtiwatchakul K, Eksaengsri A, Atsawintarangkun S. "Evergreening" patent applications of pharmaceuticals in Thailand and its impact. Health Systems Research Institute, Thailand, 2013 (Report in Thai, unofficial English translation of abstract on file with authors).

44. Moir HVJ, Palombi L. Patents and trademarks: empirical evidence on 'evergreening' from Australia. December 2013 (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2365786, accessed 8 March 2014).

45. Gopakumar KM, Landscape of pharmaceutical patent applications in India: Implications for access to medicines. In: Chaudhari et al. Five years into the product patent regime: India's response. New York: UNDP, 2010 (http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf, accessed 29 January 2014).

46. Pharmaceutical sector inquiry—final report. Directorate General for Competition, European Commission; 2009 (http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf, accessed 29 January 2014).

47. Patent landscape report on Ritonavir. Geneva: World Intellectual Property Organization; 2011 (http://www.wipo.int/export/sites/www/freepublications/en/patents/946/wipo_pub_946.pdf, accessed 29 January 2014).

48. Amin T, Kesselheim AS. Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades. Health Affairs 2012;31(10):2286-2294.

49. Stanbrook MB. Limiting "evergreening" for a better balance of drug innovation incentives. CMAJ. 2013;185(11). doi:10.1503/cmaj.130992.

50. Thorpe P. Study on the Implementation of the TRIPS Agreement by Developing Countries. Commission on Intellectual Property Rights, Study Paper 7 (http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf, accessed 8 March 2014).

51. Monographs on Selected Medicinal Plants. Volume 4. Geneva: World Health Organization, 2009.

52. Traditional Knowledge. In: Integrating intellectual property rights and development policy. Report of the Commission on Intellectual Property Rights. London: Commission on Intellectual Property Rights; 2002.

53. Murray F. The oncomouse that roared: resistance & accomodation to patenting in academic science. March 2006.

54. Ho MW, Traavik T. Why We Should Reject Biotech Patents from TRIPS. ISIS-TWN Report Feb. 2001.

55. Dutfield G. DNA patenting: implications for public health research. Bull World Health Organ. 2006;84:388-392.

56. BRCA1 and BRCA2: Cancer Risk and Genetic Testing. National Cancer Institute. National Institutes of Health, January 2014.

57. Brief of *Amici Curiae*. Information Society project at Yale Law School. Scholars in support of the petition. The Association for Molecular Pathology et al v. Myriad Genetics et al. Supreme Court of the United States (http://yaleisp.org/wp-content/uploads/2012/01/31253-BRCA-AMICUS-BRIEF-FINAL.pdf, accessed 8 March 2014).

58. Association For Molecular Pathology et al. *v*. Myriad Genetics, Inc., et al. Supreme Court of the United States, No. 12–398. Decided June 13, 2013, (http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf, accessed 29 January 2014).

59. Khor M. WHO admits patents taken on avian flu virus. Third World Network, 16 May 2007.

60. Indonesia to resume sharing H5N1 avian influenza virus samples following a WHO meeting in Jakarta. News Release. World Health Organization, 27 March 2007.

61. Landmark agreement improves global preparedness for influenza pandemics. News Release. World Health Organization, 17 April 2011.

62. Medical procedure patents in the TPP: a comparative perspective on the highly unpopular U.S. proposal. Public Citizen. November 2013 (http://www.citizen.org/documents/MedicalProceduresMemo_final%20draft.pdf, accessed 29 January 2014).

63. Teva Canada Ltd v. Pfizer Inc. 2012 SCC 60 (Supreme Court of Canada; date of decision: 8 November 2012).

64. Proposal submitted by the delegation of South Africa on behalf of the African Group and the Development Agenda Group. Standing Committee on the Law of Patents. Sixteenth Session. Geneva: World Intellectual Property Organization. May 2011.

65. Correa CM. Beyond 'patent quality': basic concepts of the patent system need to be reviewed. South Bulletin. 2012;62.

66. Correa CM. Pharmaceutical innovation, incremental patenting and compulsory licensing. Geneva: South Centre; 2011 (p. 12) (http://www.southcentre.int/wp-content/uploads/2013/05/RP41_Pharmaceutical-Innovation_EN.pdf, accessed 8 March 2014).

67. Drahos P. "Trust me"—patent offices in developing countries. Working paper. Canberra: Australian National University Centre for Governance of Knowledge and Development; 2007 (http://www.anu.edu.au/fellows/pdrahos/pdfs/2007Drahostrustmessrn.pdf, accessed 29 January 2014).

68. Using the TRIPS Flexibilities to Improve Access to Treatment. UNAIDS, UNDP and WHO Policy Brief, 2011 (http://content.undp.org/go/cms-service/stream/asset/?asset_id=3259398, accessed 22 February 2014).

69. Kolkata group against GSK's AIDS patent, Business Standard (India), 8 August 2006 (http://www.business-standard.com/article/companies/kolkata-group-against-gsk-s-aids-patent-106080801074_1.html, accessed 8 March 2014).

70. HIV drug fears: Hundreds rally at Glaxo office. The Nation (Thailand), 8 Aug 2006 (http://nationmultimedia.com/2006/08/08/headlines/headlines_30010593.php, accessed 8 March 2014).

71. GSK patents and patent applications for Combivir. GlaxoSmithKline media release, 10 August 2006.

72. Patent rejection for the antiretroviral Tenofovir. Working Group on Intellectual Property of REBRIP, of which Conectas is a member, celebrates the decision. Conectas, 7 August 2009.

73. Alcorn K. Brazil rejects tenofovir patent. London, NAM aidsmap, 2008.

74. Hidddleston S. Brazil AIDS group opposes drug patent in India. The Hindu (India), 27 June 2008.

75. Open letter from global academics in support of proposal to amend Brazil's patent law to take advantage of TRIPS-compliant flexibilities, 10 July 2013.

76. Reiffen D, Ward MR. Generic Drug Industry Dynamics. February, 2002 (http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-industry-dynamics/industrydynamicsreiffenwp_0.pdf, accessed 8 March 2014).

77. MSF. Untangling the web of antiretroviral price reductions. 16th edition, July 2013.

78. US FTA may cost drug industry $1.2 billion. Malaysia: Third World Network; 2006 (http://www.twnside.org.sg/title2/FTAs/info.service/fta.info.service036.htm. accessed 29 January 2014).

79. Impact of the EU-Andean trade agreements on access to medicines in Peru. Amsterdam: Health Action International; 2009 (http://www.haiweb.org/11112009/11Nov2009ReportIFARMAImpactStudyPeru(EN).pdf, accessed 8 March 2014).

80. Canada—patent protection of pharmaceutical products, Dispute DS 114, Panel report, 7 April 2000 (http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm, accessed 29 January 2014).

81. Obligations and exceptions. Fact Sheet: TRIPS and Pharmaceutical Patents. Geneva: World Trade Organization. (http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm, accessed 8 March 2014).

82. Grover A. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.A/HRC/11/12. 31 March 2009 (http://www.ifhhro.org/images/stories/ifhhro/documents_UN_special_rapporteur/3_4_1_en.pdf, accessed 8 March 2014).

83. Misati E,Adachi K. The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda. Policy Brief Number 7. Geneva: United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development. March 2010. (http://ictsd.org/downloads/2011/12/the-research-and-experimentation-exceptions-in-patent-law-jurisdictional-variations-and-the-wipo-development-agenda.pdf, accessed 8 March 2014).

84. Eli Lilly and Company v. Medtronic Inc., 872 F.2d 402. United States Court of Appeals, Federal Circuit. Date of Decision: March 29, 1989.

85. Dangers for Access to Medicines in the Trans-Pacific Free Trade Agreement: Comparative Analysis of the U.S. Intellectual Property Proposal and Malaysian Law. Washington, DC: Public Citizen. 2011 (http://www.citizen.org/malaysia-Trans-Pacific-FTA-chart, accessed 8 March 2014).

86. 2004 Special 301 Report, p. 4. United States Trade Representative; 2004. (http://www.ustr.gov/archive/assets/Document_Library/Reports_Publications/2004/2004_Special_301/asset_upload_file16_5995.pdf, accessed 22 February 2014).

87. Data exclusivity and other "TRIPS-plus" measures. WHO SEARO, WPRO Access to medicines briefing note, March 2006. Delhi: World Health Organization Regional Office for South-East Asia; 2006 (http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf, accessed 22 February 2014).

88. Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003. WT/L/540 and Corr.1, 1 September 2003. Geneva: World Trade Organization, 2001 (http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, accessed 22 February 2014).

89. Trade agreements and access to medicines under the Bush administration. Washington, DC: United States House of Representatives Committee on Government Reform—Minority Staff, Special Investigations Division; 2005.

90. Statement made by Teresa Stanek Rea. Hearing on international intellectual property enforcement: Protecting patents, trade secrets and market access. Subcommittee on Intellectual Property, Competition, and the Internet, 27 June 2012 (http://judiciary.house.gov/_files/hearings/Hearings%202012/Rea%2006272012.pdf, accessed 3 February 2014).

91. Health savings. Budget of the US Government, fiscal year 2013. Office of Management and Budget, Executive Office of the President of the United States (http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/budget.pdf, accessed 29 January 2014).

92. USPTO on the Hill: supporting U.S. innovators in global markets. Guest blog by United States Patent and Trademark Office Deputy Director Teresa Stanek Rea, 2 July 2012 (http://www.uspto.gov/blog/director/entry/uspto_on_the_hill_supporting, accessed 29 January 2014).

93. Timmermans K. Monopolizing Clinical Trial Data: Implications and Trends. PLoS Med. 2007; 4(2). doi:10.1371/journal.pmed.0040002.

94. R v. Licensing Authority ex p Smith Kline (H.L.) [1990] 1 A.C. 64.

95. Shaffer ER, Brenner JE. A trade agreement's impact on access to generic drugs. San Francisco, CA: Center for Policy Analysis on Trade and Health; 2009 (http://www.cpath.org/sitebuildercontent/sitebuilderfiles/cpathhaonline8-25-09.pdf, accessed 29 January 2014).

96. All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines. Oxford: Oxfam; 2007 (http://www.oxfam.org/en/policy/bp102_jordan_us_fta, accessed 3 February 2014).

97. Clift C. Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals. In: Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. Krattiger A, Mahoney RT, Nelsen L, et al) MIHR, Oxford, 2007.

98. Abbott RB, Bader R, Bajjali L, El Samen TA, Obeidat T, Sboul H et al. The price of medicines in Jordan: the cost of trade-based intellectual property. Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector. 2012;9:75-85.

99. Kessomboon N et al. Impact on access to medicines from TRIPS-plus: a case study of Thai-US FTA. South Asian Journal of Tropical Medicine and Public Health, 2010;41(3) (http://www.tm.mahidol.ac.th/seameo/2010-41-3/23-4785.pdf, accessed 29 January 2014).

100. Kesselheim AS, Solomon DH. Incentive for drug development—the curious case of colchicine N Engl J Med. 2010; 362:2045-2047 (http://www.nejm.org/doi/full/10.1056/NEJMp1003126, accessed 29 January 2014).

101. Baker B. Ending Drug Registration Apartheid—Taming Data Exclusivity and Patent/Registration Linkage. 34 American Journal of Law & Medicine, 303-344, 2008.

102. Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations. Health Canada, 11 October 2011.

103. Regulations Amending the Food and Drugs Regulations (Data Protection), P.C. 2006-1076. 5 October 2006 (Canada).

104. Research and development to meet health needs in developing countries: strengthening global financing and coordination. Report of the Consultative Expert Working Group on Research and

Development: Financing and Coordination. Geneva: World Health Organization; 2012 (http://www.who.int/phi/CEWG_Report_5_April_2012.pdf, accessed 29 January 2014).

105. Generic drug entry prior to patent expiration: an FTC study. United States Federal Trade Commission, July 2002 (http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study, accessed 3 February 2014).

106. 59 Fed. Reg. § 50338, 50343 (Oct. 3, 1994).

107. Patented Medicines (Notice of Compliance) Regulations SOR/93-133 (Canada).

108. Generic drug sector study. Ottawa: Competition Bureau; 2007.

109. Government of Canada. Canada Gazette Part II. Regulations amending the Patented Medicines (Notice of Compliance) Regulations 2006, 140 (21): 1503-1525. See also AstraZenecaCanada Inc. v. Canada (Minister of Health), 2006 SCC 49.

110. Faunce T, Lexchin J. 'Linkage' pharmaceutical evergreening in Canada and Australia. Aust New Zealand Health Policy, 2007; 4:8.

111. Commission calls on Italy to comply with EU rules on marketing authorisation of generic drugs. Press release. European Commission, 2012 (http://europa.eu/rapid/press-release_IP-12-48_en.htm?locale=en, accessed 29 January 2012).

112. IP Rights v. Public Health. London: Managing Intellectual Property; May 2006 (http://www.managingip.com/Article/627276/intellectual property-rights-v-public-health.html, accessed 29 January 2014).

113. Gerhardsen TIS. Pfizer fights IP flexibilities in the Philippines. Intellectual Property Watch, 30 April 2006. (http://www.ip-watch.org/2006/04/30/pfizer-fights-ip-flexibilities-in-the-philippines, accessed 8 March 2014).

114. Don't deal with Pfizer, consumers urge state companies. Manila Standard, 16 February 16, 2008 (http://www.pitc.gov.ph/news/02202008 dont deal w pfizer.html, accessed 8 March 2014).

115. Lawyers Collective. Supreme Court of India dismisses Bayer's plea for patent linkage. 2 December 2010.

116. Access to medicines at risk across the globe: what to watch out for in free trade agreements with the United States. Geneva: Médecins Sans Frontières; 2004.

117. Statement of the Honorable Henry A. Waxman, a Representative in Congress from the State of California, House Committee on Ways and Means, 10 June 2003 (http://www.gpo.gov/fdsys/pkg/CHRG-108hhrg91677/html/CHRG-108hhrg91677.htm, accessed 29 January 2014).

118. eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839-1841 (U.S. 2006).

119. F. Hoffman-La Roche Ltd. & Anr. v. Cipla Ltd, Delhi High Court, I.A 642/2008 in CS (OS) 89/2008, Date of decision: 19 March 2008.

120. Kesselheim AS, Misono AS, Shrank WH, Greene JA, Doherty M, Avorn J, Choudhry NK. Variations in pill appearance of antiepileptic drugs and the risk of non-adherence. JAMA Intern Med. 2013;173(3):202-208 (http://archinte.jamanetwork.com/article.aspx?articleid=1487287, accessed 29 January 2014).

121. Drug seizures in Frankfurt spark fears of EU-wide pattern. IP-Watch, 5 June 2009 (http://www.ip-watch.org/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern, accessed 29 January 2014).

122. Concerns voiced at TRIPS Council over seizure of drugs. Third World Network Info Service on Health Issues, 16 June 2009 (http://www.twnside.org.sg/title2/health.info/2009/twnhealthinfo20090602.htm, accessed 29 January 2014).

123. Flynn S, Kaminski M, Baker B, Koo J. The U.S. proposal for an intellectual property chapter in the Trans-Pacific Partnership Agreement. American University International Law Review. 2013;28(1):105-202 (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2185402 (updated and revised version), accessed 29 January 2014).

124. Cox K. Analysis of Kirtsaeng v. John Wiley & Sons (parallel importation case): Supreme Court applies international exhaustion. Washington, DC: Knowledge Ecology International, 2013 (http://keionline.org/node/1686, accessed 29 January 2014).

125. Jarvis R, Yates A. TGA pharmaceutical product information loses copyright protection in Australia. Melbourne, Davis Collison Cave Intellectual Property, 2011 (http://www.davies.com.au/pub/detail/449/tga-pharmaceutical-product-information-loses-copyright-protection-in-australia, accessed 29 January 2014).

126. China—Measures affecting the protection and enforcement of intellectual property rights. Panel report WT/DS362/R. Geneva: World Trade Organization; 2009.

127. Vietnam and the Trans-Pacific Partnership Agreement. Public Citizen and Health Gap, Briefing Memo, 16 June 2011.

128. Patent assertion and U.S. innovation. Washington, DC: Executive Office of the President, The White House; June 2013 (http://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf, accessed 29 January 2014).

129. Cox KL. The United States' demands for intellectual property enforcement in the Trans-Pacific Partnership Agreement and impacts for developing countries. Working paper. Washington, DC: Knowledge Ecology International; 2012 (http://keionline.org/sites/default/files/TPP_IP_Enforcement_4OCT2012_KLCworkingpaper.pdf, accessed 29 January 2014).

130. Highmark v. Allcare Health, United States Court of Appeals for the Federal Circuit, Appeal No. 2011-1129, (Fed. Cir. December 6, 2012).

131. Schallnau J. Resolving IP Disputes—costs in court litigation, WIPO mediation and arbitration. European IPR Helpdesk, Bulletin N°7, October-December 2012 (http://www.wipo.int/export/sites/www/amc/en/docs/adrcosts2012.pdf, accessed 23 February 2013).

132. Vartak R. On the up: patent litigation trends in India. World Intellectual Property Review, 1 December 2012 (http://www.worldipreview.com/article/on-the-up-patent-litigation-trends-in-india, accessed 23 February 2013).

133. Flynn S, Madhani B. ACTA and access to medicines, 2011 (http://rfc.act-on-acta.eu/access-to-medicines, accessed 29 January 2014).

134. Kaminski ME. An overview and the evolution of the Anti-Counterfeiting Trade Agreement (ACTA). Washington, DC: American University Washington College of Law; 2011 (http://digitalcommons.wcl.american.edu/research/17/, accessed 29 January 2014).

135. Berkeley declaration on intellectual property enforcement and access to medicines, 15 July 2010 (http://www.law.berkeley.edu/files/Berkeley_Declaration.pdf, accessed 8 March 2014).

136. Recommendation 45. WIPO development agenda. Geneva: World Intellectual Property Organization; 2007.

137. Eye on the ball: medicine regulation—not IP enforcement—can best deliver quality medicines. Oxfam Briefing Paper, 2 February 2011 (http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf, accessed 8 March 2014).

138. European Parliament rejects ACTA. Press Release. European Parliament. 4 July 2012.

139. Trading away health: how the U.S.'s intellectual property demands for the trans-pacific partnership agreement threaten access to medicines. Médecins Sans Frontières Access Campaign. MSF Issue Brief, August 2012.

140. Pharmaceutical Patents Review—Draft Report. Commonwealth of Australia; 2013 (http://www.ipaustralia.gov.au/pdfs/Draft_Report_PharmaReview.pdf, accessed 22 February 2014).

141. EPO Advisory Board publishes recommendations for improving the patent system. Press Release. European Patent Office, 2013 (http://www.epo.org/news-issues/press/releases/archive/2013/20130313.html, accessed 22 February 2014).

142. Science and technology: falling patent quality hits innovation, says OECD. OECD, 2011 (http://www.oecd.org/newsroom/scienceandtechnologyfallingpatentqualityhitsinnovationsaysoecd.htm, accessed 22 February 2014).

143. OECD Science, Technology and Industry Scoreboard 2011, 10th ed. Paris: Organisation for Economic Co-operation and Development; 2011 (http://www.oecd-ilibrary.org/science-and-technology/oecd-science-technology-and-industry-scoreboard-2011_sti_scoreboard-2011-en, accessed 29 January 2014).

144. Section 287, United States Code Title 35—Patents.

145. Patricia Asero Ochieng and Ors. v. Attorney General and Anr., Petition 409 of 2009, High Court of Kenya, Date of Decision: 20 April 2012.

146. Finger JM. The Doha Agenda and Development: A View from the Uruguay Round. Manila: Asian Development Bank, 2002, p.8 (http://www.adb.org/sites/default/files/pub/2002/wp021.pdf, accessed 8 March 2014).

147. Global Economic Prospects 2002: Making Trade Work for the Poor. World Bank, 2002, p.133 (http://go.worldbank.org/89IB58RI90, accessed 8 March 2014).

148. Seuba X, Rovira J, Bloemen S. Welfare Implications of Intellectual Property Enforcement Measures. PIJIP Research Paper no. 5. Washington DC: American University Washington College of Law, 2010 (http://digitalcommons.wcl.american.edu/research/5/, accessed 8 March 2014).

149. Cordis Corporation v. Boston Scientific Corporation 2004 US App. LEXIS 11557, United States Court of Appeals for Federal Circuit.

150. A blank cheque for abuse: the anti-counterfeiting trade agreement (ACTA) and its impact on access to medicines. Médecins Sans Frontières Access Campaign. MSF Briefing document, updated February 2012 (http://www.msfaccess.org/content/acta-and-its-impact-access-medicines, accessed 8 March 2014).

151. Apotex pays Bristol, Sanofi damages over Plavix. Wall Street Journal, 8 February 2012 (http://online.wsj.com/article/AP1014976e51794b219c841c152ddc9f8e.html, accessed 8 March 2014).

152. Merck & Co., Inc. v. Apotex Inc., 2013 FC 751 (http://www.canlii.org/en/ca/fct/doc/2013/2013fc751/2013fc751.html, accessed 8 March 2014).

153. Pay-for-delay: how drug company pay-offs cost consumers billions. An FTC Staff Study. United States Federal Trade Commission. January 2010.

154. Antitrust: Commission sends statement of objections on perindopril to Servier and others. Press Release. European Commission. 30 July 2012.

155. Lee TB. Patent trolls have a surprising ally: universities. Washington Post. 30 November 2013.

156. Shashikant S. Concerns voiced at TRIPS Council over seizure of drugs. SUNS #6717. 11 June 2009.

157. TRIPS Council. Agenda item 'M': other business—public health dimension of TRIPS Agreement. Statement by Brazil. 3 March 2009.

158. UNITAID statement on Dutch confiscation of medicines shipment. Geneva: UNITAID, 4 March 2009.

159. Freedman JM. India, Brazil complain at WTO over generic drug seizures by European Union. Bloomberg News. 12 May 2010.

160. India EU reach an understanding on issue of seizure of Indian generic drugs in transit. Ministry of Commerce and Industry, Press Information Bureau, India, July 2011.

161. Another seizure of generic medicines destined for a developing country, this time in Frankfurt. Health Action International (HAI), Oxfam International, BUKO-pharma, Medico International, Third World Network. 5 June 2009.

162. Position paper on the recast of the EU Trademark package. Médecins Sans Frontières, Oxfam International, Health Action International Europe. November 2013.

163. Public interest analysis of leaked Trans-Pacific Partnership (TPP) investment text. Washington, DC: Public Citizen; 13 June 2012 (http://www.citizen.org/documents/Leaked-TPP-Investment-Analysis.pdf, accessed 29 January 2014).

164. Baker BK. Leaked TPP investment chapter presents a grave threat to access to medicines. New York, NY: Health Gap; 2012 (http://www.citizen.org/documents/Leaked-TPP-Investment-Chapter-Presents-a-Grave-Threat-to-Access-to-Medicines_3.pdf, accessed 29 January 2014).

165. See, for instance: Faunce TA, Townsend R. The Trans-Pacific Partnership Agreement: challenges for Australian health and medicine policies. Med J Aust. 2011;194 (2):83-86 (https://www.mja.com.au/journal/2011/194/2/trans-pacific-partnership-agreement-challenges-australian-health-and-medicine, accessed 29 January 2014).

166. Kelsey J. New-generation free trade agreements threaten progressive tobacco and alcohol policies. Addiction. 2012;107(10) (http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2012.03874.x/full, accessed 29 January 2014).

167. Kelsey J. (2012) Investment developments in the Trans-Pacific Partnership Agreement. Investment Treaty News. January 2012 (http://www.iisd.org/itn/2012/01/12/investment-developments-in-the-trans-pacific-partnership-agreement/, accessed 29 January 2014).

168. Investor-state disputes arising from investment treaties: a review. Document UNCTAD/ITE/IIT/2005/4. Geneva: United Nations Conference on Trade and Development; 2005 (http://unctad.org/en/pages/PublicationArchive.aspx?publicationid=420, accessed 3 February 2014).

169. Smith S, Purse H. Some impacts of a TPPA investment chapter. Aurry Hills, NSW and Kuala Lumpur: Australian Fair Trade and Investment Network & Third World Network; 2010 (http://aftinet.org.au/cms/sites/default/files/Investment%20paper%20Santiago.pdf, accessed 29 January 2014).

170. Eli Lilly and Company v. The Government of Canada. Notice of intent to submit a claim for arbitration under NAFTA Chapter Eleven, 7 November 2012 (http://italaw.com/sites/default/files/case-documents/italaw1172.pdf, accessed 29 January 2014).

171. Eli Lilly and Company v. The Government of Canada. Notice of Arbitration. In the Arbitration under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade Agreement, 12 September 2013 (http://infojustice.org/wp-content/uploads/2013/09/Eli-Lilly-Notice-of-Arbitration-September-12-2013.pdf, accessed 22 February 2014).

172. Fergusson IF, Vaughn B. The Trans Pacific Partnership Agreement. Washington, DC: Congressional Research Service; 2011 (http://www.fas.org/sgp/crs/row/R40502.pdf, accessed 29 January 2014).

173. Proposed Trans-Pacific Partnership rules could undermine Medicare, Medicaid and Veterans Health, hurting seniors, military families and the poor (blog post). Washington, DC: Public Citizen; 14 June 2012 (http://citizen.typepad.com/eyesontrade/2012/06/tpp-could-undermine-medicare-medicaid-and-veterans-health-hurting-seniors-military-families-and-the-.html, accessed 29 January 2014).

174. Stumberg R. 2012 trade policy assessment. Prepared for the Maine Citizen Trade Policy Commission. Washington, DC: Harrison Institute for Public Law, Georgetown University Law Centre; 2012 (http://www.law.georgetown.edu/academics/academic-programs/clinical-programs/our-clinics/HIP/upload/Maine-CTPC-Trade-policy-assessment-2012.pdf, accessed 29 January 2014).

175. Humphreys G. Direct to consumer advertising under fire. Bull World Health Organ. 2009;87(8) (http://www.who.int/bulletin/volumes/87/8/09-040809/en/index.html, accessed 29 January 2014).

176. Treat SA. Pharmaceutical reimbursement restrictions and public health: analysis of US and other TPP country practices. The impact of pricing provisions on US Medicaid and other health access programs. Stakeholder presentation, Chicago Round Trans-Pacific Partnership Agreement, 10 September 2011 (http://www.reducedrugprices.org/documents/TreatPresentationTPPAStakeholderPanelChicagoFinal.pdf, accessed 29 January 2014).

177. Faunce T, Doran E, Henry D, Drahos P, Searles A, Pekasky B, Neville W. Assessing the impact of the Australia-United States Free Trade Agreement on Australian and global medicines policy. Globalization and Health. 2005;1:15. doi:10.1186/1744-8603-1-15. (http://www.globalizationandhealth.com/content/1/1/15, accessed 29 January 2014).

178. Letter from five members of the United States Congress to the United States Trade Representative, 8 September 2011 (http://infojustice.org/download/tpp/tpp-government/Five-MOCs-September-8-2011.pdf, accessed 29 January 2014).

179. The United States in the Trans-Pacific Partnership: increasing American exports, supporting American jobs. Fact sheet, June 2012. Washington, DC: Office of the United States Trade Representative; 2012 (http://www.ustr.gov/about-us/press-office/fact-sheets/2012/june/us-tpp-increasing-american-exports-supporting-american-jobs, accessed 30 January 2014).

180. Legal Aspects of Defining 'Counterfeit Medicines'. Discussion Paper. Delhi: World Health Organization Regional Office for South-East Asia; 2009.

181. Clift C. A guide to assessing the impact of TRIPS-plus provisions on drug prices in developing countries. Geneva: International Centre for Trade and Sustainable Development; 2007 (http://ictsd.org/downloads/2009/06/1_guide_impact_assessment.pdf, accessed 30 January 2014).

182. Correa C. Intellectual property and competition law: exploring some issues of relevance to developing countries. Programme on IPRs and Sustainable Development, Issue Paper, No. 21.

Geneva: International Centre for Trade and Sustainable Development Programme on IPRs and Sustainable Development. 2007.

183. Jaffe AB, Lerner J. Innovation and its discontents: how our broken patent system is endangering innovation and progress, and what to do about it. Princeton University Press; 2004.

184. To promote innovation: the proper balance of competition and patent law and policy. United States Federal Trade Commission, October 2003 (http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf, accessed 22 February 2014).

185. Correa C. Guidelines for the examination of pharmaceutical patents: developing a public health perspective. A working paper. Geneva: International Centre for Trade and Sustainable Development, United Nations Conference on Trade and Development, World Health Organization; 2007 (http://ictsd.org/downloads/2008/06/correa_patentability20guidelines.pdf, accessed 30 January 2014).