Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

The Draft Trans-Pacific Partnership Agreement and its Implications for Public Health and Access to Medicines: The UNITAID Report

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This report provides an overview of the potential impact of the draft Trans-Pacific Partnership Agreement on public health and access to medicines, in light of a recent analysis conducted by UNITAID. The international organization observed that the increased intellectual property protection endorsed in the draft agreement, which calls for the adoption of TRIPS-plus standards, is likely to severely impact generic competition, affecting the availability of medicines in developing countries, and reducing the ability of governments to set the appropriate balance between the protection of innovation and the safeguard of public health.

I. The draft TPP Agreement and the inclusion of TRIPS-plus provisions

The draft Trans-Pacific Partnership ("TPP") Agreement is a free trade agreement currently being negotiated between twelve countries in the Asia-Pacific region (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States and Vietnam). The agreement builds upon the Trans-Pacific Strategic Economic Partnership Agreement[1] (so-called "P4 Agreement"), signed by Brunei, Chile, New Zealand and Singapore in 2005, under which most tariffs on goods traded between the four countries were immediately removed, in view of a progressive elimination of the remaining trade barriers. The negotiations of the TPP Agreement, which started in March 2010, aim at creating a larger trans-Pacific free trade area, "forging close linkages among our economies, enhancing our competitiveness, benefitting our consumers and supporting the creation and retention of jobs, higher living standards, and the reduction of poverty in our countries[2]". From this perspective, the new agreement does not merely seek to include a greater number of parties in order to create a more comprehensive free trade area, but seeks to coordinate national policies that have a direct or indirect economic impact that spreads beyond national borders. These policies include, *inter alia*, those related to labour, investment, environment, e-commerce and telecommunications, competition, and intellectual property rights.

Following the publication of the draft TPP Agreement on Wikileaks[3] in November 2013, the provisions concerning the strengthening of intellectual property rights, as well as the adoption of higher standards of protection than those endorsed in the Agree-

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1 The text of the agreement is available online at http://www.mfat.govt.nz/Trade-and-Economic-Relations/ 2-Trade-Relationships-and-Agreements/ Trans-Pacific/0-P4-Text-of-Agreement.php [last visited 10 August 2014].

2 Trans-Pacific Partnership Leaders Statement of 12 November 2011, available online at http://www.ustr.gov/about-us/press-office/press-releases/2011/november/trans-pacific-partnership-leaders-statement [last visited 10 August 2014].

3 The leaked draft agreement ("draft agreement") is available online at http://wikileaks.org/Second-release-of-secret-Trans.html [last visited 10 August 2014]. Any reference to articles of the draft agreement, in the following footnotes, follow the numbering used in the Wikileaks release.

ment on Trade-Related Aspects of Intellectual Property Rights[4] ("TRIPS"), attracted significant criticism[5] in light of their potentially negative effects on access to medicines in developing countries. The criticism focused on a number of draft provisions likely to affect timely generic entry, including those that seek to preserve the monopoly of originator companies through the reaffirmation of the patentability of incremental pharmaceutical innovation, the adoption of strict data exclusivity requirements, the prohibition of pre-grant oppositions, and the implementation of stricter rules on the enforcement of intellectual property rights. Many of these draft provisions were introduced or supported by the United States, with the alleged objective of "promot[ing] innovation and the development of new, lifesaving medicines, creat[ing] opportunities for robust generic drug competition, and ensur[ing] affordable access to medicines, taking into account levels of development among the TPP countries and their existing laws and international commitments[6]". However, even within the US Congress, the opportunity of rendering these TRIPS-plus requirements binding upon all the negotiating parties was criticized as liable to alter the delicate balance between patent protection and access to affordable medicines: a group of US congressmen argued that "the long term goals of public health and other programs in TPP countries would be challenged by such provisions[7]", citing Vietnam as one of the countries most likely to experience such negative effects.

The terms of the debate are exposed in the preamble of the draft TPP Agreement, where several negotiating parties (New Zealand, Chile, Peru, Vietnam, Brunei, Malaysia, Singapore, Canada and Mexico) intended to define the key objective of the agreement as the strengthening of intellectual property rights *in a manner* that (i) promotes economic and social development, (ii) takes into account the different levels of economic development and capacity of the negotiating parties, and (iii) reaches a fair balance between the rights of all the subjects involved, preserving the public interest[8]. This proposal, which closely recalls the principles enshrined in other international instruments (Articles 7 and 8 of the TRIPS Agreement, the preamble of the Marrakesh Agreement that established the World Trade Organization[9], and paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health[10]), was opposed by the United States and Japan, despite the reaffirmation of the intangibility of the "TRIPS/health solution" contained in another provision[11], apparently unanimously accepted. On a more general level, the "TRIPS-plus" nature of the TPP Agreement has been called into question since the negotiating parties disagree on the derogatory effects of the agreement in relation to pre-existing international treaties[12].

The draft chapter on patents contains the most controversial provisions, at least from the point of view of access to medicines. In the section dedicated to patentable subject matter, the US proposed that patents should be made available for any new uses or methods of using a known product, even when the invention does not exhibit an enhanced efficacy over the known product[13], thus strengthening the protection of incremental or secondary pharmaceutical innovation. Such enhanced protection conflicts, however, with the higher standards of patentability adopted in several developing countries (e.g. Section 3(d) of the Indian Patent Act), which seek to restrict the patent reward to primary innovation. All the other negotiating parties, with the exception of Japan, opposed the proposal advanced by the US, which also called for a waiver of Article 27.3 TRIPS.

The same countries also opposed the extension of the patent term, demanded by the US for patents concerning new pharmaceutical products or methods of

4 Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

5 See Andrew D. Mitchell, Tania S. Voon, and Devon Whittle, "Public Health and the Trans-Pacific Partnership Agreement", *Asian Journal of International Law* (forthcoming), available online at http://ssrn.com/abstract=2393670 [last visited 10 August 2014].

6 Statement of the Office of the United States Trade Representative, available online at http://www.ustr.gov/tpp/Summary-of-US-objectives [last visited 10 August 2014].

7 Letter to the United States Trade Representative of 2 August 2011, available online at http://infojustice.org/wp-content/uploads/2011/08/Ten-Representatives-on-TPP-08022011.pdf [last visited 10 August 2014].

8 Article QQ.A.2 bis would further recognize the right of each country to adopt measures to promote the public interest in areas important for its social, economic or technological development, including public health and nutrition.

9 Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

10 Declaration on the TRIPS Agreement and public health, adopted at the Doha WTO Ministerial on 14 November 2001, WT/MIN(01)/DEC/2.

11 See Article QQ.A.5.

12 See Article QQ.A.6.

13 See Article QQ.E.1.

making or using pharmaceutical products, to compensate for "the unreasonable curtailment of the effective patent term as a result of the marketing approval process[14]".

The provisions on data exclusivity submitted by the US similarly attracted significant criticism by most of the countries involved in the TPP negotiations. The five-year protection period of the safety and efficacy information submitted by the right holder during the process of regulatory or marketing approval for a new drug would impact generic entry, requiring either lengthy and expensive (duplicate) clinical trials or the postponement of generic entry until the expiry of the exclusivity period[15]. The three-year protection proposed for the submission of new clinical information (except those related to bioequivalency) essential to the approval of a pharmaceutical product that contains a chemical entity previously approved for marketing in another pharmaceutical product would raise analogous concerns.

On the other hand, New Zealand, Canada, Singapore, Chile, Malaysia and Vietnam advanced a series of proposals meant to increase the flexibilities guaranteed to each party for the adoption of public policies ensuring greater access to medicines. These included[16] (i) the recognition of the right of each party to adopt or maintain measures to stimulate the timely commercialization of drugs; (ii) a commitment to streamline and improve the quality and efficiency of national patent systems; (iii) a commitment to process patent applications, as well as applications for marketing, regulatory or sanitary approval of pharmaceutical products, in an "efficient and timely manner"; and (iv) a generic obligation to address unreasonable delays in the processing of applications for patents or marketing approval. The data submitted for marketing, regulatory or sanitary approval of pharmaceutical products, according to these countries, should be protected against unfair commercial use, although without the adoption of uniform standards.

While these provisions directly affect access to medicines and generic competition, the draft TPP Agreement contains several other measures of intellectual property protection that are likely to determine similarly restrictive effects. In light of these concerns, UNITAID published an in-depth Report[17], assessing the impact of each of the main provisions of the TPP Agreement on access to medicines and public health. Based in Geneva and hosted by the World Health Organization, UNITAID was established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom, with the objective of increasing access to treatment for HIV/AIDS, tuberculosis and malaria for people in developing countries and promoting policy measures and international efforts to reduce the price of quality drugs and diagnostics and ensure their widespread availability. UNITAID invests its considerable financial resources, obtained through a levy on airline tickets in several countries, as well as through public and private donations, to negotiate price reductions, relying on its buy-side leverage. At the same time, it seeks to stimulate competition in the relevant pharmaceutical markets, creating optimal market conditions for increased access to, and availability of, medicines, as well as for new and continued investments in drug development and production. From this perspective, "[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[18]"; consequently, the implementation of TRIPS-plus provisions is generally regarded as having negative implications for the fulfilment of UNITAID's mandate.

II. UNITAID's Report: How the TPP Agreement would affect generic competition and access to medicines in developing countries

The Report analysed the potential effects of the TPP Agreement on access to medicines in the countries involved in light of the mandate of the organization.

14 See Article QQ.E.14. The provision would be accompanied by safeguard measures aimed at preventing any abuse: such measures would include a five-year extension limit, not linked to the patent term, and an obligation to start the process of marketing approval within a predefined number of years from the date of the first marketing approval in another TPP country.

15 Article QQ.E.16.

16 See, respectively, Articles QQ.E.XX.1, 2, and 3.

17 UNITAID, "The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health" ("Report"), March 2014, available online http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf [last visited 10 August 2014].

18 Ibid, p. 3.

In particular, UNITAID focused on six key areas, namely (i) patents, (ii) data exclusivity and patent linkage, (iii) trademark and copyright, (iv) enforcement of intellectual property rights, (v) investment, and (vi) pharmaceutical pricing, financing and reimbursement for medicines.

1. Patents

UNITAID noted that the lowering of patentability standards reduces the flexibility embedded in the TRIPS Agreement and goes against the recommendations formulated by UN agencies, the United Kingdom's Commission on Intellectual Property Rights and the WHO's Commission on Intellectual Property, Innovation and Public Health. In particular, the organization observed that the US suggested the adoption of lower standards for assessing novelty (with the introduction of a 12-month grace period during which any disclosure made by the patent applicant is disregarded), inventive step (requiring only "ordinary" skill in the definition of the person skilled in the art), and industrial application (merely referring to "specific, substantial and credible utility"). Further, the lowering of standards for the patentability of secondary innovation concerning new forms and uses of known products, including those that do not result in increased efficacy, is likely to cause a dual effect, resulting in the creation of patent thickets, which make it "extremely difficult for generic companies to ascertain whether there is an existing valid patent on a medicine[19]", and in the adoption of "evergreening" practices, through which originator companies extend their exclusive right beyond the original patent term.

According to UNITAID, the US proposal to require the provision of patents for plants and animals, as well as for surgical and diagnostic methods, would raise "a plethora of ethical and legal issues[20]", besides creating significant barriers for the research and academic community. Similarly, the dilution of the disclosure standards (including the possibility of presenting Markush-style claims, which list a number of alternative substances to practice the invention[21]) would affect the quality of the patents granted, while also questioning the basis of the patent reward itself, because the public would be deprived of its right to adopt and learn from patented inventions. In UNITAID's view the removal of pre-grant examination procedures does not appear to be compatible with the capabilities of the patent offices in developing countries; further, it would postpone generic entry since the patent remains in force during the post-grant opposition proceedings.

UNITAID also criticized the extension of the patent term because of its effects on generic entry, although it is necessary to keep in mind that originator companies rarely benefit from the entire duration of the patent term, given the lengthy procedures needed to conduct clinical trials and obtain regulatory and marketing approval. Proposed limitations to the Bolar exception (confined to pharmaceutical products and territorially limited), which allows generic companies to obtain provisional market approval before the expiry of the patent term, would "create significant barriers for generic medicines to enter export markets quickly[22]".

2. Data exclusivity and patent linkage

UNITAID's analysis of the provisions on data exclusivity clarified that "[i]n many countries, generic manufacturers are not required to conduct full scale clinical trials to demonstrate the safety or efficacy of already approved medicines[23]" since requiring duplicate trials would be "unethical[24]". Instead, a requirement to prove bio-equivalency is generally the only burden imposed upon generic manufacturers, if the safety and efficacy of the branded drug has already been demonstrated.

The US proposal would force generic manufacturers to either (i) conduct full scale clinical trials to demonstrate the safety and efficacy of their bio-equivalent generic medicines, or (ii) postpone their entry into the market until the end of the term of data exclusivity (a minimum of five years for new chemical entities, a minimum of three years for new clinical information related to existing molecules, and

19 Ibid, p. 27.

20 Ibid, p. 28.

21 See *Ex parte Markush*, (1925) CD 126, 340 OG 839. A Markush-type claim recites alternatives with the formula "wherein the unyielding material is selected from the group consisting of A, B, and C".

22 Ibid, p. 33.

23 Ibid, p. 40.

24 Ibid.

up to twelve years for biologicals). According to UNITAID, such TRIPS-plus provisions, which go beyond the requirements negotiated by the US in other free trade agreements, would create "an exclusivity over medicines distinct from patent protection [which] 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[25]". The Report discusses the compatibility of data exclusivity regimes with Article 39.3 of the TRIPS Agreement, observing that the notion of "unfair commercial use" should not be interpreted as extending to the use of the safety and efficacy information submitted by originator companies in the regulatory approval of a generic version of a medicine. It also argues that the impact of data exclusivity provisions on the few developing countries that implemented them (*inter alia*, Guatemala, Jordan, Thailand) has hindered generic competition, triggering a drastic rise in costs borne by consumers and public authorities. Thus, the adoption of the data exclusivity requirements proposed by the US would prevent timely generic entry, negatively affecting both access to medicines and timely generic entry[26].

UNITAID's experts are also concerned about the potential impairment of the flexibilities introduced by several countries to temper the rigour of data exclusivity regimes. Such measures, that include limiting data exclusivity to new chemical entities and undisclosed information, establishing the beginning of the data exclusivity period with reference to (prior) registration in another country, or linking it to the patent term, would not remain available under the US proposal. The lack of a requirement obliging originator companies to complete registration within a certain number of years, and not merely commencing it within that timeframe, would further resonate the combined effects of patent protection and data exclusivity.

The Report also criticized patent linkage[27], which prevents marketing approval of a generic drug until the expiration of the patent protecting the brand drug, as another TRIPS-plus provision likely to negatively affect access to medicines[28]. In particular, the organization noted that the proposal included in the draft TPP Agreement merely contains a skeleton of the system that the negotiating parties would be required to implement, potentially exposing them to the same issues experienced by the US when the patent linkage system was first introduced (abusive practices, multiple patent applications, back-to-back delays, reverse payment settlements, etc.), and requiring drug regulators to carry out technical tasks for which they lack the necessary expertise[29]. Assessing the impact of patent linkage in developing countries, UNITAID observed that "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[30]". The lack of substantial drug regulatory and infrastructure is also cited as a serious issue for the implementation of a patent linkage system in developing countries, as is the dissuasive effect that such a system could have on at-risk launches of generic products.

3. Trademark and copyright

The draft provisions on trademark protection also set a number of TRIPS-plus requirements. They prescribe that the negotiating parties should (i) abstain from requiring that a sign be visually perceptible, and from denying registration of a sign merely because it is composed by a sound or a scent; (ii) ensure that measures requiring the use of common names for goods or services do not interfere with the use or effectiveness of related trademarks; (iii) prohibit the use of similar signs for goods or services *related* (instead of *identical* or *similar*, as stated in Article 16.1 of the TRIPS Agreement) to those covered by the registered trademark; and (iv) extend the term of protection to ten years. According to UNITAID,

25 Ibid.

26 Further, market exclusivity is likely to impact the availability of traditional medicines, as happened in the case of *colchicine* in the United States (ibid, p. 42).

27 According to R. Bhardwaj, K.D. Raju and M. Padmavati, "The Impact of Patent Linkage on Marketing of Generic Drugs", 18(4) *Journal of Intellectual Property Rights* (2013), pp. 316 *et sqq.*, at p. 316, patent linkage "involves linking generic drug marketing approval with the originator drug's patent status and refusing marketing approval until the relevant patent expires".

28 See also A. Grover, "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", 31 March 2009, A/HRC/11/12, available online at http://www.ifhhro.org/images/stories/ifhhro/documents_UN_special_rapporteur/3_4_1_en.pdf [last visited on 10 August 2014].

29 Report, *supra* note 17, p. 44.

30 Ibid.

"[t]hese 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[31]", with the risk of transforming trademarks into "a form of monopoly protection rather than a means of consumer protection[32]". In relation to the pharmaceutical sector, the enhanced trademark protection envisioned in the draft TPP Agreement may prevent generic manufacturers from using colors and shapes similar to those of the equivalent branded drug. According to UNITAID, the resulting "[d]ifferences in the appearance of generic and originator products may cause confusion, reduce adherence and increase prescription/dispensing errors, with adverse consequences for patients[33]". In particular, the organization voiced concern regarding the risk that such differences may affect the patients' perception of the bioequivalence of two or more medicines, with the generic drug bearing dissimilar marks being mistakenly perceived as an altogether different medicine or confused with another brand medicine having a similar appearance. Further, the enhanced trademark protection may also impact the availability of generic medicines, affecting the use of International Non-Proprietary Names on the labels or packaging of drugs, because the parties would be required to ensure that the use of a common name for a good or service "do[es] not impair the use or effectiveness of trademarks used in relation to such good or service[34]".

In relation to copyright, the Report highlighted that the proposal to give copyright owners an exclusive right to prevent parallel imports of copyrighted works "seeks to create a new international legal requirement that would limit the ability of countries to apply their chosen regime of exhaustion[35]", contrary to Article 6 of the TRIPS Agreement. Such provision could have a negative effect on access to medicines in so far as originators could use them to prevent imports of drugs due to the presence of copyrighted materials in the packaging inserts[36]. UNITAID recognized, however, that the overall implications of the copyright provisions included in the draft agreement "are unclear at this stage[37]".

4. Enforcement of intellectual property rights

According to UNITAID, the draft TPP Agreement contains a number of problematic provisions concerning the enforcement of intellectual property rights. The presumption of validity of patents and trademarks, which extends to criminal proceedings in the case of trademarks, "is likely to make it considerably more difficult to challenge patents on medicines while increasing the risk for generic competitors in infringement proceedings[38]". The risk is exacerbated in developing countries by the relatively inexperienced and undermanned patent offices. The Report also noted that patents in the pharmaceutical sector "show on average relatively lower patent quality[39]", and highlighted the risks deriving from the potential granting of provisional measures against generic manufacturers.

The major concern voiced by UNITAID in relation to intellectual property enforcement concerns restrictions imposed upon the ability of governments to strike a balance between enforcement, public interest and development priorities. The prescribed availability of civil judicial procedures for any intellectual property right infringement, the prescriptive provisions on the calculation of damages, the requirement for policies encouraging judges to pass orders of imprisonment, the mandatory requirements for the destruction of goods, and the prescriptive requirements for ex parte orders, together with the presumption of validity, are likely to "heavily favour[40]" right holders. The organization mentioned several cases in which the courts have questioned the balance between the enforcement and protection of constitutional rights or the public interest. In these examples, the courts have tended to rule in favour of the latter, contrary to the general principles emerging from the draft TPP Agreement.

The Report observed that the granting of preliminary injunctions, even in the United States, requires

31 Ibid, p. 49.

32 Ibid.

33 Ibid.

34 See Article QQ.C.2.

35 Ibid, p. 51.

36 UNITAID observed that in some countries generic producers are required by law to use the same labelling and product information included in the packaging of the branded drug (ibid, p. 50).

37 Ibid, p. 52.

38 Ibid, p. 69.

39 Ibid.

40 Ibid, p. 70.

consideration of the public interest, a step that would be restricted under the new agreement[41]. Similarly, the right holder would be entitled to obtain, from the alleged infringer, information concerning the entire supply and distribution chain, increasing the risk that such data "may be used to harass or intimidate smaller operators in this chain[42]". From this perspective, the proposed adoption of treble damages and pre-established damages in trademark counterfeiting, modelled upon the practices adopted in the US and other developed countries (and beyond the requirements of TRIPS), would severely deter at-risk generic entry, and might not suit the legal context of developing countries and their specific needs. The impact on access to medicines would also be affected by a number of provisions allowing the seizure and destruction of generic medicines (and of the machines, chemical ingredients and packaging materials used in their manufacturing processes) in the case of trademark disputes. In this case, the draft TPP Agreement, with its emphasis on destruction as the main remedy for infringing goods, would eliminate the flexibility that governments enjoy in determining the fate of seized goods under Article 46 of the TRIPS Agreement, which authorizes their disposal outside the channels of commerce and calls for an evaluation of the proportionality between the seriousness of the infringement and the remedies ordered, sensitive to the interests of third parties, allowing, in exceptional cases (such as life-saving medicines), the simple removal of the trademark unlawfully affixed to the goods and their re-release on the market[43].

The proposed border measures related to trademarks, which would permit the seizure of medicines that are imported, exported or in transit, by customs officials, are again TRIPS-plus measures and do not implement the safeguards contained in the TRIPS Agreement (which, *inter alia*, specifically indicates who can apply for border measures and, under which circumstances, prescribe their maximum duration, and allows the competent authorities to require the claimant to provide a security or equivalent assurance sufficient to protect the defendant, as well as to order the former to pay appropriate compensation for any injury caused to the latter through the wrongful detention of the goods). UNITAID noted, in particular, that "customs officials may not be in the best position to judge whether a trademark is infringed[44]", and that the proposed measures may result in delays in the delivery of life-saving medicines. The Report also observed that a US proposal would require the 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, in the case of counterfeiting or given the presence of confusingly similar trademarks, noting that "the TRIPS Agreement, on the other hand, requires border measures only in cases of import and only in cases of trademark counterfeiting[45]". Thus, while trademark rights are territorial in nature, the proposed provision would effectively extend trademark enforcement beyond national borders, requiring customs authorities to enforce trademarks registered in other countries.

5. Investment, pharmaceutical pricing, and financing and reimbursement of medicines

Examining the provisions on investment, UNITAID highlighted three main areas of concern. First, limitations on the ability of governments to impose restrictions on the way in which foreign companies operate within their national territories may prevent the effective implementation of public health policies[46] (e.g. when a domestic generic manufacturer is acquired by a foreign investor who intends to cease production of an essential medicine in the national territory). Since intellectual property rights are considered to be "investments" according to the draft TPP Agreement, "a government measure that affects the intellectual property holding of investors may be considered an 'expropriation' or a withholding of 'fair and equitable treatment'[47]", thus preventing the use of the flexibilities embedded in the TRIPS Agreement. Given the effects of investor-state disputes, the risk of treaty-shopping, and the lack of an obligation for private arbitration panels to take into account the constitutional obligations of governments[48], the TPP Agreement draft provisions on investment may se-

41 Ibid, p. 72.
42 Ibid.
43 Ibid, p. 73.
44 Ibid, p. 74.
45 Ibid.
46 Ibid, p. 88.
47 Ibid, p. 89.
48 Ibid, p. 91.

verely reduce the enforceability of national policies meant to increase access to medicines.

The Report finally looked at the healthcare transparency annex, which is based on the principles endorsed in the KORUS Free Trade Agreement[49]. UNITAID highlighted uncertainties in the definition of essential legal concepts related to pharmaceutical reimbursement schemes (e.g. the requisite to allow "reasonable time" between the publication and the effective date of regulations, or the requirement that such reimbursement be administered in a "reasonable, objective, consistent, non-discriminatory and impartial" way), and expressed concern about the risk that provisions concerning procedural transparency in the administration of these schemes could affect reimbursement prices, "thus restricting the role of governments to regulators rather than as actors or negotiators within the market[50]". Evaluating the provisions concerning the means of determining the reimbursement amount for pharmaceuticals, the organization maintained that the proposed text may be interpreted as "discouraging or preventing the use of benefits from economies of scale, such as from pooled procurement[51]", and that any limitation on the use of reference prices may negatively impact cost-effective assessments. Generally, UNITAID noted that the agreement should not impose restrictions on the ability of governments to set reimbursement prices at levels equivalent to those derived from fair competition in the relevant markets, even where reimbursement schemes have not yet been implemented. As is the case for many developing countries, any restriction on their tailoring to the national context and priorities would likely have negative effects[52].

III. An alternative agenda?

UNITAID's analysis of the draft TPP Agreement highlighted the risk that the adoption of TRIPS-plus provisions may significantly impair access to medicines, preventing developing countries from adopting a tailored and flexible approach to set the balance between the protection of intellectual property and public health. The Report, however, also suggested a positive agenda that the negotiators may wish to consider in order to preserve the benefits of the new free trade agreement while also safeguarding important public health considerations. Firstly, the organization called for an analysis of the costs and benefits of strengthening intellectual property protection in developing countries as a necessary basis for the continued negotiations[53]. Secondly, it noted that any intervention on intellectual property law should be accompanied by an effective implementation of competition policies, "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[54]". Finally, it underlined the importance of preventing the granting of low quality patents in the pharmaceutical sector, a proposition that calls both for better monitoring and analysis, and for the reform, training and improvement of patent offices in developing countries.

As the negotiations continue, it remains to be seen whether the parties will address UNITAID's concerns, avoiding a potential clash between intellectual property protection and access to medicines, which would ultimately render any TRIPS-plus provision unsustainable in the long run.

49 United States-Korea Free Trade Agreement, signed on 30 June 2007.

50 Ibid, p. 95.

51 Ibid.

52 Ibid, p. 97.

53 Ibid, p. 101.

54 Ibid, p. 103.