6-2012

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Society of International Economic Law

Online Proceedings
Working Paper No. 2012/32

THIRD BIENNIAL GLOBAL CONFERENCE
JULY 12 - 14, 2012
NATIONAL UNIVERSITY OF SINGAPORE
NUS FACULTY OF LAW
CENTRE FOR INTERNATIONAL LAW

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June 26, 2012

Published by the Society of International Economic Law

with the support of the University of Missouri-Kansas City (UMKC) School of Law

C/O LAW DEPARTMENT
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Public Health Regulation: The Impact of Intersections between Trade & Investment Treaties in Asia

Locknie Hsu[*]

I. Introduction

As at 15 January 2012, the number of regional trade agreements (RTAs) notified to the WTO stood at 511.[1] More specifically, according to the World Trade Report 2011 of the WTO, Asian WTO members are among the most active in signing preferential trade agreements.[2]

Singapore, an early contributor to the current bilateral trade agreement trend, has signed ten bilateral free trade agreements (FTAs);[3] Malaysia has signed bilateral six agreements;[4] and China has already signed eight.[5] All are in negotiations for further preferential trade agreements. Even Japan, a relative latecomer to the FTA "circuit", has concluded 12 bilateral agreements.[6] In addition to such bilateral agreements, the ten countries in the Association of Southeast Asian Nations (ASEAN) have collectively signed regional preferential trade agreements with external trading partners such as China, India, Japan, Korea, and Australia and New Zealand.

FTAs typically cover a wide range of issues and areas of trade and investment, providing for both improved access and protection as well as new or strengthened commitments not made in other fora (such as the WTO). As a result, public health regulation – as well as any other areas of regulation - has been significantly affected by such treaties. They contain significant legal commitments that alter the regulatory flexibility of signatory states, particularly in relation to goods, services and investments that have a bearing on the protection and promotion of human life and health. Private enterprises are active in providing input for negotiating such agreements to canvass for greater protection than what may be

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1 See WTO website at: http://www.wto.org/english/tratop_e/region_e/region_e.htm.

2 See the report at the WTO website at: http://www.wto.org/english/res_e/publications_e/wtr11_e.htm.

3 See Singapore Ministry of Trade and Industry website at: http://www.fta.gov.sg/fta_ongoingneg.asp and http://www.fta.gov.sg/fta_concluded.asp.

4 See Malaysia Ministry of International Trade and Industry website at: http://www.miti.gov.my/cms/content.jsp?id=com.tms.cms.section.Section_8ab55693-7f000010-72f772f7-46d4f042.

5 See China Ministry of Commerce website at: http://fta.mofcom.gov.cn/english/fta_qianshu.shtml.

6 See Japan Ministry of Foreign Affairs website at: http://www.mofa.go.jp/policy/economy/fta/.

required under existing WTO obligations and domestic law.[7] Countries pursuing bilateral and regional trade and investment agreements need to balance the expectations of such companies which may both be exporters as well as investors in the field of pharmaceutical products, against public health concerns and needs of the country.

Bilateral treaties may commit states to obligations surpassing those in the WTO TRIPS Agreement (i.e., "TRIPS-plus" commitments), resulting in significant curtailment or reduction of regulatory rights in relation to health. While not all FTAs of Asian states contain such extensive obligations, Singapore and Korea are examples of Asian countries that have entered bilateral FTAs contain binding "TRIPS-plus" commitments. While such agreements usually also contain some exceptions relating to the protection of human health, such exceptions may not always apply to all commitments made. In addition, countries may also have made separate commitments in bilateral investment treaties ("BITs"), which often do not contain such exceptions. FTAs and BITs are becoming sources of intersecting state obligations pertaining to trade, investment, intellectual property rights (IPRs) (such as in patents for pharmaceuticals) and the regulation of public health in Asian states. The true impact and effects of this intersection will become clearer in due course but it is easy to see that such impact can be far-reaching.

While public health measures take many forms, this paper will examine the intersection of treaty obligations and public health regulation from two topical and critical angles: that of access to medicines and the regulation of tobacco-related products, both of interest and concern to many Asian members of the WTO.

Concerns and criticisms – including those over high prescription drug prices resulting from increasingly stringent patent and other IPR protection found in some FTAs - have already been raised in various countries. The current 'mega'-FTA, the Trans-Pacific Partnership Agreement (TPP) which is under negotiation among nine countries, is no exception to such criticism.[8]

Measures relating to regulation of public health have so far not been challenged under any Asian FTA dispute settlement forum, it is not inconceivable that such a challenge may emerge in future. In 2010-2011, however, disputes demonstrating

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7 See, for instance, the strong views provided by the US-ASEAN Business Council in relation to the USSFTA negotiations: www.us-asean.org/Singapore/comments_on_ussfta.doc.

8 See for instance: http://www.ftamalaysia.org/article.php?aid=291. The TPP is currently under negotiation by Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, Vietnam, and the United States, with Canada and Mexico having just announced their plan to join them (see USTR statement, 19 June 2012: http://www.ustr.gov/about-us/press-office/press-releases/2012/june/ustr-kirk-welcomes-canada-as-new-tpp-partner). Japan has indicated interest in possible participation. An open letter dated 8 May 2012 was signed by a number of academics, lawyers, former judges and other opinion-shapers, requesting the TPP negotiators to exclude investor-State arbitration, citing, *inter alia*, health regulation concerns; see http://tpplegal.wordpress.com/open-letter/.

the intersection of trade, investment and health measures arose in the form of challenges to national tobacco measures. In separate disputes and different fora, Uruguay and Australia are having their health-related, tobacco packaging laws challenged under their respective treaty obligations. These disputes have catapulted the health-trade-investment-IPRs intersection to the forefront of debate and are no doubt being watched keenly by Asian states that have similar BIT/FTA and WTO commitments, given their implications on health-related measures.[9]

In addition, many FTAs carry commitments on SPS measures that could have a bearing on health regulation, equal to or stronger than those under WTO agreements.[10] An example is the KORUS FTA, chapter 8, in which the Parties affirm their rights and obligations under the SPS Agreement of the WTO.[11]

Apart from the above, the regulation of public health issues also intersects with the regulation of environmental issues which have a public health impact. For instance, while the KORUS FTA has separate chapters on IPRs (covering, inter alia, patents, pharmaceuticals and medical devices) and the Environment, the latter chapter explicitly recognizes the connection between environment regulatory measures and public health.[12]

II. Intersections

A. Pharmaceuticals and FTAs

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9 Health-related disputes have already been seen in the WTO dispute settlement system. A key recent example – in which the complainant was Indonesia - is the dispute in *US – Measures Affecting the Production and Sale of Clove Cigarettes*, WTO/DS406/AB/R, decision of the Appellate Body (22 March 2012), which examined health-related arguments and Art. XX(b) of the GATT 1994 in the context of complaints under the Agreement on Technical Barriers to Trade (TBT Agreement). For an overview of the interplay between trade and investment liberalization agreements and tobacco regulatory issues and disputes, see the very recent report by the World Health Organization, "Confronting the Tobacco Epidemic", 2012, available at: http://whqlibdoc.who.int/publications/2012/9789241503723_eng.pdf. The report also discusses briefly the potential conflict between obligations in the Framework Convention on Tobacco Control (which many WTO members are signatories to) and those in trade and investment agreements (pp. 74-77).

10 See for example Chapter 6 of the Malaysia-India Comprehensive Economic Cooperation Agreement; text available at: http://www.miti.gov.my/cms/documentstorage/com.tms.cms.document.Document_b3c9637d-c0a8156f-5df15df1-d75dff43/MICECA%20-%20edit%20as%20at%2003052011.pdf.

11 However, that chapter has been excluded from the FTA dispute settlement process.Art. 8.4, KORUS FTA (the text of the chapter is available at: http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file267_12706.pdf). The experience of the North American Free Trade Area (NAFTA) has shown that health-related trade measures may form the subject of challenge under an FTA (note that the tribunal in that case found it lacked jurisdiction and did not proceed to hear the case): see the dispute on the US border closure to Canadian cattle, due to bovine spongiform encephalopathy ("BSE", or "mad cow disease") concerns: http://www.state.gov/s/l/c14683.htm.

12 Art. 20.11, KORUS FTA.

Much of recent literature discusses the implications of provisions in FTAs that contain "TRIPS-plus" provisions, that is, bilateral treaty provisions that provide for commitments beyond and stronger than those that have been made in the WTO under the TRIPS Agreement. The trend of such TRIPS-plus provisions has frequently been examined in the context of enhancement and increased protection of rights of patent-holders, as compared with the wider public concern of ease of access to medicines that may be subject to such patents.[13] The stronger the protection, the more obstacles will be faced by competitors, especially those who manufacture generic drugs to treat similar diseases.

An example of a concern that is the subject of ongoing debate is "evergreening", in which pharmaceutical companies holding patents seek to "stretch" or enhance the available protection of their rights. This comprises various ways of expanding/extending protection by patent-holders of their rights, by essentially building on the existing patent. They can pose obstacles to manufacturers of generic medicines seeking to enter the market by blocking or delaying their market entry.

Recent FTAs have reflected some of these practices giving increased patent-holder protection in a number of ways.

1. Patentability

Some FTAs contain enhanced patentability provisions to the benefit of patent-holders. The following illustrate this.

a) Exclusions

The USSFTA is an example of an FTA which reduces the scope of non-patentable matter, as compared with TRIPS. Art. 16.7 provides for the Parties to exclude such inventions from patentability as are provided for in Arts. 27.2 and 27.3(a) of the TRIPS Agreement. This therefore disallows them from excluding those inventions that are mentioned in Art. 27.3(b) of the TRIPS Agreement, so that there is no longer an option to exclude from domestic protection, plants, animals and biological processes originally within Art. 27.3(b). This category has similarly been excluded from non-patentability under the USSFTA.[14] As a result, Singapore enacted the Plant Varieties Protection Act 2004.[15] Other FTAs also require protection for plant varieties, such as the KORUS FTA[16] and the EU-Korea FTA.[17]

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13 For instance, for a discussion of Jordan's position as an FTA partner of the United States and her TRIPS-plus commitments in relation to pharmaceutical trade under the US-Jordan FTA, see Bashar H Malkawi, March 2009 Vol 4 No 1 Asian J of WTO & Int'l Health Law and Policy, 95-128.

14 Art. 16.7.1, USSFTA.

15 Cap. 232A, 2006 Rev. Ed. See generally, the CRS Congressional Research Report 2004 on the USSFTA and its IPR provisions:

b) Inclusions

As part of patent-holders' "evergreening" efforts to obtain further protection based on their existing patents, new uses or new methods of using, existing patented products such as patented pharmaceutical products, are claimed as new inventions meriting a new patent. While traditional patents formerly claimed rights over the original product or process, increasingly, pharmaceutical companies are claiming patents for such new uses or methods.[18]

Art. 18.8(1) of the KORUS FTA provides a specific inclusion of new uses of a known product:

> "… each Party confirms that patents shall be available for *any new uses or methods of using a known product*." (Italic emphasis added.)

2. Patent Revocation, Oppositions and Renewals

In an effort to preserve granted patents, some FTA provisions seek to limit the grounds for revocation once a patent is granted.

Art. 18.4 of the KORUS FTA, for example, limts the grounds for revocation of a patent to those for refusal for grant.

Art. 18.4 KORUS is an example. Art. 18 also prevents the State Parties to the KORUS from providing for opposition to grant of patent before a grant is made. This is a hurdle to those who may wish to block the granting of a patent without merit.

Some FTAs, such as Art. 10.35 of the EU-Korea FTA, provide for extensions of the duration of rights conferred by patents "to compensate the patent owner for the reduction in the effective patent life as a result of the first authorization to place the product on their respective markets".

3. Other Provisions

a) Marketing Approval Processes and Data Protection

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http://congressionalresearch.com/RL31789/document.php?study=The+U.S.-Singapore+Free+Trade+Agreement.

16 See Art. 18.8(2).

17 See Art. 10.39 of the EU-Korea FTA. The full text of the FTA is available at: http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/korea/.

18 See footnote 13, *supra*.

Art. 18.8(5) of the KORUS FTA requires that the use of "subject matter" of a patent should be for "generating information" to support an application for marketing approval, and any sale/export of goods using such "subject matter" should similarly only be for the purpose of supporting such an application.

Art. 18.9 of the FTA, which applies in particular to "certain regulated products" and their patents, namely, pharmaceutical products and agricultural chemical products, provides periods of blockage of grant of marketing approval to other drug manufacturers. Besides such generous blockage periods, it is noteworthy that the protection terms and periods in Art. 18.9 KORUS exceed those of Art. 16.8.1-2 USSFTA.[19]

Art. 16.8 of the USSFTA led to a new provision - section 19D - in the Singapore Medicines Act. Under this provision, where an earlier product licence has been granted with submission of safety and efficacy information for a medicinal product, no product licence is to be granted for the same product or a "similar" product on basis of the previous grant for a period of 5 years from date of the first grant, unless the earlier licence holder consents.

Art. 10.36 of the EU-Korea FTA similarly imposes a period of 5 years for the protection of data with respect to pharmaceutical products.[20]

b) Patent Linkage Obligations

As explained by one author:

> "'Patent linkage' is a practice of linking regulatory approval for a generic medicine to the patent status of the originator product."[21]

While patent linkage exists in the patent legislation of some countries (such as Singapore and the US), other countries do not make such linkages. The EU for instance is such an example.[22]

In the case of Singapore, the USSFTA came into force in 1 January 2004 and soon after, Singapore introduced amendments to its system of approval and

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19 The USSFTA commitments by Singapore on data protection can be seen in s. 19A of the Medicines Act. See also saving clause in footnote 16-14 USSFTA. Note that Chapter Five of the KORUS FTA contains separate provisions on the sale and marketing of Pharmaceutical Products and Medical Devices.

20 The full text of the EU-Korea FTA is available at: http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/korea/.

21 Hiroko Yamane, "Understanding TRIPS – Globalisation of Intellectual Property Rights and Access to Medicines", Hart Publishing, 2011, at page 445.

22 See EU Directive 2001/83/EC.

licensing of sale of medicines under the existing Medicines Act.[23] One such amendment of some significance is section 12A which established patent linkage.

The more recent KORUS FTA also imposes patent linkage obligations under Art. 18.8(5) and 18.9. Art. 18.9(4) further extends the period of protection against marketing approval in Art. 18.9(1)-(2) beyond the life of the patent in question. This means that upon the expiry of a patent during the period under those provisions, a generic manufacturer must still wait till the end of the protection period before a grant of approval can be obtained.

c) Other Related FTA provisions

Obligations on transparency of measures have been making an appearance in FTAs. These have the potential of affecting IPR-related measures and measures relating to marketing approval or licensing of pharmaceutical products. If these obligations are made subject to the FTA's dispute settlement mechanism, transparency-related claims may arise. Examples include the general transparency provisions of Chapter 19 of the USSFTA and the more specific Art. 18.12 of the Intellectual Property Chapter of the KORUS FTA.

d) Interface with Obligations in Chapter 11 Investment and Investor-State Dispute Settlement

Companies that expend time and money on the development and marketing of pharmaceutical products would expect a reasonable return on that expenditure. IPRs such as patent rights arising from such efforts may form the subject matter of covered "investments" in an FTA. An example of an association of "investment" and the research and development behind valuable undisclosed data of patent holders is that made in relation to marketing approvals for generics. [24] Moreover, many FTAs explicitly list IPRs as covered "investments".

Expansion of the scope of patentable matter (as mentioned above), additional non-patent protection for enterprises holding patents by treaty (such as the protection of test data and the imposition of significant periods of blockage of marketing approval for other similar, generic products) and removal of pre-grant opposition proceedings, all create new and additional obligations on the

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[23] Cap. 176. The amendments were introduced via the Medicines (Amendment) Act 2004 (No 26 of 2004). Concomitantly, amendments were made to the Patents Act (Cap. 221) via the Patents (Amendment) Act 2004 (No 19 of 2004).

[24] See remarks in the Report by the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) at page 14, at: http://www.iipa.com/pdf/ITAC15FinalReportKoreaApril272007.pdf.

part of the host State. This in turn expands the area of liability and potential for complaints if such rights are in some way interfered with by that State. Yet, it may sometimes be necessary for a State to take certain measures to protect the health of its citizens, perhaps in a way that may impinge on these private enterprise rights. It is then not hard to imagine an investment-related complaint when an investor's drug-related patent (or above-mentioned associated treaty rights) is seen to be affected in a manner prohibited the FTA.

For example, most FTAs contain an assurance of "fair and equitable" treatment (FET) for investors and their covered investments. Given the width of this obligation (as demonstrated by several arbitral decisions), interference with an IPR may arguably be a breach of FET. Similarly, an argument may arise as to expropriation (which may include the potentially expansive notion of "indirect" expropriation). Such complaints may be brought by an investor in investor-State dispute settlement (such international arbitration) provided for under the FTA in question.[25] As numerous prior investor-State arbitral decisions have shown, the ambit and interpretation of treaty provisions on which such complaints depend for success vary and outcomes are never totally predictable. In the case of FET obligations, while there have been a number of factors identified by such tribunals in determining if there has been a violation, their application and boundaries are not cast in concrete and could vary with the particular treaty language being interpreted.[26] Should a violation of such a treaty obligation be found, significant compensation may be payable by the State. In addition, the State may have to review its measure to avoid further complaints or compensation.

e) FTA Exceptions

Some exceptions relating to measures to protect health exist under some FTAs.

i. Explicit FTA Exceptions

a. Investment exceptions

There are some FTA provisions that provide a measure of protection to the State against complaints within the Investment Chapters themselves. An example is KORUS investment chapter Art. 11.8(3)(b). Another example is Art. 11.8(3)(c)(ii), in the same chapter, which contains an important exception on *environmental measures* that may be taken to protect human health. The Investment Chapter of the Malaysia-Australia FTA also provides a number of "General

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25 Interestingly, a recent investor-State complaint initiated in 2012 is that of *Apotex Holdings Inc and Apotex Inc v USA*, in which the claimants are manufacturers of generic drugs, making claims under the investment provisions of NAFTA; see http://www.state.gov/s/l/c50826.htm.

26 See for example the broad formulation of factors in *TecMed v Mexico*, ICSID Case No. ARB (AF)/00/2, (Award, 2003), and

Exceptions" in its Art. 12.18. It further provides in Art. 12.7.3 that a breach of another provision is not necessarily a breach of FET.

In order to provide some regulatory flexibility with regard to public health, some FTAs contain an explicit exception for such measures in relation to the definition of "indirect expropriation", such as Annex 11-B, paragraph 3(b) exception, of the KORUS FTA.

b. General exceptions

While the number of FTA provisions that have an impact on trade and investment regulation in Asian countries has been increasing, there has been another – albeit less prominent and numerous increase in health-related exceptions.

FTAs often include general exception provisions, mirroring those in GATT and GATS, to permit, for example, measures necessary for the protection of "human, animal, or plant life or health". An example is Art. 21.1 of the USSFTA. General exception provisions have been incorporated into investment chapters of some recent FTAs. An example of a general exception found in an FTA Investment Chapter is Art. 10.20 of the relatively recent Malaysia-India Comprehensive Economic Cooperation Agreement, which permits measures in the "public interest" including "measures to meet health, safety or environmental concerns" (subject to the conditions of that provision). In addition, Art. 12.1 extends the applicability of Art. XX GATT and Art. XIV GATS general exceptions to the investment chapter of that FTA.

Art. 18.8(3) of the KORUS FTA permits "limited exceptions" the exclusive rights of a patent but subject to certain conditions stipulated in it.

Another example is Art. 17(b) of the ASEAN Comprehensive Investment Agreement (ACIA), which came into force in March 2012.

It is not known yet if the current TPP negotiations will produce a specific exception applying to tobacco-related measures. An announcement has however been made by the USTR of special consideration or a carve-out for tobacco regulation.[27] While this matter remains under negotiation it is noteworthy that the TPP negotiating partners with regard to this issue (Brunei, Malaysia, New Zealand and Vietnam) have found it necessary to argue in favour of including some

[27] Information about the draft proposal is available at: http://www.ustr.gov/about-us/press-office/fact-sheets/2012/may/tpp-tobacco-proposal.

protection of regulatory powers over tobacco and tobacco-related products.

iii. Recognition of WTO flexibilities

WTO members have chosen in some recent FTAs to include the specific flexibilities provided by the TRIPS Declaration on Public Health and related waivers and amendments. An example is KORUS Art. 18.9(3).

B. FTAs, BITs and Tobacco

Over the last two years, disputes have arisen between tobacco enterprises and States with regard to so-called "plain packaging" laws. These laws seek to regulate the packaging and appearance of tobacco products, and reflect aspirations and obligations arising from the World Health Organization-driven Framework Convention on Tobacco Control (FCTC).[28] In respect of these laws, investor-State arbitration claims as well as constitutional claims in national courts have arisen. Uruguay is currently facing arbitration under the Swiss-Uruguay BIT, while Australia is facing challenges under the Hong Kong-Australia BIT, as well at the WTO. More recently, a tobacco enterprise initiated legal proceedings against Norway for her measures tightening sale and display of tobacco products. New Zealand has recently announced plans to introduce "plain packaging" laws for tobacco products as well, and already, there are indications that there may be legal challenges arising from this as well.[29]

The significance of these disputes lies in the legal claims being made and the potential impact of rulings adverse to the states in question. The claims range from investment treaty obligations such "fair and equitable" treatment and expropriation, to TRIPS-related and Technical Barriers to Trade (TBT) complaints in the WTO system.[30]

ICSID arbitral tribunals have shown in recent years a divergence in thinking in several important interpretative decisions, ranging from

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28 The text of the FCTC and related information are available at: http://www.fctc.org/.

29 See announcement by New Zealand's Associate Minister for Health on 19 April 2012: http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205403106_text and http://business.scoop.co.nz/2012/04/19/moving-towards-plain-packaging-of-tobacco-products/; and press report of reactions at: http://www.odt.co.nz/news/national/206216/cigarette-pack-rules-have-makers-fuming.

30 Ukraine and Honduras have lodged complaints under the TRIPS Agreement and TBT Agreement against Australia: see http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds434_e.htm and http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds435_e.htm respectively. The claims also include the "national treatment" provision in GATT 1994.

interpretation of the scope of the well-known FET obligation to what may or may not constitute compensable expropriation.[31] In some decisions, expansive interpretations have indeed been adopted, to the detriment of the state in question, resulting in findings of liability and orders for compensation that run into millions of dollars.

The current disputes between tobacco companies and states such as Uruguay and Australia will provide valuable insight into as-yet untested provisions in the BITs and legal provisions in question, as disputes are decided in arbitration, national courts and at the WTO in the coming months. They will also shed light into the thinking of the respective tribunals on the intersection of IPR, trade, investment law and health issues within the context of the treaties in question.

While there is currently a proposal to include tobacco in the TPP that is under negotiations and it remains to be seen what special considerations, if any, will emerge on TPP parties' rights to protect public health.[32]

III. Conclusion

The conclusion and negotiation of FTAs with strengthened IPR protection commitments by Asian states, juxtaposed with the fact that most FTAs also contain ISDS provisions, provide fertile ground for legal complaints arising from health-related measures. Examples troubling many policy-makers are the issues relating to pharmaceutical and tobacco control measures.

Existing TRIPS flexibilities are important to Asian developing states.[33] FTAs carrying TRIPS-plus obligations expand obligations of States and reduce those flexibilities in various forms. The fact that IPR obligations – including such TRIPS-plus ones – form treaty obligations and that IPRs are likely in most FTAs to be covered "investments" that are eligible for protection and to ISDS, lead to three key implications. First, TRIPS-plus

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31 On the issue of divergences and developing fault lines in investor-State arbitration jurisprudence, see Locknie Hsu (2011), "Investment Treaty Disputes: Ideological Fault Lines and an Evolving Zeitgeist", December 2011, Vol. 12 No. 6, Journal of World Trade & Investment, 827-953.

32 See the fact sheet made available recently, at: http://www.ustr.gov/about-us/press-office/fact-sheets/2012/may/tpp-tobacco-proposal.

33 See for instance the views reflected at the Regional Consultation and Planning Workshop on "Use of TRIPS Flexibilities and Access to Affordable ARVs in Asia", 29-31 May in Bangkok, Thailand: http://asia-pacific.undp.org/practices/hivaids/trips-flexibilities-workshop-may2012.html. See also UNDP/UNAIDS publication, UNDP, UNAIDS, "The Potential Impact of Free Trade Agreements on Public Health", May 2012 (available at the same link as above).

obligations can curtail or significantly reduce a country's regulatory flexibility with respect to health measures. A direct result can be the significant slowing down of generic products reaching a market, resulting in the maintenance of high prices of patented, prescription medicines. Secondly, health measures may be argued by investors who own affected IPRs – such as pharmaceutical patents – to be a failure by the State to observe its TRIPs-plus obligations. Finally, while such arguments are not guaranteed to succeed, the combination of trade, investment, IPRs, health and dispute settlement issues with availability of investment dispute settlement creates a strong temptation to test such arguments. Already, we are seeing this in the field of tobacco control measures, where arguments relating to IPR as well as investment law principles are being raised.

Given the inherent uncertainties of interpretation arising from investment decisions and the novelty of challenges of this kind in the WTO, national courts and in investment arbitration, the regulation of health continues to pose a challenge to governments who have not only committed to WTO agreements but also under bilateral and regional trade and investment treaties. A degree of clarity may yet arise when the outcomes of these pending cases are known. Until then, negotiators of FTAs and BITs will no doubt have to have their eye on these complaints while carrying on with their ongoing treaty negotiation activities.

Another factor of importance is the outcome of the TPP negotiations as its treatment of the above issues could not only have an immediate impact on its signatories (several of which are Asian), but potentially other countries, if TPP is used as a 'template' for future negotiations (particularly with regard to health regulatory issues) bilaterally or multilaterally.

For policy-makers and treaty negotiators the price of other trade and/or non-economic (e.g. political) benefits must be weighed seriously against the above implications.