7-2014

Public health regulation: Convergence, divergence, and regulatory tension: An Asian perspective

Locknie HSU
Singapore Management University, lockniehsu@smu.edu.sg

Society of International Economic Law

Online Proceedings
Working Paper No. 2014/13

FOURTH BIENNIAL GLOBAL CONFERENCE
JULY 10 - 12, 2014
WORLD TRADE INSTITUTE
UNIVERSITY OF BERN

CONVERGENCE, DIVERGENCE, AND REGULATORY TENSION – AN ASIAN PERSPECTIVE

LOCKNIE HSU
ASSOCIATE PROFESSOR, SCHOOL OF LAW
SINGAPORE MANAGEMENT UNIVERSITY

June 17, 2014

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
London School of Economics
Houghton Street
London
WC2A2AE

www.sielnet.org

SIEL 2014 Conference

10-12 July 2014

Bern, Switzerland

"Regulatory Challenges in International Economic Law: Convergence or Divergence?"

Panel Theme: Public Health Regulation and Trade and Investment Law

Draft Paper

Please note that this is a work in progress and is not to be cited or quoted from.

Public Health Regulation:

Convergence, Divergence, and Regulatory Tension – an Asian Perspective

Locknie Hsu*

1. Introduction: the Intersection of Treaties and Public Health

International economic agreements such as bilateral investment treaties (BITs) and free trade agreements (FTAs) deal primarily with economic and attendant legal issues, and disputes arising from their investment provisions usually relate to State regulatory measures which cause economic displacement and loss to foreign investors. Many such treaties in the past did not place any emphasis on the importance of treaty exceptions such as those which allow for health regulation measures. In fact, many older BITs do not mention health at all. Health exceptions have recently gained more prominence in economic treaties, some of them incorporating the familiar language of Article XX(b) of the World Trade Organization's GATT 1994, or some variant of it.[1] In some agreements, health-

* Associate Professor, School of Law, Singapore Management University, LL.B.(NUS), LL.M. (Harvard), Advocate & Solicitor (Singapore); email: lockniehsu@smu.edu.sg.

1 Art. XX(b) reads: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
…
(*b*) necessary to protect human, animal or plant life or health; …".
For examples of recent treaties with similar exception provisions, see for example Art. 17 of the ASEAN Comprehensive Investment Agreement (ACIA), signed 26 February 2009, in force from 29 March 2012.

related exemption provisions have also begun to appear in the context of explaining the scope of indirect expropriation provisions.[2]

Such textual shifts have not occurred on their own, but rather, have taken place against a broader background of legal developments. These include the rapid growth of investor-State disputes, some of which have begun to involve investor challenges to public-health protection State measures. This can be seen in the area of tobacco control, where a number of legal actions are ongoing in various fora against States for their laws on tobacco control. Some of these involve business-party claims against the State based on, *inter alia*, arguments of treaty violations in relation to the claimant's intellectual property rights.[3] States, on the other hand, argue that they have an obligation (and right) to regulate in order to protect public health. This perfectly exemplifies the emerging type of trade-investment law-public health regulation interface – and resulting regulatory tension - faced by many States today.

Apart from such instances of actual disputes, another interface between trade, investment and health regulation which has caused regulatory tension can be seen in the area of pharmaceutical regulation. Two key forces have been at work here.

First, there have been heated debates at the multilateral level – such as in international fora like the WTO and the WHO – over the balance needed between the protection of intellectual property rights (specifically, patents and confidential data) for pharmaceutical inventions to promote innovation on one hand, and public access to affordable medicines, particularly in poorer countries, on the other. Specifically, the effect of obligations in the TRIPS Agreement, flexibilities permitted to members under the Agreement and their implications for members' access to affordable medicines have come under intense scrutiny and are of deep concern to many members, especially since a majority of WTO members are developing and least developed countries. In 2013, the WHO, WTO and WIPO cooperated in a landmark trilateral study on the interface of intellectual property rights, public health and trade, reflecting further the growing interfaces of these areas, divergent views and policies on them, and resulting tensions.[4]

Access to medicines in emergencies or situations of extreme urgency in member countries has been part of this debate at the WTO, resulting in the 2001 Doha Declaration on TRIPS and Public Health, and changes to the TRIPS regime on compulsory licensing.[5]

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2 See, for example, Annex B of the US Model BIT 2012 (available at: www.ustr.gov/sites/.../BIT%20text%20for%20ACIEP%20Meeting.pdf, and Annex 3 of the *Comprehensive Economic Cooperation Agreement between the Republic of India and the Republic of Singapore* (CECA), signed 29 June 2005, in force from 1 August 2005.

3 See, for example, the arbitral action brought by Philip Morris Asia against Australia for its plain-packaging law: http://www.ag.gov.au/internationalrelations/internationallaw/pages/tobaccoplainpackaging.aspx (accessed 16 June 2014).

4 *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (2013); the study is available at: http://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

5 Members have agreed to a waiver of Article 31(f) of the TRIPS Agreement in paragraph 6 of the Declaration (the "Paragraph 6 Waiver"), pending TRIPS amendment; see WTO website at:

Secondly, a number of TRIPS flexibilities have been reduced for certain States which have entered into FTAs containing standards stricter than those in TRIPS. For example, some FTAs have resulted in limiting the flexibility as to what may be excluded from patentability, while others have imposed stricter requirements for the protection of confidential data (such as clinical tests data) than what TRIPS requires. Such provisions, called "TRIPS-plus" provisions, in effect provide rights holders with a degree of protection exceeding that under TRIPS. Moreover, because such FTAs typically permit investor-State arbitration, a rights holder gains a direct avenue of complaint against the State for any claims of violation of these provisions.

The increase in FTA commitments that have an impact both on the patenting and approval (or licensing) of pharmaceuticals contributes to this intersection in significant ways. Not only are TRIPS-plus commitments appearing, but these may vary from treaty to treaty, leading to divergent requirements in signatory states. The 2013 trilateral study mentioned above stated that convergence of international regulation on health and medical technologies "is a challenge" as countries have their own regulatory and administrative and technical systems.[6] However, the study added that "[c]onvergence of the different national systems, in conjunction with harmonization of technical requirements, can remove many of the transactional and human resource costs associated with multiple regulatory submissions in each country, including multiple testings."

Meanwhile, *demandeur* States are continuing to request stronger TRIPS-plus treaty protection in current negotiations, such as those in the Trans-Pacific Partnership Agreement (TPP). Four ASEAN states with varying levels of economic development, healthcare policies and IPR priorities are participants in these negotiations (Brunei Darussalam, Malaysia, Singapore and Vietnam). Among these, there are varying levels of emphasis on IPR protection, with Singapore being probably the strongest IPR proponent, as it explicitly aims to be an "IP hub" as well as a hub for development of biomedical products and services.[7]

In a region such as Asia which comprises high-income countries and least developed countries, differing priority health needs and ability of citizens to pay for medicines can also give rise to divergent trade, IP and health laws and policies.[8]

This article provides some examples of divergences on IP-health policies in members of the Association of Southeast Asian Nations (ASEAN)[9] and some of its regional trade partners, such as

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http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 16 June 2014). The waiver is aimed at increasing access – via a combination of compulsory licensing and permission to export (in a departure from Article 31(f)) – for members which have no capacity to manufacture necessary medicines themselves.

6 Note 4 above, at p 49.

7 See Singapore *IP Hub Master Plan – Developing Singapore as a Global IP Hub in Asia*, IP Steering Committee, 2013: http://www.ipos.gov.sg/Portals/0/Press%20Release/IP%20HUB%20MASTER%20PLAN%20REPORT%202%20APR%202013.pdf (accessed 16 June 2014). See also the Singapore Economic Review Committee Report (2003) and sub-committee reports: http://www.mti.gov.sg/AboutMTI/Pages/Economic%20Review%20Committee.aspx (accessed 16 June 2014).

8 See for example the discussions in Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries*, (2012) Oxford University Press.

China, India, Korea and Japan.[10] These represent some of the most active countries in FTA negotiations in the region over the last decade.

2. TRIPS: Convergence in WTO members' minimum requirements in intellectual property rights protection and enforcement

The TRIPS Agreement provides a minimum set of standards for protection for IPRs in WTO members. This means that while members may exceed these minimum standards or systemic requirements, they are not under any compulsion to do so. This leaves them with a degree of flexibility in regulating intellectual property rights beyond these minimum requirements. This was the nature of the agreement reached by founding members of the WTO through a series of negotiating trade-offs in various areas of trade.

In establishing minimum requirements, the TRIPS Agreement has been the catalyst for a certain degree of convergence in member States' laws on IPRs. While TRIPS does not mandate that the implementing national laws should be identical, they must at the very minimum provide for certain features (such as availability of a system for patent and trade mark registrations) and for a minimum level of enforcement and institutional structures for this purpose. With the exception of least developed countries (LDCs) that enjoy transitional exemptions, WTO members are therefore expected to comply with the TRIPS framework.[11]

3. TRIPS Flexibilities: Room for Divergence

As the TRIPS Agreement provides minimum requirements for national patent systems, WTO members enjoy a degree of flexibility with regard to national laws on pharmaceutical patents and in the regulation of pharmaceutical products. Three areas of such flexibility serve as illustrations here; these are by no means exhaustive.

First, Article 27 of TRIPS permits members – if they so choose – to exclude certain subject matter from being patentable. As a result, within this permissive framework, members have patentability provisions of varying scope in their national laws. Articles 27.2 and 27.3 provide, respectively:

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9 For ASEAN countries, regional forces such as the ASEAN economic integration plan are at work as well, with an ASEAN Economic Community (AEC) to be set up by the end of 2015. The AEC forms part of a greater integration plan which includes two other Communities or "pillars", namely, the ASEAN Political-Security Community (APSC) and the ASEAN Socio-Cultural Community (ASCC). The ASCC and other ASEAN statements have referred to the importance of ensuring affordable healthcare and medication - see for example the recent *Bali Declaration on ASEAN Community in a Global Community of Nations* (*Bali Concord III*), signed by ASEAN leaders on 17 November 2011, *Part C, Socio-Cultural Cooperation*, section 3, paragraph (c).

10 The UN Statistics Division utilizes divisions in Asia according Central Asia, Eastern Asia, Southeast Asia and South Asia; see https://unstats.un.org/unsd/methods/m49/m49regin.htm#asia (accessed 6 March 2014). The ADB utilizes a list of 48 countries as being part of Asia and the Pacific: http://www.adb.org/countries/main (accessed 6 March 2014).

11 See, for example, LDCs' TRIPS exemptions at: http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (accessed 16 June 2014).

> 2. Members *may exclude* from patentability inventions, the prevention within their 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 their law.
>
> 3. Members *may also exclude* from patentability:
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. …
> (Italic emphasis added to exclusionary language above; original footnote omitted.)

Secondly, TRIPS permits the use of exclusive data of a party provided that certain requirements are met. Article 39.3 provides:

> 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.* (Italic emphasis added.)

The origination of the data must pass a threshold test: "origination … which involves a considerable effort". Next, the protection above is directed at guarding gainst "unfair commercial use", which is not defined in the TRIPS Agreement. In addition, members may depart from protection of such data "where necessary to protect the public". This is a wide provision limited by showing "necessity", and could arguably include protection of public health.

Thirdly, TRIPS permits members to make use of compulsory licensing (i.e. licensing of a patented product without the consent of the patent owner) under certain circumstances. Article 31 allows members to determine what constitutes a national emergency or cases of extreme urgency, in which case compulsory licensing may be called into use. The Doha Declaration on the TRIPS Agreement and Public Health reiterated such flexibilities.[12] As a result, members' laws may differ on the circumstances under which compulsory licensing may be permitted.

In addition, Article 8 of the TRIPS Agreement provides a broad exception as follows:

"*Article 8*

[12] See http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 16 June 2014).

Principles

1. Members *may*, in formulating or amending their laws and regulations, *adopt measures necessary to protect public health* and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. …" (Italic emphasis added.)

Outside the WTO, several FTAs contain provisions which circumscribe such areas of flexibility mentioned. Such provisions, which impose stricter requirements than TRIPS, are often referred to as "TRIPS-plus" provisions. For example, the scope for limiting subject matter that is patentable has been restricted in some FTAs. As a result, such states are arguably at a relative regulatory disadvantage as compared with those which still enjoy the benefits of Articles 27.2 and 27.3.

Two FTAs signed by Asian states with the United States contain examples of TRIPS-plus provisions. These are the US-Singapore FTA and the Korea-US FTA. Both are high-income Asian countries with geopolitical interests in having strengthened ties with the US. Evidently, despite the fact that such provisions sacrifice some of the flexibility under TRIPS, the calculation had been made that these are acceptable provisions.[13]

4. TRIPS Flexibilities and Asia's Regulatory Divergences

Before discussion divergences in trade and health policies, it is noteworthy that in the use of TRIPS flexibilities, there is some divergence in the laws and policies of Asian countries. This is hardly surprising since, as mentioned, the TRIPS Agreement mandates minimum standards of IPR protection and enforcement, and leaves it open to member states to determine the precise content of their laws and regulations in areas within the flexibilities. The following are some examples of flexibilities used in divergent ways in Asia.

a) Patentability

As mentioned, Article 27 of TRIPS permits a degree of flexibility with regard to the scope of patentability, a basic requirement for an inventor to gain exclusive rights in the national laws of WTO members. Patentability is thus an important threshold matter which helps authorities determine whether to grant exclusive rights to a pharmaceutical innovator. Such a grant could greatly affect the price of the resulting pharmaceutical product, and therefore, the public's ultimate access to it.

In Asian patent laws, this flexibility has been exercised in a number of different ways. These include how the laws treat known pharmaceutical substances for which new uses have been found. As the

[13] See, for example, Chapters 3 and 12, eds. Tommy Koh and Chang Li Lin, *The United States Singapore Free Trade Agreement – Highlights and Insights*, Institute of Policy Studies and World Scientifc Publishing Co Pte Ltd, 2004.

TRIPS Agreement does not specifically address such "inventions" members are free to determine their patentability in national systems.

In India, for example, for a known drug to be patentable the Indian Patents Act requires proof of improvement in therapeutic efficacy; merely presenting a different form of a known drug without such proof of improved therapeutic efficacy is insufficient for the new product to be patentable.[14] Similarly, in the Philippines, "enhanced efficacy" is required before such products may be patented.[15]

Under Chinese patent law, while second medical use is not specifically addressed, the relevant provision on patentability provides as follows: "Inventions and utility models for which patent rights are to be granted shall be ones which are novel, *creative* and of practical use.… Novelty means that the invention or utility model concerned is *not an existing technology* … Creativity means that, compared with the existing technologies, the invention possesses *prominent substantive features* and indicates *remarkable advancements* … ."[16] (Italic emphasis added.)

Many other countries in Asia, however, do not explicitly require such improvement or enhancement in their patent laws, but rather, leave the national IP authorities to make an assessment based on the minimum requirements for patentability required under the TRIPS Agreement (that the invention be new, involve an inventive step and is capable of industrial application[17]). This has led to divergent practices.[18]

In Singapore, such inventions are patentable without any express legislative requirement of an improvement/enhancement in therapeutic efficacy. This can be seen from section 14(7) of the Patents Act and from Intellectual Property of Singapore (IPOS) practice.[19] Under Thai law and

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14 The Indian Supreme Court recently ruled on the relevant provision (section 3(d) of the Indian Patents Act) in a landmark case, *Novartis AG v Union of India & Others;* judgment, 1 April 2013, available at: supremecourtofindia.nic.in/outtoday/patent.pdf (accessed 13 June 2014); see esp. paras. 182-195.The Act, as amended up to 2013, is available at: ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf (accessed 17 June 2014).

15 See sections 22.1 and 26.2 of the Universally Accessible Cheaper and Quality Medicines Act 2008 (Republic Act No. 9502), and the Implementing Rules.

16 Art. 22 of the Patent Law of the PRC, amended by Decision of Standing Committee of the National People's Congress 2008; text in English available at website of the State Intellectual Property Office of the People's Republic of China, at: http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html (accessed 17 June 2014).

17 Requirements under Article 27(1), TRIPS.

18 One example is the acceptability of "Swiss-type" claims in patent applications involving known products: these appear to be acceptable in Singapore but not, for instance, in Thailand. For an explanation of a "Swiss-type" claim, see the explanation by the European Patent Office (EPO) at: http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1.htm (accessed 13 June 2014) – such claims are no longer accepted by the EPO.

19 See IPOS' *Examination Guidelines for Patent Applications at IPOS*, 14 February 2014, pp. 234-5.

practice it appears that second medical use claims are no longer patentable.[20] Lao PDR and Vietnamese law do not provide for patenting of second medical uses of known products.[21]

Such divergences have implications for countries aiming at greater integration such as those in ASEAN. This is because they affect pricing of pharmaceuticals in ASEAN member countries. They also has implications when ASEAN is negotiating an FTA with an external partner which demands, for example, increased patentability scope to include second medical uses of known medicines, contrary to some of these existing laws, as there appears to be no common negotiating position in such matters. Finally, from a foreign investor's point of view, the divergent regulatory requirements can complicate matters for innovators seeking patent protection within the region for their pharmaceutical products.[22] Such transaction costs can add to costs of the end products, which in turn affects availability to the public.

b) Flexibility Accommodating *Bolar* Exceptions

WTO case law has confirmed that members may, under the TRIPS Agreement, make use of the exception in Article 30 - in particular to permit activities for research and preparation for obtaining pharmaceutical marketing approval.[23] This case law yielded what has come to be known as the *Bolar exception*.[24] States in Asia have therefore included research and *Bolar* exceptions in their patent laws. Examples of such countries are Brunei Darussalam,[25] China,[26] India,[27] Malaysia,[28] Singapore[29] and Thailand.[30] Hong Kong[31] and Lao PDR laws, on the other hand, do not include a *Bolar* exception

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20 The practice changed in 2011; see report, http://www.asiaiplaw.com/article/41/527/ (accessed 14 June 2014).

21 For Lao PDR, see Art. 13, Law No. 01/NA, Law on Intellectual Property (as amended, 2011), text available at: http://www.wipo.int/wipolex/en/details.jsp?id=13482. For Vietnam, see Arts. 4.12, 58, 59 and 60 of Law No. 50/2005/QH11 of November 29, 2005 (as amended in 2009), on Intellectual Property, text available at: http://www.wipo.int/wipolex/en/details.jsp?id=12011 (accessed 1 May 2014).

22 While many countries in Asia are parties to the *Patent Cooperation Treaty* (PCT), done at Washington on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984, and on 3 October 2001 (text available at: http://www.wipo.int/pct/en/texts/articles/atoc.htm), which facilitates and simplifies patent filing across countries, there are some that are not, such as Cambodia and Myanmar: see http://www.wipo.int/pct/en/pct_contracting_states.html (accessed 17 June 2014). (Cambodia is however a party to the *Paris Convention for the Protection of Industrial Property*.)

23 *Canada – Protection of Pharmaceuticals Products*, WT/DS114/R, Panel Report, adopted 7 April 2000.

24 The exception derives its name from a US court decision in *Roche Products Inc v Bolar Pharmaceutical Co*, 733 F. 2d 858 (Fed. Circ. 04/23/1984). See also Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3rd Edition, Sweet & Maxwell, at pages 381-2.

25 *Patents Order 2011*, section 64(2)(b) (experimental purposes) and (2)(g) (for meeting marketing approval requirements).

26 Art. 69(5), Patent Law of the People's Republic of China; text in English available at China's SIPO website: http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html (accessed 16 June 2014).

27 Section 107A, *Patents Act, 1970*.

28 Section 37(1A), *Patents Act*.

29 Section 66(2)(g), *Patents Act*.

30 Section 36(4), *Patents Act*.

31 See Section 75 *Patents Ordinance* (http://www.asialaw.com/Article/1972094/Search/Results/Hong-Kong-Pharmaceutical-Patents-Breaking-the-Ranks.html?Keywords=Bolar+provision).

provision. Indonesian law provides for a research exception but not a *Bolar* exception.[32] Again, for ASEAN, the divergences may present a challenge should the matter arise in negotiations with an external partner regarding this type of exception.

c) Use of Compulsory Licensing

The use of compulsory licensing in Asia has also been a point of divergence. Countries such as India, Indonesia, Malaysia and Thailand[33] have utilized compulsory licensing in recent years. Notably, in Thailand, the pharmaceuticals subject to the compulsory licenses have included those for treating non-communicable diseases. Countries such as Singapore, on the other hand, have not, and Singapore has taken the further step to indicate that it would use compulsory licensing only in emergencies or extremely urgent situations.[34] China has legislated to provide for compulsory licensing although it has not issued any compulsory license yet. In 2003 and 2005, China issued measures on compulsory licenses to address public health problems.[35] In 2012, a revised set of measures was issued, which repeals these earlier measures.[36] Under the 2012 measures, Article 5 to 8 set the situations in which a compulsory license may be applied for/issued. Article 5 provides for situations of a patent holder's failure to work his patent and where a patent holder is shown to have "monopolistic actions". Article 6 permits grant of compulsory licenses in the following situations: "emergency or irregular event of the state, or for the purposes of public interest". Article 7 permits grant of compulsory licenses for manufacture *and* export of patented medicines in certain situations (reflecting the "paragraph 6" waiver mentioned earlier).

d) Limitation of Patent Opposition Opportunities

Some national patent systems provide for an opportunity to oppose a patent application. The TRIPS Agreement is silent about such proceedings. In some FTAs, however, parties have agreed to

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32 Art. 16(3).

33 See generally, Ralf Boscheck, *Intellectual Property Rights & Compulsory Licensing: The Case of Pharmaceuticals in Emerging Markets* (2012) W Comp L & Econ Rev, Volume 35 Issue 4) pp. 621 – 634; Sakda Thanitcul and Matthew Lim Braslow, *Compulsory Licensing of Chronic Disease Pharmaceuticals in Thailand*, Thai J. Pharm. Sci. 37 (2013) 61-83 and Raadhika Gupta, *Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations* (2010) JIPR Vol 15, pp 357-363 .

34 See http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (accessed 12 June 2014). In addition to Singapore, other countries taking this stance are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Chinese Taipei, Turkey and United Arab Emirates. For information on various countries' laws implementing the "paragraph 6" system, see http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm (accessed 12 June 2014).

35 *Measures of January 1, 2006, for Compulsory License on Patent Implementation Concerning Public Health Problems* (promulgated by Order No. 37 of the State Intellectual Property Office (SIPO); see WIPO website at: http://www.wipo.int/wipolex/en/details.jsp?id=6518 and http://www.wipo.int/wipolex/en/text.jsp?file_id=199481 (accessed 16 June 2014).

36 *Measures for Implementing Compulsory Licensing (No. 31) promulgated by the State Intellectual Property Office on June 13, 2003*, and *Measures of March 15, 2012, for Compulsory Licensing of Patent Implementation promulgated by Order No. 64 of the State Intellectual Property Office on November 29, 2005(SIPO).*

eliminate patent opposition proceedings prior to grant of a patent. In the US-Singapore FTA, for example, Art. 16.7 explicitly removes the right to hold any pre-grant opposition proceedings:

> "Each Party shall provide that a patent may only be revoked on grounds that would have justified a refusal to grant the patent, or that pertain to the insufficiency of or unauthorized amendments to the patent specification, non-disclosure or misrepresentation of prescribed, material particulars, fraud, and misrepresentation. *Where such proceedings include opposition proceedings, a Party may not make such proceedings available prior to the grant of the patent.*"

Any challenge has to be brought post-grant under, for example, provisions on revocation of a granted patent. Under US and EU law, post-grant proceedings are available; the US law provides a "pre-issuance protest" process while a patent application is still pending. Far from being removed or reduced in importance recently, this pre-grant process was in fact expanded by statute in 2012.[37]

Pre-grant opposition proceedings still exist in some Asian jurisdictions. These include India, Indonesia and Thailand.[38] Vietnam law permits third parties to "express opinions" on a pending application.[39]

5. Divergence in Participation in Health-Related Treaties and State Relationships with Commercial Entities in Related Industries

Not all Asian states are party to certain multilateral, health-related treaties. For example, signatories to the Framework Convention on Tobacco Control established under the auspices of the WHO,[40]

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37 *The Leahy-Smith US America Invents Act*: see http://usptopost-grant.com/2011/11/05/new-u-s-opposition-proceedings-provide-strategic-avenues-for-patent-challengers/ and http://www.uspto.gov/aia_implementation/faqs-preissuance-submissions.jsp. The implementing rules setting out an amended 'protest' process in 37 CFR § 1.291 were published in the Federal Register, Vol. 77, No. 3, 5 January 2012 (see generally http://www.pharmapatentsblog.com/2012/01/26/proposed-aia-implementation-rules-preissuance-submissions-in-pending-applications/). The US FTC has defended pre-grant proceedings under US law: see FTC, *To Improve Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003, at p. 18. For the EU, see: http://www.epo.org/applying/european/oppositions.html (accessed 8 March 2014). Under the UK Patents Act 1977 (as amended) a third party may make "observations" after publication of an application, before the grant of a patent.[37] While this step may not amount to an opposition proceeding it provides third parties with a useful opportunity to provide the Registrar with pertinent information which the comptroller "shall consider … in accordance with the rules".

38 Section 25 of the Indian Patents Act 1970 (as amended) permits this. For commentaries on this process in India, see also Jakkrit Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries*, (2010) Edward Elgar, at pp. 78-9, and Shivnath Tripathi, *Relevance of Pre-Grant Opposition under Indian Law*, 9 December 2013, at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2365463 (accessed 8 March 2014). Under Art. 45 of the Indonesian Law on Patents, Law Number 14 of 2001, a person may file comments and/or objections prior to a grant, after announcement of an application. As to pre-grant opposition proceedings under the Thai Patent Patent Act B.E. 2522 (1979), as amended by the Patent Act (No. 2) B.E 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999), see sections 31, 32 and 34. On patent opposition systems in general, see *Opposition Systems*, World Intellectual Property (WIPO) Standing Committee on the Law of Patents, document prepared by the WIPO Secretariat, SCP/14/5, 11 December 2009; available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130408 (accessed 8 March 2014).

39 Art. 112, Law on Intellectual Property, No. 50/2005/QH11.

include China, Korea, Japan and all members of ASEAN except for Indonesia. While China is a signatory, the FCTC has only been extended in a very limited way to Hong Kong.[41]

The fact that Indonesia is not a signatory leaves the most populous nation in ASEAN outside the health-protection obligations of the FCTC, while the rest of ASEAN is bound by them. This has implications as ASEAN negotiates trade and investment agreements with its external partners as a bloc (such as the ongoing Regional Comprehensive Economic Partnership Agreement (RCEP) negotiations between ASEAN and six of its major trade partners: Australia, China, India, Korea, Japan and New Zealand), or as ASEAN members which are FCTC parties negotiate with non-FCTC parties such as the US (in the TPP negotiations).[42]

Divergences in policies may also occur where they are shaped by factors such as whether there might be a state entity which is itself involved in tobacco production, distribution or sale, such as in Thailand and China), and in the area of pharmaceuticals, the kind of pharmaceutical production or R&D activities occurring in their economies.

6. Trade Negotiations and Addressing Public Health Regulation Concerns[43]

Cost-benefit analysis and trade-offs

Public authorities need to strike a balance between trade, non-trade benefits, and any disbenefits of entering a FTA, especially where the counter-Party's negotiating demands include a significant change to the existing system. An example would be public health regulations such as those affecting how medicines are approved, marketed and sold, and who may do so. Another would be balancing trade liberalization by removal of tariff and non-tariff barriers with respect to tobacco products against existing tobacco control laws, policies and international obligations. The demands of negotiation may require considering changes that bring a risk of higher pharmaceutical prices. Finally, the potential application of investor-State dispute settlement (such as arbitration) to such provisions raise the potential of costly and high-profile disputes brought by investors.

Authorities through internal consultation often make a final decision which consists of a mix of economic and political judgment. As a result, one question that Asian treaty negotiators often have to consider is how the product of the final decision will affect the country in the long term, especially where a treaty carries investor-State dispute possibilities. In coming to a decision on final trade-offs, a negotiator may have to deal with the tension of the potential trade-investment/public health interface, such as where TRIPS-plus provisions - not hitherto part of the national system - are

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40 See list of FCTC signatories at: http://www.who.int/fctc/signatories_parties/en/.

41 Through Article 153 of the Basic Law of the Hong Kong Special Administrative Region of the People's Republic of China; see *ibid.*, footnote 1 to China's entry in the list.

42 The US has signed but not ratified the FCTC: see http://www.who.int/fctc/signatories_parties/en/ (accessed 16 June 2014).

43 On the sources of tension in regulating health and trade, see, for example, some such sources identified specifically in the pharmaceutical context in Chapter 10, Abbott & Dukes, *Global Pharmaceutical Policy*, (2009) Edward Elgar.

being demanded. An Asian state may therefore aim to agree to necessary trade-offs but find it necessary to ask for safe harbor provisions, to strengthen the *quid pro quo*. An example that could help deal with the tension could be the inclusion of a clear provision for regulatory discretion for health (e.g. through GATT-type exceptions) or a request for specific carve-outs for certain measures from dispute settlement, to reduce the risk of legal exposure. In this connection, the US-Colombia FTA provides interesting language:

> "**Article 16.13: 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. …" (Italic emphasis added.)

While this provision has not been tested before a tribunal, it provides an express interpretative directive with regard to public health goals and the goal of promoting access to medicines "for all".

7. ASEAN Integration: An Opportunity for Convergence in Health Goals and Regulations

For the diverse members of ASEAN, the ASEAN Economic Community (AEC) is the process of formation and is expected to come about by the end of 2015, there is a comprehensive implementation plan.[44] At the same time ASEAN is seeking further economic integration with six of its key regional trade partners, in the negotiations for a RCEP.[45]

In the area of intellectual property policy, while ASEAN has developed an *IP Action Plan*[46] there is no explicit linkage between IP development and treatment of pharmaceutical patents and

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44 See note 9 above.

45 See text accompanying note 42 above.

46 *ASEAN Intellectual Property Rights Action Plan 2011-2015*, available at: ASEAN IP Portal at: http://www.aseanip.org/ipportal/index.php?option=com_content&view=article&id=141:asean-ipr-action-

compulsory licensing by members. Directions for initiatives on affordable healthcare are also not expressly linked to IP policy. There has been no publicly-articulated common FTA negotiating stance on provisions which may affect tobacco control. ASEAN leaders did however recently expressly resolve to ensure access to affordable healthcare, and affordable medicines (see below).[47]

The objective of providing affordable healthcare, and affordable medicines in particular, has become an increasing explicit one in recent ASEAN integration instruments, such as Ministerial declarations and integration agenda. While the AEC plans address economic integration, healthcare and related goals and initiatives fall under the purview of the ASEAN Socio-Cultural Community (ASCC) and the ASCC sets out the specific actions and initiatives to be carried out for such goals.[48] Specifically, the ASCC states as one of its "Strategic Objectives": "*Ensure access to adequate and affordable healthcare, medical services and medicine*, and promote healthy lifestyles for the peoples of ASEAN" (Italic emphasis added).[49]

In a recent Ministerial Declarations, the following important language was expressed by ASEAN heads of State:

> Consistent with the purposes and principles of ASEAN basic instruments to promote health, science and technology, education, human resources, cultural heritage, and the high quality of life, ASEAN *resolves at the global level* to:
>
> a. *Ensure access* to adequate and *affordable healthcare*, medical services, as well as accessibility to *safe, non-counterfeit, affordable, and effective medication* …[50] (Italic emphasis added.)

There is scope for tension in at least two areas, in implementing the above objectives. First, the relative appetite of ASEAN governments for increasing TRIPS-plus protection (such as for pharmaceutical patents and related rights such as data protection) in their national systems differs. Secondly, ASEAN members desire increased foreign investment and trade but will need to manage the affordability of medicines along with changes that economic integration and increasing FTA activity may bring. Related to this, ASEAN members (other than Indonesia) will also need to ensure a balance between trade and investment obligations and their health-protection obligations such as those under FCTC. However, the strong integration objective in ASEAN could also provide an opportunity for greater convergence in how to deal with health-related negotiating demands.

8. Conclusion: Seeking A Convergence of Purposes

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plan-2011-2015&catid=218&Itemid=653 (accessed 12 June 2014). The *Action Plan* does aim to develop a "strong negotiating position" via a "minimum" negotiating framework for IPRs, though (para. 25).

47 Para. C.3(a), *Bali Concord III*, note 9 above.

48 See paras B4-B5, *Roadmap for an ASEAN Community 2009-2015*; text available at ASEAN website at: http://www.asean.org/resources/publications/asean-publications/item/roadmap-for-an-asean-community-2009-2015 (accessed 13 June 2014).

49 Para. B4, *ibid.*

50 Para C.3(a), *Bali Concord III*, note 9 above.

Given divergences such as those mentioned in this article, one may question if convergence within Asia on trade, investment and health laws is relevant or feasible. For those seeking closer integration and harmonization, it is – but to a point. For this to materialize, there must first be a convergence of purposes with regard to trade and health, especially among those seeking closer economic and other regional integration. The following are some possible, practical steps toward such convergence. First, it is necessary to identify common interests and priority health goals across borders. Given that there are diverse economic and public health needs within Asia, such a first step will create a common platform for better collaborative and coordinated regulatory responses. Secondly, it is imperative to identify and express common, necessary regulatory space for public health measures in trade and investment treaty negotiations. Thirdly, a helpful step would be discussion and design for inclusion in trade/investment treaties of non-contentious, problem-solving dispute settlement methods with regard to health-related regulation disputes, so that lasting, innovative solutions that are oriented toward meeting trade and health goals can be forged. It is submitted that such steps can help policy-makers bring about greater convergence, so as to better handle tensions arising from the trade-investment-public health interface as it arises in domestic rule-making and in treaty-making.