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Regulatory flexibilities and tensions in public health and trade: An Asian perspective

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REGULATORY FLEXIBILITIES AND TENSIONS IN PUBLIC HEALTH AND TRADE — AN ASIAN PERSPECTIVE

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ABSTRACT

Regulatory issues relating to public health are a source of tensions in recent trade and investment negotiations, treaties and disputes. Issues arising from the intersection between public health regulation and trade and investment treaties have given Asian states pause for thought. They have led to a critical need to confront the scope and meaning of legal obligations vis-à-vis public health and regulatory objectives, and their implications for stakeholder interests. The intersection and resulting tensions have already led the WTO, WHO and WIPO to work together in an unprecedented manner to address some of the issues at the global level. The laws evolving around these

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issues are demonstrating a notable divergence. As an example, the debate on access to medicines demonstrates divergent approaches to solutions. This paper examines the reasons behind legal and policy divergences in public health issues in the context of treaty obligations, with examples from Asia, and suggests that a convergence of purpose(s) is needed for a convergence of solutions to be found, in order to deal with such tensions.

KEYWORDS: *trade, investment, public health, TRIPS, flexibilities, medicines, FTAs, BITs*

I. INTRODUCTION: THE INTERSECTION OF TRADE AND INVESTMENT TREATIES AND PUBLIC HEALTH

Increasingly, international agreements such as bilateral investment treaties (BITs) and free trade agreements (hereinafter "FTAs") contain provisions which have a direct or indirect impact on public health regulation powers. For the most part, such agreements still deal primarily with economic commitments (such as trade and investment liberalization), related legal issues, and disputes arising from their investment provisions. Many older treaties, particularly the bilateral investment treaties negotiated before the 1990s, do not explicitly mention health at all. Public health-related provisions, such as general exceptions permitting departures from treaty commitments, have recently gained more prominence in bilateral and regional treaties. Some of these incorporate 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-related exemption provisions have also begun to appear in the context of explaining the scope of indirect expropriation provisions.[2]

Such textual shifts have occurred against a broader background of other 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

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[1] General Agreement on Tariff and Trade [hereinafter GATT], Apr. 15, 1994, 1867 U.N.T.S. 187, art. XX 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, e.g.*, ASEAN Comprehensive Investment Agreement (ACIA), art. 17, Feb. 26, 2009 (entered into force Mar. 29, 2012), http://aseansummit.mfa.go.th/14/pdf/Outcome_Document/ASEAN%20Compre%20Invest%20Agreement.pdf.

[2] *See, e.g.*, US Model BIT 2012, Annex B, https://ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf; Comprehensive Economic Cooperation Agreement between the Republic of India and the Republic of Singapore (CECA), Annex 3, June 29, 2005 (entered in force Aug. 1, 2005), http://wits.worldbank.org/GPTAD/PDF/archive/India-singapore.pdf.

[3] *See, e.g.*, TOBACCO PLAIN PACKAGING — INVESTOR-STATE ARBITRATION, http://www.ag.gov.au/tobaccoplainpackaging (last visited Feb. 11, 2015); the arbitral action brought by Philip Morris Asia against Australia for its plain-packaging law.

that they have an obligation (and right) to regulate in order to protect public health. This perfectly exemplifies the emerging trade-investment law and public health regulation interface and resulting regulatory tension faced by many States today.

Apart from disputes, another interface between trade investment and health regulation which has at times caused regulatory tension can be seen in the area of pharmaceutical regulation. Two key forces are relevant to mention in this context.

First, debates have arisen at the multilateral level such as in international fora like the World Trade Organization (hereinafter "WTO") and the World Health Organization (hereinafter "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 Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS"), 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. This is, especially true since a majority of WTO members are developing and least developed countries.[4]

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

Secondly, a number of TRIPS flexibilities have been reduced, through what are commonly referred to as "TRIPS-plus" provisions, 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)

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[4] In 2013, the World Health Organization [hereinafter WHO], World Trade Organization [hereinafter WTO] and World Intellectual Property Organization [hereinafter 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. *See generally* WHO, WIPO & WTO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (2013), http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

[5] Members have agreed to a waiver of Article 31(f) of The Agreement on Trade-Related Aspects of Intellectual Property Rights in paragraph 6 of the Declaration (the "Paragraph 6 Waiver"), pending TRIPS amendment; *see generally* WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003). 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.

than what TRIPS requires. Such provisions 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. In the absence of such dispute avenues an aggrieved investor might have had to persuade its own government to take up its cause at another forum, such as in the state-to-state dispute system of the WTO, or in state-to-state negotiations or litigation.

The increase in FTA commitments that have an impact both on the patenting and marketing approval of pharmaceuticals contributes to this intersection in significant ways. Such commitments may be TRIPS-plus and vary from treaty to treaty, leading to divergent requirements in signatory states. The landmark 2013 trilateral study of the WTO, WHO and WIPO mentioned above recognized 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", but 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]

There are some discernible, specific reasons for tensions faced by regulators, and some of these are outlined here.

First, countries with divergent health and economic policies and priorities are finding that they have to come together either in the context of trade negotiations or other regional fora to find common ground for economic collaboration. The ongoing Trans-Pacific Partnership Agreement (hereinafter "TPP") negotiations are an example where countries including a number from Asia have to craft economic commitments that may have significant health implications. The US, for one, proposes stringent intellectual property rights protection under the agreement, while proposing to adopt a "differential approach" in relation to pharmaceutical products.[7] In the relatively new area

[6] WHO, WIPO & WTO, *supra* note 4, at 49.

[7] The 12 Trans-Pacific Partnership Agreement [hereinafter TPP] negotiating countries are Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. On the negotiating stance of the US in relation to intellectual property rights under the TPP, *see* INTELLECTUAL PROPERTY RIGHTS, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-chapter-chapter-negotiating-9 (last visited Mar. 5, 2015); *Stakeholder Input Sharpens, Focuses U.S. Work on Pharmaceutical IPR in the TPP*, THE OFFICIAL BLOG OF THE UNITED STATES TRADE REPRESENTATIVE (Nov., 2013), https://ustr.gov/about-us/policy-offices/press-office/blog/2013/November/stakeholder-input-sharpens-focuses-us-work-on-pharmaceutical-IP-in-TPP; Michael Froman, Ambassador, U.S. Trade Representative, Remarks at the Center for American Progress: A Values-Driven Trade Policy (2014), at 9, http://cdn.americanprogress.org/wp-content/uploads/2014/02/Center-for-American-Progress-Remarks-Ambassad

of biologic medicines in particular, the agreement may set new, high standards of protection for innovators which may affect competition in the supply of such products or similar products, and their prices.[8]

Another broad, important regional effort is that in the Association of Southeast Asian Nations (hereinafter "ASEAN"), which has set a target of establishing an ASEAN Economic Community by the end of 2015. ASEAN's integration plan also includes the establishment of a Political-Security Community and a Socio-Cultural Community (which addresses public health issues in ASEAN). These integration plans also require officials from ASEAN's diverse legal systems to jointly address economic and health issues (among others). At the same time, ASEAN is negotiating with six external trade partners to form the Regional Comprehensive Economic Partnership (hereinafter "RCEP") agreement.[9] In another evolving initiative under APEC, another large and diverse group of economies from the Asia-Pacific region including Canada, China, Hong Kong, Indonesia, Japan, Korea, Malaysia, Thailand, Russia, Singapore and the US are likely to launch into trade negotiations in the foreseeable future.[10] Interestingly, none of these trade groupings mentioned above so far include India, which is a large player in the manufacture of pharmaceutical products.

Secondly, countries in Asia have addressed the use of flexibilities under the TRIPS Agreement in diverse ways. For example, India and Thailand have exercised their right to make use of compulsory licensing in pharmaceuticals (not without legal challenges in courts by pharmaceutical companies) while others have not. Others, such as Singapore, have taken the stance that it would not use this unless it were a national emergency.[11]

Thirdly, *demandeur* States continue to request TRIPS-plus treaty protection in trade negotiations, such as those in TPP.[12] Four ASEAN states

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or-Froman-2-18-14.pdf. *See also* INTELLECTUAL PROPERTY, https://ustr.gov/issue-areas/intellectual-property (last visited Feb. 20, 2015).

[8] *See Hatch, Kerry Call for Strong IP Standards to Protect Biologics Data in Trans-Pacific Partnership Negotiations*, THE UNITED STATE SENATE COMMITTEE ON FINANCE (Sept. 12, 2011), http://www.finance.senate.gov/newsroom/ranking/release/?id=9fc0a1bb-e420-418a-835c-14512434a436.

[9] *See* REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP, http://dfat.gov.au/trade/agreements/rcep/Pages/regional-comprehensive-economic-partnership.aspx (last visited Feb. 20, 2015).

[10] *See* ANNEX A – THE BEIJING ROADMAP FOR APEC'S CONTRIBUTION TO THE REALIZATION OF THE FTAAP, http://www.apec.org/Meeting-Papers/Leaders-Declarations/2014/2014_aelm/2014_aelm_annexa.aspx (last visited Feb. 20, 2015).

[11] *See Decision Removes Final Patent Obstacle to Cheap Drug Import*, WTO (Aug. 30, 2003), http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

[12] *See, e.g.*, Gabrielle Chan & Michael Safi, *WikiLeaks' Free Trade Documents Reveal "Drastic" Australian Concessions*, THE GUARDIAN (Oct. 17, 2014, 9:42 AM), http://www.theguardian.com/australia-news/2014/oct/17/wikileaks-trans-pacific-partnership-drastic-australian-concessions. The U.S.' stated objectives, *see also* TRANS-PACIFIC PARTNERSHIP: SUMMARY OF U.S. OBJECTIVES, http://www.ustr.gov/tpp/Summary-of-US-objectives (last visited Mar. 5, 2015); and other statements,

with varying levels of economic development, healthcare policies and Intellectual Property Right (hereinafter "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 the development of biomedical products and services.[13]

In an economically diverse region such as Asia which simultaneously encompasses high-income countries and least developed countries, differing priority health needs and abilities of citizens to pay for medicines can also give rise to divergent trade, IP and health laws and policies. [14] As will be explained later, countries also enter into economic agreements with non-economic objectives in mind. These may include geo-political considerations, which may condition the acceptance (or not) of certain trade-offs (which may therefore have an impact on public health policy) in the negotiation of such agreements. This article provides some examples of the regulatory aspects of the IP-health nexus in member countries of ASEAN [15] and some of its regional trade partners, such as China, India, Korea and Japan. [16] These represent some of the most active countries in FTA negotiations in the region over the last decade.

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see, e.g., INTELLECTUAL PROPERTY RIGHTS**,** *supra* note 7; OUTLINES OF TPP, https://ustr.gov/tpp/outlines-of-TPP (last visited Mar. 4, 2015).

[13] *See generally* Singapore IP Steering Committee, *IP Hub Master Plan — Developing Singapore as a Global IP Hub in Asia* (2013), http://www.ipos.gov.sg/Portals/0/Press%20Release/IP%20HUB%20MASTER%20PLAN%20REPORT%202%20APR%202013.pdf. *See also* THE SINGAPORE ECONOMIC REVIEW COMMITTEE, ECONOMIC REVIEW COMMITTEE REPORT AND SUB-COMMITTEE REPORTS, *available at* http://www.mti.gov.sg/AboutMTI/Pages/Economic%20Review%20Committee.aspx.

[14] *See generally* SRIVIDHYA RAGAVAN, PATENT AND TRADE DISPARITIES IN DEVELOPING COUNTRIES (2012).

[15] For Association of Southeast Asian Nations [hereinafter ASEAN] countries, regional forces such as the ASEAN economic integration plan are at work as well, with an ASEAN Economic Community [hereinafter 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 [hereinafter ASCC]. The ASCC and other ASEAN statements have referred to the importance of ensuring affordable healthcare and medication — *see, e.g.*, Bali Declaration on ASEAN Community in a Global Community of Nations "Bali Concord III" [hereinafter Bali Concord III], Part C, Socio-Cultural Cooperation, § 3, ¶ (c) (2011), http://www. preventionweb.net/files/23664_baliconcordiii28readyforsignature29.pdf.

[16] The UN Statistics Division utilizes divisions in Asia according Central Asia, Eastern Asia, Southeast Asia and South Asia; *see* GEOGRAPHICAL REGION AND COMPOSITION, https://unstats.un.org/unsd/me thods/m49/m49regin.htm#asia (last visited Feb. 11, 2015). The Asian Development Bank [hereinafter ADB] utilizes a list of 48 countries as being part of Asia and the Pacific. *See* ADB COUNTRIES AND REGIONS, http://www.adb.org/countries/main (last visited Feb. 11, 2015).

II. TRIPS: MINIMUM REQUIREMENTS AND REGULATORY SPACE

The TRIPS Agreement provides a minimum set of standards for the protection of IPRs for 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 trademark registration), a minimum scope of what is patentable, and 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 these requirements.[17]

III. TRIPS FLEXIBILITIES

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 their implementation. Three areas of such flexibility serve as illustrations here but these are by no means exhaustive.

A. Non-patentable Subject Matter

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:

> 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

[17] LDCs' TRIPS exemptions, *see, e.g.*, RESPONDING TO EAST DEVELOPED COUNTRIES' SPECIAL NEEDS IN INTELLECTUAL PROPERTY, http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (last visited Feb. 11, 2015).

> 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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

B. Data Protection Obligations

Secondly, TRIPS permits the use of undisclosed 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*. (Emphasis added)

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

Countries in Asia/ASEAN do not all have the same standards or procedures for data exclusivity protection. Some countries such as Malaysia have developed a registration system to implement the flexibility provided by Art. 39, as will be explained below.

C. Compulsory Licensing

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.[18] 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:

> 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. (Emphasis added)

Outside the WTO, several FTAs contain provisions that circumscribe the 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 that 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 (hereinafter "USSFTA") and the Korea-US FTA (hereinafter "KORUS"). Both are high-income Asian countries with geopolitical interests in having strengthened ties with the US. Evidently, despite the fact that these provisions would sacrifice some of the flexibility under TRIPS, the calculation had been made that they are acceptable.[19]

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[18] *See generally* WTO, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001).

[19] *See generally* Ong Ye Kung, *Lessons from the USSFTA Negotiations*, *in* THE UNITED STATES SINGAPORE FREE TRADE AGREEMENT — HIGHLIGHTS AND INSIGHTS 33 (Tommy Koh & Chang Li Lin eds., 2004); Woon Yin Liew, *Intellectual Property Rights*, *in* THE UNITED STATES SINGAPORE FREE TRADE AGREEMENT — HIGHLIGHTS AND INSIGHTS 123 (Tommy Koh & Chang Li Lin eds., 2004).

IV. TRIPS FLEXIBILITIES: REGULATORY APPROACHES IN ASIA

Before discussing divergences in trade and health policies, it should be noted 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 jurisdictions, 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. Given that the 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 proof of improved therapeutic efficacy is insufficient for the new product to be patentable.[20] Similarly, in the Philippines, "enhanced efficacy" is required before such products may be patented.[21]

Under Chinese patent law, while second medical use is not specifically addressed, the relevant provision on patentability stipulates "Inventions and utility models for which patent rights are to be granted shall be ones which are

[20] 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, Civil Appeal Nos. 2706-2716 of 2013, Civil Appeal Nos. 2728 of 2013, Civil Appeal Nos. 2717-2727 of 2013 (Apr. 1, 2013), *available at* http://supremecourtofindia.nic.in/outtoday/patent.pdf; *see* especially The Patent (Amendment) Act, 1970 [hereinafter Patent Act of India], No. 39, Acts of Parliament, ¶¶ 182-95, 1970 (India), http://ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.

[21] *See* The Universally Accessible Cheaper and Quality Medicines Act of 2008, Rep. Act No. 9502, §§ 22.1, 26(b), (2008) (Phil.); Implementing Rules and Regulations of the Republic Act No. 9502, Administrative Order No. 2008-01, 2008 (Phil.).

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* . . . ."(Emphasis added). [22]

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[23]). This has led to divergent practices.[24]

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.[25] Under Thai law and practice it appears that second medical use claims are no longer patentable.[26] Lao PDR and Vietnamese law do not provide for the patenting of second medical uses of known products.[27]

These divergences have implications for countries aiming at greater integration such as those in ASEAN. This is because the patentability (or not) of pharmaceuticals for which new uses can be found may affect the pricing of such pharmaceuticals in ASEAN member countries. Divergences also have implications when ASEAN is negotiating an FTA with an external partner which demands, for example, increased patentability scope to include second

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[22] Zhong Hua Ren Min Gong Han Guo Zhuan Li Fa (中华人民共和国专利法) [The Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, effective Apr. 1, 1985) (amended by the Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective 1 Oct. 2009) [hereinafter Patent Law of PRC], art. 22 (China).

[23] Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPS] art. 27(1), Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[24] 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* EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION, *available at* http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1.htm. Such claims are no longer accepted by the European Patent Office.

[25] *See* INTELLECTUAL PROPERTY OFFICE OF SINGAPORE [hereinafter IPOS], EXAMINATION GUIDELINES FOR PATENT APPLICATIONS AT IPOS 234-35 (Feb. 14, 2014), *available at* http://www.ipos.gov.sg/Portals/0/Patents/Examination%20Guidelines%20for%20Patent%20Applications%20at%20IPOS_Feb%202014.pdf.

[26] The practice changed in 2011; *see* Jennifer D. Fajelagutan, *The End of "Swiss-type" Use Claims in Thailand*, ASIA IP (July 1, 2011), http://www.asiaiplaw.com/article/41/527/.

[27] For Lao People's Democratic Republic, *see* Law on Intellectual Property, No. 01/NA, art. 13 (as amended, 2011) (Laos), *available at* http://www.wipo.int/edocs/lexdocs/laws/en/la/la025en.pdf. For Vietnam, *see* Law on Intellectual Property [hereinafter Law on Intellectual Property of Vietnam], No. 50/2005/QH11 of November 29, 2005, arts. 4.12, 58, 59, 60 (as amended, 2009) (Viet.), *available at* http://www.wipo.int/edocs/lexdocs/laws/en/vn/vn063en.pdf.

medical uses of known medicines, contrary to some of the existing laws, as there often appears to be no common negotiating position in these 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.[28] While many other factors (such as the imposition of tariffs by States, the presence of corruption and poor health infrastructure or health products delivery) can contribute to the costs of medicines, transaction costs can also add to the costs of end-products, which in turn affects public availability.

B. Bolar Exceptions in Asia

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.[29] This case law yielded what has come to be known as the *Bolar exception*.[30] States in Asia have therefore included research and *Bolar* exceptions in their patent laws. Examples of such countries are: Brunei Darussalam,[31] China,[32] India,[33] Malaysia,[34] Singapore[35] and Thailand.[36] Hong Kong[37] and Lao PDR laws, on the other hand, do not include a *Bolar* exception provision. Indonesian law provides for a research exception but not a *Bolar* exception.[38] Again, for ASEAN, the divergences may present challenges should matters arise in negotiations with an external partner regarding this type of exception.

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[28] While many countries in Asia are parties to the Patent Cooperation Treaty. Patent Cooperation Treaty, June 19, 1970 (amended on Sept. 28, 1979, modified on Oct. 3, 2001), 9 I.L.M. 978; which facilitates and simplifies patent filing across countries, there are some that are not, such as Cambodia and Myanmar. Cambodia is however a party to the Paris Convention for the Protection of Industrial Property. *See* THE PCT NOW HAS 148 CONTRACTING STATES, http://www.wipo.int/pct/en/pct_contracting_states.html (last visited Feb. 14, 2015).

[29] *See generally* Panel Report, *Canada – Protection of Pharmaceuticals Products*, WT/DS114/R (Apr. 7, 2000).

[30] The exception derives its name from a US court decision in Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F. 2d 858 (Fed. Circ. 1984). *See also* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 381-82 (3d ed. 2008).

[31] Constitution of Brunei Darussalam (Order made under Article 83(3)), Patents Order, No. S 57, Oct., 2011, §§ 64(2)(b), (2)(g) (Brunei).

[32] Patent Law of PRC, *supra* note 22, art. 69(5).

[33] Patent Act of India, *supra* note 20, § 107A.

[34] *Id.* § 37 (1A).

[35] *Id.* § 66 (2) (g).

[36] *Id.* § 36 (4).

[37] *See* Patents Ordinance, (1997) Cap. 514, § 75 (H.K.).

[38] Law of the Republic of Indonesia Number 19 Year 2002 Regarding Copyright, art. 16(3), *available at* http://portal.unesco.org/culture/es/files/30382/11424187703id_copyright_2002_en.pdf/id_copyright_2002_en.pdf (Indon.).

C. Approaches to Compulsory Licensing and its Use in Asia

Under Art. 5(A) of the Paris Convention, a signatory state "shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

Art. 31 of the TRIPS Agreement permits the use of compulsory licensing in circumstances defined thereunder. In addition, WTO members have agreed to waive the requirements of Art. 31(f) to permit exportation of pharmaceuticals under compulsory licensing in certain circumstances, in what is known as the "paragraph 6" mechanism.[39] Compulsory licensing may, in particular, be employed to remedy the anti-competitive practices of businesses.[40]

The use of compulsory licensing in Asia in relation to patented pharmaceuticals has been divergent. In recent years countries such as India, Indonesia, Malaysia and Thailand[41] have utilized compulsory licensing. Notably, in Thailand, the pharmaceuticals subject to the compulsory licenses have included those for treating non-communicable diseases. In the case of India, the first compulsory license was issued and challenged with respect to a medicine used for cancer treatment. In a dispute by the patent-holder, Bayer Corporation, a US-based pharmaceutical company, the Bombay High Court upheld the compulsory license under India's Patents Act.[42]

On the other hand countries such as Singapore have not, and Singapore has announced that it would use compulsory licensing only in emergencies or extremely urgent situations.[43] Such use is provided for under the Singapore

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[39] *See generally* WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, *supra* note 5; WTO, *Amendment of the Trips Agreement*, WT/L/641 (Dec. 6, 2005).

[40] TRIPS, *supra* note 23, arts. 31(k), 8(2), 40; also address anti-competition measures.

[41] In 2005, Taiwan had also issued a compulsory license, for Tamiflu; *see* Kathrin Hille, *Taiwan employs compulsory licensing for Tamiflu*, FINANCIAL TIMES (Nov. 25, 2005, 4:17 PM), http://www.ft.com/cms/s/0/cebeb882-5dcb-11da-be9c-0000779e2340.html#axzz3KFBahOyn. *See generally* Ralf Boscheck, *Intellectual Property Rights & Compulsory Licensing: The Case of Pharmaceuticals in Emerging Markets*, 35(4) WORLD COMP. L. & ECON. REV. 621 (2012); Sakda Thanitcul & Matthew Lim Braslow, *Compulsory Licensing of Chronic Disease Pharmaceuticals in Thailand*, 37 THAI J. PHARM. SCI. 61 (2013); Raadhika Gupta, *Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations*, 15 J. INTELL. PROP. R. 357 (2010).

[42] *See generally* Patent Act of India, *supra* note 20. *See* Bayer Corporation v. NATCO Pharma Ltd., Writ Petition No. 1323 of 2013, Bombay H.C., *available at* http://bombayhighcourt.nic.in/generatenewauth.php?auth=cGF0aD0uL2RhdGEvanVkZ2VtZW50cy8yMDE0LyZmbmFtZT1PU1dQMTEyODEzLnBkZiZzbWZsYWc9Tg== (India).

[43] *See Decision Removes Final Patent Obstacle to Cheap Drug Imports*, *supra* note 11. 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 Members' Laws Implementing the*

Patents Act, defined not as "compulsory licensing", but under use "for the services of the Government".[44] Separately, another provision sets out the use of "compulsory licensing" for the specific purposes of remedying anti-competitive practices.[45]

China has legislated to provide for compulsory licensing although it has not yet issued any compulsory licenses. In 2003 and 2005, China issued regulations on compulsory licenses to address public health problems.[46] In 2012, a revised set of regulations was issued, which repeals these earlier measures.[47] Under the 2012 measures, Articles 5 through 8 determine the situations in which a compulsory license may be issued/applied for. 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 the granting of compulsory licenses in the following situations: "emergency or irregular event of the state, or for the purposes of public interest". Article 7 permits the granting of compulsory licenses for manufacture *and* export of patented medicines in certain situations (reflecting the "paragraph 6" waiver mentioned earlier).

It is obviously a difficult balance to achieve between providing for intellectual property protection seen to be a factor contributing to innovative activity in many Asian countries and ensuring that the public has adequate access to pharmaceuticals at affordable pricing. As in many other countries, Asian governments have the challenge of finding this balance, particularly in the face of trade partner demands, such as in the context of an FTA or other negotiations.

"Paragraph 6" System, WTO (Jan. 31, 2014), http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

[44] Patents Act [hereinafter Patents Act of Singapore], Cap. 221, §§ 56-62, (1994) (as amended, 2005) (Sing.).

[45] *Id.* § 55.

[46] She Ji Gong Gong Jian Kang Wen Ti De Zhuan Li Shi Shi Jiang Zhi Xu Ke Ban Fa (涉及公共健康问题的专利实施强制许可办法) [Measures of January 1, 2006, for Compulsory License on Patent Implementation Concerning Public Health Problems] (promulgated by Order No. 37 of the State Intell. Prop. Off., Nov. 29, 2005, effective Jan. 1, 2006) (Lawinfochina) (China).

[47] Zhuan Li Shi Shi Jiang Zhi Xu Ke Ban Fa (Guo Jia Zhi Shi Chan Quan Ju Ju Chang Ling Di 31 Hao Gong Bu) (专利实施强制许可办法（国家知识产权局局长令第 31 号公布)) [Measures for Compulsory Licensing of Patent Exploitation] (promulgated by Order No. 31 of the State Intell. Prop.Off., June 13, 2003) (Lawinfochina) (China); Zhuan Li Shi Shi Jiang Zhi Xu Ke Ban Fa (Guo Jia Zhi Shi Chan Quan Ju Ju Chang Ling Di 64 Hao Gong Bu) (专利实施强制许可办法（国家知识产权局局长令第 64 号公布）) [Measures for Compulsory Licensing of Patent Exploitation] (promulgated by Order No. 64 of the State Intell. Prop. Off., Mar. 15, 2012) (Lawinfochina) (China).

D. The Impact of FTA Commitments on Public Health Regulation in Asia: Some Examples

A number of Asian countries have been active in negotiating FTAs in the last 15 years and some of these agreements contain obligations that impact upon public health. Below are some examples.

1. Example 1: Expanding Patentable Subject Matter Beyond TRIPS Art. 27 Requirements. — Considering patentability is a key threshold requirement for the granting of a patent monopoly, it serves a critical gate-keeping function. The broader the scope of patentable matter, the greater will be the number and types of patents potentially granted.

Art. 27 of the TRIPS Agreement provides a minimum scope of patentable subject matter. Beyond this, WTO members have flexibility in determining what may *not* be patentable under their national laws. A number of FTAs now contain commitments on the scope of patentable subject matter which limits such flexibilities, primarily by increasing such scope. In other words, the commitments seek to significantly reduce what may be treated as *non*-patentable by national authorities.

The USSFTA is an example of an FTA which reduces the scope of non-patentable matter. 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 TRIPS.[48]

Another example is the KORUS, in which Art. 18.8 also reduces what may be excluded from patentability, as compared with Art. 27(3) of TRIPS.

The Japan-Switzerland Agreement, on the other hand, preserves a version of Art. 27.3(b).[49]

An important implication arising from this for pharmaceutical inventions is that it expands the potential for patentability, and therefore, the scope of patent monopolies that may be granted. In turn this means that possibly more types of pharmaceutical inventions will enjoy patent protection, to the

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[48] TRIPS, *supra* note 23, art. 27.3(b) provides for the following:

> (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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

[49] *See* Agreement on Free Trade and Economic Partnership between Japan and the Swiss Confederation, art. 117.3, Sept. 1, 2009, http://www.mofa.go.jp/region/europe/switzerland/epa0902/agreement.pdf. *See also* Bayer Corporation v. NATCO Pharma Ltd., *supra* note 42 and accompanying text.

exclusion of competitors' use or supply of such products or similar alternatives.

2. Example 2: Limitation of Patent Opposition Opportunities. — Some national patent systems provide for an opportunity to oppose a patent application, as such oppositions are viewed as a means to test the strength and legitimacy of the application. The TRIPS Agreement is silent about such proceedings. In some FTAs, however, parties have agreed to eliminate patent opposition proceedings prior to the granting 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, this pre-grant process was in fact expanded by statute in 2012.[50]

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[50] Leahy-Smith U.S. America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); *see* Ken Burchfiel, *New U.S. Opposition Proceedings Provide Strategic Avenues for Patent Challengers*, USPTO PATENT TRIALS (Nov. 5, 2011), http://usptopost-grant.com/2011/11/05/new-u-s-oppositio n-proceedings-provide-strategic-avenues-for-patent-challengers/; AMERICA INVENTS ACT FREQUENTLY ASKED QUESTIONS, http://www.uspto.gov/aia_implementation/faqs-preissuance-submiss ions.jsp (last visited Mar. 5, 2015). The implementing rules setting out an amended "protest" process in THE U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 1.291, *available at* http://www.uspto.gov/web /offices/pac/mpep/. *See generally* Courtenay C. Brinckerhoff, *Proposed AIA Implementation Rules: Preissuance Submissions in Pending Applications*, PHARMA PATENTS (Jan. 26, 2012), http://www.pharmapatentsblog.com/2012/01/26/proposed-aia-imp lementation-rules-preissuance-submissions-in-pending-applications/. *See* FEDERAL TRADE COMMISSION, TO IMPROVE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 18 (2003). For the EU, *see* OPPOSITIONS, http://www.epo.org/applying/europ ean/oppositions.html (last visited Mar. 5, 2015). 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. 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".

Pre-grant opposition proceedings still exist in some Asian jurisdictions such as India, Indonesia and Thailand,[51] while Vietnamese law permits third parties to "express opinions" on a pending application.[52]

3. Example 3: Pharmaceutical Patent Term Extensions. — Under Article 33 of the TRIPS Agreement, WTO members must provide a minimum patent protection period of 20 years from the filing date. WTO members are therefore free to provide for patent protection extensions beyond this duration. Certain FTAs include obligations to extend the duration of patents for unreasonable delays.[53] As a result several FTAs contain commitments to grant extensions to make up for delays in the patent registration process marketing approval process, or both. An example of such an FTA is the USSFTA, as a result of which Singapore added a patent extension term provision in its patent law allowing extensions of up to 5 years.[54]

4. Example 4: Patent Linkages and Data Exclusivity. — One issue which has arisen in the context of FTA commitments particularly those associated with various US FTAs is that of patent linkage. Patent registration authorities usually operate independently of pharmaceutical marketing approval authorities (and vice versa). However, certain FTAs contain commitments which link the two areas (hence, "patent linkage"), requiring the latter authorities to monitor whether pharmaceutical products which form the subject matter of marketing approval applications are covered under any existing patents. Essentially, such commitments make the marketing approval authorities a watchdog of sorts for the patent-holders, as the authorities are obliged to trigger certain processes if a patent exists for the product (or a similar product). This kind of linkage greatly facilitates the work of pharmaceutical patent-holders as the authorities serve as a notification node for obtaining alerts and information on potential competitors' products when such applications are filed. Apart from the notification function, such commitments may also require signatory states not to permit marketing approval to competitive (generic) products for a stipulated number of years if

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[51] Patent Act of India permits this. For commentaries on this process in India; *see also* JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES 78-79 (2010); Shivnath Tripathi, *Relevance of Pre-Grant Opposition under Indian Law* (2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2365463. Under the Law of the Republic of Indonesia Number 14 Year 2001, regarding Patents Law, art. 45 (Indon.), 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 Thailand 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), §§ 31, 32, 34 (Thai.). On patent opposition systems in general, *see generally* WIPO Secretariat, *Opposition Systems*, SCP/14/5 (Dec. 11, 2009), *available at* http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130408.

[52] Law on Intellectual Property of Vietnam, *supra* note 27, art. 112.

[53] *See, e.g.*, United States-Singapore Free Trade Agreement [hereinafter USSFTA], art. 16.8(4), May 6, 2003, 42 I.L.M. 1026.

[54] Patents Act of Singapore, *supra* note 44, § 36A.

such approval is sought on the basis of information or data submitted by the patent-holder for its products.

The USSFTA and KORUS also contain obligations with respect to data exclusivity for pharmaceutical enterprises. Such provisions prohibit the use of data of an innovator within a certain period for purposes of providing marketing approval to a party to produce the same or similar products, unless the production is with the consent of the innovator.[55] The recently concluded EU-Singapore FTA text (which presently awaits ratification by the EU and implementing legislation by Singapore) also contains such provisions. [56]

Such commitments clearly exceed what the TRIPS Agreement requires, and in effect create another "layer" of protection for patent-holders. Examples of these commitments can be found in KORUS and USSFTA.[57] USSFTA, Singapore amended its legislation in order to accommodate the new patent linkage system.[58] Other US FTAs containing such linkage commitments are the US-Australia, US-Chile and US-Peru FTAs. [59] The TPP negotiations will potentially introduce such provisions to participant countries as well.[60]

In 2011, Malaysia issued a *Directive on Data Exclusivity* setting out the scope of such exclusivity and the circumstances in which a departure may be permitted.[61] This implements the flexibility provided to WTO members under Article 39 of the TRIPS Agreement, outlined above. Under the Malaysian system, data exclusivity is subject to a formal application process and must be applied for from the Director of Pharmaceutical Services. The Directive governs such applications and the grounds upon which they may be granted or

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[55] USSFTA, *supra* note 53, art. 16.8; Free Trade Agreement between the United States of America and the Republic of Korea [hereinafter KORUS], art. 18.9, Mar. 15, 2012, https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf .

[56] Free Trade Agreement between the European Union and The Republic of Singapore [hereinafter EU-Singapore FTA], art. 11.33, Oct. 2014, http://trade.ec.europa.eu/doclib/docs/2014/october/tradoc_152844.pdf.

[57] *See* NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 344-46 (2010). On the KORUS patent linkage provisions, *see* Confirmation Letter (Disputes Involving Patent Linkage), KORUS, https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file941_12967.pdf; *see generally* Seong Joo Jeong, *Patent-Drug Approval Linkage in Korea Under Korea-U.S. FTA — Based on Comparative Study on U.S. Hatch-Waxman Act and Canadian Patented Medicines (Notice of Compliance) Regulation* (2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2407320. On the Singapore patent linkage provisions, *see generally* Kin Wah Chow, *Pharmaceutical Related IP Protection in Singapore*, LAW GAZETTE (2007), http://www.lawgazette.com.sg/2007-12/feature1.htm.

[58] *See* The Medicines Act [hereinafter The Medicines Act of Singapore], Cap. 176, § 12A, 1985 Rev. Ed (Sing.).

[59] *See generally* Ruth Lopert & Deborah Gleeson, *The High Price of "Free Trade": US Trade Agreements and Access to Medicines*, 41(1) J. L. MED. & ETH. 199 (2013).

[60] *See generally SOURCES: USTR to Float New Access to Medicines Ideas at Next TPP Round*, 31(8) INSIDE US TRADE (2013), http://insidetrade.com/Inside-Trade-General/Public-Content-Special-Promo/sources-ustr-to-float-new-access-to-medicines-ideas-at-next-tpp-round/menu-id-1037.html.

[61] The text of the Directive is available at Malaysia's National Pharmaceutical Control Bureau website, *see generally* DATA EXCLUSIVITY, portal.bpfk.gov.my/index.cfm?&menuid=105&parentid=82 (last visited Feb. 22, 2015).

refused. The Directive applies both to new drugs containing new chemical entities (NCE) and to second indications of a registered drug product. If an application is successful, the grant will be notified in a Register of Data Exclusivity maintained and published by the Government.[62] The public health-related departure is provided in paragraph 5:

> 5. Nothing in the Data Exclusivity shall:
> (i) apply to situations where compulsory licenses have been issued or the implementation of any other measures consistent with the need to protect public health and ensure access to medicines for all; or
> (ii) prevent the Government from taking any necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis, or other extremely urgent circumstances declared by the government.[63]

As Malaysia is a negotiating party to the TPP, it will need to carefully consider any negotiating demands that may change the scope and operation of the flexibility reflected above. By contrast, while Singapore has made commitments in the USSFTA on data exclusivity, it does not have a similar implementation regime. Rather, such protection arises from amendments made in the Patent Act, which followed the FTA.[64]

5. Example 5: Pricing and reimbursement commitments affecting pharmaceuticals. — KORUS contains obligations affecting reimbursement-related measures with respect to pharmaceutical products.[65] The EU-Singapore FTA text also contains such provisions.[66]

It could be questioned whether giving up of certain flexibilities enshrined in the TRIPS Agreement might be termed as "WTO-minus" in the sense that countries are subscribing to less than their WTO rights.[67] It is suggested here that while it would be a violation to withdraw an *obligation* from the agreement without justification, the *giving up of a right* is akin to a waiver of that right, which is open to a WTO member to do. In fact, it is often observed that the TRIPS Agreement stipulates a minimum set of requirements, so that a WTO member may choose to adopt stronger disciplines or narrower

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[62] Register of Data Exclusivity Granted in Malaysia & Register of AI Data Exclusivity Granted in Malaysia, *id.*
[63] *Id.*¶ 5.
[64] *See* The Medicines Act of Singapore, *supra* note 58, §§ 19A-D.
[65] KORUS *supra* note 55, arts. 16.7(7), (8).
[66] *See* EU-Singapore FTA, *supra* note 56, Annex 2-C.
[67] I thank the anonymous reviewer for raising this question.

protection for itself under the terms of the agreement. Such action would, indeed, by TRIPS or more broadly, WTO plus.

D. 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,[68] include China, Korea, Japan and all ASEAN members except for Indonesia. While China is a signatory, the Framework Convention on Tobacco Control (hereinafter "FCTC") has only been extended in a very limited way to Hong Kong.[69]

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 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).[70]

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, e.g. in Thailand and China, and in the area of pharmaceuticals, the kind of pharmaceutical production or R&D activities occurring in their economies.

FTA participation can lead to greater liberalization and therefore greater movement of goods, services and investments. Extending commitments in such agreements to a select and strategically chosen group or sole trading partner can speed up negotiations, in contrast to the much more (and increasingly) complex trade liberalization negotiations at the WTO. As a result, the successful conclusion of negotiations for a bilateral (or regional) FTA can bring earlier results, both in terms of implementation and economic benefits. However FTAs usually require parties to extend themselves beyond what they might have already agreed to at the multilateral level. This requires intensive negotiations, both externally and internally, and can give rise to negotiating and policy tension as such a push may be made by placing sensitive areas on the table. Examples of difficult issues that have arisen in

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[68] *See* PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, http://www.who.int/fctc/signatories_parties/en/ (last visited Feb. 14, 2015).

[69] XIANGGANG JIBEN FA art. 153 (H.K.). *See id*., China's entry in the list.

[70] The US has signed but not ratified the WHO Framework Convention on Tobacco Control. *See* PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *supra* note 68.

some Asian FTA negotiations include government procurement, intellectual property rights protection, and regulation of pharmaceutical and tobacco products.

Apart from real economic benefits that may arise from FTA participation, given the rapid rise in Asian FTAs, a fear of being left out of preferential trade and investment opportunities can constitute a real incentive for some states to initiate their own FTA negotiations. This is because FTA preferences are not required by states to be extended to other trade partners on a most-favored nation (MFN) basis and are a recognized avenue of non-MFN preferential treatment under WTO rules.[71] In particular, the allure of large preferential trading blocs such as those that might arise under the TPP, TTIP and RCEP, encourage states to join the "bandwagon".

For some Asian states, FTAs are not simply about economic considerations, but may encompass broader, geopolitical concerns. As the Chief Negotiator of Singapore for the USSFTA, Ambassador Tommy Koh, explained:

> Singapore wants an FTA with the U.S. for a combination of economic and strategic reasons. The U.S. is Singapore's largest foreign investor and second largest trading partner. The U.S. is also Singapore's most important source of technology and management know-how. Singapore's interest in the U.S., however, transcends business and economics. Singapore wishes to entrench the presence of the U.S. in the region because it underpins the security of the whole Asia-Pacific region. Singapore regards the U.S.-Singapore FTA as a symbol of continued U.S. commitment to the region. Therefore, for Singapore, the USSFTA is not just about securing tariff-free entry for Singapore's exports to the U.S. market. It is not just about attracting more Foreign Direct Investment (FDI) to Singapore. It is also about enhancing the prospects of peace and stability in the region.[72]

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[71] *See* GATT, *supra* note 1, art. XXIV.

[72] Tommy T.B. Koh, *The USSFTA: A Personal Perspective*, *in* THE UNITED STATES SINGAPORE FREE TRADE AGREEMENT — HIGHLIGHTS AND INSIGHTS 3, 7-8 (Tommy T. B. Koh, & Li Lin Chang eds., 2004).

V. TRADE NEGOTIATIONS AND ADDRESSING PUBLIC HEALTH REGULATION CONCERNS[73]

A. Negotiations 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 settlements (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 that consists of a mix of economic and political considerations. 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 being demanded. An Asian state may therefore aim to agree to necessary trade-offs but find it necessary to ask for safe harbor provisions in order to strengthen the *quid pro quo*. An example that could help ameliorate 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 the dispute settlement, to reduce the risk of legal exposure.

In this connection, the US-Colombia FTA provides the following provision of interest:

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

[73] On the sources of tension in regulating health and trade, *see, e.g.*, FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY 268-94 (2009); some such sources identified specifically in the pharmaceutical context in Chapter 10.

> 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. . . . (Emphasis added)

The KAFTA[74] also contains an express provision that when interpreting and implementing the key patent obligations provision, Art. 13.8, the parties "are entitled to rely upon the Doha Declaration".

While such provisions have not been tested before a tribunal, this provides an express interpretative directive that is clearly related to public health goals.

VI. ASEAN INTEGRATION: AN OPPORTUNITY FOR JOINT DISCUSSION AND CONVERGENCE ON HEALTH GOALS AND REGULATORY STANCES

For the diverse members of ASEAN, the ASEAN Economic Community (hereinafter "AEC") is in the process of formation and is expected to come about by the end of 2015; there is a comprehensive implementation plan.[75] At

[74] Free Trade Agreement between the Government of Australia and the Government of the Republic of Korea, art. 13.10, Dec. 12, 2014, http://www.dfat.gov.au/trade/agreements/kafta/official-documents/Pages/default.aspx.

[75] *See* Bali Concord III, *supra* note 15.

the same time ASEAN is seeking further economic integration with six of its key regional trade partners in the negotiations for a RCEP.[76]

In the area of intellectual property policy, while ASEAN has developed an *IP Action Plan*[77] there has been no explicit linkage between IP development and treatment of pharmaceutical patents and 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. Recently ASEAN leaders did however expressly resolve to ensure access to affordable healthcare, and affordable medicines (see below).[78]

The objective of providing affordable healthcare, and affordable medicines in particular, has become an increasing explicit one in recent ASEAN integration instruments, such as in Ministerial declarations and integration agenda. While the AEC plans to address economic integration, healthcare and related goals and initiatives fall under the purview of the ASEAN Socio-Cultural Community (hereinafter "ASCC"): this group sets out the specific actions and initiatives to be carried out for such goals.[79] 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".[80] (Emphasis added)

In a recent Ministerial Declaration, the following significant joint aspirations were expressed by ASEAN leaders:

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* . . . ." (Emphasis added) [81]

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) differs according to their national systems.

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[76] *See* REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP, *supra* note 9.

[77] The *Action Plan* does aim to develop a "strong negotiating position" via a "minimum" negotiating framework for IPRs, though. ASEAN Working Group on Intellectual Property Cooperation, *ASEAN Intellectual Property Rights Action Plan 2011-2015*, ¶ 25 (2012), http://119.252.161.170/ksp/wp-content/uploads/2013/03/asean.pdf.

[78] Bali Concord III, *supra* note 15, ¶ C.3 (a).

[79] *See ROADMAP FOR AN ASEAN COMMUNITY 2009-2015*, ASSOCIATION OF SOUTHEAST ASIAN NATIONS, ¶¶ B4-B5 (Apr. 9, 2009), *available at* http://www.asean.org/images/2012/publications/RoadmapASEA NCommunity.pdf.

[80] *Id.* ¶ B4.

[81] Bali Concord III, *supra* note 15, ¶ C.3(a)

Secondly, ASEAN members desire increased foreign investment and trade but will need to manage the affordability of medicines along with any changes economic integration and increasing FTA activity may bring. ASEAN members (other than Indonesia) will also need to ensure a balance between health regulation policies and economic obligations expressed in bilateral and regional trade and investment instruments. The strong integration objective in ASEAN could provide an opportunity for greater dialogue as well as development of a joint stance in how to deal with this interface and with trade negotiations that may affect it. Other countries such as China and India, with their large populations and their own economic challenges, will no doubt also need to carefully consider how to manage the health-trade-investment nexus in regulatory policies in accordance with their needs, circumstances and priorities.

VII. PUBLIC HEALTH CONCERNS AND NEGOTIATING STANCES

Immediate development of a common, integrated negotiating stance across Asia is probably unrealistic, given the diverse stages of economic development, policy priorities and public health needs throughout the region.

This does not, however, mean that it is not useful to identify steps toward crafting a set of common issues faced in FTA negotiations. The merits in such an exercise would be three-fold: first it can provide negotiators and policy-makers in Asia with a convenient reference set of questions to consider before and during negotiations. Secondly, it would serve as a negotiating template for addressing both economic and public health priorities at the negotiating table. Thirdly, in some quarters, public health impact assessment exercises are already being used to ensure that public health implications of economic treaty commitments are properly addressed when negotiating trade agreements. Such exercises could be incorporated into treaty negotiation preparations as a matter of good practice. Such tools would also better prepare negotiators for future "mega" treaties that may be negotiated, whether multilaterally, or in the context of a possible Free Trade Area of the Asia-Pacific (hereinafter "FTAAP").

In the ASEAN integration context, even if there is no immediate convergence of policies on the interface between trade, investment and health interface policies at the moment, there is an opportunity to identify a convergence of purpose(s) in this nexus. The global community is already debating how to deal with this interface in order to attain balanced and coherent-policy making. Within Asia, ASEAN, at least, in aspiring to speak with one voice in the global platform,[82] should seize this opportunity of a

[82] *Id.*; Bali Concord III, *supra* note 15, Preamble.

nascent Economic Community identity to forge a clear and coherent stance. For a start, the Plan of Action for the Bali Concord III has started a discussion on the need for examining the implications of the trade-health interface with a view to developing common strategies. It, states that one of ASEAN's planned actions is to: "Improve awareness on the impact of regional and global trade policies and economic integration on health and develop possible strategies to mitigate their negative impacts."[83]

ASEAN's regular dialogues and ongoing trade negotiations (such as those for RCEP) with its major Asian trade partners, China, India, Japan and Korea, can also provide opportunities to discuss this interface and the similar as well as different challenges faced. At the same time, certain ASEAN countries are participating in the TPP negotiations,[84] in which intellectual property rights and health-related regulatory issues (such as regulation of tobacco and pharmaceutical products) potentially form part of new, possibly stricter, commitments than in prior agreements.

The following are some practical steps that could be taken toward this end. First, it is necessary to identify common interests and common priority health goals across borders, first within ASEAN, and broadly, among Asian trade partners. Given that there are diverse economic and public health needs within Asia, and even within the sub-set of ASEAN, 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, when negotiating trade treaties it may be useful to consider the adoption of an approach that utilizes public health impact assessments. Such a step would provide objective insight into the public health implications of proposed trade obligations. Fourthly, 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. This would ensure that lasting and innovative solutions that are oriented toward meeting trade and health goals can be worked out. It is submitted that such steps can help policy-makers bring about greater coherence to better handle tensions arising from the trade-investment-public health interface as it arises in domestic rule-making and treaty-making

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[83] ASEAN, *Bali Declaration on ASEAN Community in a Global Community of Nations "Bali Concord III" Plan of Action 2013-2017*, ¶ 3(a)(xiv) (2012), http://www.kemlu.go.id/ptri-asean/Magazines/Bal i%20Plan%20of%20Action%20Three.pdf.

[84] The ASEAN countries participating in the TPP negotiations are Brunei Darussalam, Malaysia, Singapore and Vietnam. Outside of ASEAN, Japan is also a TPP negotiating party. Significantly, China, Korea and India are not TPP negotiating parties; however, plans have been announced to explore a Free Trade Area of the Asia-Pacific (FTAAP); *see* ANNEX A – THE BEIJING ROADMAP FOR APEC'S CONTRIBUTION TO THE REALIZATION OF THE FTAAP, *supra* note 10.

VIII. CONCLUSION

As countries in the Asian region engage in more negotiations for trade and investment partnership agreements it can be expected that the trade and health interface will be a recurring issue. This is particularly true given the diversity in economic and health policies in these countries, and their negotiating counterparts. As ambitious agreements such as the TPP and in time to come, perhaps the FTAAP throw the trade-health interface into even sharper relief, economies grapple with the difficult task of balancing the desire for economic growth and investment with ensuring affordable and accessible healthcare and pharmaceuticals for their citizenry. Already, a number of flexibilities under the TRIPS Agreement have been limited in certain FTAs, such as in the areas of patentability, pre-grant opposition opportunities in patent applications, data exclusivity and patent linkages. For ASEAN, as it evolves toward greater integration and development of a common voice on global issues, it will be particularly important to consider what that voice will say with regard to negotiating trade and public health issues. A number of useful steps as outlined above can already be taken in this regional context to set the scene for better informed and possibly, common, negotiation stances.

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