Free Trade Agreements in Asia – Part of the Solution or Part of the Problem?

Joint Session of the Intellectual Property, Cross-Border Investment and International Trade Committees

Trade/Investment Issues Surrounding

Health-Based Regulatory Impairment of 'Unhealthy Lifestyle' Product IP (TMs, Packaging and Promotion/Advertising)

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Inter-Pacific Bar Association Annual Meeting/Conference

Seoul, South Korea

April 20, 2013

I. Non-Trade/Investment Sources of International Health Initiatives (Treaties, Soft Law)

A. UN High Commissioner on Human Rights ("UNHCHR")

1. UN Universal Declaration of Human Rights ("UDHR" 1948) (Art. 25(1))
   a. The right to a standard of living adequate for health and well-being.
2. UN Int'l Covenant on Economic, Social and Cultural Rights ("ICESCR" 1966, 1976) (Arts. 6, 11(1))
   a. The right to adequate food (quantitative and qualitative)
3. UN Convention on the Rights of the Child ("CRC" 1989, 1990) (Arts. 24(1)-(2))
   a. The right to highest attainable standard of health via provision of adequate nutritious foods and reduced mortality.
4. Report Submitted by the Special Rapporteur on the Right to Food (A/HRC/19/59), 12/6/11)
   a. Implement nationally the right to adequate food.
   b. Regulate/reduce the marketing of food products high in saturated fats, trans-fatty acids, sodium and sugar (HFSS foods) to children and to other groups.
   c. Implement nationally WHO Int'l Code of Marketing of Breast-milk Substitutes (and associated recommendations).

B. UN World Health Organization ("WHO")

1. Global Non-communicable Diseases ("NCDs") are a 'Public Interest'
   a. Chronic Respiratory Disorders; Cancer; Cardiovascular Diseases; Diabetes
   b. Contribute to high healthcare costs, lost economic productivity.
   b. NCDs allegedly driven by product globalization, associated FDI, inappropriate marketing/promotion practices.
2. Governments Must Reduce NCD Risks via Prevention and Control
   a. ***Tobacco*** – WHO Framework Convention on Tobacco Control ("FCTC") (entered into force 2005) -Articles 11 (Packaging and Labeling of Tobacco Products) and 13 (Tobacco Advertising, Promotion and Sponsorship)
      i. Art. 11 - Restrict use of trademarks, logos, trade dress that misrepresent/mislead/deceive about product safety or healthfulness.
      ii. WHO Guidelines for Implementation of FCTC Art.11 – Only brand names and product names. Restrict or prohibit use of logos, colours, brand images or promotional information on packaging, except in a standard color and font style ('plain packaging').
      iii. Art. 13 - Ban all product advertising, promotion and sponsorship if permitted by national constitution. If not permitted b/c of property rights, apply advertising, promotion and sponsorship restrictions.
      iv. WHO Guidelines for Implementation of FCTC Art.13 – Black/white or two other contrasting colors. Nothing other than a brand name, a product name and/or manuf'r's name. Prescribed font style and size; and standardized shape, size and materials.

v. End Result - If plain packaging not mandated, restrict as many as possible of the design features that make tobacco products more attractive to consumers.

b. ***Harmful Alcohol Use*** –

i. WHO Global Strategy to Reduce Harmful Use of Alcohol (2010), aff'd by World Health Assembly Res. WHA63.13 (May 2010)
(Identifies harmful use of alcohol as one of the four most preventable NCDs. Recommends regulation of content and volume of direct/indirect marketing in certain or all media, and sponsorship activities promoting alcholic beverages).

c. ***Unhealthy Diets*** –

i. WHO Global Strategy on Diet, Physical Activity and Health (2004), aff'd by WHA Res. WHA57.17 (May 2004)
(Address sponsorship, promotion, advertising of food/beverages contributing to unhealthy dietary practices of children; ensure health-related messages on food/beverage product labels do not mislead re nutritional benefits/risks).

ii. WHO Set of Recommendations on Marketing of Foods & Non-Alcoholic Beverages to Children (2010)
(Reduce exposure of children to HFSS foods marketing/promotion; mandatory national regulation or industry self-regulation restricting use of marketing techniques having a particularly powerful effect; rules should cover marketing to 3rd countries also).

iii. 2008-2013 Action Plan for the WHO Global Action Plan for the Global Strategy for the Prevention and Control of Non-Communicable Diseases
(Implement a framework and/or mechanisms for promoting the responsible marketing of HFSS foods and non-alcoholic beverages to children).

iv. WHO International Code of Marketing of Breastmilk Substitutes (1981)
(Curtailment via nat'l legislation of public marketing/promotion of breastmilk substitutes, including infant formula, animal milk products, foods, bottles, teats resulting in reduced breastfeeding and associated nutrition; preclude manuf'r/distrib of informational/educational equipment/materials without written gov't approval; permit use of company name, marks, logos, but NO reference to proprietary products; restrict distribution to healthcare system; NO point-of-sale advertising, sampling, or other promotion devices to induce sales to consumers at retail level; product labeling not to discourage breast-feeding – NO superiority or 'equal' claims; NO health/nutrition claims; NO 'idealizing infant formula use text or images; NO infant/family images).

v. WHO Package of Essential ('PEN') Non-Communicable Disease Interventions (for prevention and control of NCDs) (2010)

(Exclusive breastfeeding <u>for 6 months</u>; Nutritionally adequate and safe complementary feeding from 6 mos., breastfeeding up to 2yrs. or beyond; Restrict marketing of and access to HFSS food; institute tobacco and alcohol controls; tobacco preventation/cessation programs).

vi. <u>2012-2016 WHO Europe Action Plan</u>
(Promote healthy consumption/marketing policies; impose fiscal policies and marketing controls to reduce demand for tobacco, alcohol and HFSS foods; ban tobacco promotion/advertising; enforce advertising bans on/restrict retail access to alcohol; impose labelling and marketing controls on processed HFSS foods).

II. National Sources of Health Measures Implementing International Treaty and Soft Law Health Initiatives

A. ***Tobacco*** – (National Government Implementation of FCTC)

1. <u>Australia Plain Packaging Law</u> – (The Tobacco Plain Packaging Act 2011; implementing Tobacco Plain Packaging Regulations 2011; Trade Marks Amendment Act 2011)

a. <u>Packaging</u> –

i. Drab dark brown in a matt finish.

ii. No other colours, nor logos, nor brand features visible on the package .

iii. Brand and variety name can appear only in a standard form and font below a graphic health warning that occupies 75 per cent of front surface and 90% of back surface of packaging.

b. <u>Effect</u> –

i. Reduces distinctive features which a consumer might associate with a particular brand of tobacco products on product packaging.

ii. <u>Word Marks</u> - Restricts brand name use in its permissible size and appearance. Will appear on the packaging in exactly the same size and font as competitors (e.g., Benson & Hedges vs. Pall Mall).

iii. <u>Non-Word Marks</u> – Bans device, figurative or stylised marks (e.g., logos and combined marks containing stylised letters, shape marks the colours marks).

c. <u>Rationale</u> – *JT International SA v Commonwealth of Australia British American Tobacco Australasia Limited v The Commonwealth* (Australia Supreme Court)

i. TM law grants only rights to exclude 3rd parties and gov't from use ('negative' rights).

ii. TM law does not grant rights 'to use' free from other legal restrictions ('positive rights'). <u>TMs are positive rights inherently susceptible to modification or extinguishment in the 'public interest'</u>, such as to promote public health.

iii. Distinctiveness need not be 'eye-catching. Well-known brand names still serve to distinguish one registered owner's goods from those of another.

iv. Brand names alone can indicate the quality of goods sold, and still serve to promote sales.

v. While regulatory restrictions may reduce value of TMs, associated goodwill and product sales, they should be viewed as a cost of doing business.

vi. Australian constitution not designed to preserve value of commercial business property unlike US Constitution 5th Amend.

2. New Zealand – MOH Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand: Consultation Document (July 2012)
   a. NZ Gov't filed WTO notification announcing decision to introduce plain packaging regime for all tobacco products (G/TBT/NNZL/62) (Feb. 19, 2013). Purpose - to reduce the prevalence of smoking in NZ.
3. United Kingdom - Held public consultation on the standardized packaging of tobacco (concluded 8/10/12) with expectation of follow-up action from UK Department of Health (DH).
4. Uruguay – Regulations restricted branding that could be featured on cigarette packages, requiring that 80% of cigarette packs display graphic health warnings.
5. Thailand – Draft Tobacco Consumption Control Act modeled on Australia law. Purpose – to reduce teen smoking.
   a. Current (1992) law required cigarette packs to include graphic health warnings covering 55% of front/back of pack; banned smoking in most places; NO marketing/advertising of tobacco products; graphic pictures required.
   b. Current law not as effective as hoped.
6. Norway/Iceland/Lichtenstein – Each adopted visual display bans of tobacco products at points of sale under the terms of the European Economic Area Agreement ("EEA").
7. European Union - Public Consultation on revision of Tobacco Products Directive 2001/37/EC (to implement WHO FCTC of which the EU is a signatory).
   a. Possible plain packaging of tobacco products, and graphic images of the risks of smoking on all cigarette packaging.
   b. Would seek to prohibit use of all TMs (and other IPRs) on tobacco products, other than word marks in standard size, type face and plain color.
8. Ireland – Healthy Minister Announced Will Provide Memorandum to Gov't providing for the introduction of plain packaging on tobacco products (3/28/13).

B. ***Unhealthy Diets*** –
   1. 'Junk Food' - National Government Initiatives
      a. European Union – Workshop on Packaging of Unhealthy Products (Sept. 2012) (EU Parliament Committee on Environment, Public Health and Food Safety)

i. Developing regulatory framework for packaging, labelling and marketing of products.
ii. Focused on tobacco, alcohol and HFSS food products.
iii. Labelling must provide adequate information to consumers and not mislead consumers about health impacts.
iv. But, plain packaging restrictions may lead to misleading practices, as useful ingredient information may disappear from standardised packaging. A product-specific approach may be preferable.

b. Peru – Proposed law to reduce consumption of 'junk food'.
i. HFSS food products to bear label w/ warning: "Excessive consumption of this product is harmful to health") and an image related to the health damage that could result.
ii. HFSS food products within public and private schools prohibited.
iii. No advertising of HFSS foods from 6 a.m. to 10 p.m.
iv. No celebrity or animated character endorsement of HFSS foods.

c. Philippines – Department of Trade and Industry ("DTI") announced its support for Consumers International's (CI) Recommendations for an International Code on Marketing of Food to Children.
i. Ban radio/TV advertising/promotion of HFSS food between 6AM and 9PM;
ii. No new media (social network, texting) marketing of HFSS foods;
iii. No in-school promotion of HFSS foods;
iv. No point-of-sale gifts, toys, or collectables for children to promote HFSS foods;
v. No celebrity, animated character endorsement of HFSS foods.

d. New York City – 'Sugary Drinks' Restrictions (intended to stem obesity)
i. NO offering for sale/sale of soft drinks in restaurants, movie theaters, stadiums and arenas of more than 16 ounces (473 milliliters)/cup where more than 25 calories/ounce.
ii. Sodas, energy drinks, sports drinks, juice drinks, slushies and smoothies, etc.

e. Boston –
i. Banned sweetened soda and junk food from school vending machines in 2004.
ii. Mayor ordered a phased sugar-drink ban in all municipal buildings and city-sponsored events (2012).

2. Breast-Milk Substitutes – National Government Initiatives
a. Philippines - Executive Order 51 (10/20/86) ('Milk Code') implementing Art. 11 of WHO Int'l Code of Marketing of Breastmilk Substitutes
ii. PH Revised Implementing Rules and Regulations ("RIRR") of Milk Code – No promotion as equal to or superior to breastfeeding (Sec. 13). NO use of text idealizing use of infant and milk formula (Sec. 15(c)).
iii. DOH Admin. Order No. 2006-0012 (5/12/06) – 4(f), 11 and 46 Banned promotion/advertisement of breast milk substitutes. PH

Supreme Court (10/9/07) declared such provisions unconstitutional b/c comm'l free speech rights and unduly restrictive.

iv. PH DOH Circular No. 2008-0006 – Specific Guidelines for principal display panel for breastmilk substitutes. No use of brand name or TMs or word marks to make nutritional, healthful, and superlative claims.

v. PH DOH Memorandum to FDA (9/5/11) – NO TM use to contain health and nutrition claims that may undermine breast-feeding and breastmilk on the labels of infant formula. PH DOJ Upholds legality of PH DOH Memo (5/11/12).

vi. PH House Bill 3396 ('Milk Code 2') - (re: infant formula, follow-up/follow-own formula, complementary food, feeding bottles, teats, pacifiers, other (nonhuman) milk products). NO advertising/promotion/marketing to infants or young children up to 3 yrs (Sec. 13). Labels (broadly defined) must contain: notice indicating breastfed milk is only ideal milk/warning there is no substitute for; notice to seek advice of health professional before supplementing/replacing breastmilk; warning that not a sterile product possibly contaminated by microorganisms; statement that NO follow-up formula to be used for infants less than 6 mos; no images/text discouraging breastfeeding (Sec. 17).

b. Hong Kong - (Voluntary) Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children (Oct. 2012)

i. NO development/distribution of informational or educational materials re: formula milk feeding to general public/pregnant women/mothers of children aged 36 months or less. Specific brands of formula milk and related products may be on website, at retail premises, or in health facilities if technical/textual information appearing on product label. NO graphics/pictorials other than to guide preparation. (Art. 4.1.1.b).

ii. NO brand name, logo or TM of any formula milk and related product displayed on donated/distributed materials or in performed educational activities. (Art. 4.3.1.a).

iii. NO manuf'r/distributor promotion of formula milk and related products. (Art. 5.1). (NO advertising; special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts; samples (Art. 5.4)). Can promote non-formula milk child food products, but not at healthcare facilities (Art. 5.2).

c. Malaysia Ministry of Health - Code of Ethics for the Marketing of Infant Foods and Related Products (2008) (to curb unethical marketing of infant foods)

i. Monitors manuf'r/distributor compliance w/marketing of infant formula, follow-up formula, special formula, feeding bottles, teats and pacifiers and complementary foods.

ii. NO food label may contain words indicating grading, quality or superiority (Art. 18(1A), Food Act 1983).
iii. MOH Correspondence (2/23/11) – NO words idealizing formula feeding per Food Act 1983 Art. 18(1A) and Point 6.3.1(m) of Code of Ethics.

III. Judicial Challenges to 'Unhealthy Lifestyle' Product Bans and Restrictions

A. Tobacco Visual Display Ban - Court Adjudication
1. *Philip Morris Norway AS and Staten/Helse-og omsorgsdepartementet* – Filed at Oslo District Court, which sought advisory opinion from EFTA Court on interpretation of EEA Agreement (Case E-16/10) (2010).
a. Challenged (non-EU) Norway/Iceland/Liechtenstein point-of-sale visual tobacco product display bans – since 2010 in enclosed cases.
b. Norwegian visual display ban deemed an obstacle to trade under EEA if effectively favored imported Norwegian tobacco products previously produced domestically by virtue of prior consumer purchasing habits.
c. Display ban adoption permitted under precautionary principle (PP).
i. PP normally invoked when uncertain hazard.
ii. Here, PP invoked when hazard was certain, but effect of ban was uncertain – i.e., no proof ban would stem tobacco consumption.

B. Alcoholic Beverage Ban - Court Adjudication (pending)
1. EFTA Court - *HOB-vín ehf v. The State Alcohol and Tobacco Company of Iceland (ÁTVR)* – Filed at Icelandic Court, which sought advisory opinion from EFTA Court on interpretation of EEA Agreement (Case E-2/12) (2012).
a. Icelandic importer's alcoholic cider beverages sold in Denmark and marketed in stylish and attractively decorated 33cl aluminium cans, featuring artful drawings, including colorful illustrations of women's legs with some apparently naked skin.
b. Challenged denied access/ban of its products from Icelandic market.

C. 'Big Sugary Drinks Ban' – Court Adjudication (appealed)
1. NY State Supreme Court decision (2013)
a. Ordinance ruled invalid ('arbitrary and capricious') b/c it:
i. Applied to some but not all food establishments in the city;
ii. Excluded other beverages w/significantly higher concentrations of sugar sweeteners and/or calories;
iii. Loopholes in rule, including no limitations on refills, and ability to buy cluster packs of smaller volumes undermined purpose of the law.

IV. World Intellectual Property Organization ("WIPO") Treaty Violations Engendered by Health Measures Imposing Plain Packaging/Labeling and Product Promotion Restrictions

A. Art. 6bis – (Protection of well-known marks from confusion created by other marks on same or similar goods)
B. Art. 6quinques – (Guaranteed protection of duly registered TMs of one Union country in another Union country)
   1. Upon presentment of certification of registration from 1st country (A)(1).
   2. Except where contrary to morality or public order (B)(3).
C. Art. 7 – (Nature of goods to which mark applies cannot serve as obstacle to registration)
D. Art. 10bis – (Guranteed protection against 'unfair competition')
   1. Any act of competition contrary to honest practices in industrial or commercial matters (2);
   2. Indications/allegations liable to mislead public re: product's nature, mfg. process, characteristics suitability for purpose(s).

V. World Trade Organization ("WTO") Violations Engendered by Health Measures Imposing Plain Packaging and Product Promotion Restrictions

A. 3 WTO Cases - Challenging Australia 'Plain' Packaging Law: WT/DS434/11 (Aug. 17, 2012) (Ukraine case); WT/DS435/1 (April 10, 2012) (Honduras case); WT/DS441/15 (Nov. 14, 2012) (Dominican Republic case). (*No monetary awards available – only cessation of offending conduct*).
   1. Issues Raised Potentially Apply Also to Future WTO Challenges of Unhealthy Foods, Beverages and Infant Formula Laws/Standards.
B. **TRIPs Agreement Violations** – (Evaluating bans & restrictions of TMs/logos/trade dress.
   1. Claims
      a. Art. 1.1 – Measures implementing TRIPs in manner affording less protection than required.
      b. Art. 2.1 – Measures failed to comply with WIPO Arts. 6bis, 6quinquies, 7 and 10bis which are incorporated in TRIPs, by not accepting TMs/trade dress/logos 'as-is', discriminating against nature of product, and not protecting against competitor acts likely to cause confusion. (*Similar to TBT Art. 2.1 claim).
      c. Art. 15.1 – Measures failed to give legal effect to obligation to ensure that any distinctive sign must be capable of constituting a TM.
      d. Art. 15.4 – Measures effectively presented obstacle to registration/protection of TMs (ncluding names, letters, numerals, figurative elements and combinations of colors and/or signs).
      e. Art. 16.1 – Measures render ineffective TM owners' exclusive right to use signs and prevent 3rd parties from using similar signs (right to enjoy).
      f. Art. 16.3 – Measures fail to provide addt'l protection for well-known TMs by not permitting product TMs to demonstrate entitlement to such addt'l protection.
      g. Art. 20 – Measures constitute unjustifiable encumbrance on use of TMs by imposing use of TM in special form, and in a manner detrimental to TM's

ability to distinguish goods of one undertaking from those of another. (*Must adduce sufficient evidence, similar to TBT Art. 2.2 claim).

2. Defenses
   a. Art. 8.1 – Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition.
      i. TRIPs provides NO positive rights to exploit or use certain subject matter. Only provides for the grant of negative rights to prevent certain acts.
   b. Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* ("*EC Trademark & Geographical Indications*") WT/DS290/R (adopted 20 April 2005), at pars. 7.245-7.246 –
      i. Members may pursue legitimate public policy objectives which lie outside the scope of IP rights and do not require a TRIPs exception.

C. **TBT Agreement Violations** – (Evaluating Labeling Requirements and Promotion Bans/Restrictions *other than on food safety grounds*)
1. Does the measure qualify either as a 'Technical Regulation' or as a 'Standard'?
   a. Annex 1.1 – 'Technical Regulation' - Document must lay down product characteristics or their related PPMs, including applicable administrative provisions, with which compliance is mandatory.
      i. Must 'notify' of products to be covered, but needn't explicitly mention a product for it to be identifiable. *EC-Asbestos Appellate Body Report*, at par. 70.
      ii. Product characteristics may include any definable 'features', 'qualities', 'attributes' or other 'distinguishing mark' of a product. *Id*., at par. 67.
      iii. Taking into account all factors, must lay down, set forth, stipulate, or provide product characteristics (e.g., qualities or attributes) in a binding or compulsory fashion. *Id.*, at pars. 64, 67-69, 75.
   b. Annex 1.2 – 'Standard' - Document approved by a recognized body, providing, for common and repeated use, rules, guidelines or characteristics for products or related PPMs, with which compliance is not mandatory ('voluntary').
      i. May deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product or PPM.
      ii. Can be based on int'l community standard approved by consensus, or approved by a 'recognized non-governmental body' but not based on int'l consensus.
2. Does technical regulation (or standard) result in treatment less favorable to 'like' imported products? (*Similar to TRIPs Art. 2.1 claim).
   A. Arts. 2.1, 4.1; Annex 3.D –

i. ‘Likeness’ – four general criteria: (a) properties, nature and quality of products; (b) end-uses of products; (c) consumers’ tastes and habits—more comprehensively termed consumers’ perceptions and behavior—in respect of products; and (d) product tariff classification.

A. ‘Likeness’ should be determined based on the competitive relationship between and among the products, and not on the legitimate objectives and purposes of technical regulation, which can distort that competitive relationship. *US-Clove Cigarettes* Appellate Body Report at par. 112.

B. Health risks associated with a given product may be relevant to ‘likeness’ analysis if have an impact on the competitive relationship between and among the products concerned (i.e., consumer perceptions). *Id*., par. 119.

ii. ‘Less Favorable’ Treatment - Compare treatment accorded to imports of complaining Member with that accorded to ‘like’ domestic products and like products of any other origin. *Id*., par. 190 (national treatment/nondiscrimination).

A. Must have sufficiently close competitive relationship. *Id*., par. 191.

B. Must focus on treatment accorded a *group* of “like” products (not individual products). *Id*., par. 194.

C. Must show detrimental impact on imports that does not stem exclusively from a legitimate regulatory distinction. *EC-Asbestos* Appellate Body Report, pars. 174–75, 181–82; *US-Tuna* Appellate Body Report, par. 215, but stems from measure’s arbitrary or unjustifiable design or application. *US-COOL* Appellate Body Report, par. 293.

D. Must show detrimental impacts modify competition in relevant market to the detriment of imported product(s). *US-COOL* Panel Report, par. 7.298; *Clove Cigarettes* Appellate Body Report, par. 177-179.

3. Does the technical regulation create an unnecessary obstacle to trade that is more trade-restrictive than necessary to fulfill a legitimate objective? (Similar to TRIPs Art. 20 claim).

a. Arts. 2.2, 4.1; Annex 3.E -

i. Is measure “in accordance with” an international standard? Does the int’l standard contain rules on the specific wording of labels or educational or promotional materials?

A. If yes, rebuttable presumption it is valid.

B. If no, burden is on Host Gov’t to justify.

ii. Is the technical regulation “Trade-Restrictive”?

A. Does it impair the competitive opportunities available to imported products? Trade ‘effects’ need not be demonstrated. *US-COOL* Panel Report, par. 7.572. Some

trade-restrictiveness is allowed. *US-COOL* Appellate Body Report, pars. 268, 375.

iii. Does the technical regulation pursue a "legitimate" objective?

A. Members have a right to regulate in order to pursue certain legitimate objectives, and to establish for themselves the objectives of its technical regulations. *TBT Preamble*, 6th Recital; *US-Clove Cigarettes* Appellate Body Report, pars. 94-95; *US-COOL* Panel Report, par. 7.584.

B. TBT Committee notifications submitted pursuant to TBT Art. 2.9 enjoy a rebuttable presumption of truthfulness and good faith under int'l law. *US-COOL* Panel Report, pars. 7.605-7.606.

C. Is stated objective included in the non-exclusive open list of legitimate objectives? Inter alia: national security requirements; the *prevention of deceptive practices; protection of human health or safety*; animal or plant life or health; or the environment. *Id*., pars. 7.632–7.634.

iv. Does the technical regulation 'fulfill' the identified objective(s)?

A. It must make a contribution to the objective pursued – i.e., there must be a genuine relationship of ends and means between the objective pursued and the measure at issue. *US-COOL* Panel Report, par. 7.693.

B. Must focus on *the degree of contribution, however minimal*, that the technical regulation makes towards the achievement of the underlying legitimate objective. *Id*; *US-Tuna* Appellate Body Report, par. 329.

v. Is the technical regulation more trade-restrictive than necessary to fulfill the objective(s) concerned?

A. Must discern whether the measure's trade-restrictiveness is required to fulfill the legitimate objectives pursued by the Member at its chosen level of protection. *US-Tuna* Panel Report, par. 7.460.

B. Do the trade restrictions exceed what is necessary to achieve the *degree of contribution* that a technical regulation makes to the achievement of a legitimate objective? *US-Tuna* Appellate Body Report, pars. 318-319.

vi. Is there a less trade-restrictive alternative available?

A. *Consider w/respect to disputed measure*: (i) the degree of contribution it makes to fulfilling legitimate objective at issue; (ii) the trade-restrictiveness of said measure; and (iii) the nature of the risks at issue and the gravity of consequences that would arise from non-fulfillment of the Member's objective through said measure. *US-Tuna* Panel Report, par. 7.465; *US-Tuna* Appellate Body Report, par. 322.

B. *Consider whether the proposed alternative measure*: a) is "less trade restrictive"; b) "would make an equivalent contribution to the relevant legitimate objective, taking account of the risks non-fulfillment would create"; and c) "is reasonably available." *Id*.

vii. What risks are engendered if the available less trade-restrictive alternative cannot equally fulfill the identified objectives?

A. Consider the likelihood and the gravity of potential risks (and any associated adverse consequences) if the legitimate objective being pursued would not be fulfilled." *US-Tuna* Panel Report, par. 7.467.

B. In assessing such risks, may use relevant available scientific and technical information, related processing technology, or intended end-uses of products", etc. *Id*., par. 7.466.

viii. *See* Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating Whether A Non-Tariff Measure Has Matured Into An Actionable Non-Tariff Barrier To Trade*, 28 American University International Law Review 101-280 (2013)

D. **Sanitary and Phytosanitary ("SPS") Agreement** (Re: product promotion bans and labeling restrictions on food safety grounds)

1. Art. 2.1; Annex A(5) - Members may take SPS measures necessary to protect human, animal or plant life or health, at the level of protection they deem appropriate, provided they are not otherwise inconsistent with the SPS Agreement.
2. Art. 2.2 – Measure must be based on scientific principles and cannot be maintained without 'sufficient scientific evidence'.
3. Art. 5.1 - Measure must be in accordance with relevant int'l standards (e.g., Codex Alimentarius Commission food safety standards or WHO guidelines/standards on unhealthy foods and beverages, infant formula, formula-related products)

a. If not based on a relevant int'l standard, a measure must be narrowly drafted/justified to protect against a genuine ascertainable risk, as determined by the application of best available science. *Measures Affecting the Approval and Marketing of Biotech Products ("EC Biotech Products")* WT/DS291/R, WT/DS292/R and WT/DS293/R (Sept. 29, 2006).

i. There is only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1. *Id*., at par. 7.3234.

ii. Annex A(4) – 'Risk Assessment' – the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

iii. If no risk assessment performed under Art. 5.1, the measure will not satisfy Art. 2.2.

4. Art. 5.7 – ('Precautionary Approach') –
   a. A Member may invoke a provisional measure if all four conditions are met:
      i. Relevant scientific information is 'insufficient';
      ii. Said measure is adopted on the basis of available pertinent information;
      iii. Member must seek to obtain additional information necessary for a more objective assessment of risk; and
      iv. Member must review the measure periodically. *Id*., at par. 7.3218, citing Appellate Body Report, *Japan – Agricultural Products II*.
   b. Cannot bypass Art. 5.1 risk assessment requirement. *EC Biotech Products*, at Appendix K, par. (a); par. 7.3233, citing Appellate Body Report, *Japan – Apples*, par. 179; *Japan -- Measures Affecting Agricultural Products (Japan-Varietals)*.
      i. Scientific uncertainty no excuse not to conduct a risk assessment. No PP in SPS Agreement. *EC Biotech Products* at par. 7.3220; *EC Measures Concerning Meat and Meat Products (EC Hormones)*.
5. Art. 5.6 – Measure cannot be more trade-restrictive than necessary to achieve their appropriate level of SPS protection, taking into account technical and economic feasibility (cost-benefit)
   a. Footnote 3 - A measure is not more trade-restrictive than necessary *unless* another reasonably available measure achieves the appropriate level of SPS protection at lower cost/effort (i.e., is significantly less trade-restrictive.

E. **GATT 1994** (if measure does not qualify as technical regulation)
1. Art. III:4 (nondiscrimination) –
   a. Measure results in treatment less favourable to imported products than to 'like' products of national origin.
2. Art. XX (Exception)
   a. Available, if *no* arbitrary or unjustifiable discrimination between countries where the same conditions prevail, and if *no* disguised restriction on international trade).
   b. If exception is available, measure may be adopted and enforced:
      i. Art. XX(a) - Necessary to protect public morals;
      ii. Art. XX(b) - Necessary to protect human, animal or plant life or health.
3. Art. XXIII(1)(a) (Nullification and Impairment)
   a. Where a WTO violation nullifies or impairs the benefits a State Party expected from the Agreement.
      i. DSU Art. 3.8 - An infringement of the obligations assumed under a covered agreement is considered prima facie to constitute a case of nullification or impairment.

ii. There is a presumption that the breach of the rules has an adverse impact on other Members. The burden is on the respondent to rebut the charge.

VI. Bilateral Investment Treaty ("BIT") Violations Engendered by Health Measures Imposing Plain Packaging and Product Promotion Restrictions (Pursued by investors to secure monetary damages)

A. Plain Packaging BIT Arbitration

1. *FTR Holding S.A. (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v Oriental Republic of Uruguay* (ICSID Case No ARB/10/7); *FTR Holding S.A. (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay)*, Request for Arbitration', ICSID Case No ARB/10/7 (Feb. 19, 2010)
   a. Switzerland-Uruguay BIT – (pending)
      i. Uruguay's anti-tobacco policies described as an implementation of its obligations as signatory to WHO FCTC.
         A. Required use on packaging of MOH-designed pictograms depicting disturbing images of health impacts of tobacco.
         B. Prohibited tobacco manufrs from marketing more than one product under a single brand name, which could mislead Uruguay consumers about relative harmfulness of products.
         C. Increased size of package health warning from 50% to 80% of the front and back of the cigarette packages.
      ii. BIT recognized each Party's right not to allow economic activities for reasons of public security and order, public health or morality.
         A. Since such measures were defined outside BIT, they could not be subject under an investor-State claim to "fair and equitable treatment" or other BIT standards.
2. *Philip Morris Asia Limited (Hong Kong) v. The Commonwealth of Australia* (Written Notification of Claim by Philip Morris Asia Limited to the Commonwealth of Australia (June 27, 2011) (UNCITRAL Arbitration Rules of 2010)
   a. Agreement between the Government of Hong Kong and the Government of Australia for the Promotion and Protection of Investments (pending)
      i. Complainant alleged that plain packaging law would:
         A. Expropriate its IP; and
         B. Fail to accord its IP 'fair and equitable' treatment.
      ii. Australia Gov't counterclaimed NO tribunal jurisdiction to hear dispute b/c:
         A. An investor 'cannot buy into a dispute by making an investment at the time when a dispute is either existing or highly probable'. (PM acquired its 100% shareholding in PM Australia 10 mos. following announcement that plain packaging would be introduced - in full knowledge and

with expectation that Austr. Gov't would implement plain packaging measure).

B. Cannot determine breaches of WTO Agreements or Paris Convention which treaties do not establish rights for private parties and contain their own dispute settlement procedures.

C. Claimant lacks any 'protected' 'investments' under BIT, which protects only indirect investments where companies incorporated in a third State qualify as investors under the Treaty. The assets of PM Australia and PML—two Australian-incorporated companies—do not enjoy protection as investments. (*See* BIT Art. 13(1) - A company duly organised under the law of a Contracting Party shall not be treated as an investor of the other Contracting Party, but any investments in that company by investors of that other Contracting Party shall be protected by this Agreement).

iii. Independent Commentary/Review of Case (Jurisdictional) *See* Tania Voon and Andrew Mitchell, *Time to Quit? Assessing International Investment Claims Against Plain Tobacco Packaging in Australia*, 14 J. Economic Law (2011), at pp. 6-7.

A. Art. 1(e)(ii) – PM Asia ("PMA") holds investments in Australia that are covered by BIT b/c PMA owns 100% of the shares in PM (Australia) Limited, which owns 100% of the shares in PM Limited ("PML").

B. Art. 1(e)(iv) - PMA also owns/controls investments in form of IP rights covered by BIT, including rights with respect to TMs and goodwill b/c PML owns/licenses TMs relating to brands - Marlboro, Alpine, and Peter Jackson — the use of which has generated 'substantial goodwill' in PML.

C. PMA 'investment' does not fall within meaning of BIT term that goes beyond mechanical application of asset types listed in Art. 1(e) under *Salini* test. (*Salini Costruttori S.p.A. and Italstrade S.p.A. v Kingdom of Morocco*, ICSID Case No. ARB/00/4, Decision on Jurisdiction, July 23, 2001, 42 ILM 609 (2003). *Salini* holds that for jurisdiction to be established, the Claimant must show that there is both an "investment" under Article 25(1) of the ISCID Convention ("Article 25(1)"), as well under the BIT. See *Malaysian Historical Salvors SDN, BHD v The Government of Malaysia*, at par. 43).

D. PMA did not make a commitment of a sufficient duration entailing an element of risk that contributes to the economic development of the host State. While such investment contributed some job creation, its tobacco products also imposed significant health and financial

burdens on Australia - (rather than contributing to Australia's economic development, PMA's investment contributes to the deaths of more than 15,000 Australians a year, at a social cost of $31.5 billion per annum).

iv. Independent Commentary/Review of Case (Merits) *Id*., at pp. 14-22; 23-24.

A. Art. 2(2) – Expropriation –
The degree and duration of interference with the investor's property. PMA could claim that law would significantly and permanently interfere with its property in terms of the value of its shareholdings in Australia and use/enjoyment of its registered TMs. *This will take time and evidence to demonstrate*.

B. *The acquisition, taking or appropriation of 'control, use or enjoyment of property through the exercise of State powers'*. PMA could not claim that Australian Gov't or any 3rd party was acquiring any of those rights or otherwise appropriating control over PMA's investment.

C. *The nature of the measure: whether it entails an exercise of the State's sovereign police powers*. PMA would find it difficult to prove that regulatory measures pursued for legitimate objectives can be regarded as indirect expropriation', given the legitimate public health purpose of such law.

D. *The existence of proportionality between the public interest pursued and the interference with the investor's property*. Will depend on final requirements implemented and evidence surrounding utility of those requirements from a health perspective. Expression of support for Australia's law from WHO and WHO FCTC Secretariat enhances Australia's position that plain packaging is a proportionate response to the adverse health effects of tobacco products.

E. *The legitimate expectations of investors (including the existence of specific assurances of protection by government).* PMA could not be regarded as having a legitimate expectation that a measure such as plain packaging would not be introduced in Australia at the time it made its investment.

AA. Art. 2(2) - 'Fair and Equitable' Treatment –
Was Gov't conduct reasonable, consistent, non-discriminatory, transparent and consistent with due process?

BB. *Were PMA's legitimate investor expectations undermined by enactment of plain packaging legislation?*

CC. Australia's legitimate regulatory interests in protecting and promoting public health are relevant in assessing PMA's legitimate expectations.

DD. The rational relationship between Australia's public health objectives and the plain packaging measure suggests that the measure is not arbitrary and cannot be said on the basis of arbitrariness to violate PMA's legitimate expectations.

EE. PMA cannot reasonably have expected that regulatory environment for its tobacco products would remain frozen at time of its investment; nor did Gov't make assurances to PMA or other HK investors.

AAA. Art. 2(2) - 'Unreasonable Impairment' –
Obligation not to impair investors' use of their investments has much in common with obligation to accord investors and investments 'fair and equitable treatment'.

BBB. If Gov't cannot show that its 'conduct bears *a reasonable relationship to some rational policy'* then this will be unfair and inequitable, as well as unreasonable.

B. Other BIT Issues for Consideration

1. Does a BIT claimant have a 'covered' investment in the territory of the other State Party?

a. Must the investment contribute to the 'economic development' of the host country to be 'covered'?

i. A tribunal ought to interpret the word "investment" so as to encourage, facilitate and promote cross-border economic cooperation and positive development. *Malaysian Historical Salvors SDN, BHD v The Government of Malaysia*, at pars. 66, 68. See also *Salini Costruttori SPA v Kingdom of Morocco (Decision on Jurisdiction)* (ICSID Arbitral Tribunal, Case No ARB/00/4, 23 July 2001).

ii. Is it a 'protected' investment? – Must the investment be in a project classified by the appropriate government Ministry as an 'approved project'? What type of approval is necessary to meet this requirement?

A. Does the Gov't require that investors wishing to be protected must identify themselves, such that that only 'specifically approved investments' will give rise to benefits under the relevant treaty? Does Gov't exercise a qualitative control on the types of investments which are indeed to be promoted and protected. *Desert Line Projects LLC v. The Republic of Yemen*, at par. 108.

B. Investments 'in accordance with' domestic law effectively require substantive certification that the investment has indeed been accepted. *Id.*, at pars. 110-111. But, a certification as mere formality constitutes an artificial trap

depriving investors of the very protection the BIT was intended to provide. Such an idea must give way – in the absence of an explicit and compelling demonstration to the contrary. *Id*., at pars. 106, 116.

C. The effectiveness of the approval requirements will depend on the clarity of the language used in the treaty and the circumstances of the relationship between the investor and the State. It is critical to be precise when crafting the requirement. IISD, *Registration and Approval Requirements in Investment Treaties* (2012) at pp. 7-9.

D. The mere fact that an approval and registration earlier given by the host State continued to be operative after the entry into force of the *1987 ASEAN Agreement among Brunei Darussalam, Indonesia, Malaysia, the Philippines, Singapore, and Thailand for the Promotion and Protection of Investments* for that State was not sufficient grounds to find that an investment qualified as a 'protected' investment under Art. II(3) of said Agreement. The investment had not been specifically approved and registered in writing after said IGA entered into force for Myanmar in 1997, as had been required. *Held*, an express subsequent act amounting to written approval and registration after the Agreement's entry into force was required to gain protection under the Agreement. *Yaung Chi Oo Trading Pte Ltd v Myanmar*, Award, ASEAN Case No ARB/01/1; IIC 278 (2003); 42 ILM 540 (2003).

E. Where a BIT covered only investments that had been classified as "approved projects" by the "appropriate Ministry", but the investment in question entailed merely a purchase of securities by a Belgian resident in Luxemburg which in turn reflected a portfolio partially acquired on the Kuala Lumpur Stock Exchange, said investment would not be such an "approved project" *Philippe Gruislin v. Malaysia*, Award (ICSID Case No. ARB/99/3), November 27, 2000, because the event would not be entirely unknown to any Malaysian official. *Desert Line Projects LLC v. The Republic of Yemen*, at par. 112.

iii. Does BIT refer to investments "accepted in accordance with respective laws and regulations of either Contracting State"?

A. Such references are intended to ensure the legality of the investment by excluding investments made in breach of fundamental principles of the host State's law, e.g. by fraudulent misrepresentations or the dissimulation of true ownership. *Inceysa (Inceysa v. Republic of El Salvador*, ICSID Case No. ARB/03/26, 2 August 2006) and *Fraport*

(Fraport AG Frankfurt Airport Services Worldwide v. Philippines, ICSID Case No. ARB/03/25, 16 August 2007), referenced in *Desert Line Projects LLC v. The Republic of Yemen*, at par. 104.

B. Is required compliance a mere formality? A project involving hundreds of millions of dollars, considerable technical and security risks, mobilization of vast resources from the very country which had co-signed the BIT, leading to objectives of national strategic importance in terms of commercial and social integration, security, and cross-border flows of goods and services, should not be deprived of protection due to the failure to have obtained some unspecified stamped or signed form from a governmental subdivision. *Desert Line Projects LLC v. The Republic of Yemen*, at par. 119.

C. "Principles of fairness should require a tribunal to hold a government estopped from raising violations of its own law as a jurisdictional defense when it knowingly overlooked them and endorsed an investment which was not in compliance with its law." *Id.*, at par. 120, referencing *Fraport* at par. 346.