Patent provisions and Health: The evolution of international investment agreements

New Generation of FTAS and their implications on health systems and policies

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Introduction: recent trends

- Intellectual Property Rights as an Investment
- Emerging trends in international investment law, as it relates to intellectual property
  - Realisation that IPRs are in fact an investment
  - Increasing number of disputes – and 'risk' to the ability of governments to protect health
  - Increased fragmentation / blurring of TRIPS and international investment agreements
  - Reactive negotiating/drafting

Ripple in still water…

- Recent IP-related claims
  - *FTR Holdings S.A. (Switzerland) et al. v Uruguay* (October 2010)
  - *Philip Morris Asia (HK) v Australia* (June 2011)
  - *Eli Lilly v Canada* (November 2012)

FTR Holdings S.A. (Switzerland) et al. v. Oriental Republic of Uruguay

- Measures
  - Prohibited brand variation; a company is only lawfully allowed to sell one product variety.
  - Enlarges mandatory warning labels from 50% to 80% of the front and back panels.
  - Requires inclusion of “shocking and sensational images designed to evoke emotions of repulsion and disgust, even horror” as part of the health warnings on packaging.
- Claims
  - Most notable claims: NT, expropriation and unreasonable or discriminatory
  - Now “virtually impossible for the companies to use their brands and trademarks to promote their own products or even distinguish them from other brands”
  - Most other countries consider a health warning of 50% of the packaging to be “more than sufficient to clearly communicate the well-known health effects of smoking”.

Philip Morris v Australia

- Measures
  - Plain packaging of tobacco products
- Claims
  - Constitutes unlawful expropriation of PMA's investments and intellectual property without compensation (Article 6.1);
  - Fails to provide for fair and equitable treatment to PMA's Australian investments (Article 2(2));
  - Unreasonably impairs PMA's investments in Australia (Article 2(2));
  - Fails to provide full protection and security for PMA's investments in Australia (Article 2(2)); and
  - Breaches Australia's international obligations in relation to PMA's investments (Article 2(2)) by violating the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property and the WTO Agreement on Technical Barriers to Trade.

Eli Lilly v Canada

- Measures
  - Court invalidated several Eli Lilly patents
  - Complaint against Canada's strict patentability requirements applied since 2005 regarding 'utility' ('promise doctrine') and a 'new, non-statutory disclosure obligation'
- Claims
  - expropriation and FET – invalidations 'are contrary to Canada's international treaty obligations' (i.e. TRIPS, NAFTA and the Patent Cooperation Treaty)

Emerging Trends

- 1. Realisation that IPRs are an investment
- 2. Incorporating TRIPS into a clarification of (indirect) expropriation
- 3. More precisely defining the scope of the protection
- 4. Product specific exceptions

1. IPRs as an investment

- Germany-Pakistan BIT (1959), Art 8(1)(a)

  'The term "investment" shall comprise capital brought into the territory of the other Party for investment in various forms in the shape of assets such as foreign exchange, goods, property rights, patents and technical knowledge.'

1. IPRs as an investment

- Most FTAs define investment broadly
  - "every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk"

- This is usually followed by forms in which the investment could take and explicitly include
  - "intellectual property rights"; and
  - "other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens, and pledges"

1. IPRs as an investment

- Other IIAs do not explicitly include IPRs in its definition of investment, but…see ie NAFTA:
  - 1139(g): . "real estate or other property, tangible or intangible, and any related property rights such as lease, liens and pledges, acquired in the expectation or used for the purpose of economic benefit or other business purposes."
  - 1110(7): "[expropriation] does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (IP)."
  - 1108(5): "Articles 1102 (NT) and 1103 (MFN) do not apply to any measure that is an exception to, or derogation from, the obligations under Article 1703 (IP NT) as specifically provided for in that Article"

1. IPRs as an investment

- Who/what is covered, and when? IPRs – covered investments
  - Registered IPRs, such as patents and trademarks, are covered investment
  - Unregistered rights, such as copyright, trade secrets and unregistered trademarks (where allowed by law)

- Applications for IPRs – covered investments?
  - patents, industrial designs and (in non-common law countries) trademark require registration
    - Legitimate expectations, potential profits and value
    - Ability to sell/assign the IPR
    - Limited rights

1. IPRs as an investment

- Applications for IPRs – covered investments?
  - Some IIAs refer not to IPRs themselves as being included as an "investment" under the agreement but to "rights *with respect to* copyrights, patents, …" or even refer to "*patentable* inventions".
  - Some IIAs provide protection (including national treatment and MFN) in the pre-establishment phase to both investors and to the investment

2. Indirect Expropriation and IPRs?

- What is an indirect expropriation relating to IPRs?
  - Compulsory license
  - Limitation or revocation of rights (for public policy purposes)
    - i.e. revocation of patent rights for applicants that fail to disclose the origins of genetic materials contained in those patents
    - i.e. government narrowly interprets a substantive standard/right (i.e. utility)
    - i.e. plain packaging of cigarettes limiting use of the trademark

2. Indirect Expropriation and IPRs?

- KORUS, Article 11.6.5 of the KORUS FTA
  - "[The Agreement's Article on expropriation] does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter Eighteen (Intellectual Property Rights)"
- Annex 11-B(3)(b) of the KORUS FTA
  - "Except in rare circumstances, such as, for example, when an action or a series of actions is extremely severe or disproportionate in light of its purpose or effect, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, the environment, and real estate price stabilization (through, for example, measures to improve the housing conditions for low-income households), do not constitute indirect expropriations."

2. Indirect Expropriation and IPRs? – You, who choose to lead, must follow

- EU-Singapore (See also CETA, Article X.11)
  - Article 9.6(3) This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, to the extent that such issuance is consistent with [TRIPS].
  - Annex 9-C For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter Eleven (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter Eleven (Intellectual Property) of this Agreement does not establish that there has been an expropriation.

2. Indirect Expropriation and IPRs? – If you should stand then who's to guide you?

- EU-Singapore, Annex 9-A
  - For greater certainty, except in the rare circumstance where the impact of a measure or series of measures is so severe in light of its purpose that it appears manifestly excessive, non-discriminatory measure or series of measures by a Party that are designed and applied to protect legitimate public policy objectives such as public health, safety and the environment, do not constitute indirect expropriation.

3. Typical FET Arguments – If I knew the way I would take you home

- Claim is often based on three arguments:
  - a lack of fairness and proportionality of the legislation;
  - the 'legitimate expectations' of the investor;
  - inconsistencies with the relevant international framework (i.e. WTO and Paris Convention).

- Success against a legitimate health measure?
  - Is the measure manifestly unfair or inequitable?
  - What are 'legitimate expectations'?
  - Consistent with an international treaty?

3. Australia–Hong Kong BIT, Art 2(2)

- Investments and returns of investors of each Contracting Party shall at all times be accorded fair and equitable treatment and shall enjoy full protection and security in the area of the other Contracting Party. Neither Contracting Party shall, without prejudice to its laws, in any way impair by unreasonable or discriminatory measures the management, maintenance, use, enjoyment or disposal of investments in its area of investors of the other Contracting Party.

3. KORUS, Article 11.5

- 1. Each Party shall accord to covered investments treatment in accordance with customary international law, including fair and equitable treatment and full protection and security.
- 2. For greater certainty, paragraph 1 prescribes the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to covered investments. The concepts of "fair and equitable treatment" and "full protection and security" do not require treatment in addition to or beyond that which is required by that standard, and do not create additional substantive rights. The obligation in paragraph 1 to provide:

3. EU-Singapore, Article 9.4 Canada-EU, Article X.9

- A Party breaches the obligation of fair and equitable treatment … where a measure or series of measures constitutes:
  - Denial of justice in criminal, civil or administrative proceedings;
  - Fundamental breach of due process [Can: including a fundamental breach of transparency, in judicial and administrative proceedings];
  - Manifest arbitrariness;
  - [Can: Targeted discrimination on manifestly wrongful grounds, such as gender, race or religious belief];
  - Abusive treatment of investors, such as coercion, duress and harassment [Sing: or similar bad faith conduct]; or
  - a breach of the legitimate expectations of a covered investor arising from specific or unambiguous representations from a Party so as to induce the investment and which are reasonably relied upon by the covered investor. [Can slightly different placement and wording]
  - A breach of another provision of this Agreement, or of a separate international Agreement, does not establish that there has been a breach of this Article

4. Tailoring to provide for certain measures – And if you go no one may follow

- Other provisions
  - Clause modelled on Article XIV of the GATS
  - Carve outs

Comparisons

- Lessons – treaty language matters
  - Philip Morris v Australia – Compare possible arguments for expropriation and FET under the relevant treaty vs new generation treaties (ie KORUS, EU-Singapore)
  - Eli Lilly v Canada – Is this an IP or investment case? Compare possible arguments for expropriation and FET under the relevant treaty vs new generation treaties (ie KORUS, EU-Singapore).
  - Could the WTO claim against India for failing to register patents in the 'mailbox' have been brought in as an investment claim?
  - Could India's strict laws on patentability or loose compulsory licencing laws be deemed inconsistent with an investment agreement?

Conclusion – There is a road, no simple highway

- More claims will be filed – Danger to 'health' from the 2500+ older-style IIAs
- Drafting trend in mega-regionals are largely positive
- Continued link to other international regimes, as opposed to standards
- Existing treaties contain various standards – fragmentation (and risk) remains