Observations: the Role of the Multilateral Framework
Observations: the Role of the Multilateral Framework

TRIPS contains not only minimum standards, but also flexibilities and limits to IP protection (ceilings). Art. 7 & 8 TRIPS express this balance and guide TRIPS interpretation.

Bilateral and regional treaties amongst WTO Members addressing IP are inter-se modifications of the WTO/TRIPS framework.

As such, they may not derogate from TRIPS rules which are crucial for giving effect to the object & purpose of TRIPS. Thus, flexibilities crucial for the balance which Article 7 establishes should not be restricted.
TRIPS Article 7 & 8

Article 7
Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8
Principles

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

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.
IPRs in FTAs Index 2016
Overview
The IPRs in FTAs Index

- **Caveat! This is not a review of the country’s IPR laws**
  - *We therefore cannot say the extent an agreement may surpass TRIPS or any existing domestic laws*
- Calculated for the 80 agreements that include IPR provisions
  - Scaled to range from 0 to 100
- Based on tallying points for the presence of provisions concerning:
  - Cooperation
  - Reaffirming international obligations
  - WTO coverage
  - Commitments to technology transfer and access to technology
  - Competition and consumer protection
  - Coverage of the different types of IPR (1-3 scale)
  - Enforcement
Proliferation of IPR Inclusive Agreements
Introduced by advanced economies
Distribution of Index scores

Agreement reaffirms TRIPS  |  Agreement does not reaffirm TRIPS

[Graph showing the distribution of index scores for various countries, with a clear distinction between those that reaffirm TRIPS and those that do not.]
More innovative countries sign more comprehensive agreements

Correlation between mean IPR index and Global Innovation Index by country

\[ y = 0.6044x + 31.539 \]

\[ R^2 = 0.35 \]
A reflection of domestic policy?

Correlation between mean IPR index and Ginarte-Park IPR protection index

y = 0.029x + 3.207
R² = 0.2397
## Top participants and partners

<table>
<thead>
<tr>
<th>Top Asia-Pacific Countries</th>
<th>Number of IPR inclusive Agreements</th>
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<th>Minimum Overall Index</th>
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Agreements involving developed countries are more comprehensive.

Distribution of IPR Index by agreement member’s status

- Australia - U.S.
- China - Chile
- TPP

Index value

- Developing countries
- Developed countries
- Developing and developed countries
Ratcheting up?

Mean, Minimum, and Maximum IPR Index per year

No. Agr.  0   0   1   0   1   0   1   1   1   1   4   4   10  10  5   9   4   8   8   3   3   3   1
Or business as usual?

Mean IPR index per year and member status

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A means to complement multilateral agreements
IPRs in FTAs Index 2016
Focusing on patents
Patent Index

• Constructed in a similar manner as the IPR index

• Covers:
  • Specific pharmaceutical provisions
  • Compulsory licensing
  • Exceptions to patent rights
  • Patentability criteria
  • Test data exemption
  • Patent linkage
  • Term extensions
  • Patenting period
  • Security exemptions
  • Parallel importing
  • Border measures
  • Novelty grace period
Example of provisions related to patents

• Score of 1: New Zealand – China

  Article 159  Definitions

  For the purposes of this Chapter:

  intellectual property rights refers to copyright and related rights, rights in trade marks, geographical indications, industrial designs, patents, layout designs of integrated circuits, and rights in plant varieties as defined in the TRIPS Agreement.

• Score of 2: Japan – Philippines

  Article 123  Patents

  Each Party shall, in accordance with its laws and regulations, ensure that any applicant for a patent may file a request to the competent authority that his application be examined promptly.

  Note: For the purpose of this Article, the term “competent authority” means, for the Philippines, the Director of the Bureau of Patents of the Intellectual Property Office.
Examples of provisions related to patents

• Score of 3: EU – Korea, Rep.

### Article 10.30
**Term of protection**

1. The duration of protection available in the Parties following registration shall amount to at least 15 years.

2. The duration of protection available in the European Union and Korea for unregistered appearance shall amount to at least three years.

### Article 10.31
**Exceptions**

1. The European Union and Korea may provide limited exceptions to the protection of designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

2. Each Party shall contribute to the implementation of and shall respect the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration, as well as the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2003.

3. The protection of a design under the law of copyright is not granted automatically, but granted only if a design qualifies for protection in accordance with the law of copyright.
Patent index also rising

Mean Patent index per year

More comprehensive agreements cover patents more comprehensively.

Correlation between IPR index and Patent index

- AUSTRALIA-US
- KOREA-US
- US-SINGAPORE
- JAPAN-SWITZERLAND
- TPP
- EFTA-KOREA
- US-LAO
- EU-KOREA
- TRIPS
- JAPAN-VIET NAM
- JAPAN-INDONESIA
- ASEAN-KOREA
- CHILE - HONG KONG, CHINA
- KOREA-SINGAPORE
- KOREA-CHILE
- JAPAN-MALAYSIA
- JAPAN-PERU
- ASEA-AUSTRALIA-NEW ZEALAND
- COSTA RICA-CHINA
- MALAYSIA-CHINA
- MALAYSIA-AUSTRALIA
- AUSTRALIA-CHILE
- EFTA-HONG KONG, China
- NICARAGUA-TAIWAN,POC
- CHINA-SWITZERLAND
- EU
- KOREA
- NEW ZEALAND-MALAYSIA
- JAPAN-CHILE
- COSTA RICA-CHINA
- TRANS-PACIFIC SEPA
- CHILE
- NEW ZEALAND

Patent Index

IPR Index
Patent specific clauses
Health-Relevant Provisions?
Example of compulsory licensing

- In the Investment Chapter of Australia – US Agreement
- Most agreements follow exactly this structure

**ARTICLE 11.7: EXPROPRIATION AND COMPENSATION**

1. Neither Party may expropriate or nationalise a covered investment either directly or indirectly through measures equivalent to expropriation or nationalisation (“expropriation”), except:
   - (a) for a public purpose;
   - (b) in a non-discriminatory manner;
   - (c) on payment of prompt, adequate, and effective compensation; and
   - (d) in accordance with due process of law.

2. The compensation referred to in paragraph 1(c) shall:
   - (a) be paid without delay;
   - (b) be equivalent to the fair market value of the expropriated investment immediately before the expropriation took place (“the date of expropriation”);
   - (c) not reflect any change in value occurring because the intended expropriation had become known earlier; and
   - (d) be fully realisable and freely transferable.

3. If the fair market value is denominated in a freely usable currency or the Australian dollar, the compensation referred to in paragraph 1(c) shall be no less than the fair market value on the date of expropriation, plus interest at a commercially reasonable rate for that currency, accrued from the date of expropriation until the date of payment.

4. However, if the fair market value is denominated in the Australian dollar and the Australian dollar is not transferable on the date of payment at the market rate of exchange, or if it is denominated in another currency that is not freely usable, the compensation referred to in paragraph 1(c) – converted into the currency of payment at the market rate of exchange prevailing on the date of payment – shall be no less than:
   - (a) the fair market value on the date of expropriation, converted into a freely usable currency at the market rate of exchange prevailing on that date, plus
   - (b) interest, at a commercially reasonable rate for that freely usable currency, accrued from the date of expropriation until the date of payment.

5. This Article 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 Seventeen (Intellectual Property Rights).
Example of Test data exemption

• From Japan – Switzerland agreement

Article 121
Treatment of Test Data in Marketing Approval Procedure

1. Each Party shall prevent applicants for marketing approval for pharmaceutical products which utilise new chemical entities from relying on or from referring to test or other data submitted to its competent authority by the first applicant for a certain period of time counted from the date of approval of that application. As of the date of entry into force of this Agreement, such period of time is stipulated as being no less than six years by the relevant laws of each Party.

2. Each Party, when requiring, as a condition for approving the marketing of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall ensure that, in accordance with its relevant laws and regulations, applicants for marketing approval are either:

(a) prevented from relying on or from referring to such data submitted to its competent authority by the first applicant for a period of at least ten years counted from the date of approval of that application; or

(b) required generally to submit a full set of test data, even in cases where there was a prior application for the same product, for a period, counted from the date of approval of a prior application, of at least ten years.
Example of novelty grace period

• Australia – Malaysia

Article 13.11
Patents

1. Subject to the exceptions set out in Article 27 of the TRIPS Agreement, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.\(^{32}\)

2. Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure:

   (a) was made or authorised by, or derived from, the patent applicant, and

   (b) occurs within 12 months prior to the date of filing of the application in the territory of the Party.

3. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

4. Nothing in this Article will limit the scope of exceptions to patentability available in each Party’s laws and regulations at the time that this Agreement enters into force.
Example of term extension

• US – Lao PDR

10. Each Party shall provide a term of protection for patents that shall not end before the expiration of a period of twenty years counted from the date of filing. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.
Example of Pharma.-specific provisions

** CHAPTER FIVE **

** PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES **

** ARTICLE 5.1: GENERAL PROVISIONS **

The Parties recognize that while there are differences between each Party’s health care system, the Parties share a commitment to promoting the development of and facilitating access to high-quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their nationals. In pursuing these objectives, the Parties affirm the importance of:

(a) adequate access to pharmaceutical products and medical devices in providing high quality health care;

(b) patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;

(c) sound economic incentives and competitive markets for the efficient development of and access to patented and generic pharmaceutical products and medical devices;

(d) appropriate government support of research and development in academic and commercial laboratories, intellectual property protections, and other incentives for innovation in the research and development of pharmaceutical products and medical devices;

(e) promoting innovation and timely and affordable access to safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party’s ability to apply appropriate standards of quality, safety, and efficacy;

(f) ethical practices by pharmaceutical and medical device manufacturers and suppliers and by health care providers on a global basis in order to achieve open, transparent, accountable, and reasonable health care decision-making; and

(g) cooperation between the Parties, including each Party’s regulatory authorities, to improve the safety and efficacy of pharmaceutical products and medical devices.

- Korea – US
- These provisions are only present in developed – developed agreements
- Reimbursement by market means (FRAND), transparency of government regulation, marketing, ethical business practices, Medicines and Medical Devices Committee.
Setting the stage for discussions

IP as a Trade-off:

1. Concessions driven by export interest do not always lead to a mutually beneficial regulation of IP
2. Trade preferences obtained may be eroded as soon as similar or better preferences are granted to other countries

Increasing Comprehensiveness erodes Policy Space:

1. IP rules become increasingly comprehensive and prescriptive, transplanting detailed rules from the IP-demanding country
2. As treaty obligations, these rules are almost cast in stone – with little options to adapt to changing domestic needs

Lack of Transparency, Inclusiveness & Equal Participation:

These deficits cannot be corrected in implementation processes if detailed rules leave no flexibility for a tailored implementation
Recommendations by Dr. Grosse Ruse-Khan

Negotiation Mandate & Process:
1. Countries facing IP demands should adopt a proactive agenda on IP, based on input from all stakeholders.
2. No country should demand or agree to IP provisions which have not been subject to a public negotiation process where all stakeholders have an opportunity for review and comment.

The negotiated Outcome:
1. TRIPS-plus rules should still allow for policy space, respect core TRIPS flexibilities and all other int. rules applicable between the parties.
2. Agreements should contain review clauses to assess the impact of IP rules and an option for renegotiating IP provisions in light of an impact assessment.
Interpretation and Implementation:

1. All other applicable int. law forms the interpretative context.

2. Interpretation should be in light of TRIPS balancing objectives. TRIPS-plus rules should be constructed to allow for sufficient policy space to implement this balance. → When implementing them, states have the right to draft appropriate exceptions and limitations (E&Ls)

3. The notion of IP protection and enforcement encompasses also E&Ls and other balancing rules. This allows for a wider understanding of MFN: → Countries facing IP demands should claim concessions regarding E&Ls secured by other (similar) countries.

4. IP-demanding countries should not use unilateral assessments of compliance; nor should they unilaterally withdraw benefits.