INTELLECTUAL PROPERTY RIGHTS IN BILATERAL AND REGIONAL TRADE AGREEMENTS

TRADE, INVESTMENT AND INNOVATION DIVISION
Teemu Alexander Puutio
Luca Parisotto

UNITED NATIONS
ESCAP
Economic and Social Commission for Asia and the Pacific

11 March 2016

Observations: the Role of the Multilateral Framework

Part 1
Part 2
Part 3
Part 4

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

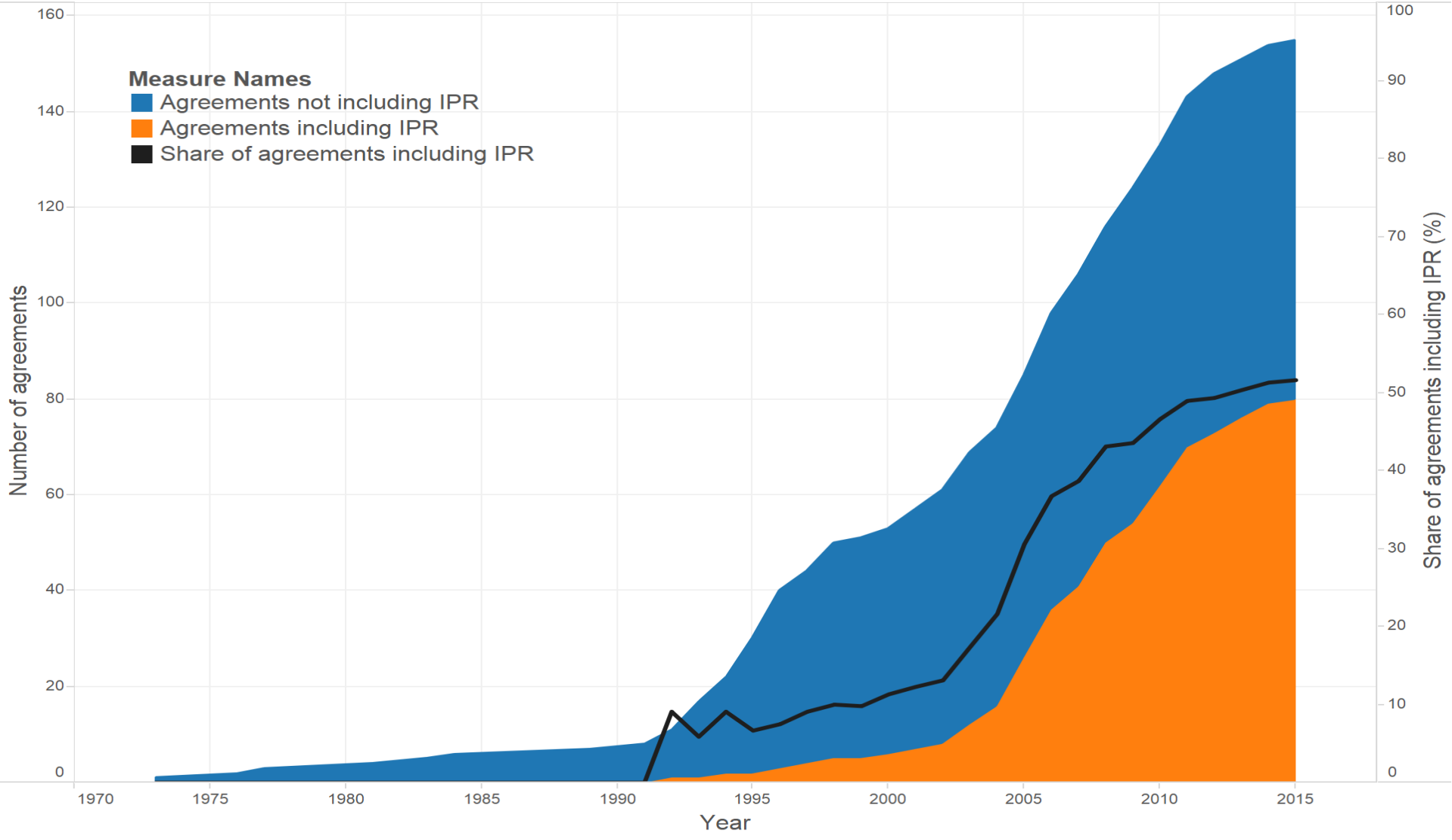
IPRs in FTAs Index 2016
Overview

Part 1
Part 2
Part 3
Part 4

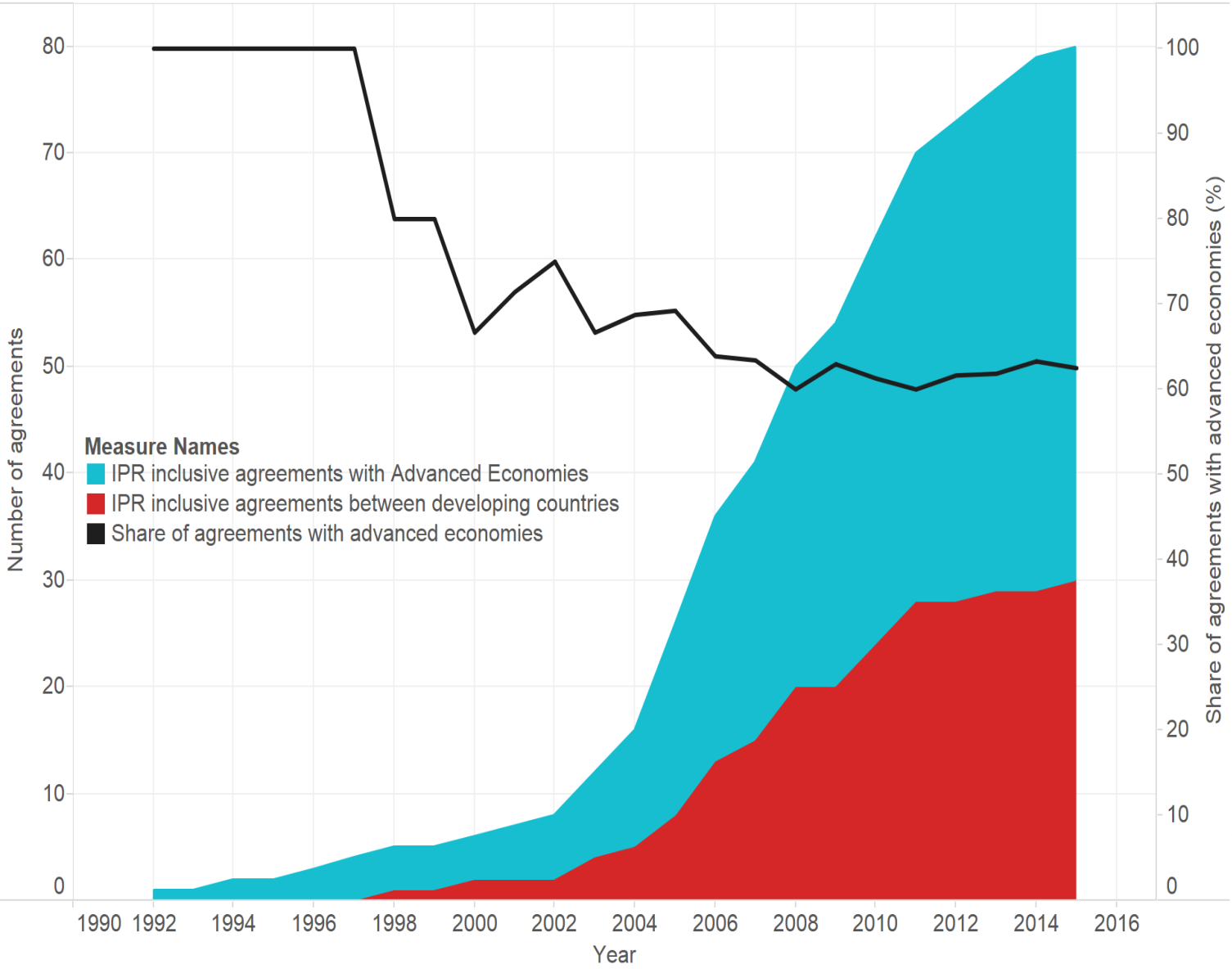
The IPRs in FTAs Index

- **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



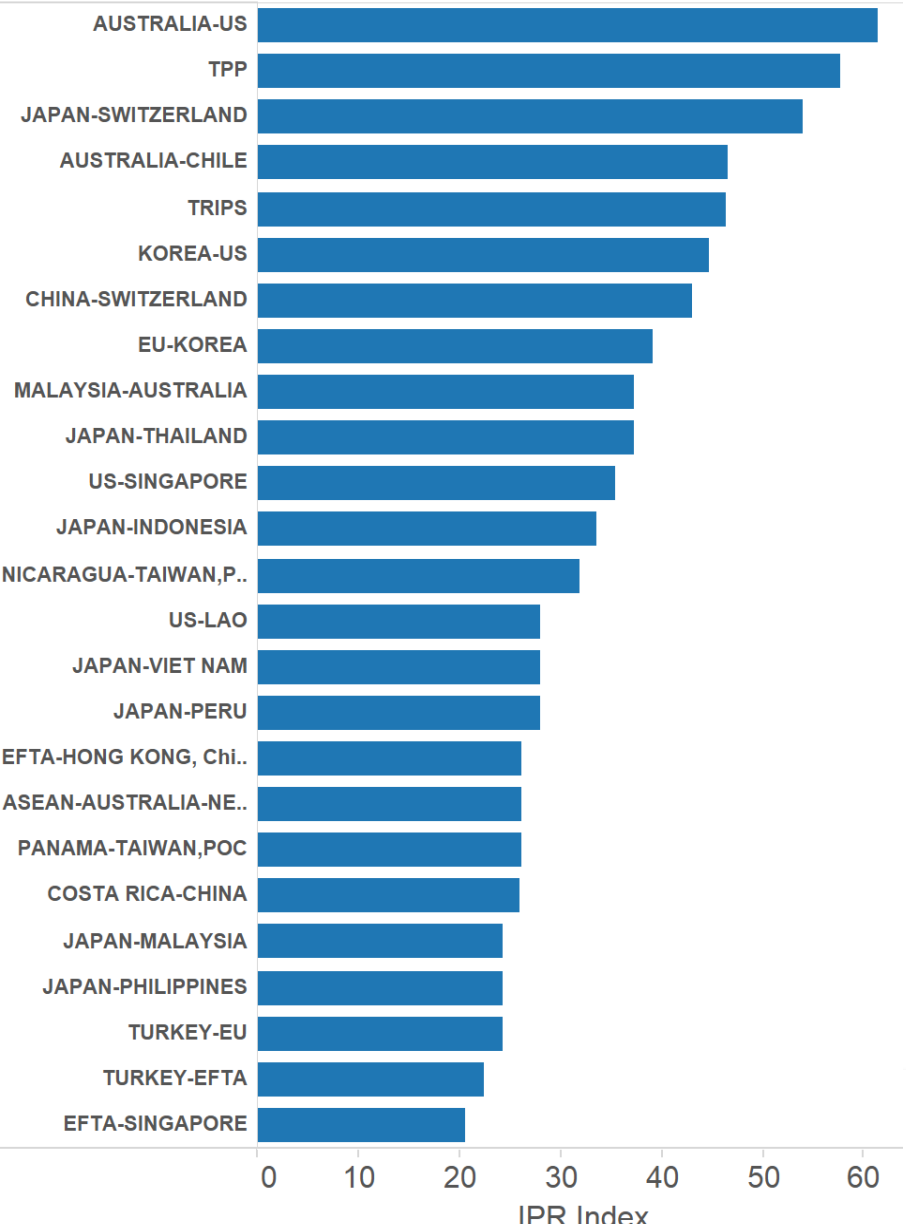
Introduced by advanced economies

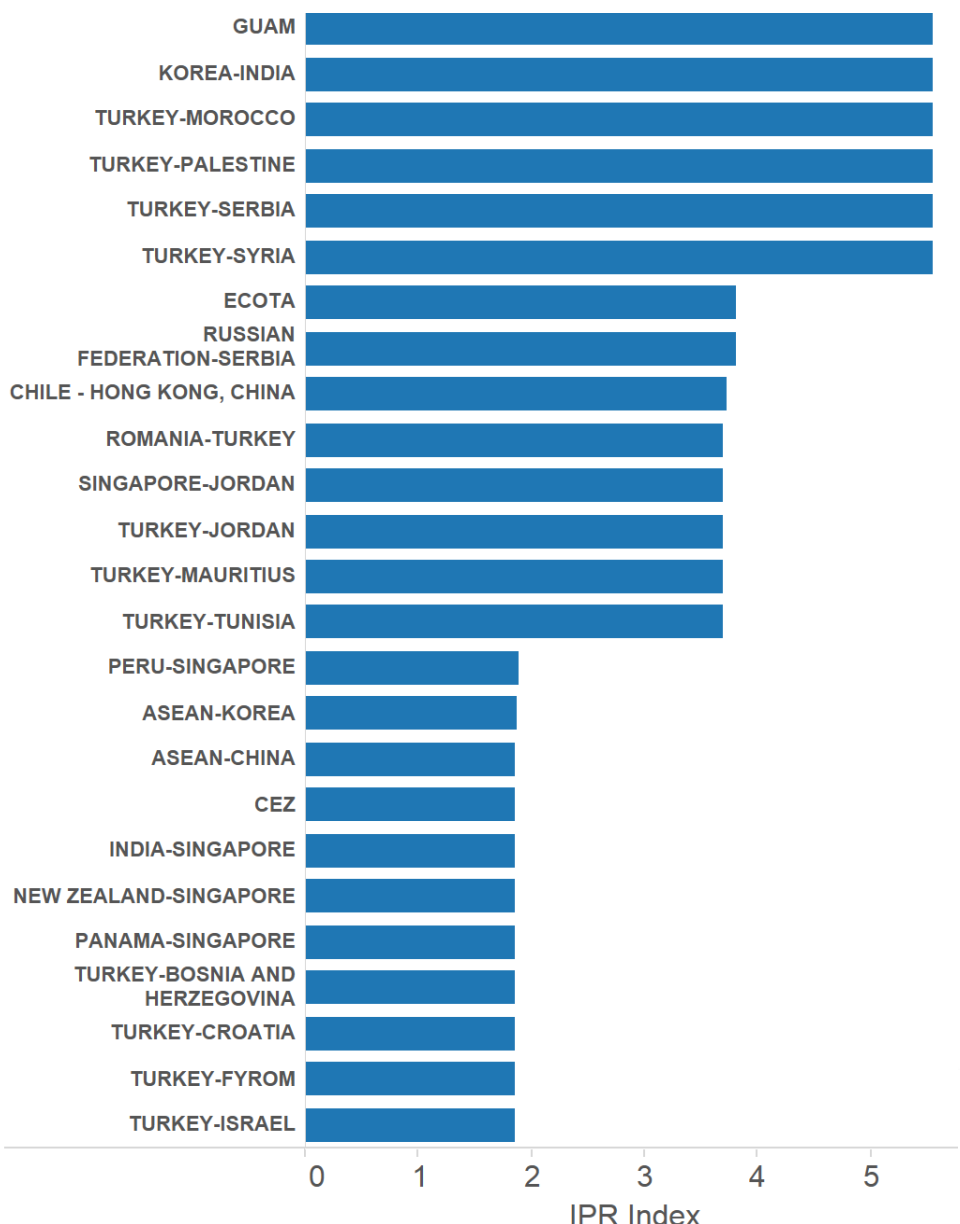


Top Asia-Pacific Countries	Number of IPR inclusive Agreements
Turkey	21
Singapore	15
Japan	12
Korea, Rep.of	9
Malaysia	8
New Zealand	7
Australia	6
China	6
Thailand	6
Brunei Darussalam	5
Taiwan, POC	5
India	4
Indonesia	4
Lao PDR	4
Philippines	4
Viet Nam	4
Cambodia	3
Hong Kong, China	3
Kazakhstan	3
Myanmar	3

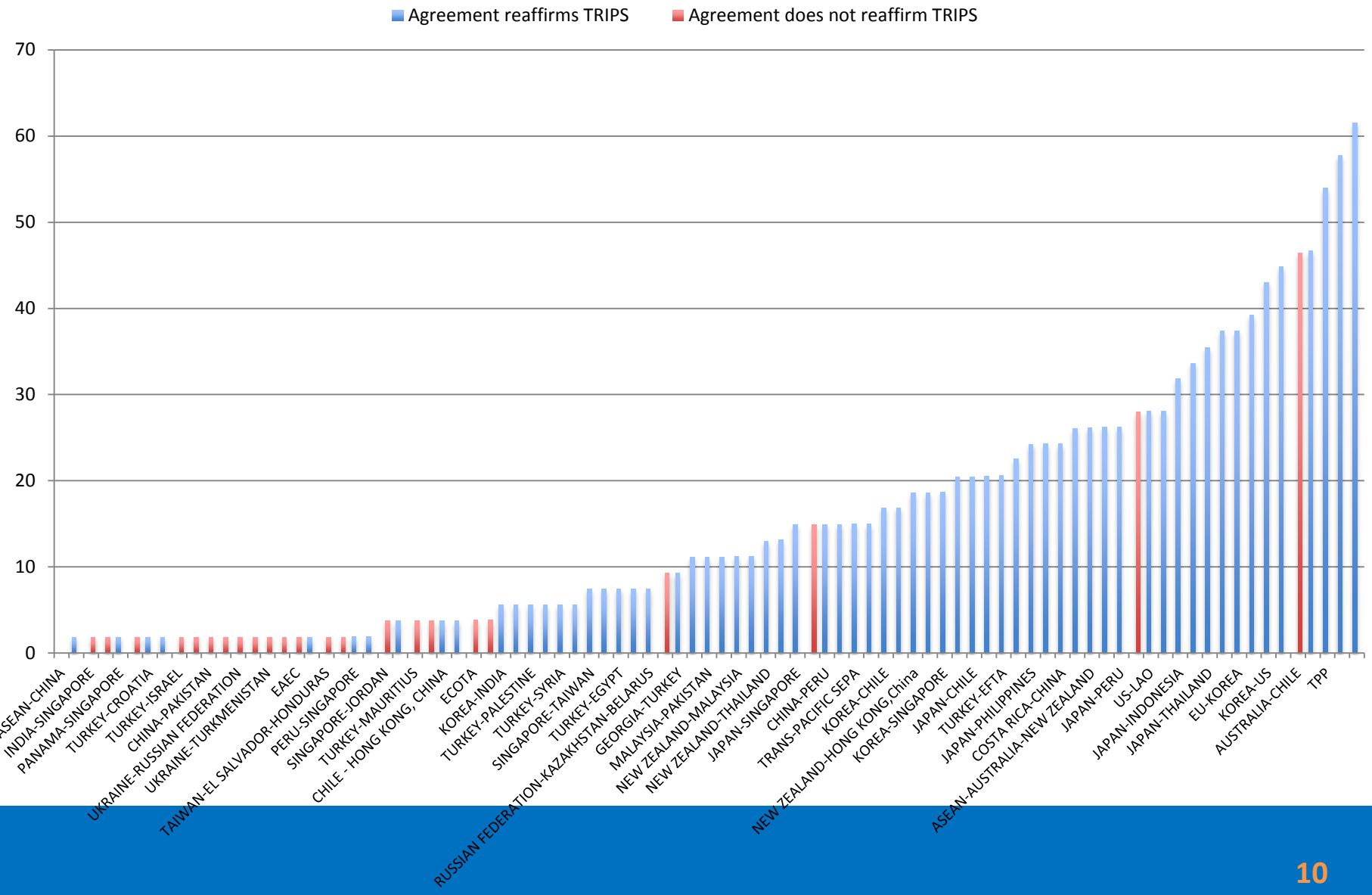
Top Partners	Number of IPR inclusive Agreements
Chile	7
EFTA	4
Peru	4
United States	4
EU	2
Total	78

Highest and Lowest rated agreements

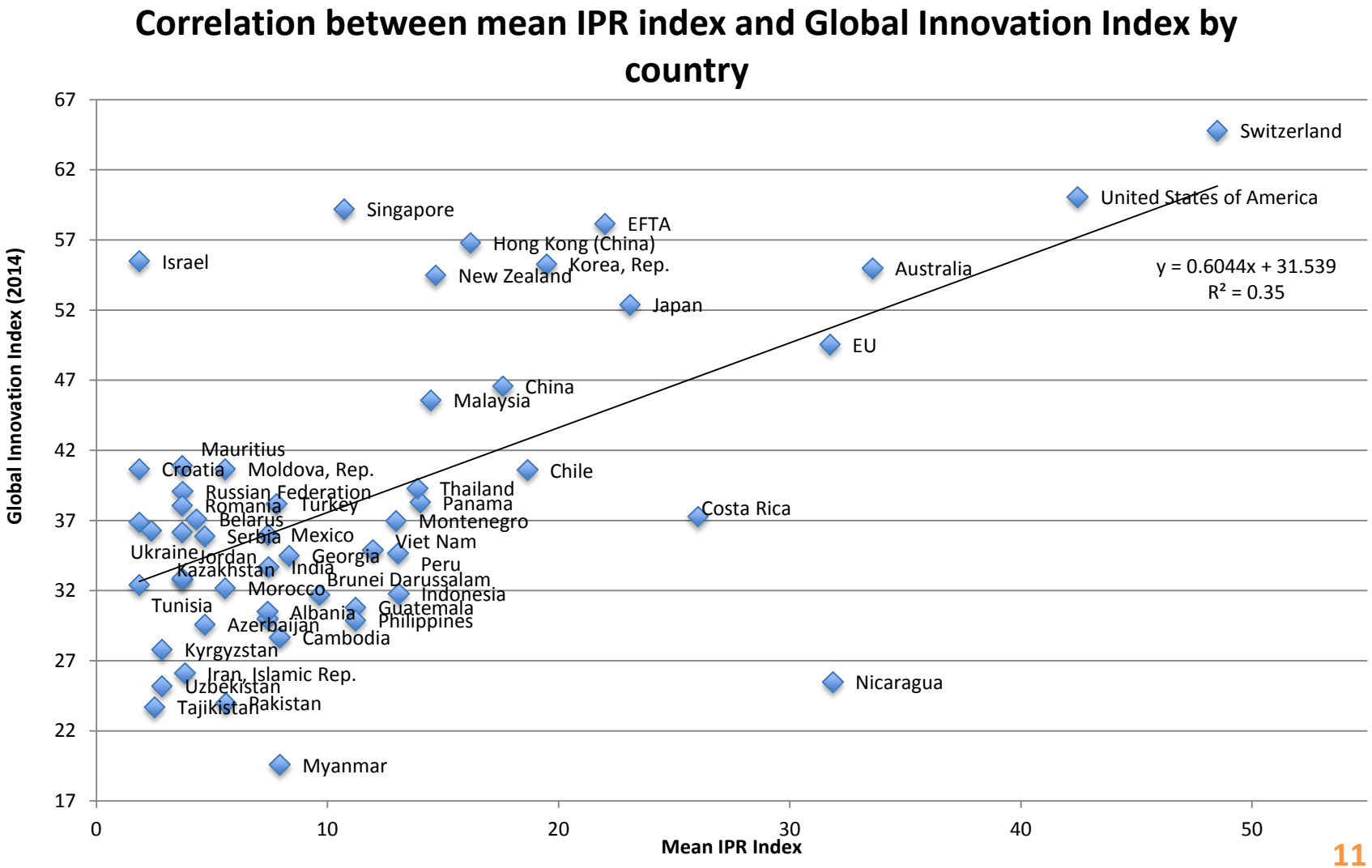




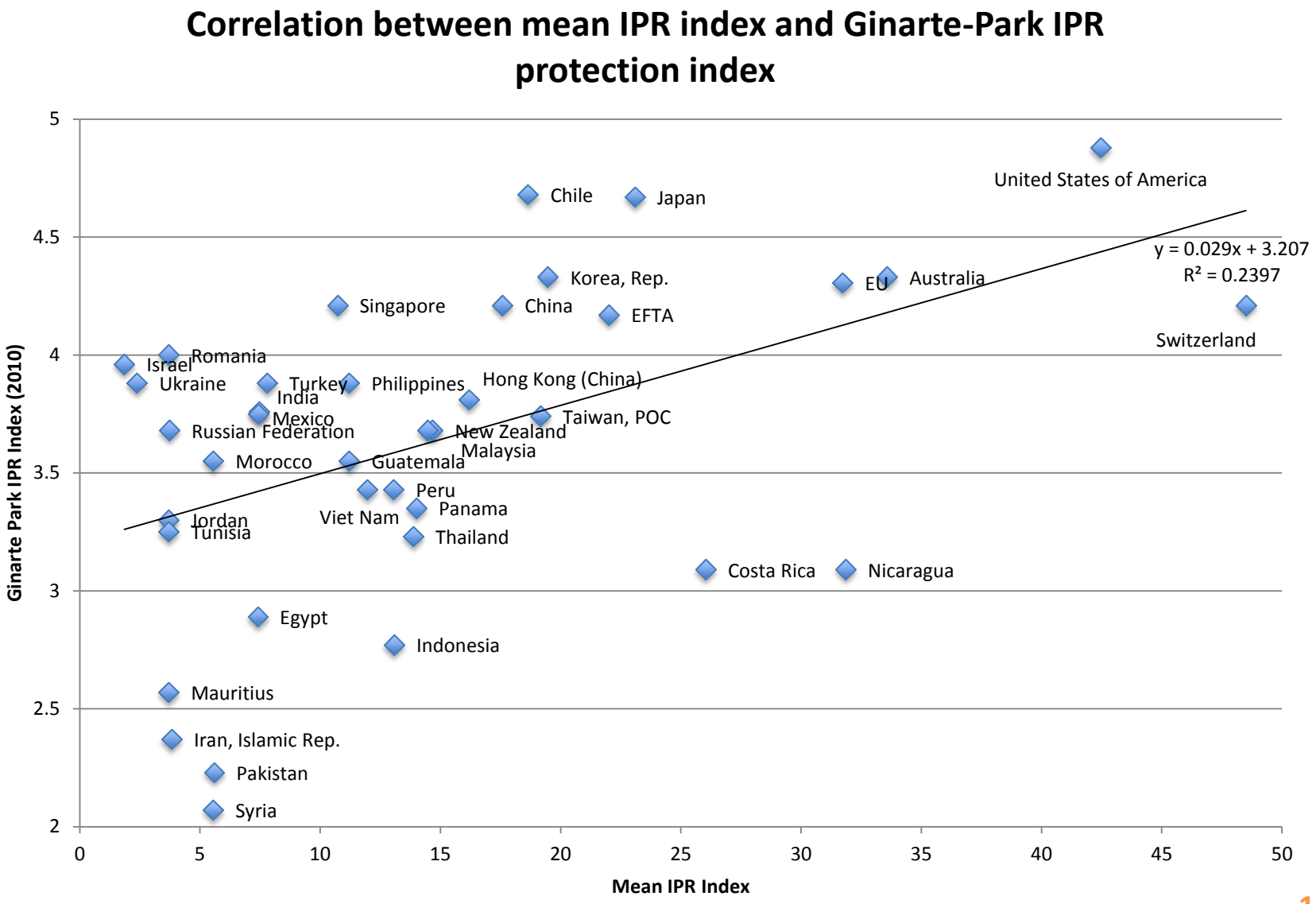
Distribution of Index scores



More innovative countries sign more comprehensive agreements



A reflection of domestic policy?

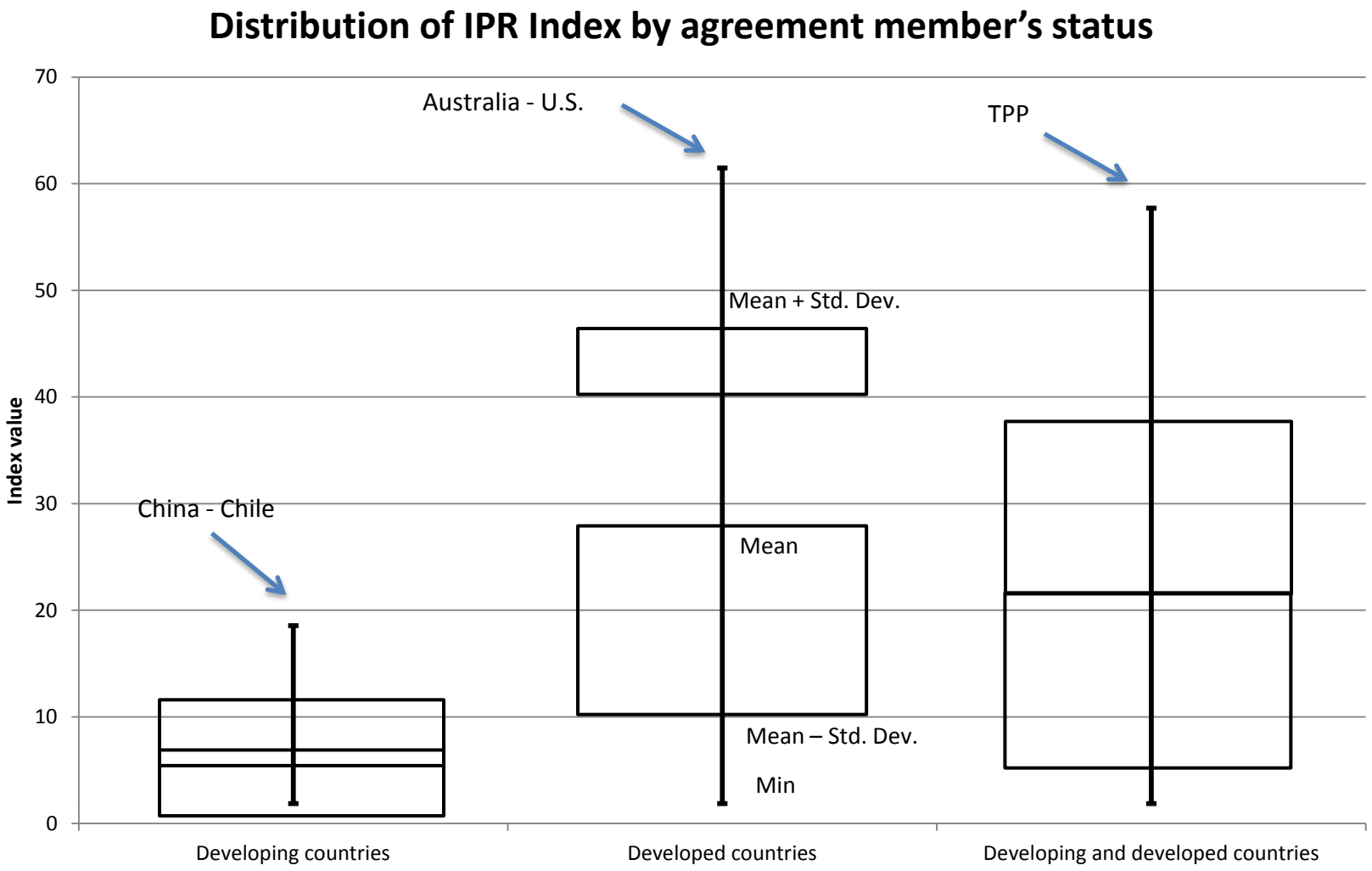


Top participants and partners

Top Asia-Pacific Countries	Number of IPR inclusive Agreements	Mean Overall Index	Minimum Overall Index	Maximum Overall Index	Standard deviation Overall Index
Turkey	21	7.79	1.85	24.24	6.82
Singapore	15	10.72	1.85	35.45	10.66
Japan	12	23.09	1.85	53.97	13.84
Korea, Rep.of	9	19.47	1.86	44.79	14.53
Malaysia	8	14.47	1.85	37.36	13.40
New Zealand	7	14.68	1.85	26.18	7.43
Australia	6	33.58	14.85	61.48	18.53
China	6	17.58	1.85	43.03	14.27
Thailand	6	13.88	1.85	37.34	13.77
Brunei Darussalam	5	9.64	1.85	26.18	9.86
Taiwan, POC	5	19.16	7.41	31.85	11.71
India	4	7.45	1.85	14.94	6.75
Indonesia	4	13.07	1.85	33.62	15.58
Lao PDR	4	11.96	1.85	28.07	13.86

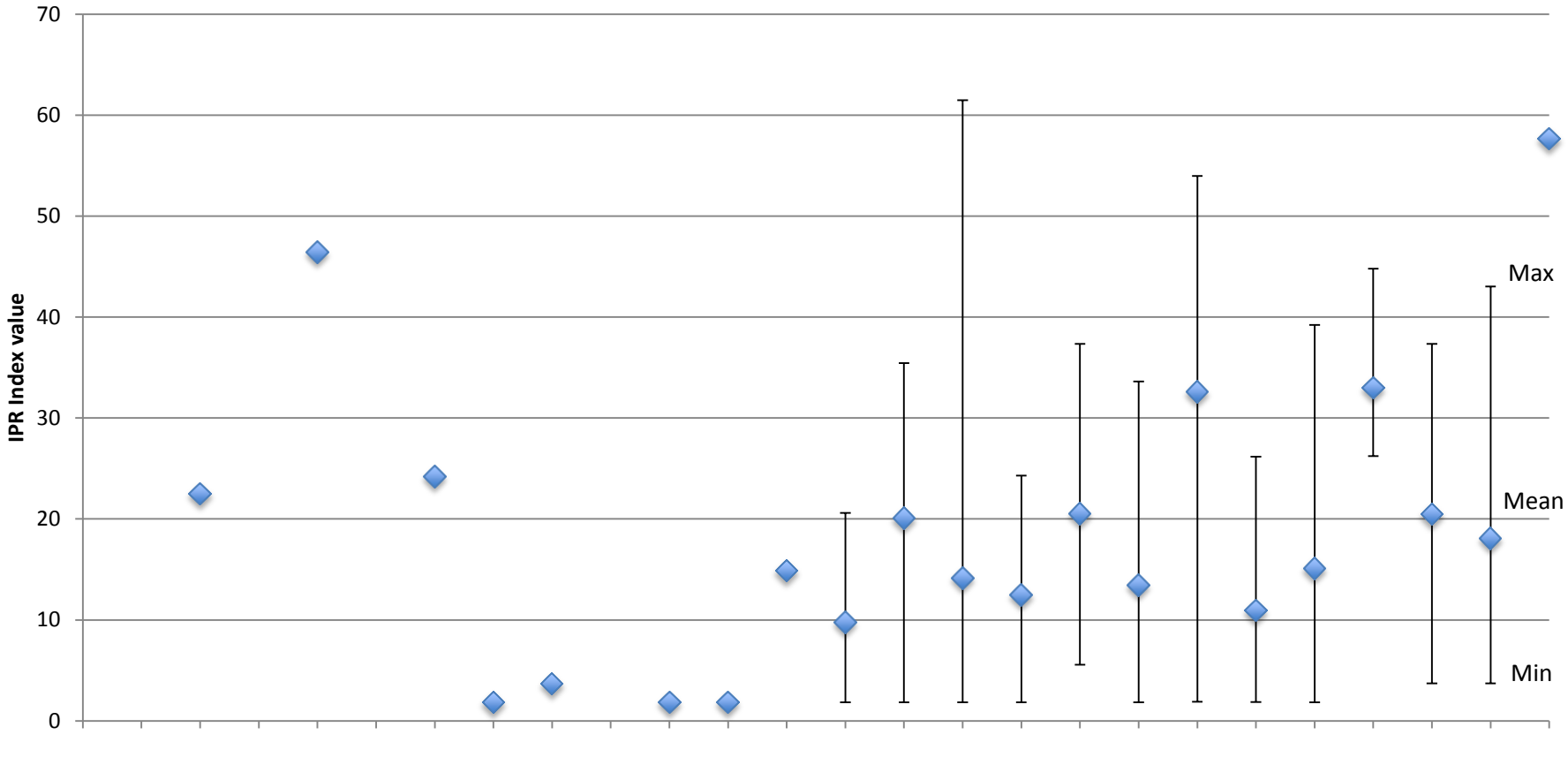
Top Partners	Number of IPR inclusive Agreements	Mean Overall Index	Minimum Overall Index	Maximum Overall Index	Standard deviation Overall Index
Chile	7	18.64	3.73	46.66	13.63
EFTA	4	22.00	18.70	26.22	3.21
Peru	4	13.05	1.89	27.98	11.30
United States	4	42.45	28.07	61.48	14.42
EU	2	31.73	24.24	39.22	10.59
Switzerland	2	48.50071	43.02849	53.97293	7.738893
Total	78	12.97	1.85	61.48	13.18

Agreements involving developed countries are more comprehensive



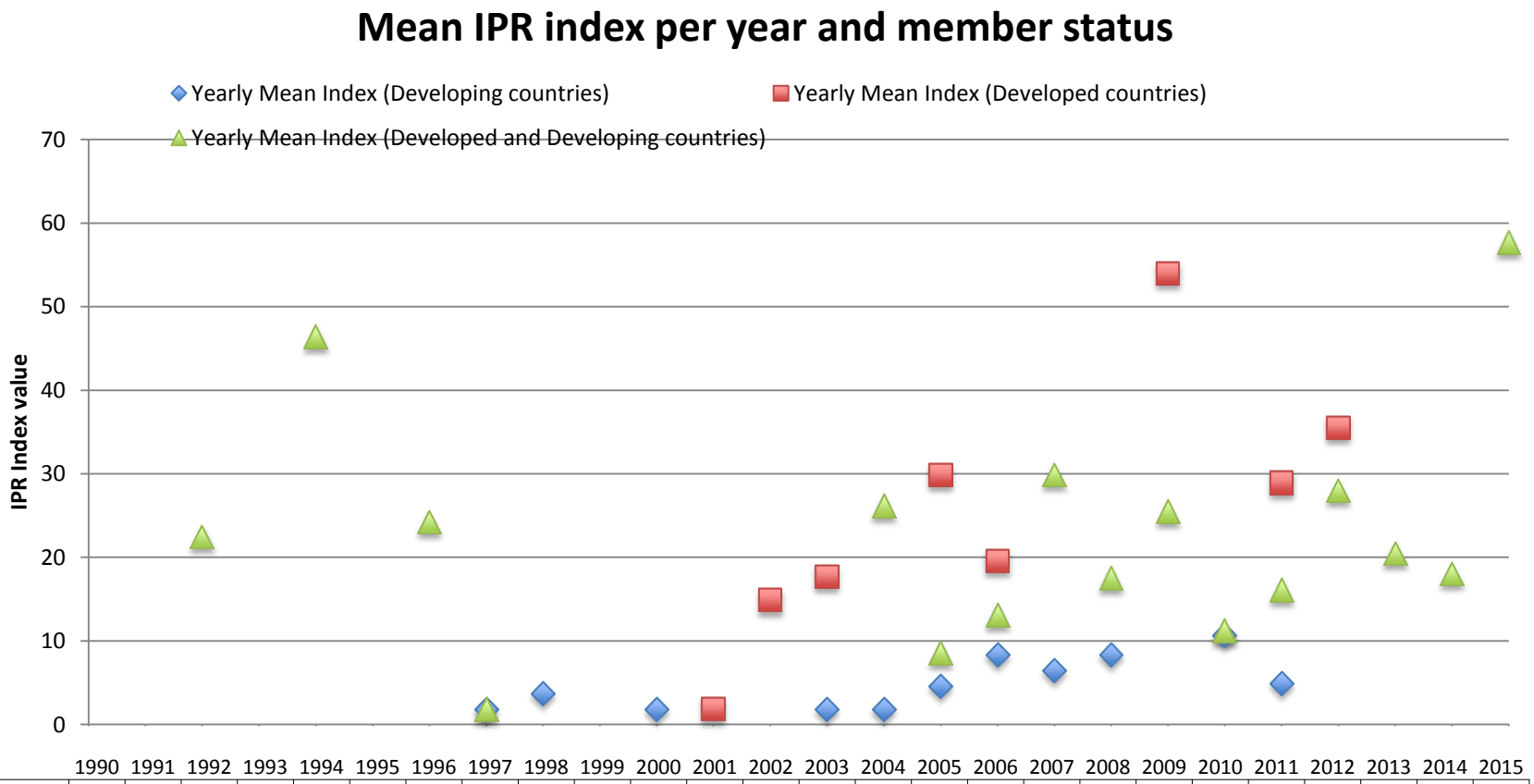
Ratcheting up?

Mean, Minimum, and Maximum IPR Index per year



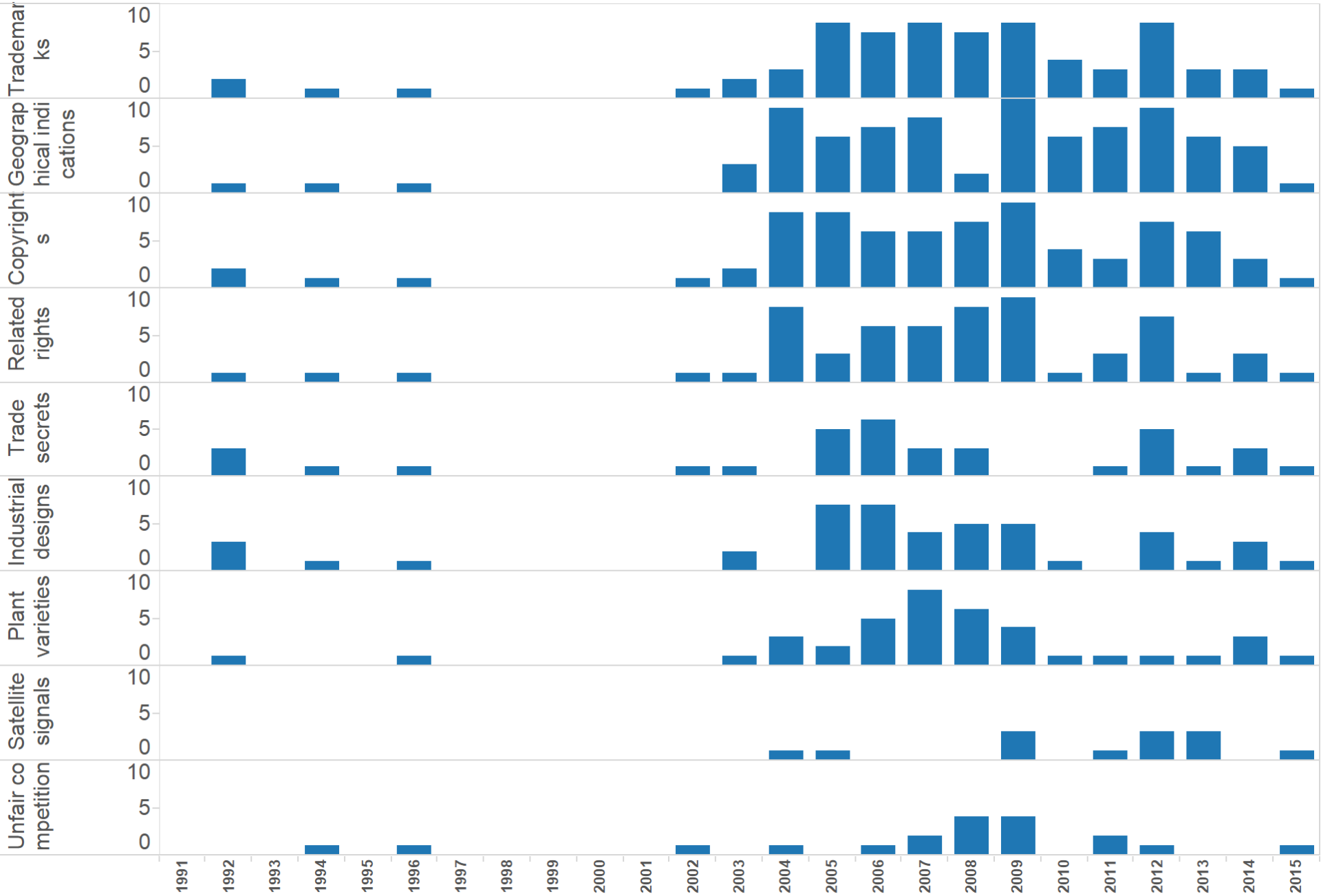
	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
No. Agr.	0	0	1	0	1	0	1	2	1	0	1	1	1	4	4	10	10	5	9	4	8	8	3	3	3	1

Or business as usual?



	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
No. Developing Agr.	0	0	0	0	0	0	0	1	1	0	1	0	0	2	1	2	4	2	4	0	4	3	0	0	0	0
No. Developed Agr.	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	3	2	0	0	1	0	2	2	0	0	0
No. Developed and Developing Agr.	0	0	1	0	1	0	1	1	0	0	0	0	0	0	3	5	4	3	5	3	4	3	1	3	3	1

A means to complement multilateral agreements



IPRs in FTAs Index 2016
Focusing on patents

Part 1
Part 2
Part 3
Part 4

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.

(61) For the purposes of this Article, the European Union and Korea consider that 'unregistered design' and 'unregistered appearance' have a similar meaning. The conditions for protection of 'unregistered design' or 'unregistered appearance' are provided for:
(a) by Korea in the Unfair Competition Prevention and Trade Secret Protection Act (Act No. 8767, Dec. 21, 2007); and
(b) by the European Union in Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs, as last amended by Council Regulation (EC) No 1891/2006 of 18 December 2006.

(62) For the purposes of this Article, the European Union considers 'presenting' as 'offering' or 'putting on the market' and Korea considers 'presenting' as 'assigning, leasing or exhibition for assigning or leasing'.

Sub-section E

Patents

Article 10.33

International agreement

The Parties shall make all reasonable efforts to comply with articles 1 through 16 of the Patent Law Treaty (2000).

Article 10.34

Patents and public health

1. The Parties recognise the importance of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 (hereinafter referred to as the 'Doha Declaration') by the Ministerial Conference of the WTO. In interpreting and implementing the rights and obligations under this Sub-section, the Parties are entitled to rely upon the Doha Declaration.

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 2005.

(63) 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.

Article 10.35

Extension of the duration of the rights conferred by patent protection

1. The Parties recognise that pharmaceutical products (64) and plant protection products (65) protected by a patent in their respective territories are subject to an administrative authorisation or registration procedure before being put on their markets.

2. The Parties shall provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the first authorisation to place the product on their respective markets. The extension of the duration of the rights conferred by the patent protection may not exceed five years (66).

Article 10.36

Protection of data submitted to obtain a marketing authorisation for pharmaceutical (67) products

1. The Parties shall guarantee the confidentiality, non-disclosure of and non-reliance on data submitted for the purpose of obtaining an authorisation to put a pharmaceutical product on the market.

2. For that purpose, the Parties shall ensure in their respective legislation that data, as referred to in Article 39 of the TRIPS Agreement, concerning safety and efficacy, submitted for the first time by an applicant to obtain a marketing authorisation for a new pharmaceutical product in the territory of the respective Parties, is not used for granting another marketing authorisation for a pharmaceutical product, unless proof of the explicit consent of the marketing authorisation holder to use these data is provided.

3. The period of data protection should be at least five years starting from the date of the first marketing authorisation obtained in the territory of the respective Parties.

(64) As defined in Annex 2-D (Pharmaceutical Products and Medical Devices).
(65) Plant protection products, in the form in which they are supplied to

Article 10.37

Protection of data submitted to obtain a marketing authorisation for plant protection products

1. The Parties shall determine safety and efficacy requirements before authorising the placing on their respective markets of plant protection products.

2. The Parties shall ensure that tests, study reports or information submitted for the first time by an applicant to obtain a marketing authorisation for a plant protection product are not used by third parties or relevant authorities for the benefit of any other person aiming at achieving a marketing authorisation for a plant protection product, unless proof of the explicit consent of the first applicant to use these data is provided. This protection will be hereinafter referred to as data protection.

3. The period of data protection should be at least 10 years starting from the date of the first marketing authorisation in the respective Parties.

Article 10.38

Implementation

The Parties shall take the necessary measures to ensure full effectiveness of the protection foreseen in this Sub-section and actively cooperate and engage in a constructive dialogue in that regard.

Sub-section F

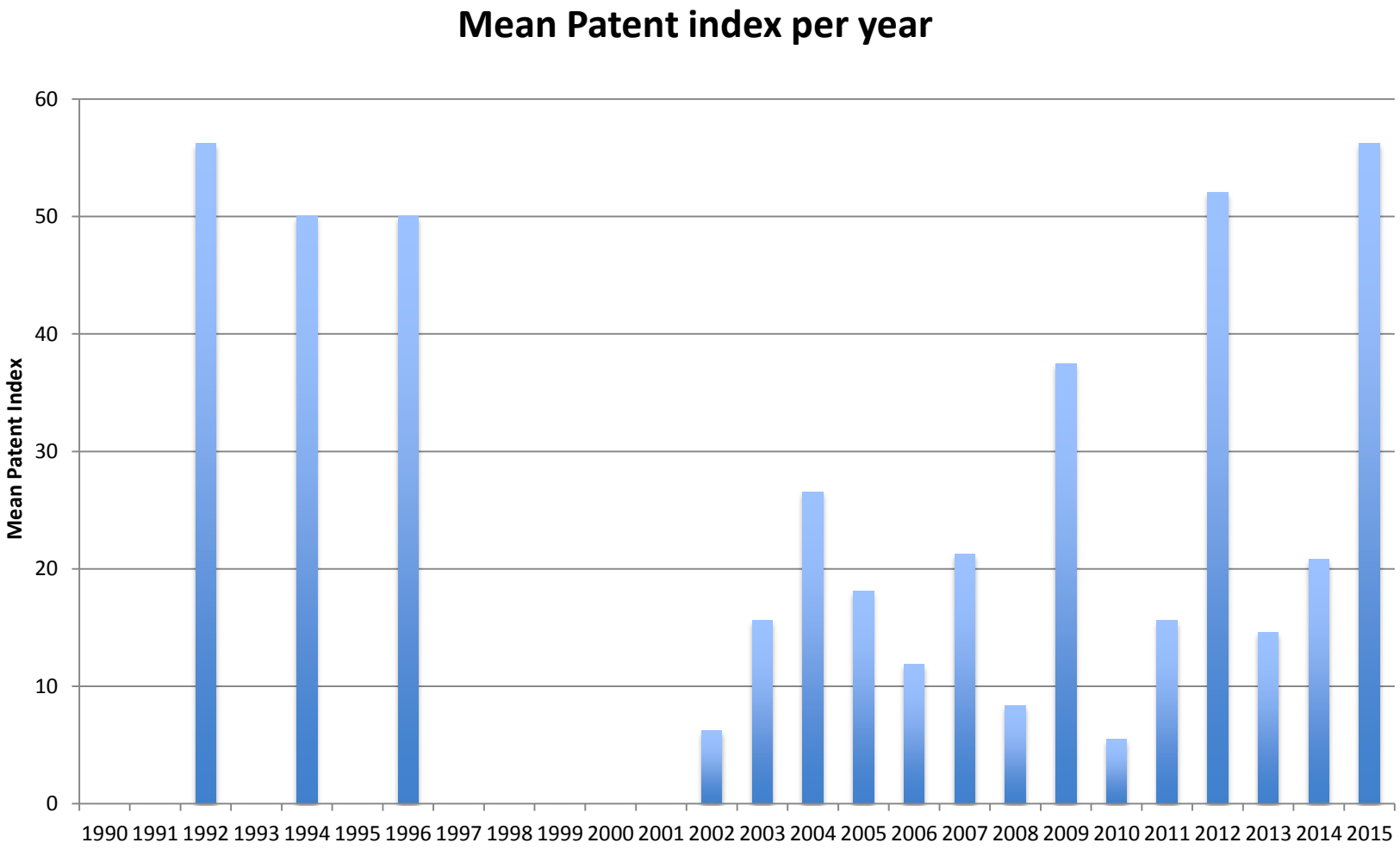
Other provisions

Article 10.39

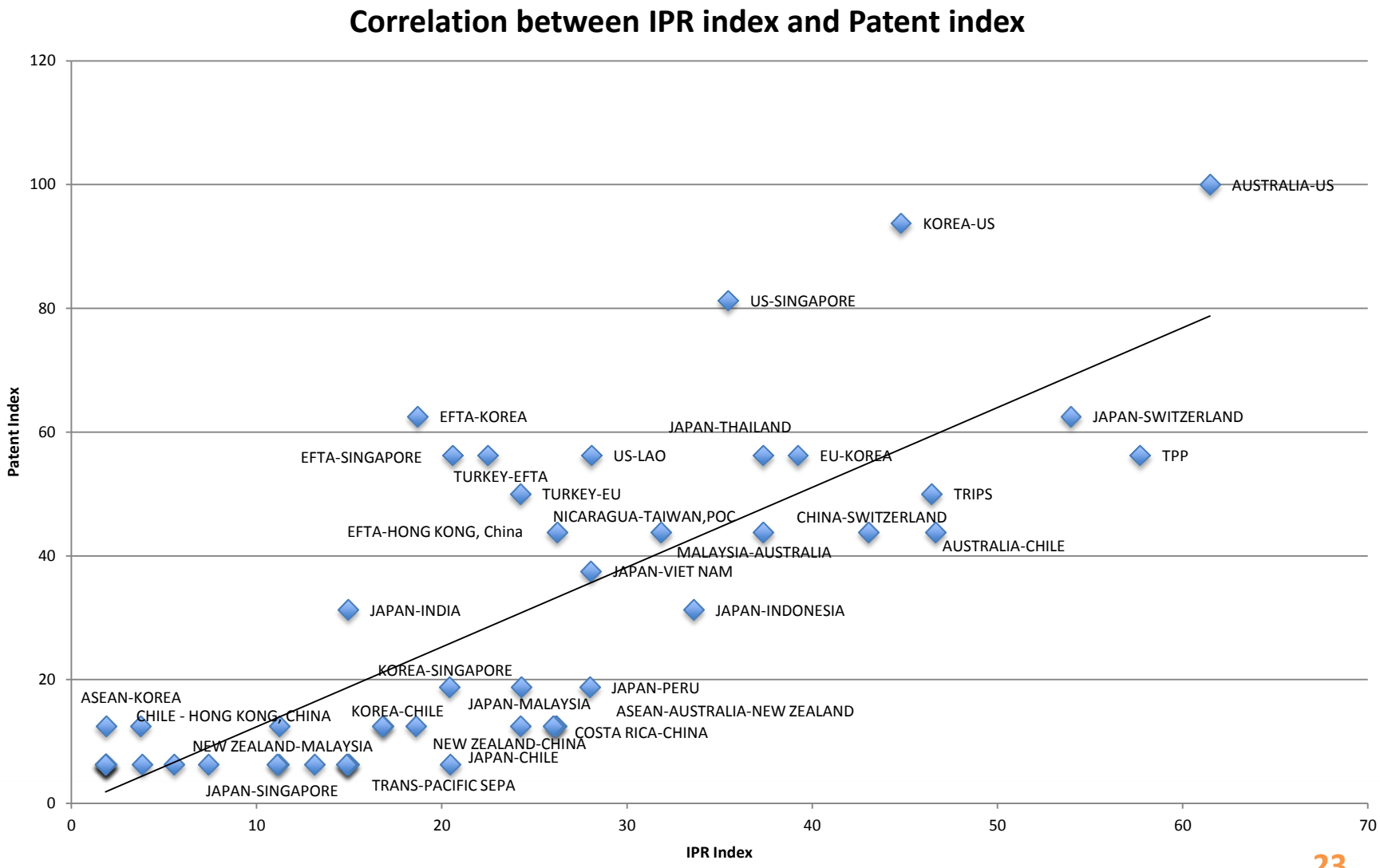
Plant varieties

Each Party shall provide for the protection of plant varieties and comply with the International Convention for the Protection of New Varieties of Plants (1991).

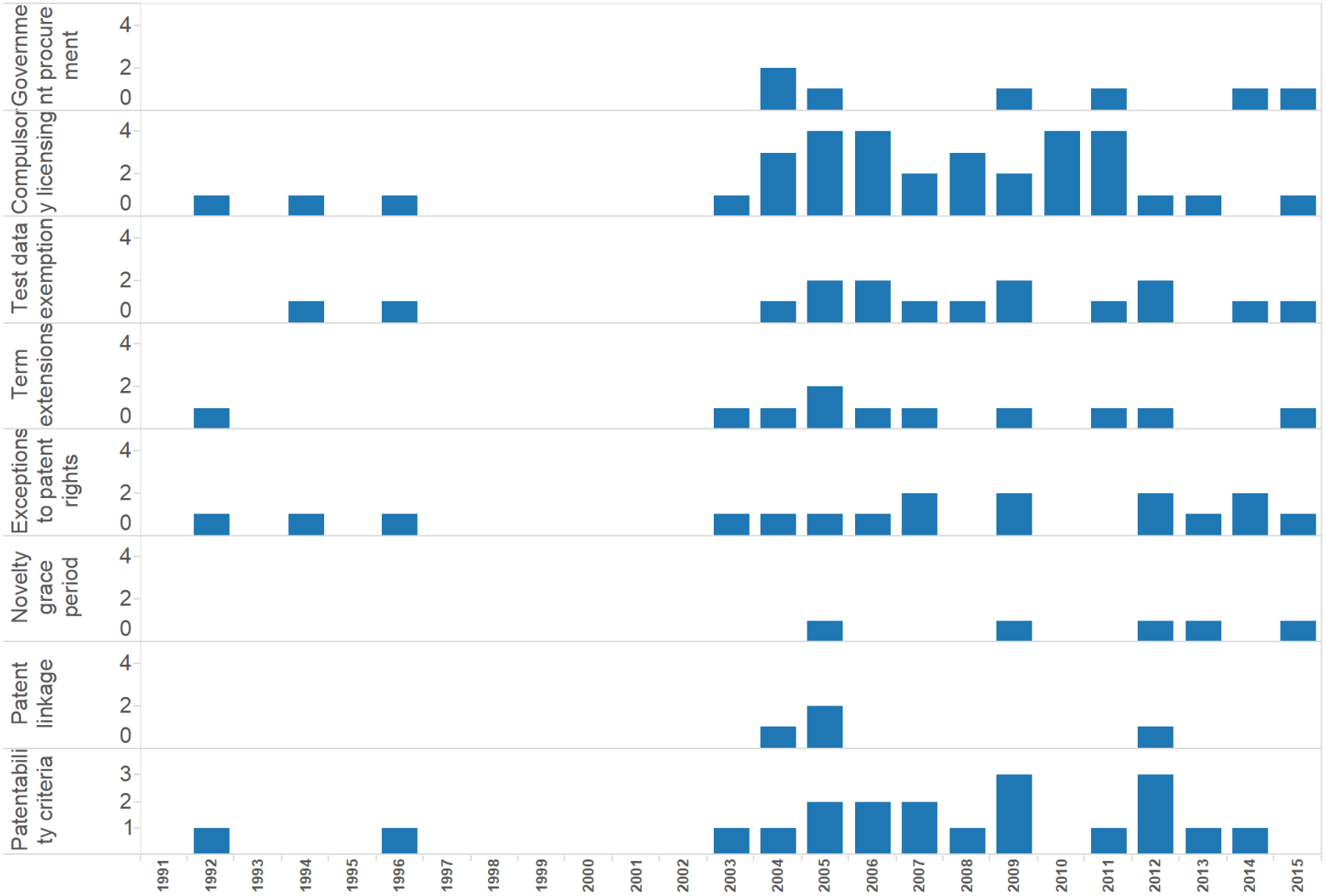
Patent index also rising



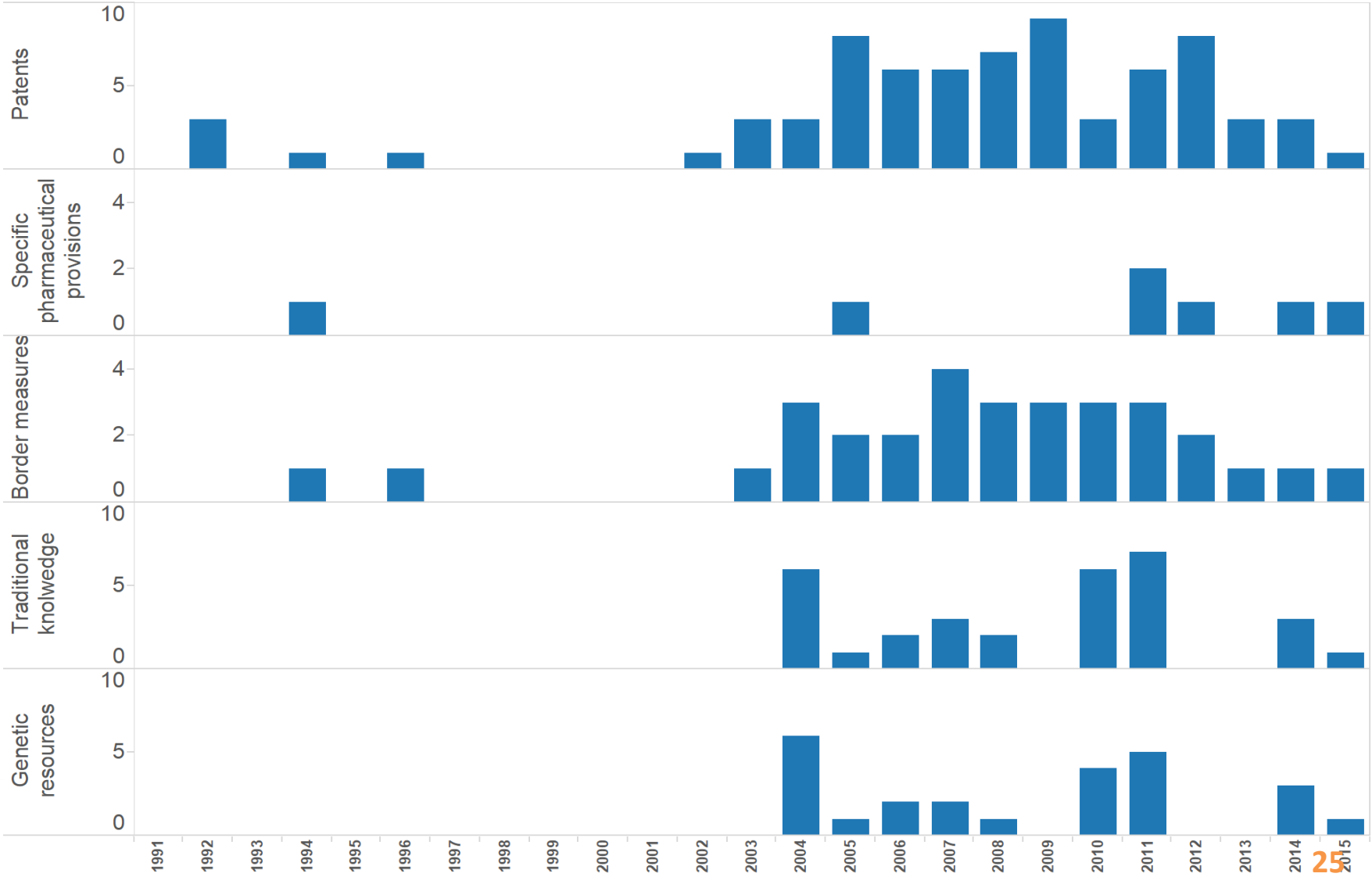
More comprehensive agreements cover patents more comprehensively



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 [11-2]

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).[11-3]

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

- 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.

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.

Setting the stage for discussions

Part 1
Part 2
Part 3
Part 4

Observations and Problems associated with FTA IP Provisions

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 asses the impact of IP rules and an **option for renegotiating IP provisions** in light of an impact assessment.

Recommendations by Dr. Grosse Ruse-Khan

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**.