

Third CPD Anniversary Lecture

Health and Global Trade Regime Is It Affecting Equal Access to Medicines?

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Third CPD Anniversary lecture

Trade and Health



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Health and trade



- × Opposition to new trade agreements over public health consequences
- × Global public health crisis: inadequate innovation for critical needs e.g. antibiotics
- × Global public health crisis: millions lack access to medicines in developing countries; escalating prices of branded medicines in developed countries and developing countries

21st century trade agreements



**CONSEQUENCES FOR GLOBAL HEALTH
INEQUALITY**

TPP opposition: not only on trade and employment but on environment, intellectual property and health.....



× US AFL-CIO

“TPP will not create jobs, protect the environment or ensure safe imports....instead the TPP contains strict, clear protections for foreign investors and pharmaceutical monopolies.”

<http://www.aflcio.org/Issues/Trade/Trans-Pacific-Partnership-Free-Trade-Agreement-TPP>

× Joseph Stiglitz (Nobel laureate)

“The problem is not so much with the agreement’s trade provisions, but with [the “investment” chapter](#), which severely constrains environmental, **health**, food safety regulation, and even financial regulations with significant macroeconomic impacts.”

<https://www.theguardian.com/business/2016/jan/10/in-2016-better-trade-agreements-trans-pacific-partnership>

Evolution of world trade agreements



- × 1948 – GATT: reduction in tariffs
- × 1994 - WTO multilateral agreements: tariffs plus ‘behind the border’ issues e.g. TRIPS, sanitary and phytosanitary measures, services, etc. that affect investment.
- × 2001 – Doha Round: development agenda e.g. agricultural support in US, EU. Negotiations stalled since 2008.
- × 2000’s – Proliferation and importance of bilateral and regional trade agreements, especially led by the US with broader agendas: more ‘behind the border’ investment provisions.
- × 2016 – Bilateral and Regional FTAs (TISA, RCEP, CETA, EU-ASEAN, EU-India...) and Mega regional agreements: Trans Pacific Partnership Agreement (TPP) agreed, TTIP under negotiations – overtaking the WTO agreements with strong ‘behind the border’ provisions
- × 2017 – demise of TPP/TTIP, uncertainty, bilateral agreements?

21st century trade agreements – trade & investment agreements



- × Scope and depth: no longer about tariffs and trade, more about investments – promoting investment returns
- × Format: bilateral/regional not multilateral (WTO) - less coordinated, strengthens power of large countries
- × Process: negotiated in secret, not subject to political debates, but with strong private sector participation
- × Implications: more intrusive to national policy making e.g. for public health priorities

TPP agendas: focus foreign investment

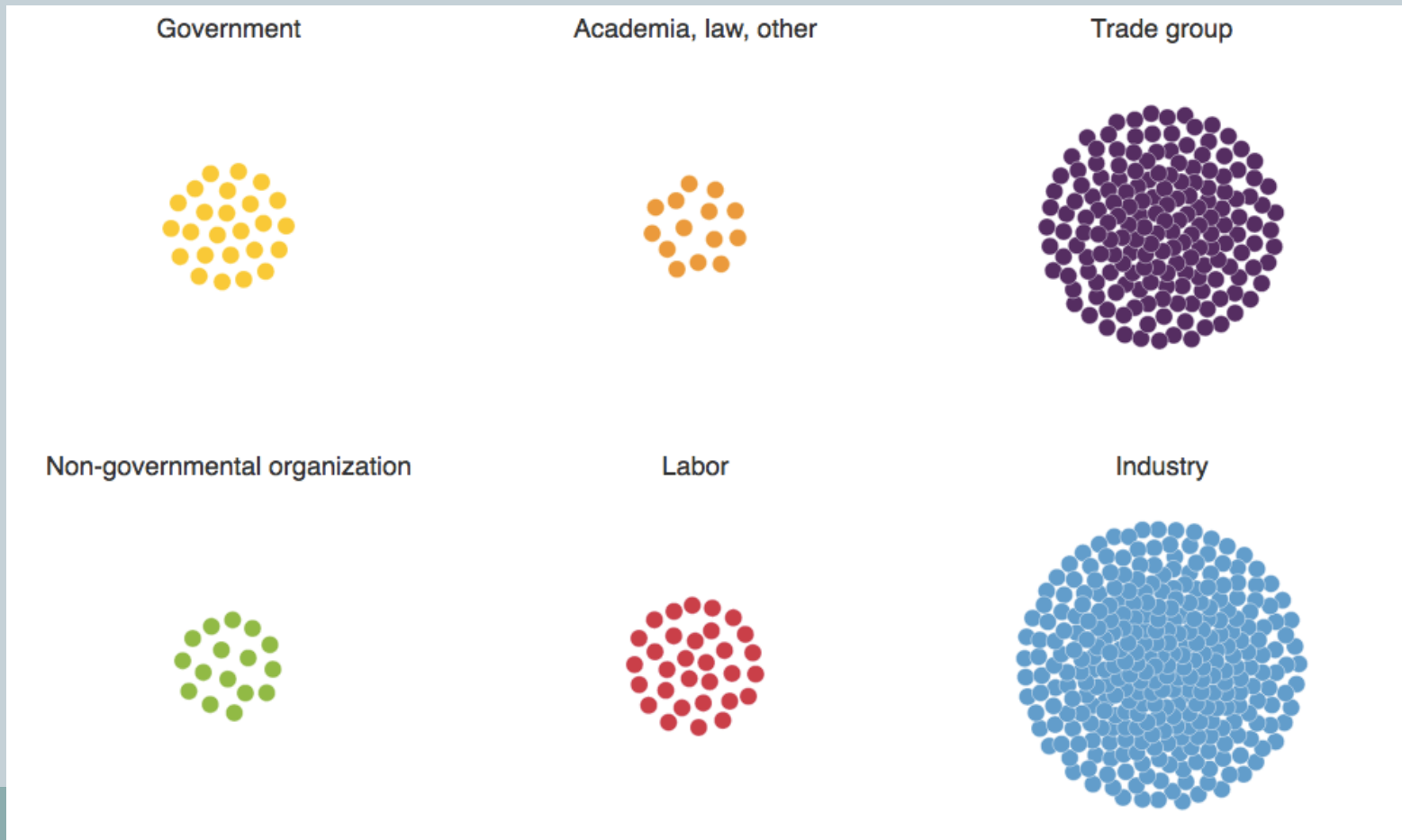


- × 30 chapters - Only 5 on trade
- × 25 chapters on “regulatory discipline” in international economy: investment, financial services, intellectual property, government procurement, state owned enterprises, dispute settlement, sanitary and phytosanitary measures, competition and business facilitation, administrative and institutional provisions, etc.
- × Provides unprecedented rights of market access, investment protection and retaliation, and enforcement through punitive legal and financial measures.

US Process: non transparent and important corporate influence



- × Process – negotiated in secrecy, lack of public consultation. Confidential to Congress and public.
- × Of the 566 individuals involved, private industry and trade groups represent 480, or 85% of the total:



Economic growth and job creation



- ✗ Standard argument for free trade: efficiency, growth and job creation

- ✗ US Int'l Trade Commission estimates for 2032 (15 yrs) based on general equilibrium model:
 - ✦ US GDP - \$42.7 (0.15% higher than baseline scenario)
 - ✦ US real annual income - \$57 billion (0.23%)
 - ✦ US employment – 128,000 full time (0.07%)
 - ✦ exports - \$34.6 billion (18.7%)
 - ✦ imports - \$23.4 billion (10.4%)
 - ✦ Benefit: ‘establish trade-related disciplines’ especially intellectual property rights, technical barriers to trade, etc.....



Economic effects cont'd



× Petri, Plummer and Zhai, 2012

	Exports (%GDP)	Net Exports (% GDP)	GDP %
<i>Australia</i>	4.5	0	0.6
<i>Japan</i>	14.0	0	2.2
<i>Malaysia</i>	12.4	0	6.1
<i>Canada</i>	2.6	0	0.5
<i>Peru</i>	7.1	0	1.4
<i>USA</i>	4.4	0	0.4
<i>Viet Nam</i>	37.3	0	13.6

Employment effects by 2025 - negative



× Capaldo, Izurieta, Sundaram, 2016 – competition on labor costs, race to the bottom.

	Labor share of GDP (%)	Employment ('000)
<i>USA</i>	<i>-1.31</i>	<i>-448</i>
<i>Canada</i>	<i>-0.86</i>	<i>-58</i>
<i>Japan</i>	<i>-2.32</i>	<i>-74</i>
<i>Australia</i>	<i>-0.72</i>	<i>-39</i>
<i>Brunei, Malaysia, Singapore, VN</i>	<i>-0.99</i>	<i>-55</i>
<i>Mexico</i>	<i>-0.70</i>	<i>-78</i>
<i>Chile, Peru</i>	<i>-0.54</i>	<i>-14</i>

ISDS and other provisions reduce policy space for public health priorities



- × ISDS - ‘Regulatory chill’ - threat of costly arbitration discourages policies to protect public health and provide accessible medical services for all citizens.
- × Transparency and Procedural Fairness chapter – could restrict use of pharmaceutical price control and reimbursement mechanisms.
- × Technical barriers to trade chapter – restricts government ability to require companies reveal financial data.
- × UK – concern that ISDS will threaten the National Health Service with costly (UK Faculty of Public Health Report on the TTIP 2015).

TPP provisions – obstacle to public health



- × Intellectual property provisions strengthens patent protection beyond TRIPS:
 - ✂ lengthen patent terms;
 - ✂ lower patentability criteria to include modifications “evergreening”;
 - ✂ data exclusivity – barriers to introduction of generics after patent expiry;

- × Investor-state dispute settlement (**ISDS**):
 - ✂ foreign investors to challenge national laws for depriving future/anticipated profits;
 - ✂ foreign investors equal treatment as host country investors;
 - ✂ separate, parallel channel of dispute resolution outside of host country legal system

- × Transparency annex, government procurement, state enterprises etc. constrain national governments scope of action for public health priorities e.g. management of medicines prices
 - × Example: Brunei: Drug purchasing is performed by the Department of Pharmaceutical Services, Ministry of Health. The agency negotiates with pharma corporations on pricing prior to importing medicines. TPP Transparency & Corruption and Government Procurement chapters would require agency to make their decisions public and subject to appeal by corporations submitting bids for supplying the drugs.

Health – contradicts human right duties



- × Human rights carry correlate obligations
- × Government duties to:
 - + respect
 - + protect
 - + fulfill
- × Corporations – Guiding principles on business and human rights – framework of:
 - + protect
 - + respect
 - + remedy



ACCESS TO MEDICINES AND INNOVATION

UN SG High Level Panel on Access to Medicines 2016



Mandate to:

“Review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of investors, international human rights law, trade rules and public health in the context of health technologies”.

Misalignment between need, innovation and access



- × Innovation gaps: Inadequate R&D for global priorities: antibiotics, TB, neglected tropical diseases (NTDs), ebola, zika.....
- × Access gaps: Prices of life saving medicines out of reach: HIV retrovirals in the 2000's, cancer and Hep C drugs today; spiraling prices of medicines putting pressure on household and public budgets in rich countries.

Neglected Tropical Diseases



- × 26 (NTDs) contribute to 14% of the global disease burden, but only 1.4% of global health-related R&D expenditure (2013);
- × only 4 products registered 2000-2011

Innovation gap: Antimicrobial resistance (AMR)



- × drug resistant viruses cause 700,000 deaths/year
- × if unchecked, would cause 10 million deaths by 2050
- × only one novel class of antibiotics developed in 40 years
- × drug resistance due to over-use; inappropriate use in medicine, food/agriculture
- × market based incentives inadequate to meet the need for R&D investment in new antibiotics.
- × UN GA political declaration 2016 called for:

Innovation gap: Tuberculosis



- × TB is treated with antibiotics. When bacteria becomes resistant to these antibiotics, patients can develop and spread multi-drug resistant (MDR) TB.
- × Only two new drugs approved in 50 years.
- × Underinvestment due to low financial incentives for companies leading to stalled scientific progress and commercial development
- × Declining investment, 1/3 lower than in 2011, since 2012 Pfizer, Astrazeneca, Novartis, Zertek pulled out.
- × 95% of TB cases are in low-middle income countries
- × Private-sector investment in TB R&D has fallen by a third since 2011
- × United States government and the Bill & Melinda Gates Foundation [Gates Foundation] together accounted for 57 percent of TB R&D funding 2011-2015

TB in Bangladesh



- × 81,000 deaths in 2014 – 4th in the world for infection and mortality
- × Multi-drug resistant TB emerging: 1.4% of new, 22% previously diagnosed cases.
- × Key drugs:
 - × Bedaquiline - patent expires in 2023, price per month US\$136. On WHO essential medicines list.
 - × Delamanid - patent expires in 2023, price per month US\$3,108. On WHO essential medicines list.
- × These are the first new drugs for TB in 40 years

Hepatitis C



- × Sovaldi
 - × Original research by Pharmasset, cost US\$376,355 financed by US public funds
 - × Pharmasset announced price US\$36,000 for course of treatment
 - × Pharmasset purchased by Gilead for US\$11 billion
 - × Gilead then charges US\$84,000 for full course of treatment (US\$1,000 per pill)
- × Generic version is sofosbuvir - created in Bangladesh for US\$840 for full round of treatment (US\$10 per pill)
 - × Cost of drug driven by high cost of API imported from India
 - × API under patent in India, including when exported for generic manufacture



“The supplier defends this price by pointing to the great value to the patient and to those affected by the patient’s illness. But such costs make healthcare unaffordable. If the Netherlands continues in this way, it will become nearly impossible to reimburse patients for these medications”

Ministry of Foreign Affairs, the Netherlands (2016)

Access gaps: cancer drugs

New drugs approved US, 2016



Prices doubled over last decade.. 11 of 12 medicines approved were priced above \$100,000 per year.

- × Tecentriq (atezolizumab): Biologic to treat bladder cancer. US\$12,500 / month.
- × Venclexta (venetoclax): Chronic Lymphocytic Leukemia. US\$109,500 / year.
- × Keytruda (pembrolizumab): Biologic used to treat Head and Neck cancer. US\$12,500 / month.
- × Opdivo (nivolumab): Biologic used to treat Hodgkin Lymphoma, non-small cell lung cancer, kidney cancer, melanoma skin cancer, and head and neck cancer. \$US12,500 / month
- × Halaven (eribulin): Liposarcoma. This drug is already approved to treat breast cancer. US\$4,977 per treatment cycle
- × Xalkori (crizotinib): Biologic for non small cell lung cancer. US\$115,000 / year.

Intellectual Property and Public Health



- × Social compact to promote innovation
- × IP provides a *temporary* monopoly
- × IP policy design to serve public priorities:
 - + weak patents in technology follower phase to promote access to technology and capacity building (Japan until 1970s, India.....);
 - + exemption of essential products for public health (India)
 - + many developing countries did not grant patents on pharmaceutical products in early 1990s
- × Leads to high prices (prices set at what market will bear, not by market competition amongst producers)
- × Does not create incentives for innovation in public health priorities without high market return

TRIPS flexibilities



- × Safeguards to protect public health priorities and comply with obligations to fulfill right to health.
- × “Members may.... adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement’.
- × Main mechanisms: Compulsory Licensing; Parallel Imports; Patentability etc.
- × LDCs – extension of transition period to 2021 in general, and pharmaceutical products until 2033.

Implementation of flexibilities



- × 1990s – application of flexibilities challenged by pharmaceutical industry and governments.
- × Doha Declaration on the TRIPS Agreement and Public Health (2001): “TRIPS agreement does not and should not prevent members from taking measures to protect public health..... can and should be interpreted in a manner supportive of WYP members’ right to protect public health, and in particular, to promote access to medicines for all.”
- × 2001-present: proliferation of TRIPS plus IP provisions; rare use of CL and other flexibilities; retaliation, political pressure and other obstacles to use

Current approach to addressing gaps

Access – mostly voluntary, negotiated case by case

- × Voluntary donations
- × Tiered pricing
- × Voluntary licenses
- × Generic competition (some cases e.g. HIV antiretrovirals)

Innovation – limited in scope and scale, uncoordinated

- × Private/public partnerships for product development
- × Public funding
- × Philanthropic funding
- × Pooling of patents/patent donations

Need for sustainable solutions



- × **Alternative business models – delinkage - R & D financing from high prices and volumes:**
 - ✦ Push mechanisms - public and philanthropic financing
 - ✦ Pull mechanisms – prizes, tax breaks, incentives, prizes, advance market commitments
 - ✦ Pooling – funding, data and IP pooled to facilitate R&D
 - ✦ Open collaborative research
 - ✦ Public-private partnerships and product development partnerships – target public priorities making use of above mechanisms for financing and foregoing exclusivities

- × **AMR Political Declaration from High Level session of UN GA September 2016 called for new incentives for investment in R & D, emphasizing affordability and access as a global priority:**
 - + delinking cost of investment from price and volume of sales
 - + pursue innovation models that address unique set of challenges of AMR including rational use and promoting access to affordable medicines
 - + affordability and access, a global priority

Sustainable solutions



Transparency needed for public funders, public policy

- × Cost of R&D non-transparent
- × Estimates contested, varying from \$100/150 million to 4.2 billion

More public funding and global effort

- × Set priorities/Committee
- × International treaty

Sustainable solutions



× TRIPS flexibilities

- + national governments promote full use, amend national laws to curtail evergreening, facilitate issuance of CL,
- + WTO to monitor retaliatory measures

× TRIPS plus in trade agreements

conduct health impact assessments in negotiating trade agreements

Background: UN Sustainable Development Goals (SDGs)



Goal 3 – Ensure healthy lives and promote well being for all at all ages

- × Target 3.7 – Achieve universal health coverage (UHC), including financial risk protection, access to essential health-care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all.
- × 3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.
- × Overall theme: ‘Leave no one behind’.

Thank you !



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[HTTP://WWW.UNSGACCESSMEDS.ORG/HLP](http://www.unsgaccessmeds.org/hlp)**

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