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Health, Trade and Investment

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INSIDE THIS ISSUE

Research, Reports, News

Research

Impact assessment of the TPP outlines four ways in which the agreement poses risks to public health.

Health impact assessment of the TPP reports that its obligations conflict with several sustainable development goals because of the risk it poses to: spreading unhealthy commodities; limiting equitable access to essential health services, medicines and vaccines; and reducing government regulatory flexibility.

Paper outlining the importance of trade and trade agreements in tackling antimicrobial resistance.

Special issue in *Politics and Governance* on EU institutional politics of secrecy and transparency in foreign affairs examines transparency in TTIP negotiations.

Paper outlining a conceptual framework for exploring the impacts of investment agreements on noncommunicable diseases.

Reports

OECD report on costs and benefits of investment agreements concludes that few claims on their societal benefits and costs have been empirically tested, and where tested have been confirmed empirically.

New report by Corporate Observatory Europe outlining efforts by big business to undermine civil society organisations opposing trade and investment agreements.

EPHA analysis of the key issues for pharmaceutical policy in the EU raises several health and trade-related issues, including concerns about supplementary protection certificates (see pages 3-4).

News

Latest overview of FTA and other trade negotiations. As multilateral negotiations have stalled, behind the border provisions in FTAs have assumed greater importance (see, for example, EU-Mexico text proposals, where investment liberalisation is sought beyond CETA).

HAI and European Public Health Alliance reaction to leaked documents on EU-Mercosur trade talks (pages 3-4).

Text relating to the EU-Japan Economic Partnership Agreement has now been released (pages 3-4).

Investor-State Dispute Settlement

In November 2017, states convened at the United Nations Commission on International Trade Law (UNCITRAL) to discuss possible reform of investor-state dispute settlement. In accordance with a UNCITRAL mandate the Working Group will consider the desirability of reform and make recommendations to the Commission. Recordings of the sessions of the Working Group are available here.

Report by Trade Justice Movement outlining alternative approaches to investment protection in South America, Asia, Africa and Europe.

Briefing note by the Trade Justice Movement on third-party companies underwriting funding for arbitration cases.

Joint report by the Center for International Environmental Law (CIEL) and Seattle to Brussels Network on the EU's position on negotiations under the auspices of UNCITRAL for a Convention establishing a multilateral court for the settlement of investment disputes. The EU is pushing for an appeal tribunal and seeks to create full time, secured jobs for judges who would be subject to strict ethics rules and appointed through a transparent and objective process. In addition, it proposes that the court be subject to transparency rules and that third parties be allowed to submit interventions to the court if they have a direct and existing interest in the outcome of the dispute.

investors brought most of the known cases (led by those in the Netherlands, the US and UK).

A recent Canadian press report suggests that Canada and Mexico are applying pressure on the US to decide whether it wants to be part of NAFTA's investor-state dispute mechanism and threatening to sideline it unless it commits to participating fully.

Report by Trade Justice Movement outlining alternative approaches to investment protection in South America, Asia, Africa and Europe.

Leaked letters reveal how Novartis has threatened Colombia with international investment arbitration to prevent a compulsory licence being issued for its leukemia drug Gilvec. See background material here.

Petition by Friends of the Earth Netherlands to the Dutch Foreign Trade Minister to omit ISDS in future trade and investment agreements.

"An estimated 23 international arbitration funders operate in the UK. According to one study, £1.5 billion in assets is now under management by the UK's top funders of domestic and international litigation, representing a 743% growth in the industry between 2009 and 2015....The potential of ISDS to generate significant income for funders was illustrated in April 2016, when New York based Tenor Capital received 35 percent of a $1.4 billion ruling against Venezuela, in a case brought by Crystallex, a return of over 1,000 percent on the $36 million that the funder had provided for the legal costs" (Keenlyside, 2017).

UNCTAD REVIEW OF ISDS

UNCTAD's latest review of investor-state dispute settlement notes 60 per cent of decisions were decided in favour of investors and 40 per cent in favour of states in 2016.

Health Services

EU-Japan Economic Partnership Agreement (EPA)

The EU and Japan finalised trade negotiations on the EPA in December. An Annex to the draft text outlines exceptions to the services investment liberalisation chapter, reflecting the approach taken in CETA. The chapter does not include investment protection provisions, which are likely to require closer negotiation with Member State governments. A new chapter applies to domestic regulation provisions, mutual recognition and universal services-related issues. This chapter seems to apply to all services and covers licensing and qualifications to requirements of objectivity and impartiality with respect to all suppliers as well as language on universal services provision in the context of specific text on postal services. Services negotiations in the agreement seem to reflect what was sought in the context of the EU-Canada Agreement (CETA) and, to some extent, in plurilateral Trade in Services Agreement (TiSA), with a negative listing of services and a number of annexes representing limitations to general provisions. In contrast to the WTO General Agreement on Trade in Services (GATS) these new agreements are based on negative listing, which requires governments to list what they do not want to include, rather than making explicit decisions of what they want to include.

The EU-Japan agreement also includes a chapter on regulatory practices and cooperation. The section focuses on the European Union level It contains a general statement that nothing in the chapter should affect the parties' right to "define or regulate its own level of protection in furtherance of its public policy objectives" and provides examples of areas to which this applies (such as public health, occupational health, the environment). More generally, the chapter mimics the approach taken under TTIP which sought to enable stronger corporate involvement in policy and regulatory rule making and is likely to create barriers to

developing policies and regulations against corporate interests. Although specific exceptions are made for services of general interest (Nothing is construed as to hinder a Party to provide or support services of general interest, including those related to water, health, education or social services), services of general interest tend to be interpreted narrowly as those where there are no economic interests. This implies that EU level regulatory measures in ALL sectors and services would be potentially included. The chapter can best be described as "TTIP-lite" in so far as it does not seem to extend directly to members states, but potentially strengthens corporations' involvement in policy making and would make it harder in future to intervene against corporate interests at the European level.

EU-Mexico Agreement

The EU's approach to services in negotiations with Mexico seems to be more expansive than that taken with Canada and Japan. The latest draft of the proposed EU-Mexico agreement suggests that the EU has sought more extensive liberalisation. National treatment for investment is to be applied to all sectors irrespective of exclusions EU Member States have specified in annexes. This approach was first used in the context of TTIP. The approach is likely to permit existing legislation, but stymie efforts to roll back liberalisation in health services where their effect is to disadvantage foreign investors relative to domestic providers.

Trade in Services Agreement (TiSA)

Although Trade in Services (TiSA) negotiations have been suspended, a recent workshop has reappraised how its economic benefits have been assessed. A presentation by Werner Raza, head of ÖFSE, on the EU's impact assessment of TiSA, reported that: projected benefits (0.1% increase in EU GDP) were insignificant; the EU's modeling was based on unrealistic assumptions; its methodological approach failed to account for important economic and social effects, such as unemployment, distribution and inequality.

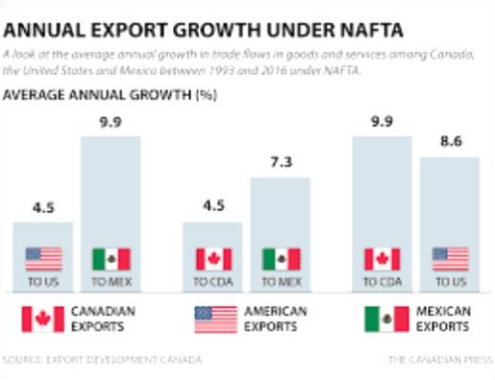
TiSA-SIA macroeconomic results

	Real National Income*	GDP (quantity index)*	Consumer Prices	Total Exports	Total Imports
EU	**0.1**	**0.1**	**0.0**	**0.2**	**0.2**
Max	1.2 *(Hong Kong)*	1.1 *(Hong Kong)*	-0.8 *(Mauritius)*	2.6 *(Mauritius)*	1.9 *(Hong Kong)*
Weighted Average	0.05	0.05	-0.0	0.4	0.3
Min	0.0 *(var.)*	0.0 *(var.)*	0.1 *(var.)*	0.1 *(var.)*	0.1 *(var.)*
USA	0.0	0.0	0.0	0.6	0.4
LDC	0.0	0.0	0.0	0.0	0.0

* GDP measures changes in aggregated quantities; real national income reports deflated value of national production (profits, wages and indirect taxes) (see also Ecorys/CEPR 2017a: 31).

Reproduced from Raza. W.and Tröster, 2017.

CPTPP Countries



Export Growth under NAFTA

FAST FACTS

12.9%

GDP value of global GDP covered by CPTPP

14.9%

Global trade volumes covered by CPTPP

JORGE BERMUDEZ AND VIROJ TANGCHAROENSATHIEN

"Implementing TRIPS flexibilities, a legal right by all WTO members to safeguard public health interests of their population..faces challenges such as the use of compulsory licensing of Efavirenz for HIV by Thailand, and Imatinib for treatment of leukemia in Colombia. Implementing compulsory licensing, especially for countries considered Upper Middle-Income economies, faces considerable retaliation and political pressures from governments in certain high-income countries and industry. As a result, a study predicts a low probability of continued implementation of compulsory licensing. Hence, further systematic assessment of global health governance on the current patent regime including TRIPS flexibilities, is required."

Pharmaceuticals and Intellectual Property

Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTTP)

The effect of the IP chapter in the Trans-Pacific Partnership (TPP) on pharmaceutical prices was widely regarded as inflationary. A major concern related to how it went beyond the TRIPS Agreement on pharmaceutical products. The chapter included provisions which would have allowed: the patenting of second uses of known substances; extended patent terms for delays in patent grants or marketing approval; and the introduction of "patent linkage" and data exclusivity provisions that are not required by TRIPS. Following the US's withdrawal from negotiations, the IP chapter has been amended significantly in the newly proposed CPTTP, which supersedes the TPP. Most IP provisions relating to copyright term, patent extension, and biologics protection in the TPP seems to have been suspended (see here). One important question concerns whether the new changes have gone far enough. Differences between CPTPP and TPP for New Zealand have been traced here: patent term extensions and the threat to pharmaceutical management agency, Pharmac, seem to have abated.

European Union Agreements

The influence of IP rights on access to medicines looks set to increase as a result of both a more aggressive position taken by the United States and the EU's efforts to establish a higher level of IP protection in regional and bilateral trade negotiations with high and middle-income countries (see below). Notwithstanding this, it is becoming increasingly clear that IP rights and public health issues are no longer solely an issue for lower income countries. The effect of IP chapters in trade and investment agreements on access to medicines may, consequently, become a more contested issue.

EU Member States' views of the high price of medicines have grown more critical. This is reflected in conclusions of the Council in 2016, which drew attention to the effect of IP rights and incentives for pharmaceutical innovation on prices. Civil society organisations have also called for supplementary protection certificates (SPCs)

for medicinal products to be reassessed and/or removed and for the Commission to no longer seek the inclusion of SPCs – or similar mechanisms, such as patent term extensions – in trade and investment agreements. A study on the economic impact of both SPCs and incentives and rewards for pharmaceutical innovation in Europe (which emerged from the Council's conclusions) is forthcoming.

SPCs provide an example of how domestic concerns about access to, and prices of, pharmaceuticals may potentially alter the negotiating position of parties to proposed trade and investment negotiations. This may prove to be more relevant to the EU-Japan EPA (as opposed to the EU-Mexico and EU-Mercosur agreements) given that Japan has been a keen proponent of IP rights

The EU-Japan EPA also includes supplementary protection certificates and text on trade secrets (covering, for instance, civil law procedures and remedies against the misappropriation of trade secrets). Although these may not extend corporate rights contained in existing EU legislation, they may lock in existing rights, making them harder to repeal.

An open letter by civil society organisations on the EU-Mercosur trade can be accessed here. The letter notes that despite the EC having undertaken not to seek IP protection measures that go beyond what was agreed in TRIPS, "the (IP Rights) Chapter of the negotiating text released in November 2016 included demands, such as extension of patent protection terms and data exclusivity" (see further below). The letter also notes that the EC is reported to be proposing the inclusion of SPCs in the agreement, which are described as "an artificial extension of the patent term of protection".

WHO's global strategy and plan of action on public health, innovation and intellectual property

The WHO's global strategy and plan of action on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines. It outlines a policy framework which aims to change health research and development priorities to reflect developing countries' needs and facilitate access to medicines and other health products. A panel of experts convened to review the strategy has recently published its report, which found that lack of access to health products in developing countries remains deeply problematic. The report makes several useful observations relevant to IP including encouraging the use of TRIPs flexibilities, greater transparency in patenting and licensing, and expanding patent pooling. Amongst other things, the report notes that flexibilities in the TRIPs Agreement are often not incorporated into national laws or are adopted with limitations, including a narrow scope for the research exception and burdensome procedures for granting compulsory licences. Compulsory licences involve states granting licences to third parties to produce or import patented products without the consent of the patent holder. Their use was clarified and reinforced by the Doha declaration. However, a 2012 survey found that most compulsory licences: were granted between 2003 and 2005 (the number tailing off significantly after 2006); are rarely issued by less developed countries; and primarily relate to drugs for HIV/AIDS. The panel also reported that efforts to extend IP protection beyond that required in the TRIPS Agreement were commonplace in during negotiations on trade and investment agreements between developed and developing countries. It noted that these typically took the form of provisions that either increased the scope for patenting or extended market exclusivity in ways not required by the Agreement. The panel recommended that the WHO Secretariat advocate for the development of national legislation to reflect the flexibilities provided in the TRIPs Agreement (including those recommended in the Doha Declaration) and that members states take into account the impact on public health of adopting provisions that go beyond the requirements of the TRIPS Agreement. It also urges Member States to support the WHO Secretariat in promoting transparency in the costs of research and development (relevant, for instance, to purchasers' ability to determine a fair price). See here for comment.

NAFTA

A statement of nongovernmental organisations on the renegotiation of NAFTA reports that the negotiating parties are considering changes to NAFTA's IP chapter that would further expand the monopoly protections of prescription drug corporations and thus thwart market competition from generic products. The statement also notes that the pharmaceutical industry is calling for the United States to demand so-called transparency rules that would restrict governments' rights to control prices of medicines and set reimbursement and formulary policies.

FOR MORE INFORMATION

Southcentre IP monitor covers WTO, WIPO and TRIPS council negotiations in detail. On public interest discussions in the TRIPS Council it notes that, "Brazil referred to a recent judicial decision in Germany to grant a provisional compulsory licence on an antiretroviral medicine Raltegravir on the ground that there is need for certain patients with HIV/AIDS to receive this medicine." The January issue of its Southviews publication provides a view on 2018 access to medicines issues by Jorge Bermudes and Viroj Tangcharoensathien. It has also started to report on antimicrobial resistance and provides a monthly newsletter on development, innovation and intellectual property programme on new materials in the area.

Non-Communicable Diseases (Tobacco, Alcohol and Food) and Sustainable Development

Tobacco

Documents released by Reuters highlight the importance that Philip Morris International (PMI) attaches to trade and investment regulation in combatting the implementation of the World Health Organization Framework Tobacco on Tobacco Control (FCTC) and, in particular, the introduction of standardized packaging for tobacco products (see graphic to the right). The documents dating from 2009 to 2016 illustrate the multi-venue approach PMI has taken to undermining the FCTC. The news agency's analysis suggests PMI's efforts have been instrumental in keeping tobacco within the ambit of trade and investment agreements; allowing the industry to use the threat of investment arbitration to contest tobacco regulations. At the sixth session of the Conference of the Parties (COP) to the FCTC in Moscow Malaysia put forward a proposal requesting Parties to "exclude tobacco from trade and investment agreements…in the course of negotiations." In the event, this was replaced by a provision reminding Parties of the "possibility to take into account their public health objectives in their negotiations of trade and investment agreements." A PMI email following the session described this as a "tremendous outcome" that "meets all of our trade related campaign objectives: avoiding a declaration of health over trade; avoiding a recommendation to exclude tobacco from trade and investment agreements; avoiding a recommendation to use FCTC dispute settlement mechanisms in place of other international dispute settlement mechanisms; and avoiding the recognition of the FCTC as an international standard." The outcome is consistent with PMI's aim to shift the composition of delegates to the COP, away from health officials and toward policy actors representing finance and trade ministries. This is reflected in changes in the balance of delegates over time (see graphic to the right).

Alcohol

Following an editorial in the *New Zealand Medical Journal* calling for increased excise taxes on alcohol, the New Zealand government has stated that its participation in the CPTPP will not prevent future increases in alcohol excise taxes, "provided 'like' domestic and imported products are treated the same."

Australia has launched a WTO case targeting Canadian wine rules – based on a U.S. complaint first brought during the Obama administration. New Zealand, the U.S., Chile, Argentina, and the E.U. have requested to join the consultations.

Food

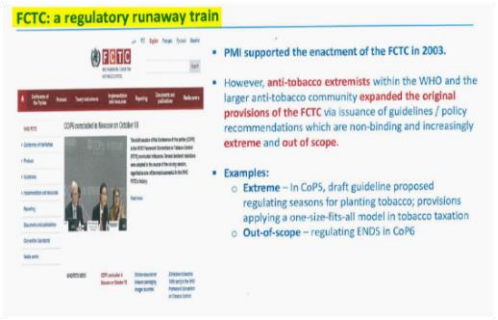
Recently published report on behalf of Foodwatch covering FTA negotiations between the EU and Japan, Vietnam, Indonesia, Mexico and Mercosur (Brazil, Argentina, Paraguay and Uruguay) suggests that the proposed EU-Mercosur agreement may significantly increase meat production in South America with severe consequences for the environment. The report also suggests that the proposed deal with Japan would lead to food products with higher pesticide residues being imported into the EU (and the precautionary principle being undermined).

NCDs and Sustainable Development

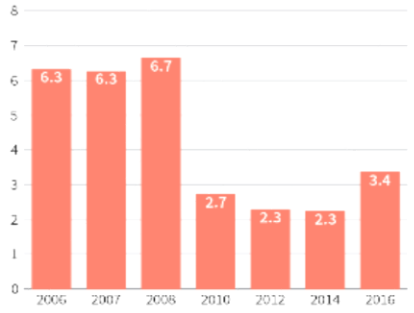
A forthcoming joint event organised by the World Intellectual Property Organization, World Health Organization, and World Trade Organization focuses on the importance of "innovative technologies" in promoting "healthy lives and well-being". Meanwhile, a joint statement by NGOs raises concerns over the impact of trade agreements on governments' policy space to control the market environment for products implicated in risk factors for non-communicable diseases. The statement emphasises that: "It is crucial that trade and investment policy neither weakens the ability of the EU, its member states or partner countries to take action to ensure the prevention and management of NCDs and infectious diseases, nor impedes efforts to promote universal health coverage and access to affordable medicines."

SELECTED PMI DOCUMENTS FROM RECENTLY PUBLISHED REUTERS REPOSITORY

PMI slide highlighting the importance of trade and investment agreements to preventing the introduction of standardized (plain) packaging.



PMI slide pointing to "extremists within the WHO" who have "expanded the original provisions of the FCTC" via guidelines that are "non-binding" and "increasingly extreme and out of scope".



Ratio of health to finance delegates at sessions of the COP to the FCTC 2006-2016. Figures based on an analysis by Reuters of national delegation members categorized according to keywords in their titles and agencies (graphic reproduced from Kalra, A., Bansal, P., Wilson, D. and Lasseter, T. 2017).

The Environment and Sustainable Development

International Institute for Sustainable Development (IISD) analysis on environmental and public interest issues with respect to NAFTA renegotiation.

The sustainable development chapter of the EU-Japan economic partnership agreement has been published alongside other chapters. A brief analysis from Greenpeace of an earlier version suggests that its sustainable development provisions are weaker than those in both CETA and the TPP. For a potentially contrasting view, see here.

French foreign affairs minister announces that the EU will no longer make trade deals with countries that do no implement the Paris climate agreement.

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