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Health, Trade and Investment

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INSIDE THIS ISSUE

Research, Reports, News

Research

Critical review of quantitative approaches exploring the relationship between trade and investment and diet, tobacco, alcohol, and related health outcomes. Little research on alcohol use found. No studies have yet used the prevalence of tobacco or alcohol use as outcomes. Childhood obesity has not been examined with reference to global trade and investment policies.

Analysis of trade challenges relating to food, beverage, and tobacco regulations among WTO members (1995-2016). 93 food, beverage, and tobacco regulations were challenged at the WTO. 'Unnecessary' trade costs were the focus of 16% of challenges. Only one challenge escalated to a trade dispute. 42% of challenges focused on labelling regulations, 19% focused on quality standards and restrictions on products (e.g. processed meats and cigarette flavourings). High-income countries raised 77.4% of all challenges against LMICs.

Reports and Cases

The WTO panel ruling on Australia's Tobacco Plain Packaging reaffirms existing WTO jurisprudence that "few interests are more "vital" and "important" than protecting human beings from health risks' and that the 2001 Doha Declaration on TRIPS and Public Health is a subsequent agreement (to TRIPS) under the Vienna Convention. Interpretation of the TRIPS Agreement must therefore give due weight to its object and purposes clauses, which recognise the importance of public health and other societal interests (see Tobacco below).

Major European Court of Justice ruling on ISDS between member states (see ISDS below).

Recent study suggests that the negotiations of the Regional Comprehensive Economic Partnership are non-transparent. Business groups are reported to have undue influence in the negotiations.

News

EU update on trade negotiations.

Mandates published by the European Commission for negotiation of agreements with New Zealand and Australia.

Cost to Australian taxpayers of the Australian government's six-year legal battle over plain packaging reveal to be Aus$38.9m.

Investor-State Dispute Settlement

The European Court of Justice has ruled that ISDS between two EU member states is incompatible with EU law on the basis that arbitration clauses remove the resolution of disputes from domestic courts which may concern the application or interpretation of EU law. The case concerned an investment tribunal decision under a Dutch-Slovak bilateral investment treaty (BIT). The tribunal had awarded Achmea (a Dutch insurance company, providing health insurance in the Slovak Republic) €22.1m in damages following the Slovak government's decision to partially reverse an earlier decision to privatise its health insurance market. Achmea had argued that the decision effectively destroyed the value of its investment. The Slovak government challenged the award, arguing that it lacked jurisdiction to hear the dispute. Strictly speaking, the ruling only applies to bilateral investment agreements between EU member countries. However, the basis of the ECJ's decision suggests that it may have greater relevance to the standing of arbitration decisions across EU member states. The ECJ found that investment arbitration provisions are not compatible with EU law, where the investment tribunal is not part of the EU judicial system but may still resolve disputes that are liable to relate to the EU law and those decisions are not adequately reviewable by a Member State court. This suggests that the decision may, in-time, apply to non-EU countries. A summary of the issues can be found here, here and here.

CIVIL SOCIETY OBSERVER'S ACCOUNT OF UNCITRAL REFORM

"The arbitration industry dominated observer and governmental delegations in…formal sessions [of the April 2018 UNCITRAL meeting in New York]. 37 of the 44 non-governmental observer organizations represented private lawyers and arbitrators, while only 7 represented broader civil society interests."

"During the UNCITRAL meeting, an official US government delegation representative took the floor and invited all the government delegates to an evening event hosted by his law firm, King and Spalding. The firm has represented corporations in some of the most egregious ISDS claims, including the infamous Chevron v. Ecuador case. No one in the room seemed to question the propriety of a private law firm that earns millions from the ISDS system speaking on behalf of the US government delegation to invite delegates at an intergovernmental meeting to that law firm's event" (St. Louis, 2018)

BITESIZED SUMMARY OF THE RISKS ISDS POSES TO HEALTH

"Investment arbitration represents a very specific exception to the rule of sovereign immunity – in which a country cannot be sued outside of its own state courts. States consent to jurisdiction under this system as a concession to investors who have had a historical difficulty seeking redress for economic wrongs in the domestic courts of the investor's host state. However, the political economy of investment disputes has fundamentally changed, as doctrines such as Fair and Equitable Treatment have been interpreted expansively to render a range of public regulation vulnerable to ISDS challenge, in a system with no appellate mechanism." (Garcia, et al, 2018)

An informed and fascinating polemic against ISDS by leading international arbitration lawyer, George Kahalle III. Kahalle argues that "speculation and shoddy reporting in newspapers passes as evidence" and that "misrepresentations of fact and gross mis-citations of authorities are rampant and, when discovered, usually go unpunished." Kahalle also refers to cases in which: laws and court decisions have been mistranslated and misquoted to say something different from what they say in the original version; cases and documents are cited for propositions they do not remotely support; and wholesale invention of legal principles. Kahalle's observations on how claims are quantified highlight the importance of further research in this area. Among other things, he notes that claimants have convinced tribunals to apply discounted cash flow methodology to investments without a track record of profitability (contrary to World Bank Guidelines) and then follow this by providing an array of technical analyses to support excessively optimistic cash flow projections.

Analysis of 742 investment disputes, assesses some of the central claims about ISDS and concludes that the regime has undergone an important shift: most contemporary claims are concerned with regulation, rather than direct takings by "low-rule-of-law countries". Further, these "indirect expropriation" claims have seen a significant decrease in their odds of success and are far less likely to result in early settlement. The analysis concludes that these trends may be a result of a rise in strategic litigation by investors whose aim is to encourage "regulatory chill".

An excellent summary of the role of third-party litigation funding (TPF) notes that TPF funders' preliminary evaluation of a potential claim takes account of the fact that the vast majority (88%) of all claimant investors are from high income countries, and that developing countries win only half as often as developed countries. The summary also contests access to justice arguments used by TPF funders to legitimize TPF and proposes that TPF in ISDS is "primarily about balance-sheet management, offering well-resourced claimants the ability to minimize the risk associated with bringing a claim."

UNCTAD REVIEW OF ISDS

UNCTAD's latest review of investment arbitration cases notes that ISDS tribunals rendered at least 62 substantive decisions in 2017, 34 of which are in the public domain. Of the public decisions, more than half of the decisions on jurisdictional issues were decided in favour of the State. Those on the merits were mostly decided in favour of the investor. Investors from developed-countries investors brought most of the 65 known cases in 2017 (those from the Netherlands and US initiated the most (8) cases. The majority of the IIAs invoked in 2017 date back to the 1980s and 1990s. The agreements most frequently invoked in 2017 were the Energy Charter Treaty (with six cases), the Austria–Croatia BIT (three cases) and NAFTA. In total, 20 per cent of all known cases have invoked the Energy Charter Treaty (113 cases) or NAFTA (61 cases).

Useful thematic summary of current efforts to reform investment arbitration.

Report of Working Group on ISDS reform reveals that of the27 groups listed as non-governmental observers, all but two represented the arbitration industry. Many government delegations to the meeting also included ISDS lawyers and arbitrators. Some governments, including Mauritius, Iceland and Bahrain, were solely represented by practicing arbitrators.

Belgium has requested an opinion from the European Court of Justice regarding the Investment Court System (ICS).The request specifically directs the European Court to consider the compatibility of the ICS with: the exclusive competence of the European Court to provide the definitive interpretation of European Union law; the general principle of equality and the 'practical effect' requirement of European Union law; the right of access to the Court; and the right to an independent and impartial judiciary. In respect of the latter, Belgium has requested the court to consider: the conditions regarding the remuneration of the members of the Tribunal and the Appeals Body of the ICS; the appointment of members of the Tribunal and the Appeals Body; the release of members of the Tribunal and the Appeals Body; the guidelines of the International Bar Association regarding conflicts of interest in international arbitration and the introduction of a code of conduct for the members of the Tribunal and the Appeals Body; the external professional activities related to investment disputes of members of the Tribunal and the Appeals Body. The request has a direct bearing on CETA (see February newsletter) which makes provision for the ICS.

Well-researched new book providing a historical institutionalist explanation of ISDS.

Blog post providing extracts of states' key concerns about ISDS expressed in the first two meetings of the UNICTRAL Working Group sessions (see February newsletter).

Health Services

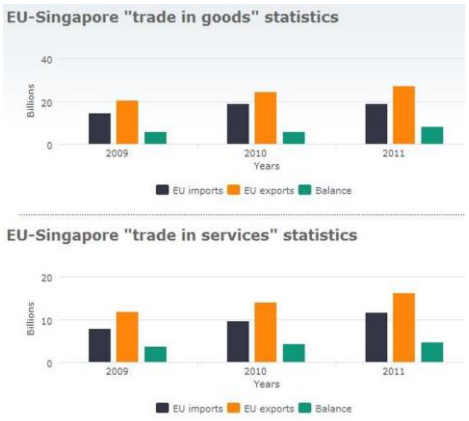
EU Single Market

Background paper on the future of health in the EU highlights tensions between the "standardisation" of health services and public health. The paper highlights the activities of CEN/CENELC on standards for medical services, in respect of which industry played a leading role. It goes on to note that discussions that have taken place regarding CEN/CENELEC have "resulted in an improved understanding of the need for all parties to respect the division of competencies established by EU law". The fact that the CEN/CENELC Focus Group on Healthcare Services has now been disbanded is described as "an encouraging step", although the paper also notes that "some questions about future standardisation activities remain open." The paper invites the Council to consider how Member States can shape the EU agenda on health in a way that is consistent with EU primary law and identify areas "that provide added value" for closer-co-operation/standardisation.

EU-Singapore FTA

Negotiations on the EU-Singapore FTA are close to being concluded. The agreement text includes the following statement reaffirming the right to regulate, "Each Party retains the right to regulate and to introduce new regulations to meet legitimate policy objectives in a manner consistent with this Chapter". It remains to be seen how this will be interpreted in the light of other aspects of the agreement.

A separate Investment Protection Agreement to be ratified between the partners is presented with the main agreement text.



It is not equal to the chapter in CETA and in practice seems to empower national treatment obligations and regulatory standstill with investment protection obligations (excluding only narrowly defined public services not competing with commercial services and audio-visual services). The wording of Article 2.3 is complex, but seems to set out requirements outlining the extent to which governments may impose new or stricter regulations (even in sectors and services not scheduled as part of the agreement). As Singapore has been active investor in health services in European Member States this may come back and bite Member States if they ratify the agreement on the assumption that it will not have implications for health systems.

Letter to MPs of national parliaments on the EU-Japan Economic Partnership Agreement. One area listed as a concern relates to its negative list approach for services (see February newsletter). The letter argues that this severely limits governments' ability to create, expand, and regulate public services and reverse failed liberalisations or privatisations, and makes it extremely hard to protect high-quality services such as water, transport, education, social and health care, as well as attempts to provide public services in line with public interest goals.

Pharmaceuticals and Intellectual Property

Pharmaceuticals and Supplementary Protection Certificates (SPCs) within the EU

The EU is preparing the ground to embed supplementary protection certificates (SPCs) in trade negotiations (see last newsletter). A proposal for an amendment to the existing EU regulation on SPCs for medicinal products follows the European Commission Single Market Strategy of October 2015, which identified a need to consolidate IP rights to "stimulate innovation and growth within the EU" and reform the patent system in Europe for pharmaceuticals. The proposal aims to introduce an "SPC manufacturing waiver" for export purposes, which removes the competitive disadvantages faced by EU-based manufacturers of generics and biosimilars relative to manufacturers operating outside of the EU (where SPC protection does not exist or has expired). While the waiver can enhance access to medicines, it may also, potentially, strengthen the role of SPCs in future. More specifically, the waiver will allow manufacturers to export products to non-EU markets where SPC protection does not exist or has expired during the term of SPCs. Another aim of the waiver is to permit EU manufacturers to enter the EU market immediately after SPC expiry by allowing them to build up production capacity whilst SPC are in place.

The proposal risks reducing member states discretion over granting SPCs, as decision-making on SPCs progressively shifts to the EU level. In addition, it serves to further entrench the legitimacy of SPCs and underpins efforts by the Commission to include protection certificates in trade agreements.

Competence is a key issue given that Member States ultimately bear the cost of pharmaceuticals. As indicated in the

February newsletter, the European Council (2016) raised concerns over the effect of IP rights and incentives for pharmaceutical innovation on prices. Research funded by the commission at the request of the Council found that the effective protection period for medicinal products (which, amongst other things, included data and market protection, market exclusivity for orphan medicinal products, and SPCs) in a dataset of 558 unique medicinal products (1996 to 2016) had declined from an average of 15 years to 13 years during the period 1996 to 2016. The research also found that: the average development time of a medicinal product (the time that elapses from the first patent filing protecting the molecule to the first marketing authorisation of the final product in the EU) had increased from 10 years to 15 years; 62% of medicinal products enjoyed an effective protection period of between 10 and 15 years; 24% enjoy an effective protection period between 15 and 20 years; 10% enjoy more than 20 years of protection (attributable to secondary patents). Patents were the last measure of protection to expire in respect of 51% of medicinal products (including secondary patents). SPCs or one of the other incentives and rewards were the last measure of protection to expire for the remaining 49%.

Civil society organisations campaigning for access to affordable medicine regard SPCs as a method for restricting legal and policy channels that facilitate access to generic medicines (see here and here).

FAST FACTS

45%

Medicinal products from a database of 558 unique medicinal products (1996 to 2016) that had obtained an SPC in at least one EU country (Copenhagen Economics, 2018).

10%

Medicinal products from a database of 558 unique medicinal products (1996 to 2016) that had enjoyed an effective protection period (time elapsed from when a product obtains a marketing authorization until the last measure of protection expires) greater than 20 years in at least one EU country (Copenhagen Economics, 2018).

HAT COMMENT ON PROPOSED CHANGES TO SUPPLEMENTARY PROTECTION CERTIFICATES

The proposed EU regulation on SPCs appears to be part of a broader process aimed at reducing Member States' influence over pharmaceutical policy in order to privilege corporate interests at the European Union level. This is consistent with the proposed new regulations governing health technology assessment which claims to operate in line with and amend Directive 2011/24/EU, but drops Article 168 (Public Health) from its legal basis to Article 114 (Internal Markets) only.

The Political Economy of Innovation and Access to Medicines

An accessible primer on the historical development of IR rights for pharmaceuticals, pricing, and contemporary ownership structures of the pharmaceutical industry. To be read in conjunction with this study showing that all medicines approved for market by the FDA between 2010 and 2016 originated in research conducted in government laboratories or in university labs funded by the National Institutes of Health and this critique of industry estimates of drug development.

A Financial Times report outlining price rises for pharmaceuticals in the US, comes on the back of slower growth in prescription drug spending and calls for stronger Federal and state controls over drug prices. These developments reflect concerns within the EU over prices (see February newsletter) and the fact that compulsory licensing for access to medicines was considered but declined in May in Norway. The price of pharmaceuticals is increasingly becoming a problem for high-income countries (also see here and here on the ongoing dispute between the UK and Vertex Pharmaceuticals over the pricing of its cystic fibrosis medicines).

A new policy paper by the Commons Network outlines a new commons approach to the development and distribution of pharmaceuticals. Recommendations include: shifting incentives to needs-driven innovation (through innovation inducement prizes, open source dividends, and tax credits dependent on the health-needs focus of declared expenditure); knowledge sharing (through open science, open access publishing, open data, and socially responsible licensing); managing knowledge as a commons (through patent pools, which create opportunities to accelerate innovation, and shared virtual spaces where scientists can work with the digital objects of biomedical research); public civic partnerships (where research priorities are set by citizens from the bottom-up and non-profit product development partnerships develop affordable biomedical solutions for people affected by poverty-related and neglected diseases); open source research where any developments are open and not patented (based on the open software model); a biomedical research and development convention (where countries agree to a sustainable system of medical innovation with adequate and predictable financing). See here for a summary.

The WHO annual report on access to essential medicines provides a short commentary on the Fair Pricing Forum on medicines. The latest report of the Forum outlines the results of a cursory analysis of the manufacturing costs and prices of medicines on the essential medicines list. The analysis found that the price of production for most generic medicines was low. Further, when compared with medicine prices from India, South Africa, and the United Kingdom it was found that government procurers often pay many times more than the cost of production. The report suggests, but does not make explicit, that there is also considerable variation between what governments in different countries pay and that price transparency represented one way of reducing high generic prices. The report also recommends further research into the link between shortages for specific medicines and low profit margins. It was suggested that the WHO link new data on the production costs of essential medicines that are frequently in shortage with their procurement price and supplier trends.

The report also summarises a discussion of research and development costs for new medicines. It notes that the Forum discussed Morgan, et al.'s systematic review of published estimates of the costs of developing new drugs, which found a 10-fold variation in estimates (reported in the Forum report as US$180m to US$2.6bn adjusted to 2014 dollars and taking into account the cost of capital).Whilst this partly reflects methodological differences (the highest estimates of research and development costs, for instance, focus on the costs of developing new chemical entities), the report notes that more clarity is needed on the costs of research and development. The possibility of insisting on greater transparency from the pharmaceutical industry was discussed who could make

medicine-specific data on research and development public. Scepticism was expressed about the professed linked between prices increases and increasing research and development investments. The findings of the US Congressional enquiry into sofosbuvir were noted, which concluded that its pricing was not related to research and development costs, but rather focused on maximizing revenue ("even as the company's analysis showed a lower price would allow more people to be treated").

Finally, on the issue of the limited take up for compulsory licenses by governments, the report noted, "inconsistency with broader trade objectives, national intellectual property policies, and opposition from patent-holders and certain governments, which may exercise diplomatic or economic pressure to discourage their use."

The report of the WHO Informal Advisory Group on the Availability and Affordability of Cancer Medicines notes that there is a lack of knowledge about the clinical benefits and risks of many newer cancer medicines, particularly at launch when initial pricing and coverage is determined. The report also recommends expanding the use of voluntary licensing, as well as taking advantage of the flexibilities offered in the TRIPS Agreement.

FOR MORE INFORMATION

Project investigating legal questions surrounding the (high) price of medicines aims to feed into current debates about the unacceptability of high drug prices and the societal responsibility of the pharmaceutical industry. The research involves EU competition law, tort law and human rights law and investigates whether the high price of drugs in specific cases violate these legal standards.

For more information go to the project website or contact Prof Brigit Toebes b.c.a.toebes@rug.nl.

EU-Japan FTA

The EU-Japan FTA IPR chapter contains a section on principles which lists several aims. The importance of striking a balance between right holders and users is no longer explicitly mentioned. The section also addresses "standards" concerning IP and seems to tighten trade secret requirements (see February newsletter on regulatory cooperation).

Non-Communicable Diseases

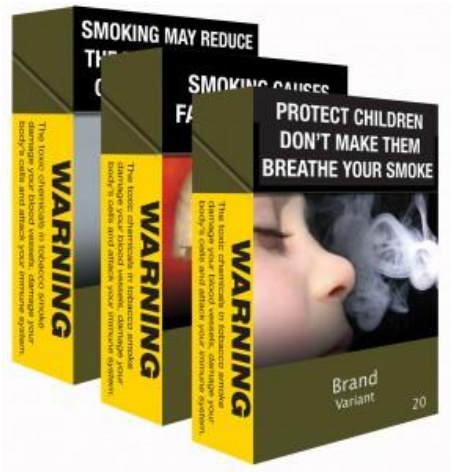
Tobacco

The WTO dismissed claims brought by Cuba, the Dominican Republic, Honduras and Indonesia challenging Australia's plain packaging laws. The complainants had claimed that: a) plain packaging was 'more trade restrictive than necessary' to protect public health (art. 2.2 of the TBT Agreement); b) plain packaging violated IP protections required under the TRIPS Agreement. The panel rejected both arguments. In relation to a) it found that: plain packaging makes a real contribution to reducing tobacco use and exposure (a legitimate objective of protecting public health); whilst plain packaging is trade-restrictive (in that it reduces the volume of imports of tobacco products), this had to be weighed against the contribution the policy makes to public health; there was no less-trade-restrictive alternative that would provide an equivalent level of protection for health given the risks. In relation to b) the panel found that TRIPS creates 'negative rights' (rights to prevent others from using the trademark, which are not affected by plain packaging) rather than a right to use a trademark and that plain packaging is not an 'unjustifiable' encumbrance by special requirements (art. 20 of the TRIPS Agreement).

On this second point, the Panel concluded that the 'special requirements' imposed by plain packaging are adopted to protect an important societal interest (i.e. an "exceptionally grave domestic and global health problem involving a high level of preventable morbidity and mortality") and that standardizing tobacco packaging is an important part of achieving this interest in so far as it removes design features on packaging and cigarettes, which reduce the appeal of tobacco products and increase the effectiveness of graphic health warnings. Accessible analyses of Panel's key findings can be found here and here.

The notice of appeal filed by Honduras requests a review of the Panel's assessment of the evidence that was presented on the degree of contribution of plain packaging to the achievement of Australia's identified legitimate objective. Honduras submits that the Panel failed to conduct an "objective examination" of the evidence on plain packaging's contribution to reducing the use of tobacco products in violation of its obligation under Article 11 of the Dispute Settlement Understanding.

A comparison of legal challenges to minimum unit pricing for alcohol (Scotland) and the legality of specific aspects of the 2014 Tobacco Products Directive (UK) under EU law explores three key questions: to what extent does EU law afford corporations opportunities to challenge national-level health regulations; to what extent do EU legal and political processes provide opportunities for positive pro-health supranational regulation; how do EU market-building processes differ from those of more narrowly drawn trade agreements and organisations in their implications for health?



Alcohol

Newly published research suggests that provisions for the labelling of wine and spirits beginning to appear in regional trade agreement may pose problems for governments wishing to apply and strengthen alcoholic beverage warning labels. Amongst other things, the provisions include the requirement that parties allow wine and spirits suppliers to place country-specific information on a supplementary label (rather than the main label). The provisions aim to promote regulatory harmonization. The analysis notes that their interpretation in the context of a complaint or dispute may create uncertainty amongst public officials who may be deterred from requiring health warning labels and other information.

The EU is reported to be pressing India to reduce alcohol taxes in renegotiations of the EU-India FTA.

Food

Reports indicate that the Office of the United States Trade Representative is pushing to limit the ability of NAFTA members to require consumer warnings on the front of sugary drinks and fatty packaged foods. The US wants to include a provision in NAFTA to prevent any warning symbol, shape or color that "inappropriately denotes that a hazard exists from consumption of the food or nonalcoholic beverages." The US Trade Representative has defended the policy, claiming that food label warning requirements are being used "to create a protectionist environment".

New research suggests that listeria and salmonella remained active after chlorine washing (used by many US poultry producers). Chlorine washing induced listeria and salmonella to enter a viable-but-nonculturable state: the process simply seems to make it impossible to detect these bacilli using culture-based detection methods.

New York Times article suggests US officials threatened Ecuador with "punishing trade measures" to dissuade it from introducing a resolution to the World Health Assembly to encourage breast-feeding. The move is discussed here as part of a broader pushed against consumer and environmental regulation in the US and internationally. It also reflects several references to codes of practice and regulations relating to infant formula milk in the 2018 National Trade Estimate Report on Foreign Trade Barriers. Initiatives cited as significant barriers to US exports, include Indonesia's food and drug regulatory agency's draft regulation (2016) concerning labelling and advertisement of food. This aims to prohibit advertising or promotion of milk products for children up to two years of age, as well as any functional claims on foods for children under three years of age. The regulation also aims to restrict the infant formula industry's interactions with health care providers (the draft also contains additional restrictions, including a ban on advertising for alcohol and requirements for nutrition labeling). The United States has asked Indonesia to notify the measure to the WTO TBT Committee before finalising the regulation.

The report also discusses Thailand's marketing code for infant and young child food and related products. In December 2015, following repeated requests from the US, Thailand notified a draft of the code to the WTO. The code proposed to restrict the use of trademarked brand names, packaging, symbols, and educational, promotional, and marketing activities, for modified milk for infants, follow-up formula for infants and young children, and supplemental foods for infants. In its original form the code covered children up to 36 months of age. In April 2017, the National Legislative Assembly passed a revised version of the Code. This removed the advertising restrictions for products for young children between 12 and 36 months but maintained other marketing restrictions on foods for young children, as well as penalties for violating the code. In late January 2018, Thailand issued several draft regulations under the code addressing advertising and marketing. These regulations were notified to the WTO and Thailand provided 60 days for comment. The National Trade Estimate Report notes that, "the US has engaged extensively with Thailand both bilaterally and at the WTO and continues to monitor developments, particularly any potential regulations relating to restrictions on products for young children".

The Environment and Sustainable Development

Friends of the Earth Europe's analysis of the EU-Indonesia CEPA trade deal gives it a score of 4.5/20 for sustainability.

The Transnational Institute and Corporate Observatory Europe have produced an excellent report on the Energy Charter Treaty (ECT), an international agreement covering investment promotion and protection, trade, transit, and energy efficiency. The report argues that the operation of the ECT discourages governments from transitioning to clean energy. It outlines how oil, gas, and coal companies have used the ECT to challenge oil drilling bans, the rejection of pipelines, taxes on fossil fuels, and moratoria on and phase-outs of controversial types of energy.

Friends of the Earth Europe has produced a new report outlining concrete proposals for a new trade agenda that serves citizens and the environment. It outlines seven principles necessary to shift the emphasis of EU trade and investment policy and treaties.

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