Trade and Investment Agreements and the Global Politics of Health

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Abstract and keywords

This chapter examines the politics of trade and investment agreements, and the ways in which these interact with the politics of health, at the global and domestic levels. The chapter first examines the operation of the World Trade Organization (WTO) and its implications for health, illustrating this with a WTO dispute between Indonesia and the USA involving the latter's ban on flavoured cigarettes. It then examines aspects of the "next generation" of trade and investment agreements that have particular implications for health policy, notably investor-state dispute settlement and regulatory cooperation. The analytical focus of this chapter is on the political processes and actors at the global and domestic levels that interact to produce trade policy and its impacts upon health.

Keywords: trade and investment agreements, World Trade Organization, investor-state dispute settlement, regulatory cooperation, political actors

Abbreviations

BAT	British American Tobacco (BAT)
BITs	bilateral investment treaties
CETA	Comprehensive Economic and Trade Agreement
DSB	Dispute Settlement Body
FDA	Food and Drug Administration
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
HICs	high-income countries
ISDS	investor-state dispute settlement
LMICs	low and middle-income countries
PMI	Philip Morris International
SPS	sanitary and phytosanitary measures
TBT	technical barriers to trade
TPP	Trans-Pacific Partnership
TTIP	Transatlantic Trade and Investment Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property
WTO	World Trade Organization

The politics of health are intimately tied to the politics of trade and investment. At the national level, the latter usually revolves around the presumed benefits for populations of greater trade and investment liberalisation (in terms of economic growth), its potential for harming domestic businesses and (by extension) certain workers through increased competition, and the apparent advantages it bestows on large transnational corporations (TNCs). At the global level, the politics of trade and investment agreements primarily take the form of bargaining between nation states, but other global actors, most notably TNCs and various civil society organisations, are increasingly making their presence felt. The key actors at both the national and global levels are thus states, corporations and civil society organisations and movements. However, these can be further disaggregated in that states, as well as negotiating with one other, have varied internal political institutions that govern how international negotiations are approached and how, once agreed, they are ratified. Furthermore, corporations in different industrial sectors, and even within them, have different interests. Civil society organisations and social movements that mobilise around (and often against) trade and investment agreements may also contain diverse sets of actors with very different interests (only some of which are directly concerned with health issues). All of these actors are influenced, in turn, by competing political and economic discourses about the costs and benefits of "free" markets and international trade. Since the 1980s, a dominant "neoliberal" discourse has assumed that less regulated markets are better than more regulated ones, although the reality of international trade is that it is a managed system, which is the product of inter-state bargaining, rather than one of entirely open borders.

Trade negotiations between states, and conflicts over trade within them, are focused principally on perceptions of relative economic benefits. Yet, as the system of international trade and investment has developed, it has become apparent that these same negotiations and conflicts can also have important implications for health. Health concerns have therefore moved from the margins of such processes to attain greater recognition, so that trade and investment agreements are acknowledged as important (actual or potential) causes of health outcomes for the populations involved. Such concerns have often revolved around the constraints that trade and investment agreements may impose upon governments' ability to make public policy that protects and enhances the health of their citizens.

In this chapter, we first outline the key processes of the World Trade Organization (WTO), which is the multilateral organisation that brings together almost all countries on trade issues, provides a forum for them to negotiate trade deals and resolve disputes, and provides the principal legal and normative frameworks governing international trade. We examine an important WTO dispute, between Indonesia and the United States (US) concerning flavoured cigarettes, to illustrate the way the WTO system works, the roles of states and corporations within it, and its implications for health politics. We then briefly discuss a number of other key disputes with important implications for health. Following this, we analyse the "next generation" of trade and investment agreements, focusing on two key aspects that are relevant to health: investor-state dispute settlement (ISDS) mechanisms and regulatory cooperation. Finally, we discuss political struggles over these new agreements, demonstrating once again how domestic and global factors interact in the politics of trade and health.

The World Trade Organization and the global politics of health

The WTO was established in 1995, following the Uruguay Round of trade negotiations. It is the successor to the multilateral trade system centred on the General Agreement on Tariffs and Trade (GATT), which governed international trade during the post-World War Two period. The GATT system, and the WTO system that succeeded it, operates on the basis of periodic "rounds" of trade negotiations by member states, which negotiate with each other to bargain down tariff rates and other trade barriers. The Uruguay Round agreed to create the WTO and added to the GATT a series of new trade agreements, including the General Agreement on Trade in Services (GATS), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement, concerned with regulations to protect human, animal and plant life and health), and the Technical Barriers to Trade (TBT) Agreement.

WTO agreements, and most other trade agreements, are based on a set of principles aimed at ensuring that agreements to remove or reduce trade barriers are applied in a non-discriminatory manner. The most important of these principles are the "most favoured nation" principle, which stipulates that concessions made to one party are extended to all other parties; and the "national treatment" principle, which holds that foreign goods, services and intellectual property (depending on the scope of the agreement) must be treated no less favourably than like domestic ones once they have entered the market.

When agreeing on the creation of the WTO, the Uruguay Round also created a new dispute settlement system, which replaced the weaker dispute settlement process of the GATT system. Under the new system, if a member state believes that another member state has

violated a WTO agreement or commitment, it can initiate a dispute via the Dispute Settlement Body (DSB). If the parties cannot agree, the dispute is then ruled upon by a panel composed of trade experts, with a right of appeal to an Appellate Body. Once a panel's (or the Appellate Body's) ruling is adopted by the member states meeting as the DSB, the losing party must comply with the decision, negotiate compensation to the other party or face retaliation in the form of the suspension of concessions (i.e. the imposition of trade sanctions such as tariffs).

The WTO's agreements, and its dispute settlement process, have become important to health policy because a number of provisions of the agreements may be seen as placing constraints on the scope that governments have to implement domestic laws and regulations in the pursuit of health objectives. Put differently, the WTO regime may limit governments' "policy space". Most WTO agreements have provisions that make exceptions for national laws or regulations that, while otherwise violating WTO commitments, are necessary for the protection of human, animal or plant health. However, such measures are subject to a "necessity" test, according to which they must be as least trade restrictive as possible, and they must be applied in a non-discriminatory manner, based on scientific evidence and international standards, and not a disguised form of protection (WHO/WTO, 2002).

Indonesia v the USA on cigarette flavourings

We can illustrate the way the above described system works, and the implications for health politics, by examining actual cases of WTO disputes relevant to health. We examine here the dispute between Indonesia and the US over the latter's banning of flavourings in cigarettes

via the Family Smoking Prevention and Tobacco Control Act of 2009 (hereafter 'the Act'). The Act asserted the Food and Drug Administration's (FDA) authority to regulate tobacco products, including by setting public health standards for them such as by specifying legal levels of tar or nicotine; introduced limitations on the color and design of packaging and advertising; and introduced new measures to protect children (Jarman, 2015: 62). As part of the latter, the Act banned characterising flavours from cigarettes, including candy, fruit, clove and cinnamon, but exempted menthol. The intent was to protect youth and children from smoking, since it was believed that they are more likely to be attracted to flavoured cigarettes.

In June 2010, Indonesia requested the establishment of a WTO dispute panel, arguing that the banning of clove cigarettes was discriminatory, given that menthol cigarettes had been exempted. Indonesia is the world's fifth largest cigarette market, with the tobacco industry exerting a high level of influence on government policy (Hurt et al., 2012: 306). Clove cigarettes (known as "kreteks") are the main form of tobacco consumption in Indonesia. The country is the largest exporter of such cigarettes to the US and other countries. While the clove cigarette market is small in the US, most clove cigarettes are imported, whereas most menthol cigarettes are produced domestically (Jarman, 2015: 64). Menthol is the most popular flavoured cigarette in the US, with a large market among African Americans. The Indonesian government argued that the differential treatment of clove and menthol cigarettes, which should be regarded as like products, was discriminatory and therefore violated both the GATT and the TBT Agreements, and further that the US measure was more trade restrictive than necessary to protect human health (WTO, 2014).

The WTO dispute panel concluded in September 2011 that the US act violated WTO law, by treating like products differently, although it rejected Indonesia's claim that the US measure was more trade restrictive than necessary. The US then appealed, with the Appellate Body upholding the panel's original ruling, although with some minor differences in the interpretation of the relevant agreements (see McGrady and Jones, 2013, for a full legal analysis). Given that the banning of clove cigarettes, alongside the continuing allowance of the sale of menthol cigarettes, constituted discrimination between like products under WTO law, the US government faced the choice of whether to bring its laws into conformity with WTO law, by allowing the sale of clove cigarettes or banning menthol cigarettes, or refuse to do so and face sanctions.

The manner in which the dispute was ultimately resolved tells us as much about the global politics of trade and health as it does about the formal legal processes within the WTO. First, the US government had to consider the domestic implications of banning menthol cigarettes. Both scientific and political considerations were relevant. In terms of the scientific evidence on the effect of menthol in masking the harshness of tobacco, the US argued in the dispute that clove cigarettes were more attractive to young people, and therefore posed a greater health risk than menthol cigarettes. However, the panel and the Appellate Body ruled that menthol and clove cigarettes had the same characteristics in terms of their effect on rates of youth smoking (McGrady and Jones, 2013). The US also argued that it was legitimate to exempt menthol cigarettes from the ban because to include them might lead to a large number of citizens experiencing sudden withdrawal from nicotine addiction, and a large rise in illicit trade. Both claims were rejected by the Appellate Body, since ordinary cigarettes would still be available (McCabe Centre for Law and Cancer, 2014).

When first passing the Act, the US government had in fact postponed a decision on whether to ban menthol cigarettes, instead asking the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) to investigate the issue. The TPSAC reported that menthol cigarettes have an adverse impact on public health because they increase the likelihood of experimentation by young people and African Americans; increase the likelihood of addiction and the degree of addiction in youth smokers; decrease the likelihood of smoking cessation, particularly for African American smokers; and that marketing of menthol cigarettes increases the prevalence of smoking for the whole population, for youths and for African Americans (TPSAC, 2011). Especially concerning was "the high rate of menthol cigarette smoking among youth and the trend over the last decade of increasing menthol cigarette smoking among 12-17 year olds, even as smoking of non-menthol cigarettes declines" (TPSAC 2011: 220). A further report was commissioned from the FDA, arriving at similar conclusions to the TPSAC report (FDA, 2013), and a consultation on the issue held in 2013, following the ruling of the WTO's Appellate Body.

However, the banning of menthol cigarettes would have constituted a political problem. Menthol cigarettes comprised at least 20% of the overall US cigarette market. Approximately 29% of all menthol smokers are African American, and more than 80% of African American smokers use menthol cigarettes (Rock et al., 2010: 117-119). As a distinct population of voters, African American smokers represented a potential political obstacle to the banning of menthol cigarettes, with some African American organizations publicly criticizing the idea of a ban (Glanton, 2010). Other African American organizations saw the exemption of menthol from the ban as a form of discrimination against the African Americans whose health would inevitably be harmed by the continued consumption of menthol cigarettes (Glanton, 2010). Some authors highlighted the concerted menthol

cigarette marketing campaigns tobacco companies had run over a number of years, specifically targeting African Americans in low-income urban areas (Cruz et al., 2010). The issue was then seen as one of social justice as well as of public health (Gardiner and Clark, 2010). Seven former federal health secretaries, from both Democratic and Republican administrations, sent a letter to members of the Senate and the House of Representatives arguing that the exemption of menthol "caves to the financial interests of tobacco companies and discriminates against African-Americans… It sends a message that African American youngsters are valued less than white youngsters" (cited in Saul, 2008).

The tobacco industry constituted a further political obstacle to a menthol ban. The main producer of menthol cigarettes in the US was Lorillard, which earned approximately 90% of its revenues from just one menthol brand, with Philip Morris and R.J. Reynolds (RJR) having smaller shares of the menthol market (Zajac, 2011). Large tobacco companies engage extensively in lobbying in the US and elsewhere (Givel and Glantz, 2001; Holden and Lee, 2009). Lorillard and RJR had in fact sued the FDA, arguing that key members of TPSAC had conflicts of interest that should have barred them from participating in the report (Zajac, 2011). While this legal challenge was ultimately rejected on appeal (Myers, 2016), the case indicates an attempt by Lorillard to discredit the findings of TPSAC. Furthermore, there was strong opposition to a ban on menthol from Republicans, who held a majority in the House of Representatives. It has been observed that President Obama may have been reluctant to engage in another political battle while embroiled in defending his healthcare reforms and negotiating over the federal deficit (Zajac, 2011; Siegel, 2011). Furthermore, the tobacco control community was split on the issue of exempting menthol, since this was the result of an uneasy compromise between the industry and some tobacco control advocates (Siegel, 2011). Tobacco control advocates supporting this compromise argued that it was a necessary

trade-off to ensure the industry conceded the FDA's authority to regulate tobacco products, which the industry had previously been successful in legally challenging (Jarman, 2015: 64). However, the divisions among public health advocates on this issue allowed the tobacco industry to dominate the public discourse, claiming that a ban on menthol cigarettes would lead to an increase in illicit trade (Cheyne et al., 2014).

A WTO ruling in a case such as this would normally lead to a change in national-level law or relevant regulations to bring it into compliance. In this case, this would have meant the US government either banning menthol cigarettes too or allowing the sale of clove cigarettes. However, the evidence in favour of a ban on flavoured cigarettes in general, including clove, had already been accepted by the US government when passing the Act, and had also been accepted by the WTO panel and Appellate Body as legitimate (as long as undertaken in a non-discriminatory manner). Thus, amending the Act to allow the sale of clove cigarettes was not a satisfactory solution. The domestic political obstacles to US compliance, therefore, led the US to take measures short of banning menthol, including releasing the FDA's scientific evaluation of menthol cigarettes, developing a youth education campaign, providing information on the health risks posed by menthol cigarettes through a website, and educating the public through the National Cancer Institute website (McCabe Centre for Law and Cancer, 2014). Where a complaining member state believes a defending state has not complied with a WTO disputes ruling, the affected state can apply for the right to suspend concessions (i.e. implement sanctions), as Indonesia then did. When the US objected, the matter was referred to WTO arbitration. However, before an arbitration decision was returned, the two governments announced a memorandum of understanding and the WTO process then ceased.

Under the negotiated settlement, the US Act remained in force, but the US government agreed not to impede market access by Indonesian clove cigars and cigarillos, at least until new non-discriminatory measures could be introduced (ICTSD, 2014; McCabe Centre for Law and Cancer, 2014). This was in the context of Indonesian clove cigarette manufacturers having adapted clove cigarettes into cigars and cigarillos to circumvent the ban. The settlement also involved a number of trade-related matters not directly connected to the clove cigarettes dispute. These included a commitment by the US that it would not submit a WTO challenge regarding unrelated mineral export restrictions imposed by Indonesia; a commitment by the US to grant additional "facilities" to Indonesia should Congress reauthorize the Generalized System of Preferences, a trade program to support less-developed countries; and that the two countries would intensify negotiations to strengthen intellectual property rights in Indonesia (ICTSD 2014; Needham 2014). They also agreed to intensify their cooperation via the Indonesia-US Trade and Investment Framework Agreement (TIFA), a mechanism for regular trade talks between the two countries.

The extent to which the final settlement benefits Indonesia is unclear. It appears that the domestic political obstacles to US compliance with the WTO panel and Appellate Body led the government to seek a solution via direct negotiation with Indonesia. This raises important questions about the informal power that states with large economies like the US have within the WTO system, and the actual capacity of low and middle-income countries (LMICs) to use and benefit from the dispute settlements process. The WTO operates on the formal basis that member states are equal within its processes, and it was assumed that the move to binding third-party arbitration upon the implementation of its dispute settlement process in 1995 would favour poorer and smaller states (Smith, 2004). Yet, the uneven wealth and power of WTO members means that this may not be the case in practice. LMICs often lack the legal

capacity to prepare and carry through disputes to the same extent as high-income countries (HICs), thus affecting decisions about whether to initiate and prosecute disputes (Guzman and Simmons, 2005; Busch et al, 2008). HICs may also threaten to withdraw other benefits such as aid or trade preferences, putting informal pressure on potential complainants (Smith, 2004: 548). Despite the formal legal process of WTO dispute settlement, inter-state bargaining takes place throughout it, including before the formal initiation of a dispute; during the dispute process; and following a ruling, where agreement on implementation can avoid the application of formal sanctions (Tallberg and Smith, 2014). States with greater market size and, therefore, lower vulnerability to sanctions are more able to resist or delay compliance, even when they have been found in breach of WTO law (Tallberg and Smith, 2014).

The Indonesia-US dispute thus demonstrates how domestic and international politics, and the varied actors within each that assert their interests, serve to intertwine the politics of trade and health. In this case, the US was able to work out an uneasy compromise that allowed it to continue to ban most flavoured cigarettes, which may be regarded as a positive development for the protection of health. Yet menthol cigarettes and clove cigars continue to be sold despite scientific evidence that banning them would advance public health. Furthermore, the final agreement between the US and Indonesia was reached outside the formal mechanisms of the WTO dispute process, in a manner that suggests that large or high-income countries such as the US can circumvent panel rulings in ways that smaller or lower-income countries would not be able to.

Other WTO disputes and the global politics of health

Other WTO disputes involving tobacco control also illustrate the implications of WTO law for the global politics of health. A GATT dispute between the US and Thailand in 1989 was instrumental in forcing the Thai government to allow transnational tobacco companies (TTCs) access to the Thai market (Vateesatokit et al., 2000). More recently, disputes involving tobacco have been increasing within the WTO, in many cases with LMICs the complainants, despite their relative lack of legal capacity. In such cases, these governments may act as surrogates for TTCs, which have been marginalised from the policy-making process in many HICs (Eckhardt et al, 2016). A particularly important example is the WTO disputes initiated by Ukraine (later withdrawn), Honduras, Dominican Republic, Cuba and Indonesia against Australia's introduction of plain packaging, claiming intellectual property rights violations, with Philip Morris International (PMI) and British American Tobacco (BAT) paying the legal expenses of some of the complainant countries (Eckhardt et al., 2016). Lobbying and various forms of assistance or inducement may therefore lead to WTO member states acting as proxies for corporate interests, with a shift from HICs to LMICs as the complainants (Eckhardt and De Bievre, 2015).

WTO agreements also have implications for the politics of other major health issues. For example, the TRIPS Agreement may impact on the affordability of medicines in LMICs (Smith et al., 2009). GATS, meanwhile, has potentially far-reaching consequences for the delivery of health services, primarily because it raises questions about the extent to which governments can protect state provided or financed services from commercial competition (Holden, 2014). While there has not yet been a significant GATS dispute relating to health services, there have been important WTO disputes in other areas relating to health. For

example, the US and Canada initiated a dispute against the European Union (EU) in 1996 to challenge the latter's imposition of a ban on the import of hormone-treated beef (WTO, 2016). While the case is extremely complex, the panel found in favour of the US and Canada on the basis that there was not sufficient evidence of the harmfulness of the hormones. The dispute is of particular relevance because it casts doubt on the extent to which WTO panels will take account of the "precautionary principle", which states that, in the absence of scientific consensus, the burden of proof that something is not harmful rests with those taking the relevant action (in this case, using certain hormones in the rearing of beef). The WTO agreement dealing most explicitly with food standards, the SPS agreement, allows governments to put in place provisional measures to protect health where scientific evidence is inconclusive, but these must be temporary while further information is sought to clarify the risk (WHO/WTO, 2002: 67-68). In another example, Canada filed a complaint against France in 1998, arguing that France's imposition of a ban on chrysotile asbestos treated imported asbestos less favourably than domestic asbestos substitutes. In this case, the WTO Appellate Body ruled in France's favour on the basis that the ban was a legitimate measure to protect health (WTO, 2010; WHO/WTO, 2002).

However, it is not only WTO agreements that are significant for health. Recent decades have seen the emergence of numerous bilateral and regional trade and investment agreements, which have potentially wide-ranging health impacts. A key feature of the WTO system is that it is premised upon bargaining between states, which have *de jure* equivalence, despite their *de facto* differences in terms of their economic and political power. This inter-state bargaining has led to deadlock in the most recent WTO negotiating round, the Doha Round. China's increased weight in the global economy, and its membership of the WTO since the beginning of the Doha Round in 2001, has allowed it to build an alliance with other "BRICS"

countries (Brazil, Russia, India and South Africa) that has led to stalemate in WTO negotiations with the US and the EU. This stalemate was the spur for the launch by the US and the EU of negotiations for a new set of trade and investment agreements outside of the mechanisms of the WTO. In the next section, we discuss some of the health implications of these "next generation" agreements.

Conflicts over "next generation" trade and investment agreements

Given the continued foundering of WTO negotiations, the two most important among the new agreements are the Transatlantic Trade and Investment Partnership (TTIP) and the Trans-Pacific Partnership (TPP). TTIP is a proposed agreement between the EU and the US, whereas TPP includes the US and 11 countries in the Pacific Rim. At the time of writing, negotiations for TTIP were ongoing and, while the TPP negotiations had been finalised, the agreement had not been ratified prior to the US Presidential elections in November 2016. Following the election of Donald Trump, it remained unclear whether either agreement would be successfully concluded and enter into force. A third agreement, the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada was signed on 30th October 2016 and, at the time of writing, was awaiting ratification by the Canadian government, EU institutions, and the 28 member states. While it would be possible to provisionally apply CETA pending its ratification, this process may be further complicated by the decision of the United Kingdom (UK) to leave the EU, and the subsequent negotiations over the terms of exit. Despite the uncertainty surrounding these agreements, they remain important to discuss because they illustrate the partial bypassing of the WTO system. They also typify the kind of provisions that the world's most powerful states have

sought to incorporate in parallel structures, which may form the basis of future trade agreements, but which have given rise to extensive controversy.

Provisions contained within TPP, TTIP and CETA are noteworthy for the ramifications they are likely to have for the wider global trading system. These agreements signified a substantial, qualitative change in the very nature of international trade agreements. It has been argued that the current generation of agreements are not, in fact, trade agreements at all in the traditional sense. Historically, such agreements have dealt principally with trade in goods, rather than services, and with the removal of tariffs and tariff-equivalent measures such as quotas. However, for countries such as the US and EU member states, much of the heavy lifting has already been completed in these areas by successive advances in the multilateral trading regime. Despite some exceptions, tariffs on the trade of manufactured goods between advanced economies have fallen to historically low levels in recent decades. The pursuit of further trade liberalization among these states has therefore shifted its focus to other, more indirect, non-tariff barriers to trade, which are seen as having significant trade-distorting effects. These include measures that are less about trade, in a straightforward sense, and more about transnational investment arrangements and "behind the border" measures affecting national regulatory standards. The focus on such measures necessitates even greater engagement with domestic laws and public policies, which may deliberately, or inadvertently, have trade-diversionary or discriminatory effects. If concluded, these agreements would create a powerful precedent regarding the type of provisions that should be included in future trade and investment agreements. Two aspects of this shift are particularly important for the politics of health: investor-state dispute settlement (ISDS) and regulatory cooperation. Below, we discuss each of these in turn, before concluding with a discussion of

the political struggles around the adoption of the agreements and the incorporation of these measures within them.

Investor-state dispute settlement, corporate interests and health

ISDS mechanisms have existed for some time within Bilateral Investment Treaties (BITs) dating back to the Germany-Pakistan BIT in 1959. The number of BITs expanded hugely during and after the 1990s, with over 2,500 now in existence. However, the principle of ISDS became increasingly controversial following its proposed incorporation within TPP, TTIP and CETA. ISDS mechanisms seek to reassure transnational investors – predominantly TNCs – that their investments will be safe from arbitrary expropriation, and that they will be subject to "fair and equitable treatment", and thus allow them to initiate disputes directly with governments where such guarantees appear to have been violated (McGrady, 2012). ISDS mechanisms were introduced initially in BITs between high-income and low-income countries, as an antidote to concerns about the effectiveness of legal systems in LMICs receiving investment and the ability of investors to be able to fully guarantee their property rights within existing legal structures. The proposed inclusion of ISDS provisions within TTIP – an agreement between two advanced capitalist economies with highly developed independent legal systems – has proved particularly controversial. Civil society movements across the relevant countries have mobilised against all three agreements, and subsequent opposition by some leading politicians and major political parties has meant that the passage of the agreements through the relevant parliaments is far from guaranteed, as we explain below.

ISDS has been particularly controversial because of the direct, and exclusive, rights it gives to corporations to initiate disputes with governments. While in the WTO system corporations can lobby member states to initiate disputes on their behalf, under ISDS mechanisms corporations have legal standing to initiate disputes directly with "host" governments. ISDS mechanisms are also not overseen by a multilateral body such as the WTO, but operate on the basis of a variety of *ad hoc* panels composed of trade and investment lawyers who, it has been argued, have a material interest in ruling in favour of corporations in order to ensure a continued flow of cases (Eberhardt and Olivet, 2012). The fragmentary nature of this system also means that the outcomes of arbitration processes are often inconsistent and highly unpredictable, with disparate judgements in multiple tribunals precluding the emergence of a unified and coherent body of trade and investment case law (Van Harten, 2007).

The important implications of ISDS mechanisms for health are highlighted by the initiation of two BIT disputes by PMI, against the Australian and Uruguayan governments, contesting their respective regulations on cigarette packaging (Hawkins and Holden, 2016). In both the case against Uruguay under the Switzerland-Uruguay BIT and against Australia under the Australia-Hong Kong BIT, PMI argued that by placing extensive limits on the design of cigarette packs these governments had deprived the company of its intellectual property rights and prevented it from freely using its trademarks. While the panels in both disputes ultimately found in favour of the respective governments, there is evidence that the initiation of these disputes has worked as a disincentive to other governments, particularly LMICs, to pursue similarly stringent cigarette packaging requirements for fear of incurring similar legal action (Hawkins and Holden, 2016). Moreover, the governments in both cases incurred substantial legal costs and devoted significant human resources to defending their policies.

These resources were thus diverted from other governmental tasks, including the provision and management of health services.

Hawkins and Holden (2016) argue that the fragmentation and complexity that characterise the international trade and investment regime, where a "spaghetti bowl" of WTO, regional and bilateral agreements overlay each other, presents a multiplicity of channels through which corporations may challenge laws designed to protect public health, but which work against their business interests. The conclusion of each new agreement that includes ISDS provisions creates an additional potential "veto point" (Hawkins and Holden, 2016). This allows TNCs to "venue shop", that is, to seek out and exploit the agreements under which they are most likely to achieve their goals. Corporations may initiate parallel disputes in any of these potential venues, including suits within domestic legal systems, challenges lodged by governments on corporations' behalf within the WTO system, and direct disputes initiated by TNCs using ISDS mechanisms within bilateral or regional agreements. Precisely such an array of disputes was initiated by TTCs against the Australian government's plain packaging law. For corporations, the intent is to overturn the targeted law, and discourage other governments from adopting similar measures. Such tactics are likely to be particularly effective against LMICs which have limited capacity to fight such legal disputes on any one, let alone all, of these fronts. In response to the threat of trade litigation by TTCs, Bloomberg Philanthropies and the Bill and Melinda Gates Foundation created an Anti-Tobacco Trade Litigation Fund in March 2015, to support LMICs being sued by tobacco companies (Tobacco Free Kids, n.d.).

Regulatory cooperation and health

As discussed in the previous section, ISDS measures introduce a mechanism through which investors can seek *ex post* remedies to unfair or discriminatory practices which contravene the principles of trade agreements. Both TPP and TTIP, however, proposed moving beyond this to include more robust *ex ante* mechanisms to ensure national laws remain in accordance with a state's obligations under the agreement. While the TPP includes a chapter on "regulatory coherence", the draft TTIP agreement includes chapters on both regulatory coherence and "regulatory cooperation". The latter is designed as a form of monitoring and oversight of proposed domestic legislation before its adoption. However, since the TTIP agreement remains under negotiation, the precise details of how this would function in practice, the institutional structures which would oversee and administer it, and the degree of access this would afford to private stakeholders such as TNCs remains uncertain. This section focuses principally on TTIP, as the most far-reaching set of proposals in this area, but many of the concerns raised here are pertinent to discussions about the impact of other agreements such as TPP.

The process of negotiation at an inter-regional level for TTIP is analogous to that undertaken within the EU during the completion of the single internal market (SIM) (see Egan, 2001). In order to create a genuinely European market, the European Commission sought to harmonize production and safety standards in specific areas to create common benchmarks, which all producers must adhere to regardless of national origin. In other areas, where harmonization was deemed unnecessary or impractical, the norm of mutual recognition was established whereby products legally produced, and deemed safe to bring to market in any member state, must be accepted within other EU states. Like the SIM project, TTIP necessitates the

formulation of either common standards (harmonization), on issues such as food safety and a range of other issues, or mutual recognition of standards between the US and the EU. Regulatory cooperation mechanisms are designed to ensure that proposed laws do not undermine either regime. If ISDS is a mechanism of redress, in cases in which the fundamental principles of the agreement are seen to have been infringed by government acts, regulatory cooperation is designed to avoid such instances occurring in the first place.

Critics of TTIP have highlighted the importance of the Regulatory Cooperation Chapter within the agreement on similar grounds to ISDS mechanisms. The establishment of processes and structures which would see draft laws on both sides of the Atlantic scrutinized prior to their adoption, and perhaps even their formal proposal, has clear implications for democratic accountability and legislative sovereignty. It affords corporate actors a potentially powerful mechanism through which to influence policy at the pre-proposal stages of the legislative process. The ability to set agendas and shape legislation at the very earliest juncture has long been identified as a key aspect of the exercise of political power (Bachrach and Baratz, 1962). Similarly, scholars of behavioural economics have long understood the importance of initial proposals in 'anchoring' subsequent negotiations (Tversky and Kahneman, 1974). This has fuelled concerns that, like ISDS, regulatory cooperation may have a "chilling effect" on legislative programs, with governments reluctant to regulate in the public interest in areas such as health and safety, the environment and social policy, where these may be seen by businesses as imposing burdens. Where governments are prepared to propose new measures, the existence of regulatory cooperation mechanisms may create an additional veto point (or potentially a series of veto points) in ways which have been explored above in relation to ISDS mechanisms (Hawkins and Holden, 2016). Without previous, real world examples to examine, as in the case of ISDS, we are forced to speculate about the

effects on health. However, it is highly likely that health policies, where they might undermine corporate profits or business models, would be challenged through such measures, creating a bias towards the *status quo*.

The ability of external actors to see and comment on domestic legislation, prior to its adoption by democratically-elected governments, represents a key development in the international trading regime. It creates the potential for foreign governments and transnational corporations to influence policy debates at the earliest stage of the process; the stage at which it is most likely these actors can amend proposals and shape the content in ways amenable to their particular interests. The proposals would create a potential pre-legislative "veto point", which proposals would have to negotiate before becoming law. The ability to stymie or water down proposed measures, before they come into force, offers a significant strategic advantage to corporate actors wishing to shape the regulatory environment. In this sense, regulatory cooperation mechanisms may represent an even greater cause for concern for global health advocates than ISDS mechanisms, if they are able to block or dilute proposals for food safety standards or other laws designed to protect public health.

Political struggles over the new agreements

The controversy around the issues discussed in this section led to the mobilisation of civil society groups against TPP, TTIP and CETA, and a heated debate in all countries party to the agreements. Against the backdrop of the PMI ISDS disputes with Uruguay and Australia, this led to discussion during the negotiation of the TPP as to whether tobacco should be

"carved out" of the agreement's ISDS provisions (Sy and Stumberg, 2014). In an unprecedented move, it was ultimately agreed that there should be a form of tobacco carve out from the ISDS provisions of the TPP, although states would have to "opt in" to these alternative arrangements. This significantly weakens the carve out, and means industry actors can lobby governments on an individual basis not to apply it. Moreover, as McGrady (2007) has observed, the exclusion of tobacco from one trade or investment agreement may be undermined by its inclusion in other agreements, given TTCs' ability to venue shop. Moreover, while specific carve outs for tobacco products may be regarded as a step forward for tobacco control, they raise questions about the adequacy of protections for other areas of public health policy under trade and investment agreements, including those related to alcoholic drinks and processed foods (Hawkins and Holden, 2016).

In the TTIP negotiations, the ISDS provisions became so controversial that the European Commission proposed replacing *ad hoc* adjudication panels with a permanent investment court system (ICS). This idea has now been incorporated within CETA. Similarly, initial proposals for a highly-institutionalized form of regulatory cooperation, through the creation of a Regulatory Cooperation Council, were watered down in draft texts of the agreement released by the European Commission in March 2016. These were replaced by vaguer commitments to create regulatory cooperation mechanisms which may be less formalized, but also less transparent and equally able to shape policy debates. Delaying agreement on the precise form of the mechanism until after the agreement is finalized grants far-reaching delegated powers to the European Commission and the US government to put in place practices with significant democratic consequences, without the degree of scrutiny to which they are subjected during formal trade negotiations and ratification procedures.

The processes of ratification of trade and investment agreements allow us to see the importance of domestic political institutions for the success or otherwise of such agreements. National parliaments, as well as the European Parliament, have an important role in deciding whether agreements are ratified, and can therefore exert influence over the contents of those agreements, even where they cannot directly amend them. In the US, Congress is required to ratify such agreements, but "fast track" or "trade promotion" authority has usually been granted to the President, under which Congress' power is limited to passing or rejecting the treaty text as whole, without the ability to make detailed amendments to its provisions.

In the EU, where an agreement is designated as a "mixed" agreement, that is, an agreement that includes areas of national as well as EU competence, agreements must be ratified not just by the European Parliament but by national governments in accordance with their own constitutional requirements. This requires the agreement of 28 national and 10 regional parliaments. In the case of CETA, the signing of the agreement was delayed due to the opposition of the Walloonian regional government in Belgium. A last-minute round of shuttle diplomacy between Canada, the EU member states and regional administrations led to the addition of supplementary protocols to the agreement to provide the Walloonian Assembly with further guarantees of its right to regulate in the public interest, and its ability to guarantee strong labour market, environmental and consumer standards. The agreement was signed in a rearranged ceremony on 30th October 2016, two days later than planned. At the time of writing, the ratification process was yet to be completed.

National governments must also take account of public opinion on agreements when seeking re-election, with TTIP becoming a key political issue in many EU member states. In the US, both TTIP and TPP, as well as the existing North American Free Trade Agreement (NAFTA)

between the US, Canada and Mexico, were key issues in the 2016 Presidential election, with Donald Trump stating that he would withdraw the US from TPP on entering office and seek to renegotiate NAFTA. The degree to which TTIP became a political issue on both sides of the Atlantic may explain why it ultimately may not be enacted.

Conclusions

Trade and investment agreements have important implications for health, and tend to reduce the "policy space" within which national governments can make health policy. Measures to protect public health, that would otherwise violate trade law, must be justified on the basis of necessity and formulated so as to be as least trade-restrictive as possible. The WTO is the primary multilateral forum within which states can negotiate trade deals, and initiate disputes with each other where they think these have been violated. Yet WTO agreements are not the only form of international trade law; the multilateral trade regime encapsulated within the WTO is overlaid with multiple bilateral, regional and plurilateral agreements, which together constitute a confusing "spaghetti bowl" of agreements (Hawkins and Holden, 2016). Nevertheless, the WTO has provided an overarching institutional structure which, since its creation in 1995, has provided a relatively ordered and primarily multilateral approach to trade bargaining. This multilateral regime began to come under strain as the Doha Round fell into deadlock, with the US and the EU, in particular, seeking new "mega-regional" agreements outside of the WTO's auspices. These new agreements, in turn, provoked substantial civil society opposition in both the US and the EU, as citizens began to question the value of ever-greater liberalisation and new pro-corporate legal mechanisms.

As the politics of trade becomes increasingly more contentious in the second decade of the 21st Century, it remains unclear whether there will be a continued move to greater trade and investment integration globally. The election of Donald Trump, and the 'Brexit' vote in the UK, indicated a rising tide of economic nationalism and a backlash against neo-liberal forms of globalisation. While the UK government's vision, at the time of writing, was one of continuing neoliberal integration within the world market outside of the EU, in the US President Trump had indicated a desire to abandon TPP and possibly TTIP, to renegotiate NAFTA, and even to take protectionist measures against other states in a manner that might violate WTO law. Trump's agenda has caused greater uncertainty about the progress of the global trade system, with a turn away from the post-World War Two liberal trading order towards a more volatile and nationalistic approach to international relations. It signifies a more instrumental approach to international politics, where the stability of global governance is of secondary importance to power-play between states, so that key aspects of contemporary global governance may be threatened, including the pre-eminence of the WTO in trade relations. It is unclear precisely what the impact of these developments might be on health policy at the national and global levels, although it raises the spectre that health issues may be sacrificed to the pursuit of a more narrowly-conceived view of national economic interest.

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