

Global Health Governance, Trade Governance and the Regime of the Framework Convention on Tobacco Control

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This paper analyzes the tussle between global health governance and trade governance regarding tobacco control and the role of the Framework Convention on Tobacco Control (FCTC). We explore the FCTC regime: its genesis, politics, and polemics on trade and health governance and examine legal proceedings initiated by transnational tobacco companies in courts of law and arbitral tribunals challenging the implementation of FCTC-compliant tobacco control measures. We conclude by distilling the lessons learned from the analysis of the politics of trade v. health debate in global tobacco control, investigating pertinent legal documents as well as scrutinizing related legal cases.

Keywords: FCTC, health governance, trade governance

INTRODUCTION

Consumption of tobacco reflects the success of transnational tobacco companies (TTCs) that attempt to manipulate consumer behavior for profit and to resist governments' efforts to reduce the use of tobacco products. Regulating the behavior of TTCs as vectors of tobacco-induced diseases is an essential part of comprehensive prevention programs and has generated controversy about consistency with international trade obligations. The Framework Convention on Tobacco Control (FCTC), the first and only treaty under the World Health Organization (WHO) auspices, contains multiple provisions that mandate parties to the treaty to implement rules that contravene free trade ethos and specific rules contained in free trade agreements. This paper analyzes the issue of the seeming tussle between health governance and trade governance as it relates to tobacco control worldwide and the role of the FCTC regime. Part II situates tobacco trade and tobacco control efforts within the larger trade versus health debate in global governance. Part III explores the FCTC regime: its genesis, politics, and polemics on trade and health governance issues. Part IV examines recent legal proceedings initiated by the TTCs in national and international courts of law, arbitral tribunals, etc. challenging the implementation of FCTC-compliant tobacco control measures. The article concludes in Part V by distilling the lessons learned from the preceding analysis of the politics of trade v. health debate in global tobacco control, investigation of the pertinent legal documents as well as the scrutiny of the eight related legal cases.

Global Health and Global Trade Governance

Objectives of free trade in the liberal international order often conflict with a range of other areas of domestic and international activity, including broad sustainability issues of the environment, human rights, conditions of labor, and even preservation of indigenous culture. These conflicts raise major questions about the power of the World Trade Organization (WTO), its responsiveness to important non-trade and non-market values, and its role and influence in public affairs- both domestic and international. Indeed, a growing global public policy concern is that multinational, regional and bilateral free trade and investment agreements privilege commercial interests and the objectives of trade policy over public policy. Negotiations concerning international trade are often conducted by experts in international law, trade, finance, and foreign affairs, without the input from public health professionals. This is worrisome as those involved in trade negotiations typically treat health as a sector just like any other, such as electronic commerce, agriculture or banking and investments. On the other hand, public health experts often have limited understanding of broader trade and investment considerations impinging on global health issues. (Friel, S. 2015; Smith, R, 2006)

Trade agreements often negatively affect governments' prerogative to freely choose and develop their political, social, and cultural systems- for example, their capacity to implement laws, policies, and programs to promote and protect public health. This is because trade liberalization entails lowering of barriers to trade including tariffs and subsidies. Therefore, measures such as laws and regulations that constitute non-tariff barriers to trade deemed in the public interest may also be constrained by such agreements. For example, WTO rules may be interpreted as impeding tobacco control policies by requiring states to remove barriers to trade that affects efforts to reduce tobacco consumption by raising prices through progressively higher taxes and duties on tobacco products, limiting exposure to tobacco advertising and through threats of trade sanctions. (Nikogoshian, H. 2018; Callard. C, 2001)

Balancing Trade and Health Objectives in WTO and WHO

WTO agreements are “directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations.” (WTO agreement, 1994, p.9) Subject to this fundamental objective, WTO agreements do affirm the right of its members to take measures necessary for the protection of human health, while seeking to prevent the creation of unnecessary obstacles to international trade. However, while the value of health is recognized, the aim in all cases is to strike a balance between trade and health objectives. A hierarchy of importance-say health over trade-is not espoused. (WTO/WHO: 2002)

Article XX of the General Agreement on Tariffs and Trade (GATT) and Article XIV of the General Agreement on Trade in Services (GATS) set out the general exceptions from obligations under the Agreements. Both of these provisions affirm the right of members to pursue objectives “necessary to protect human, animal or plant life or health” (GATT 1994 Article XX, GATS 1995 Article IV), even if, in doing so, members act inconsistently with obligations set out in other provisions of the respective agreements but ensuring that measures undertaken are not “applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade”. (GATT 1994, Article XX, GATS 1995 Article IV)

Similarly, the objective of the Technical Barriers to Trade (TBT) Agreement is to ensure that technical regulations and standards in member-states are non-discriminatory and do not create unnecessary obstacles to international trade. At the same time, the agreement confers WTO members the right to implement measures to achieve legitimate policy objectives including the protection of human health and safety and protection of the environment. Another goal of the agreement is to create a predictable trading environment. To that end, while assuring regulatory autonomy, it encourages members to base their measures on common international standards. (TBT, 1995)

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement allows its members to “adopt measures necessary to protect public health and nutrition” as well as to “promote the public interest in sectors of vital importance to their socio-economic and technological development”. However,

all such measures must be “consistent with the provisions” of the TRIPS Agreement.” (TRIPS, 1994 Part 1. Article 8)

The objective of the WHO is “the attainment by all peoples of the highest possible level of health” (WHO, 2006, Article 1). To achieve this objective, the functions of the WHO include acting as “the directing and co-ordinating authority on international health work”; “to propose conventions, agreements, and regulations, and make recommendations with respect to international health matters” and to “study and report on... administrative and social techniques affecting public health and medical care”. (WHO, 2006, Article 2)

Under WHO auspices are two legally binding instruments- International Health Regulations (IHO) and FCTC. IHO’s mandate is to “provide a public health response to the international spread of disease” but “in ways that are commensurate with and restricted to public health risks” and which avoid “unnecessary interference with international traffic and trade.” (IHO, 2005 Article 2) FCTC is discussed in later sections of this paper.

Trade Liberalization and Tobacco Control

The effects of trade liberalization on trade in tobacco products has been extensively researched and points to a) increased competition in domestic markets; b) price reductions due to increased competition as well as savings from reduced tariffs being passed on to consumers; and c) increases in advertising, trade promotion and consumer promotion by domestic companies to protect their market share and by TTCs to gain access to the market. The net effect of tobacco trade liberalization in previously closed markets then is a possible increase in demand and consumption of tobacco, though this cause and effect relationship is more surmised than proven. Also, to the extent implementation of non-tariff barriers to trade is curtailed in the quest for trade liberalization, domestic regulatory freedom gets limited to such an extent that effective tobacco control becomes difficult. (Lal. P. 2014, Bettcher, D. 2001)

Trade and investment treaties have the potential to impose significant internal constraints on a government’s right to choose appropriate tobacco control policies. The TTCs have argued that many tobacco control measures violate WTO Members’ legal obligations. The main grounds include the soundness and reasonableness of evidence-based regulation to justify tobacco control measures; claiming that while conducting a cost-benefit analysis, there is a heavy burden of proof where the government wants to displace fundamental freedoms and property rights secured in international law and trade agreements; proportionality (trade-health balance); and the imperative to seek the least trade-restrictive/least burdensome alternatives. More insidiously, the inherent uncertainty of the judicial process contributes to what is commonly known as ‘regulatory chill’ –the reluctance of governments to introduce domestic public health laws for fear of inviting trade disputes- domestic or international. Thus, ambiguity as to the scope of trade obligations discourages, if not outright dissuades, anti-tobacco regulation. In fact, it is likely that TTC challenges are deliberately designed to deter other countries from introducing similar tobacco control measures. The chilling effect is stark when it comes to implementing potentially revenue-harming measures such as large pack warnings and plain packaging. ((Lal. P. 2014; WHO, 2012; Bettcher, D. 2001)

FCTC: An Overview

Adopted by the WHO in 2003, FCTC- the foundation of the global regime on tobacco control-entered into force in 2005 and by July 2020, has 181 parties to the Treaty representing 90% of the world population, making it one of the most extensively adopted treaties in the UN system.

The Foreword to the treaty declares:

The WHO FCTC was developed in response to the globalization of the tobacco epidemic. The spread of the tobacco epidemic is facilitated through a variety of complex factors with cross-border effects, including trade liberalization and direct foreign investment. Other factors such as global marketing, transnational tobacco advertising, promotion and

sponsorship, and the international movement of contraband and counterfeit cigarettes have also contributed to the explosive increase in tobacco use. (WHO, 2003, p. v)

The FCTC contains both demand reduction and supply reduction provisions. Key obligations in the treaty are to:

- a) enact comprehensive bans on tobacco advertising, promotion, and sponsorship
- b) increase tobacco taxes
- c) adopt and implement large, clear, visible, legible and rotating health warnings on tobacco products and their packaging
- d) protect people from exposure to tobacco smoke from indoor work and public places
- e) ban the use of terms such as “light” and “mild”
- f) f) implement measures to combat the smuggling of tobacco products.

The treaty also contains numerous other measures designed to promote and protect public health, such as mandating the disclosure of ingredients in tobacco products, providing treatment for tobacco addiction, encouraging legal action against the tobacco industry, and promoting research and the exchange of information among countries. (WHO, 2003)

FCTC as a Reaction to Globalization, Free Trade Ethos, and the Success of the WTO

As transnational corporations (TNCs) truly become global—with global procurement, manufacturing, financing, and marketing—they increasingly come under the scrutiny of international governmental organizations attempting to regulate various aspects of their business practices. For example, tobacco control had traditionally been viewed as being almost exclusively a national concern. This suited the TTCs well because they were largely able to manage the tobacco control policy process at the national level to maintain a commercial advantage. However, their very success in expanding their market globally and in thwarting the development and implementation of effective tobacco control policies at national and sub-national levels led to the emergence of a strong transnational anti-tobacco advocacy network. This network alleged that the increasingly global nature of the tobacco industry and the risks it poses to public health demonstrates the limitations of national health governance in a globalizing world. Hence, their advocacy of the bold undertaking to exercise for the first time WHO’s capacity to develop a binding public health treaty-FCTC—a major innovation in health governance capable of effectively regulating TNCs. FCTC negotiations raised fundamental questions about the public health impacts of the globalization of trade, marketing, and investments—particularly the negative impact of extended promotion and marketing of harmful commodities like tobacco. (Mukherjee, A, 2017, Mukherjee, A & Ekanayake, E, 2009, Mamudu, H. 2008)

From the TTC perspective, globalization has the clear potential benefits of facilitating access to markets around the world through trade liberalization and specific provisions under WTO; enhanced marketing, advertisement, and sponsorship opportunities via global communication systems; and enhanced economies of scale by strategically dispersed production facilities, improved access to larger markets, and the development of global brands. But for the global alliance against tobacco marketing, the future of the industry would have been bright indeed in the low and middle-income countries with its rising income, trade liberalization, lessening social taboos against women smokers, and increasing exposure to sophisticated mass marketing campaigns. Juxtaposed against the globalization opportunity of the TTCs, however, is the anti-globalization threat of the FCTC—a major blow to the worldwide expansion strategies and marketing practices of TTCs. At the strategic level, segmenting the market by age, targeting “new” users (overwhelmingly pre-adults in most societies), and positioning the product to appeal to this segment are banned. At the tactical level, there are stringent controls on the contents of the product, packaging, promotional, and distribution methods as well as pricing to end-consumers. As expected, the industry vehemently opposed the treaty, lobbying instead for codes of conduct, self-regulatory bodies, public reporting, coordinated corporate-giving programs, and regulation by the market. (Mukherjee, A, 2017, Mukherjee, A & Ekanayake, E, 2009, Mamudu, H. 2008, Warner 2005)

Balancing Trade and Health Objectives in FCTC

Parties to different multilateral and bilateral treaties may find themselves having conflicting obligations under different treaties. Could countries implementing tobacco control measures under the FCTC find themselves breaching their international trade law obligations? A 2002 joint report (WTO/WHO, 2002) by the WTO and the WHO examined tentative provisions of the then draft FCTC with WTO agreements and concluded that none of the proposed provisions of the FCTC were inherently WTO-inconsistent. The report concluded that many of the restrictions called for by some of the proposed FCTC rules might well be determined to be “necessary” for health protection under WTO rules.

Multiple rounds of multilateral negotiations leading up to the adoption of FCTC by the WHO in 2003 intensely debated the issue of international trade versus public health over the preceding four years. Draft treaty language proposed ranged from a pro-trade position such as “Trade policy measures for tobacco control purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade” to a pro-health position such as “Priority should be given to measures taken to protect public health when tobacco control measures contained in this Convention and its protocols are examined for compatibility with other international agreements”. In the end, the treaty as adopted avoided taking a firm position on the issue, do not directly declare the primacy of health over trade when competing interests collide but in the Preamble to the Convention urges parties “to give priority to their right to protect public health”. (Mamudu et. al. 2011; WHO, 2002).

The ultimate FCTC stance of neutrality or silence on the issue was the result of a bitter compromise between for and against health-over-trade positions. As is to be expected, TTCs vehemently opposed FCTC every step of the way in their attempt initially to thwart adoption of FCTC by the WHO, and then at least to subordinate FCTC to WTO rules. They challenged the legitimacy and necessity of an FCTC health-over-trade provision arguing that WTO specifically allows member-states regulatory autonomy to enact tobacco control measures, indeed authority to impose health-related restrictions impacting global trade in tobacco products thereby making an FCTC health-over-trade provision redundant. (Weishaar et. al., 2012, Mamudu et. al. 2011)

The health-over trade position was supported by several governments, but principally by the civil society represented by the Framework Convention Alliance (FCA)-an umbrella organization that represents (as of March 2020) nearly 500 anti-tobacco NGOs from over 100 countries. FCA was concerned that absent an explicit FCTC health-over-trade provision, litigation over tobacco control initiatives might be decided under a WTO regime whose trade-centric perspective often views national health and safety regulations as forms of disguised protectionism. Consequently, it argued that a health-over-trade provision was vital to uphold the rights of parties to the convention to establish tobacco control policies without fear of losing a WTO case or fear of retaliation from countries with a vested interest in tobacco trade as tobacco cultivating or TTC headquartered country. It alleged that some WTO Panel and Appellate Body decisions placed an unreasonable burden on WTO members to justify public health measures by proving that both the intent and effect behind a challenged regulation were both ‘necessary’ and ‘least restrictive’ as well as non-discriminatory. (Mamudu & Glantz, 2009) When it became apparent that the dispute over health-over-trade provision was intractable and a threat to the successful conclusion of the convention, a compromise position emerged that essentially ignored the issue by being silent. The parties merely agreed to wording in the preamble giving priority to governments’ right to protect public health. There was also a belief by some parties to the convention that post-FCTC trade-health conflicts would be resolved in favor of health under international jurisprudence around precedence of international law. This is because FCTC was more recent and product-specific than generic WTO and would prevail under the Vienna Convention on Law of Treaties (Article 30) according to which ‘the more recent treaty will be applied in precedence over the older one’ and ‘the more specific treaty will be applied in precedence over the more general one.’ (Mamudu et. al. 2011)

Resistance to TTC Participation in the FCTC Regime

In the relational dynamics among business, government, and society, both business and civil society attempt to influence public policy. In our case, business and civil society wrestled in the WHO arena over

the FCTC in which FCA, representing the civil society at FCTC negotiations, won by being able to better convince the decision-makers as to the needs of the FCTC by relying on and successfully disseminating, its knowledge, expertise, and ideas. (Mukherjee & Ekanayake, 2009)

Initial discussions in the 1990s at the WHO on tobacco control and the proposal for FCTC were open to TTC viewpoints and possibly even active participation. However, sensing covert resistance and bad faith, a WHO-appointed Committee of Experts produced a report in 2000 entitled “*Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization* (WHO, 2000) detailing TTC strategies to systematically undermine tobacco control research and policy at WHO. This 260-page exposé based entirely on internal TTC documents seriously undermined the credibility of TTC positions in the tobacco control debate and led to the industry’s eventual exclusion from formal FCTC negotiations. In the end, the Preamble to the FCTC recognized the Parties’ “need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts”. Further, Article 5.3 of the Convention required that “in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law”. Guidelines for implementation of Article 5.3 stress that Parties should limit their dealings with the tobacco industry and avoid providing the industry with incentives for investment. (WHO, 2003; WHO FCTC COP)

TTC Resistance to FCTC: A Multifaceted, Comprehensive Approach

Extensive research has been conducted on TTC interference in the initial establishment of the FCTC and subsequent implementation in member states. These point to the fact that TTCs have utilized a variety of tactics including questioning WHO’s legal authority to develop a tobacco control treaty; staging events to divert attention from the public health issues raised by tobacco use; attempting to reduce budgets for the scientific and policy activities carried out by WHO; pitting other UN agencies against WHO; seeking to convince developing countries that WHO’s tobacco control program was a rich nation agenda carried out at the expense of the poorer nations; distorting the findings of WHO studies on the detrimental health effects of tobacco use; depicting tobacco control activists as extremists, radical and not credible; and claiming that FCTC conflicts with international trade agreements. (WHO, n.d.; WHO, 2008; Gilmore, AB. 2012, Weishaar, H et. al 2012)

Legal Challenges to Tobacco Control Measures as Conflicting With International Trade Agreements

There have been several legal proceedings in national and international courts of law, arbitral tribunals, etc. challenging the implementation of FCTC-compliant tobacco control measures. We discuss below few of the recent cases that shed light on the trade versus health debate in global governance.

British American Tobacco Kenya, PLC v. Ministry of Health of Kenya (2019)

British American Tobacco (BAT) Kenya filed a petition to the Supreme Court of Kenya appealing a Court of Appeal decision that upheld nearly all provisions of Kenya’s Tobacco Control Regulations of 2014. The Supreme Court found in 2019 that the tobacco company’s appeal was without merit, dismissed the petition in its entirety and affirmed the decision of the lower court. In its decision, the Supreme Court stated, “The ratification of the (FCTC) treaty imposed an obligation on Kenya as a state to implement measures to protect its present and future generations from the devastating social and environmental consequences of tobacco consumption and exposure to tobacco smoke. It follows that the enactment of the Tobacco Act... can only be viewed as an attempt to fulfil this obligation.” (Kenya Law, 2020, para. 119)

The Court of Appeal upheld nearly all elements of the Tobacco Control Act, including a) a 2% (of the value of tobacco products manufactured or imported) ‘compensatory’ annual contribution to help fund tobacco control education, research, and cessation efforts; b) pictorial health warnings; c) ingredient

disclosure; and d) regulations limiting interaction between the tobacco industry and public health officials. (Tobacco Control Laws, 2020a)

British American Tobacco-Uganda Ltd. v. Attorney General of Uganda (2019)

BAT-Uganda filed a lawsuit in the Constitutional Court of Uganda in 2016 challenging the constitutionality of several key regulations in the Tobacco Control Act of 2015. In 2019, the Court dismissed the Petition in its entirety and awarded costs to the government. In its judgment, the court extensively cited broad WHO research publications and specific FCTC obligations undertaken by Uganda to conclude that the petition “is part of a global strategy by the Petitioner and others engaged in the same or related trade to undermine legislation in order to expand the boundaries of their trade and increase their profits irrespective of the adverse health risks their products pose to human population”. (Uganda Legal Information Institute, 2020, p. 53) The challenged provisions upheld by the Court include a) requiring 65% or larger pictorial health warnings; b) banning all tobacco advertising, promotion, and sponsorship, including product displays at points of sale; and c) implementing FCTC Article 5.3. which requires Parties to protect tobacco control policies from commercial and other vested interests of the TTCs. (Tobacco Control Laws, 2020b)

Australia-Tobacco Plain Packaging Bill, WTO Panel 2018

In 2011, Australia passed a momentous legislation to introduce the plain packaging of tobacco products mandating that tobacco products be sold logo-free in “plain, drab, dark brown packets.” Dominican Republic, Honduras, Cuba, Indonesia and Ukraine brought a complaint before the Dispute Resolution Panel of the WTO in 2012 claiming that such measures would have serious economic consequences for them and that these were counter to WTO rules governing intellectual property rights and technical barriers to trade.

Australia justified this legislation as a legitimate public health initiative to curb tobacco use by its citizens. The WTO panel agreed with the justification pointing to evidence that “overall smoking prevalence in Australia continued to decrease following the introduction of the [plain packaging] measures”. On the issue of abiding by the TBT Agreement, the panel did not find that Australia's tobacco plain packaging measures are more trade-restrictive than necessary to achieve the legitimate objective of “improv[ing] public health by reducing the use of, and exposure to, tobacco products.” According to the panel, the measures were trade-restrictive, only insofar as they resulted in a reduced volume of imports. With respect to the TRIPS Agreement, the panel found no evidence that the measures unjustifiably impede the use of tobacco trademarks in the course of trade. Recognizing the need for “effective tobacco control measures” in the interests of public health, the panel noted that Article 8.1 of the TRIPS Agreement “expressly recognizes public health as ... a societal interest.” (Rimmer, 2018)

BAT (Panama) v. Ministry of Health, Panama 2016

In 2010, Executive Decree 611 of Panama banned advertising, promotion and sponsorship of tobacco products including a ban on tobacco product display at the point of sale. BAT Panama filed an unconstitutionality claim requesting an order from the Supreme Court declaring the Decree void. BAT Panama argued that the cardinal principles of free economic competition and the free market do not allow radical and absolute interference with freedom of commerce or enterprise, including freedom of access and the presence of legal products on the market. They also argued that the Decree violated the right to property including intellectual property and consumers' right to access information. The Supreme Court upheld the Decree noting that all such freedom could be restricted if needed to protect public health; that there was no violation of trademark rights as trademark registration and use still were allowed; and that consumers' right to access information was assured through the use of the textual listing of products and their prices and health warnings on packages. Furthermore, the Court cited official WHO Guidelines for the implementation of Article 13 (Advertising, Promotion, and Sponsorship of Tobacco) of the FCTC as justification for Decree 611, which conforms with the Guidelines. According to the Supreme Court ruling, Panama, through Decree 611, fulfilled its obligation under the Vienna Convention on the Law of Treaties

to adjust domestic law to such international law commitments as the FCTC. (Tobacco Control Laws, 2020c)

Philip Morris SARM v. Uruguay (2016)

In February 2010, three subsidiary companies of Philip Morris International (PMI) initiated an investment arbitration claim at the International Centre for the Settlement of Investment Disputes (ICSID), an arbitration panel of the World Bank. PMI alleged that two of Uruguay's tobacco control laws violated a Bilateral Investment Treaty (BIT) with Switzerland. The two challenged measures required a) large graphic health warnings covering 80% of the front and back of all cigarette packets; and b) the Single Presentation Requirement (SPR) limiting each cigarette brand to just a single variant or brand type (eliminating brand families with potentially misleading variants implying some cigarettes are less harmful than others). PMI argued that the SPR and the 80/20 regulation constituted indirect expropriation of its brand assets, including intellectual property and the goodwill associated with each of its brand variants. Also, the 80% health warnings requirement left insufficient room on the packs for it to use its trademarks and branding, wrongfully infringing on its intellectual property rights and thus reducing the value of its investment. The claimant also alleged that the SPR substantially affected the company's value since it had to pull out 7 of its 13 product variants and it could not market some of its well-known brands such as Marlboro Gold. Therefore, according to PMI, Uruguay had breached the terms of the BIT because the disputed regulations *expropriated* the property rights in PMI's trademarks without compensation; were arbitrary as they were not supported by evidence to show they would work and so did not accord PMI with *fair and equitable treatment*; and did not meet PMI's *legitimate expectations* of a stable regulatory environment or to be able to use their brand assets to make a profit. (Schacherer, S, 2018; Tobacco Control Laws, 2020d)

The panel of three arbitrators dismissed all PMI's claims, awarded Uruguay its legal costs (\$7 million) and upheld the legality of the two tobacco control measures enacted to protect public health. The tribunal held that the responsibility for public health measure rests with the government and that investment tribunals should pay great deference to governmental judgments for national needs in matters such as the protection of public health. According to the arbitral panel, the measures did not have the effect of substantial deprivation of business investment since PMI was able to continue its business of selling tobacco products in Uruguay. This ruling highlighted the importance of the FCTC in setting tobacco control objectives and establishing the evidence base for measures. It approved the wide 'margin of appreciation' and deference provided to sovereign states in adopting regulations concerning public health and ruled that a state need not prove a direct causal link between a tobacco control initiative and any observed public health outcomes – rather that it was sufficient that measures are taken in good faith and an attempt to address a public health concern. (Schacherer, S, 2018; Tobacco Control Laws, 2020d)

BAT v. UK Department of Health (2016)

The UK Standardized Packaging of Tobacco Products Regulations (2015) introduced plain or standardized packaging and prohibitions concerning the labeling of tobacco products to restrict the branding permitted on tobacco packaging. Four TTCs-BAT, Imperial Tobacco, Japan Tobacco International (JTI) and Philip Morris- brought legal challenges to the regulations to the High Court of Justice of England and Wales on the grounds that standardized packaging a) constitutes a disproportionate restriction on the TTCs fundamental rights and freedoms; b) tantamount to expropriation of property without compensation; and c) is a breach of the freedom to conduct legal business. (McCabe Center, 2020)

The judgment dismissed all grounds of challenge against the regulations. On whether plain packaging amounts to an expropriation of the tobacco trademarks, the Judge commented 'It is no part of international, EU or domestic common law on intellectual property that the legitimate function of a trademark... should be defined to include a right to use the mark to harm public health'. (BAT v. Dept. of Health, 2016, para. 40). In denying TTC claim for compensation, the Judge remarked that the tobacco companies 'seek compensation for the loss of the ability to promote a product that is internationally

recognized as pernicious and which leads to a health “epidemic”. (BAT v. Dept. of Health, 2016, para. 794). On the relevance of the FCTC and its guidelines, the Judge wrote that the FCTC contains “at its heart two propositions of real significance for the present case: The first is that tobacco use is an “epidemic” of global proportions which exerts a catastrophic impact upon health.... The second... is that the tobacco companies have over multiple decades set out, deliberately and knowingly, to subvert attempts by governments around the world to curb tobacco use and promote public health.” (BAT v. Dept. of Health, 2016, para:18). On the issue of compatibility with the TRIPS agreement, the Judge commented that ‘TRIPS and the FCTC can be read together without any risk of them colliding or being mutually inconsistent’. (BAT v. Dept. of Health, 2016, para 186). Drawing on the TRIPS Agreement, the Court noted that intellectual property rights: ‘are not absolute and must be balanced against other competing public interests. ... What is however clear is that intellectual property rights can be derogated from in the name of public health since this is one of the few public interests which is explicitly identified.’ (BAT v. Dept. of Health, 2016, para 186; McCabe Center, 2020)

Philip Morris Brands SARL et al. v. Secretary of State for Health (2016)

A challenge to the validity of the European Union's (EU) Tobacco Products Directive (TPD) brought by Philip Morris and BAT was dismissed on all grounds by the Court of Justice of the European Union (CJEU). The aim of the TPD, adopted in 2014, is to provide a harmonized regulatory environment for tobacco products across the EU (including on emissions, plain packaging, 65% pictorial health warnings, labeling and reporting requirements) to assist the free movement of these goods. The TPD also includes a provision that member states may adopt further measures concerning the standardization of tobacco packaging. (Tobacco Free Kids, 2020)

Philip Morris and BAT brought a judicial review against the UK based on the government’s intention to implement the TPD requirements. They claimed that parts of the TPD and the Directive as a whole, were invalid because it was incompatible with the EU Treaties; was not proportionate or supported by evidence; and contravened the principle of subsidiarity (the principle that political decisions should be taken at a local level if possible, rather than by a central authority). The UK court hearing the case referred questions on the interpretation of EU law to the CJEU. The CJEU upheld all aspects of the TPD, including provisions to require pictorial warning labels, to prohibit menthol and similarly flavored cigarettes, and to allow countries to prohibit cross-border sales and to adopt additional packaging restrictions, such as plain packaging. According to the Court, “the interference with the freedom of expression and information that has been found to exist meets an objective of general interest recognized by the European Union, namely, the protection of health. Given that it is undisputed that tobacco consumption and exposure to tobacco smoke are causes of death, disease and disability, the prohibition...contributes to the achievement of that objective in that it is intended to prevent the promotion of tobacco products and incitements to use them.” (Philip Morris, 2016, Para 152) The court found that the packaging and labeling requirements were proportionate and did not go beyond what was necessary and appropriate, observing that ‘the EU legislature cannot be accused of having acted arbitrarily in selecting a figure of 65% for the area reserved for combined health warnings... that selection is based on criteria deriving from the FCTC recommendations and, in making it, the EU legislature acted within the bounds of its broad discretion.’ (Philip Morris, 2016, Para 208) Emphasizing the importance of the FCTC as a tool for interpretation, the Court stated that FCTC could have a 'decisive influence' on the interpretation of both EU law and Member States' tobacco control legislation. The Court of Justice also confirmed that TPD permits the EU Member States to introduce measures to standardize the packaging of tobacco products. (Tobacco Control Laws, 2020e)

Japan Tobacco International et al. v. Ministry of Health (2016)

In 2016, France adopted measures for plain packaging of tobacco products in conformity with the European Directive on Tobacco Products (Directive 2014/40/UE). The same year, JTI, Imperial Tobacco, Philip Morris, and BAT filed legal appeals to the Council of State, the highest administrative jurisdiction in France challenging various provisions of the plain packaging regulations including directives on health

warnings. Earlier in the year, the Constitutional Council of France had upheld the tobacco control directives as being in accordance with the constitution. According to the TTCs, these provisions infringed on their property rights; disregarded the principle of free enterprise; violated intellectual property rights; and contravened the TRIPS agreement as well as France's international commitments regarding free circulation of products within the EU. (Tobacco Free Kids, 2020; Tobacco Control Laws, 2020f)

The Council of State dismissed all the claims and held that considering the particular importance attached to the protection of public health, neither the legislature nor the regulatory authorities have disregarded a fair balance between the requirements of public interest and the protection of the right to property. The council acknowledged plain packaging as an infringement of property rights but maintained that this infringement is justified given the public health objective pursued and because the measure regulates the use of trademarks but does not completely ban them. With regard to the principle of proportionality in the domain of public health, the Council ruled that each EU member state can decide on the appropriate level to ensure the protection of public health and on how such level should be achieved in their own country. Furthermore, according to the Court, EU laws allow restrictions on the free circulation of goods if needed for the protection of human life or health. (Tobacco Free Kids, 2020; Tobacco Control Laws, 2020f)

CONCLUSION

Our analysis of health governance and trade governance issues related to global tobacco control indicates that the corpus of international trade and investment law can accommodate health objectives underlying tobacco regulation and countries can retain regulatory autonomy to support tobacco control while entering into trade and investment agreements. However, tobacco control measures must not be disguised protectionism and must be consistent with the core principles of international trade including ensuring that the WTO principles of non-discrimination (both most favored nation and national treatment) are abided by; there is a legitimate objective and transparent purpose in introducing the regulation; the proposed measure is both reasonable and proportional response to, as well as is the least trade restrictive means of, achieving the objective; and there is a strong evidential basis and justification for the measure. (Lal, 2014)

The FCTC elevated a significant public health initiative to the status of an international treaty. The dynamics in trade and health governance is now changed and regulated by legally binding obligations from both health and trade perspectives and not only from the pre-FCTC trade perspective of WTO. It is evident that the two legal frameworks of WTO and FCTC could be implemented without contradiction as long as the FCTC is implemented in a non-discriminatory fashion and for reasons of public health. The FCTC expresses the determination of countries to give priority to their right to protect health. The WTO rules contain provisions in support of public health, such as exceptions and flexibilities to implement measures necessary to protect health. In addition, WTO rules emphasize the need to protect intellectual property rights in ways conducive to social and economic welfare and seeking a balance of rights and obligations in the domain of public health. (Lieberman, J, 2014)

Our legal case studies reveal that the FCTC has made a significant contribution to the deliberation of judicial bodies in the matter of tobacco control litigation. Both the inclusion of tobacco control within public health powers and responsibilities and the weight that is given to tobacco control measures are strengthened by their inclusion in a binding international treaty like the FCTC. The FCTC has influenced the legal framework for the execution of tobacco control measures in many countries, either by providing a basis for defending governments' anti-tobacco measures, or through providing guidance on the applicability of constitutional provisions on public health. The FCTC has been invoked in many ways, both as a binding legal instrument and as a source of technical and scientific knowledge. The FCTC has supported findings of the efficacy and reasonableness of tobacco regulation, helped to more sharply delineate the competing interests at stake and led to more judicial scrutiny of arguments proffered by the TTCs. It has played a key role in translating a large and intricate body of scientific evidence into a format that is understandable to legal institutions as indicated by the use of the FCTC to support evidentiary

claims, show international consensus in support of a measure, establish a bona fide public health rationale and demonstrate reasonableness of tobacco control measures undertaken. (Zhou et. al 2019)

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