CONFRONTING THE TOBACCO EPIDEMIC

IN A NEW ERA OF TRADE AND INVESTMENT LIBERALIZATION

World Health Organization

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For general information on WHO's work in tobacco control including trade-related issues, or information specifically related to this paper, please contact WHO/TFI at tfi@who.int

CONTENTS

ABBREVIATIONS

AFTA	ASEAN Free Trade Area
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of South East Asian Nations
BIT	Bilateral Investment Treaty
COP4	Fourth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control
DSB	Dispute Settlement Body of the WTO
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Commission
EEA Agreement	Agreement on the European Economic Area
EFTA	European Free Trade Association
EU	European Union
FDI	foreign direct investment
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade (1994)
ICSID	International Centre for Settlement of Investment Disputes
MERCOSUR	Southern Common Market
MFN	most-favoured-nation
MSA	Master Settlement Agreement
NAFTA	North American Free Trade Agreement
PMI	Philip Morris International
PMPMI	Philip Morris Philippines Manufacturing Inc.
SCM	Agreement on Subsidies and Countervailing Measures

SPS	Sanitary and phytosanitary
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
SPS Committee	Committee on Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
TBT Committee	Committee on Technical Barriers to Trade
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
USTR	Office of the US United States Trade Representative
Vienna Convention	Vienna Convention on the Law of Treaties
WHA	World Health Assembly
WHO	World Health Organization
WHO FCTC	WHO Framework Convention on Tobacco Control
WTO	World Trade Organization
WTO Agreement	Marrakesh Agreement Establishing the World Trade Organization

EXECUTIVE SUMMARY

In 2001, the World Health Organization Tobacco Free Initiative published a landmark paper entitled *Confronting the tobacco epidemic in an era of trade liberalization*. The paper, authored by Douglas Bettcher et al., suggested that trade liberalization and foreign direct investment in the tobacco sector may stimulate demand for tobacco products. More specifically, the evidence suggested that the opening of traditionally closed tobacco markets in low- and middle-income countries increased the prevalence of tobacco use in those countries. The paper also identified a risk that rules in trade agreements governing non-tariff barriers to trade (such as regulatory measures) could limit the autonomy of States to implement effective tobacco control measures. More than 10 years after the paper by Bettcher et al., this paper provides an update on the issues.

Since 2001, a handful of empirical and descriptive studies have examined the links between trade liberalization and tobacco consumption and between foreign direct investment and tobacco consumption. These studies also tend to confirm trade theory, and suggest that liberalization increases competition, which leads to lower prices and other

practices such as increased marketing, thereby stimulating demand. The sum of the evidence does not suggest that every act of trade liberalization or foreign direct investment will stimulate demand. Nonetheless, the evidence suggests that the risks are real and that governments should cater for and counter them in policy-making.

The most significant developments since 2001 in terms of knowledge and scholarship have occurred in the legal sphere. Many aspects of the law of the World Trade Organization (WTO) have been clarified through dispute settlement. WTO panels and the Appellate Body have proven to be more deferential to non-trade goals than some commentators once feared they would be. Although WTO claims relating to tobacco control measures have been a rarity, there are some new developments to report, including disputes that are underway at the time of writing. In *Dominican Republic – Importation and Sale of Cigarettes*, tax stamp measures designed to address illicit trade in tobacco products were found to have been implemented in a way that violates the General Agreement on Tariffs and Trade (GATT 1994). In *Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines*, a WTO Panel found that Thai tobacco tax measures had been implemented in a discriminatory manner inconsistent with the GATT and the Customs Valuation Agreement. In *United States – Clove Cigarettes*, Indonesia challenged United States restrictions on flavoured tobacco products that prohibit clove cigarettes but not menthol cigarettes. These restrictions were found to be discriminatory in violation of Article 2.1 of the Agreement on Technical Barriers to Trade (TBT Agreement). Whereas the first two of these disputes do not appear to have wide-ranging implications for tobacco control, the third may be significant *(1)*.

At the time of writing, Australia is in formal consultations under WTO law with Ukraine and Honduras. Ukraine and Honduras each requested formal consultations with Australia concerning legislation that will require plain packaging of tobacco products from December 2012.[2] Under WTO law, making a Request for Consultations triggers a period of negotiations and is the first step in dispute settlement. If the matter is not settled within 60 days of the request the WTO Member that made the request is entitled to request the establishment of a panel to adjudicate a formal complaint.

Regional and bilateral free trade agreements, which have become more common since 2001, provide another avenue through which tobacco control laws may be challenged. A contemporary example of this is found in a challenge made by Philip Morris (Norway) under the European Economic Area Agreement (EEA Agreement) against Norwegian bans on the display of tobacco products at the point of sale. This is a direct challenge to the legitimacy of limitations on point-of-sale display under the agreement and, by proxy, under European Union law.

Another significant development is the rise of international investment arbitration since 2001. Disputes under international investment agreements between foreign investors and States have become more common. Philip Morris (Switzerland) has recently brought a claim of this type against Uruguay, arguing that Uruguay's tobacco packaging measures violate a bilateral investment treaty between Switzerland and Uruguay. Philip Morris has also brought an investment claim against Australia in respect of the plain packaging of tobacco products. This claim is made under the bilateral investment treaty between Australia and Hong Kong (1993).

Although international investment agreements often afford States a wide degree of autonomy to regulate in the public interest, there are steps that States can take to minimize uncertainty and protect themselves from claims of this type. These steps include ensuring that specific commitments are not made to foreign investors in the tobacco industry, monitoring incoming investment and refusing establishment of investment if it is appropriate and lawful to do so, clarifying the scope of key provisions when future international investment agreements are negotiated and clarifying the scope of existing international investment agreements.

The most important normative development since 2001 is the entry into force of the WHO Framework Convention on Tobacco Control (WHO FCTC). The Convention obliges Parties to implement a variety of tobacco control measures. In some instances, the Convention also

recognizes the rights of Parties under international law to implement tobacco control measures. In the trade and investment context, the Convention is directly relevant in three ways. Firstly, Article 5.3 of the Convention and, specifically guidelines for implementation of that provision, provide that Parties should not grant the tobacco industry incentives for investment and should restrict their dealings with the industry. Secondly, the Convention may be used in the interpretation of international trade and investment agreements, making those agreements more sensitive to tobacco control. Thirdly, the Convention sets out rules governing conflicts between itself and other treaties, including trade and investment agreements.

Since 2001, there have also been other normative developments in respect of trade and health. The Doha Declaration on the TRIPS Agreement and Public Health has helped clarify the flexibilities that permit WTO Members to protect health under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Resolution WHA59.26 on international trade and health highlighted the need for WHO Member States to seek coherence in their trade and health policies. Finally, the Punta del Este Declaration on Implementation of the WHO FCTC reinforces the flexibility that Parties have in implementing tobacco control measures.

The ways in which the tobacco industry exploits international trade and investment agreements have also become more apparent. The industry continues to lobby bodies such as the Office of the United States Trade Representative in order to gain access to, and legal protection in, markets abroad. Recent lobbying by Philip Morris International (PMI) in respect of the Trans-Pacific Partnership Agreement provides one example of the industry seeking protection from regulation abroad. Similarly, through foreign direct investment in the Philippines, Philip Morris has gained preferential access to other Asian markets and had a WTO complaint brought on its behalf. The tobacco industry also draws on international trade and investment agreements in attempts to resist regulation. Recent examples of the way the industry gives misleading accounts of the law and places pressure on decision-makers are found in its responses to Australia's move to plain packaging of tobacco products and to Canada's restrictions on flavoured tobacco products, respectively.

At the domestic level, international trade and investment agreements pose two overarching challenges. The first challenge concerns the way that States coordinate their trade, investment and health policies so as to protect health while also maximizing any potential economic benefits of trade and investment. There is no universal approach to meeting this challenge, but there are some examples of how States have addressed the issues, e.g. through impact assessment and interdepartmental dialogue. The second challenge is a legal capacity challenge that concerns the ability of States to identify their rights and obligations under international trade and investment agreements. These highly specialized areas of law present capacity challenges for many States, and these challenges are amplified where trade and health intersect. There is also no universal solution to this problem. There is a clear need for capacity building, but there may also be merit in the provision of more specialized assistance to States on a case-by-case basis.

I. INTRODUCTION

In 2001, the WHO Tobacco Free Initiative published a landmark paper titled *Confronting the tobacco epidemic in an era of trade liberalization (3)*. In the paper, Bettcher et al. highlighted how the tobacco industry had pursued trade liberalization as a means of expanding foreign tobacco markets, particularly in developing countries. Tobacco companies in developed countries were successful in their attempts to pry open the previously closed tobacco markets of a number of developing countries.

The paper also examined the links between higher rates of tobacco consumption and factors such as trade openness and foreign direct investment in the tobacco industry. The authors concluded that there was a growing evidence base to suggest that trade liberalization may contribute to higher levels of tobacco consumption. The links were found to be strongest in the context of low- and middle-income countries. Similarly, it was concluded that increased levels of foreign direct investment may lead to higher rates of tobacco consumption, and that foreign direct investment can be an alternative pathway to accessing a foreign market with high barriers to trade.

As the authors recognized, the empirical evidence discussed in the paper tended to confirm established trade theory. In this respect, trade theory suggests that the liberalization of markets will increase competition and efficiency in the supply of a product to the market. One effect of increased competition, and also of cutting trade barriers such as tariffs, is that prices tend to fall. Given the established relationship between the price of tobacco products and consumption, trade theory suggests that liberalization will stimulate consumption by placing downward pressure on prices. The authors of the paper identified a number of other factors that may have caused increases in consumption, including increased marketing, brand proliferation and the targeting of previously untapped markets, such as women and children.

The 2001 paper also identified a risk that trade liberalization could undermine tobacco control by reducing policy space and domestic regulatory autonomy. More specifically, rules governing non-tariff barriers to trade, such as those found in the WTO covered agreements, could limit the ability of domestic regulators to implement tobacco control measures.

This paper, which is intended to update and build on the 2001 paper, is divided into this introduction (Part I), three substantive parts (Parts II-IV) and concluding comments (Part V). Part II provides an update of the links between trade and investment liberalization and tobacco control. On the one hand, there has not been a great deal of empirical research on the links between trade and investment liberalization (or domestic protection) and tobacco control since 2001. On the other hand, much has been learned about the permissiveness of the WTO covered agreements. Although there has not been a deluge of tobacco control disputes, other health-related disputes have helped to clarify the extent to which WTO Members enjoy the autonomy to regulate in the public interest. Thus, it is worthwhile to examine the state of the law.

Recent controversies have also brought the impact of trade rules on tobacco control back into the spotlight. For example, Indonesia (a non-Party to the WHO FCTC) brought a WTO complaint against the United States of America *(4)* (likewise a non-Party) concerning the latter's restrictions on flavoured cigarettes. Philip Morris (Norway) has also challenged Norwegian point-of-sale display bans, arguing that the measures violate the European Economic Area (EEA) Agreement *(5)*. In the field of international investment law, foreign investors have sought to use international investment agreements to challenge regulatory measures. More specifically, Philip Morris (Switzerland) and related companies brought a claim against Uruguay. The claim argues that a bilateral investment treaty between Switzerland and Uruguay obliges Uruguay to roll back packaging and labelling laws and pay compensation to Philip Morris for damage done to its business. Philip Morris (Asia) Limited has brought a similar claim against Australia concerning plain packaging of tobacco products.

The landscape of international law relevant to trade and tobacco control has also changed significantly since 2001. The entry into force of the WHO Framework Convention on Tobacco Control in 2005 has significant implications for the resolution of trade and investment disputes, giving strength to public health arguments. The Convention and its subsidiary instruments, such as guidelines for its implementation, provide guidance for decision-makers in the context of trade and investment disputes and are likely to be used in interpretation of trade and investment agreements. The Convention also sets out rules governing conflicts between the WHO FCTC and subsequent treaties, and in so doing, expresses the determination of the Parties to give priority to the right to protect public health.

Part III outlines two ways in which the tobacco industry has sought to exploit trade and investment agreements. Firstly, the tobacco industry uses trade and investment agreements in domestic debates about implementation of tobacco control measures by putting forward one-sided arguments to the effect that legitimate tobacco control measures are prohibited by international trade and investment obligations. Secondly, the tobacco industry continues to use trade and investment agreements as a vehicle to seek either enhanced market access or protection from regulation abroad.

Part IV of the paper examines the challenges that trade and investment agreements continue to pose for tobacco control at the domestic

level. Two primary challenges are identified. Firstly, trade and investment agreements pose a challenge in terms of policy coherence. Lack of policy coordination undermines the ability of governments to ensure the protection of public health while, at the same time, maximizing any economic benefits flowing from trade and investment. Secondly, tobacco industry arguments about the lawfulness of measures under international trade and investment laws may undermine the domestic political will necessary to implement tobacco control measures. This is particularly the case in countries that have limited in-house legal capacity in the contexts of trade and investment law.

II. UPDATE OF THE LINK BETWEEN TRADE, INVESTMENT AND TOBACCO CONTROL

Section 1 provides a summary of empirical studies examining the links between trade and investment liberalization and tobacco consumption. Section 2 then examines new developments in the field of international law that affect tobacco control.

A. Update of empirical evidence

In their 2001 paper, Bettcher et al. reviewed existing empirical studies of the link between trade liberalization, foreign direct investment and tobacco consumption. The authors also conducted their own empirical study of the issues, concluding that import penetration positively contributed to tobacco consumption in low- and middle-income countries and that increased levels of foreign direct investment should lead to higher levels of cigarette consumption *(6)*. Additionally, the authors recognized the need for further empirical research in country-specific situations and for the examination of a wider range of explanatory variables that reflect changes in prices or tobacco control policies *(7)*. However, since 2001, there have been only a handful

of studies examining the impact of trade and investment liberalization on tobacco consumption.

In a 2005 study, Chih Cheng Hsu et al. sought to determine what the prevalence of tobacco use would have been in Taiwan, China in the absence of market opening *(8)*. Hsu et al. used four sets of data to project what consumption would have been if the market had not been opened. The data included consumer surveys conducted by the Monopoly Bureau between 1965 and 1996, a Health Interview Survey conducted in 2001, annual tobacco consumption reports published by the Directorate-General of Budget, Accounting and Statistics over a 40-year period and annual official statistics for domestic cigarette production and tobacco import data from the Directorate-General of Customs.

The authors concluded that, if the market had not been opened in 1987, smoking prevalence rates would have been 12% and 202% lower for males and females respectively in the year 2001 *(9)*. In respect of female smokers, the increase was small in absolute terms but large in percentage terms, owing to the low prevalence of smoking among females as compared with males. For example, in the case of adult females, there was an increase in the prevalence of tobacco consumption from 2.5% in 1986 to 4.2% in 2001 *(10)*. On a per capita basis, significant increases in consumption were also observed after market opening, although these were consistent with pre-market-opening trends.

The data used by the authors also showed that there was a spike in the prevalence of consumption after market opening, but that after a few years prevalence resumed a downward trend. This was attributed partly to implementation of tobacco control policies.

In another 2005 study, CP Wen et al. examined the impact of the opening of the cigarette market in Taiwan. China *(11)*. Using the same datasets as the study conducted by Hsu et al., the authors observed that smoking prevalence among men aged over 35 increased by 6% within three years of market opening.[1] The authors also observed an increase in female smoking prevalence (across all age groups) from 3.6% in 1986 to 5.1% in 1990. The authors noted other factors that

1 The authors refer to the years 1986–1990, so it is unclear exactly which years they studied, since they also identify the period as a three-year period.

may have contributed to increased prevalence of tobacco consumption, such as aggressive advertising and promotion *(12,13)*. Unlike the earlier study, the authors did not seek to quantify the impact of market opening on tobacco consumption. Rather, the approach merely observes a correlation between market opening, other factors such as aggressive advertising, and increases in the prevalence of tobacco consumption.

Another 2005 study of the Taiwan, China market conducted by Chih Cheng Hsu et al. *(14)* found similar results. The study observed that smoking prevalence rates rose 7–10% for males and 39–75% for females in the first three years after market opening. As with the study by Wen et al., this study observed the increases from pre-existing prevalence figures and did not ascribe causation to market opening.

In another study from 2005, Anna Gilmore and Martin McKee examined the correlation between foreign direct investment by the tobacco industry and changes in per capita tobacco consumption in countries of the former Soviet Union between 1991 and 2000 *(15)*. The authors observed significant increases in tobacco consumption in countries where the tobacco industry engaged in foreign direct investment. Increases in consumption of approximately 56% were recorded for countries that received major tobacco industry investment, whereas a 1% drop in consumption was recorded in those countries that did not receive any such investment *(16)*. There were a number of limitations on the study, which was a descriptive study that set out to identify a correlation between foreign direct investment and per capita consumption rather than to attribute causation. Accordingly, as the authors themselves noted, the study did not control for other variables such as changes in price, incomes, advertising and the limited supply of tobacco products prior to market opening (which might have created artificially low consumption). Nonetheless, Gilmore and McKee provide a useful descriptive account of the correlation between foreign direct investment by the tobacco industry and market opening in the former Soviet Union.

In an earlier (2004) and related study, Gilmore and McKee examined foreign direct investment by the tobacco industry in the former Soviet Union as an indicator of the political and economic leverage of tobacco companies.*(17)*. The authors observed a correlation between foreign di-

rect investment by the tobacco industry and tobacco control laws. In those countries where foreign direct investment was relatively large, tobacco control laws were observed to be relatively weak. This study only observed a correlation between foreign direct investment and weak tobacco control laws and did not seek to establish causality. Nonetheless, the observations made tend to corroborate the theory that significant foreign direct investment by the tobacco industry may increase the industry's political leverage in respect of public health policy.

Although each of these studies tends to confirm the existing theories of trade and investment liberalization identified above, it appears that there is still much to learn about the impact of these processes on tobacco consumption and tobacco control. This raises the question why so few studies have been conducted. Without doubt, one answer lies in the difficulty of gathering reliable information about economies in transition. This problem also increases the difficulty of controlling for other factors, such as tobacco advertising or tobacco control measures. Another possible explanation is that further studies may provide limited predictive value for policy-makers beyond that already offered by pre-existing theory. Put another way, the literature has reached a point where it is safe to assume that there is a risk that trade liberalization and foreign direct investment may stimulate competition and consumption in the tobacco sector and consumer demand. Governments may rely on this general conclusion as they go about making policy specific to their own circumstances.

B. Update of legal issues concerning domestic regulatory autonomy

This part examines application of the legal provisions of international trade and investment agreements and considers how these agreements restrict the autonomy of States to implement tobacco control measures. Section 1 examines the extent of domestic regulatory autonomy under WTO law by reference to case-law and other developments since the issues were explained in the 2001 paper. Section 2 outlines the emergence of international investment agreements and their implications for tobacco control. Section 3 discusses the coming into force of the WHO FCTC and its implications for trade and investment law. Section 4 then identifies other normative developments that have affected the trade and health landscape more generally.

This part is not intended to constitute a comprehensive treatment of how international trade and investment laws apply to tobacco control. Many of these issues have been addressed in more detail elsewhere *(18)*. Rather, the intent is to give a brief explanation of relevant aspects of the law, directed at a non-specialized audience.

1. INTERNATIONAL TRADE LAW

In the 2001 paper by Bettcher et al., the WTO Secretariat outlined the key features of the WTO covered agreements and how they apply to tobacco control measures. The WTO Secretariat identified the GATT 1947 Panel report in *Thailand – Cigarettes* and the WTO Appellate Body report in *European Communities – Asbestos* as cases illustrating the way WTO law applies to health measures.

With this prior work in mind, this section gives a very brief explanation of the features of international trade law most relevant to tobacco control. The central requirements of the GATT, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the TBT Agreement, the TRIPS Agreement and the General Agreement on Trade in Services (GATS) are examined.[2] Disputes directly relevant to tobacco control are then examined before a brief discussion of free trade agreements and customs unions.

(i) GATT

GATT governs trade in goods and is relevant to virtually every tobacco control measure. In order to determine whether a measure complies with the GATT, it is necessary to carry out a two-stage analysis. The first stage is whether any GATT prohibitions have been contravened. Where a contravention is established, it will be necessary to examine

2 Although the WTO Agriculture Agreement would govern certain measures relating to tobacco leaf, such as subsidies, these measures are not central to tobacco control and are therefore not addressed in this paper.

whether a WTO Member can invoke an exception so as to excuse the contravention. The case-law since 2001 suggests that it is more difficult to violate a GATT prohibition than once thought, and also that it is easier to justify health measures under exceptions than once thought.

The most relevant GATT prohibitions

A central requirement of the GATT is found in Article II, which prohibits each WTO Member from levying Customs duties (tariffs) above the levels specified in a Member's Schedule of Concessions. This requirement is relevant to all goods, including tobacco leaf and various types of tobacco products. Nonetheless, the requirement is of limited relevance to tobacco control because it only limits the use of tariffs, which are discriminatory taxes applied to imported goods.

The focus of disputes under the GATT is usually on compliance with other provisions governing non-tariff barriers to trade. In this respect, the most relevant prohibition concerns what is referred to as the principle of non-discrimination between imported and domestically produced goods. Article III:4 of the GATT prohibits a WTO Member from treating imported tobacco products less favourably than like products of national origin in respect of laws and regulations affecting the internal sale, purchase, transportation, distribution or use of those goods. Laws may not discriminate through their form (such as open discrimination based on the origin of a product) or their effect (such as where imported products are treated less favourably even though this is not immediately apparent). Article III:2 sets out similar requirements in respect of taxation measures. The principle of non-discrimination is elaborated below in the discussion of recent disputes relevant to tobacco control.

Another relevant provision is Article I of the GATT, which governs most-favoured-nation treatment. This provision sets out a principle of non-discrimination between imported goods emanating from one WTO Member or any other country as compared with those of another WTO Member. The provision applies in much the same manner as Article III, except for the focus on discrimination between goods imported from different WTO Members or from any other country.

Another GATT prohibition of significance for tobacco control is the prohibition on quantitative restrictions in Article XI:1 of the GATT. This provision prohibits WTO Members from imposing prohibitions or restrictions on the importation or exportation of products, other than duties, taxes or charges. The dominant view is that Article III limits the application of Article XI. More specifically, behind the border domestic regulations that happen to be enforced for imported goods at the border are subject to Article III, whereas pure border measures (applied only to imported goods) are subject to Article XI *(19,20)*. This distinction limits the application of Article XI:1 in respect of tobacco control measures because they will most often constitute internal regulations that happen to be enforced at the border.

GATT exceptions: Article XX(b)

In the event that a tobacco control measure contravenes one of these prohibitions, the Member implementing the measure may seek to invoke one of the exceptions in Article XX of the GATT. The most relevant exception is found in Article XX(b). Article XX(b) provides broad protection for health measures and also sets out principles relevant to the other WTO covered agreements. Article XX(b) states:

> Subject to the requirement that such measures 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, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures: [...]
>
> (b) necessary to protect human, animal or plant life or health;

Analysis under Article XX(b) proceeds in four stages. In the first stage, a panel determines whether the measure violating a GATT prohibition could be described as a measure for the protection of human life or health *(21)*. The panel determines whether a risk to health exists and, if so, the objective of the measure will be assessed to determine whether the policy underlying the measure is to reduce that risk *(22)*. The risks posed by tobacco products are well established, suggesting

that tobacco control measures will ordinarily pass the first stage of analysis without much difficulty.

In the second stage, a panel weighs and balances a range of factors in order to make a preliminary determination of whether the measure could be considered necessary to achieve the Member's regulatory purpose. The factors to be weighed include, but are not limited to, the contribution of the measure to the regulatory goal and the restrictive impact of the measure on international trade. This process of weighing and balancing is carried out in light of the relative importance of the interests or values furthered by the challenged measure *(23,24,25)*. The more important the values or interests at stake, the easier it is to accept that a specific measure furthering those interests is necessary *(26)*. The case-law has treated the protection of human health as vital and important to the highest degree *(27, 28)*.

If the measure survives this preliminary determination of necessity, the panel will engage in the third stage of analysis. This requires it to examine whether reasonably available alternatives consistent, or less inconsistent, with the GATT could also achieve the Member's regulatory goal. In order for a measure to constitute a less trade-restrictive measure that is reasonably available, it must achieve the policy goal pursued, be less restrictive of trade, be reasonably available to the Member and be an actual alternative measure and not a cumulative or complementary measure.

Where a measure survives the first three stages of the analysis, it will be considered necessary to protect human health or life. In the fourth stage of the analysis, a panel examines compliance with the introductory clause (chapeau) of Article XX. The chapeau of Article XX prevents a Member from invoking Article XX(b) if the measure in question is "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". The requirements of the chapeau are designed to prevent abuse of the Article XX exceptions and relate to the manner in which a measure is applied rather than to the form of the measure itself *(29)*. The chapeau is an expression of the principle of good faith *(30)* and is animated by the idea that "a balance must be struck between the right of a member to invoke an exception under Article XX and the duty of that same member to respect the treaty rights of other members" *(31)*.

A good example of the application of Article XX(b) can be found in *Brazil – Retreaded Tyres (32)*.Brazil invoked Article XX(b) to justify a ban on the importation of retreaded tyres. Brazil argued that retreaded tyres have a shorter lifespan than new tyres and that the importation of retreaded tyres increases the accumulation of waste tyres to a greater degree than importation of new tyres. Brazil further argued that waste tyres pose threats to human health, such as providing a breeding ground for disease-carrying mosquitoes and releasing harmful chemicals when burnt *(33)*. The Panel found that the import ban contributed to Brazil's goal of preventing the generation of tyre waste and that the ban was necessary to protect human health. In reaching this conclusion, the Panel rejected arguments from the European Communities to the effect that taking steps to clean up waste tyres and encourage domestic retreading constitute a reasonably available alternative to a ban designed to prevent their accumulation *(34,35)*. The Panel and Appellate Body both recognized a distinction between alternative measures and measures that are cumulative or complementary. This is important in the context of tobacco control because it suggests that different types of tobacco control measures, such as taxes and restrictions on advertising, are not likely to be considered alternatives to one another.

Notwithstanding the necessity of the measures, Brazil ultimately lost the dispute. Exemptions in place for tyres from MERCOSUR countries and those resulting from domestic court injunctions were found to undermine the effectiveness of the measure and go against its purpose. As such, it was concluded that the partial approach adopted by Brazil did not comply with the chapeau of Article XX. Nonetheless, the fact that a measure banning importation of waste tyres was found to be necessary to protect human health demonstrates that WTO Members have a good deal of regulatory autonomy under the GATT. The concept of necessity elaborated in the case-law defers in a significant way to the policy goal of protecting human health.

Box 1. Invoking the GATT Article XX(b) exception

Step 1. Does the measure fall within the range of policies considered to protect human health?

1. Does a risk to human health exist?
2. If so, is the policy goal underlying the measure to reduce that risk?

Step 2. The panel will weigh and balance relevant factors in light of the importance of the regulatory goal in order to reach a preliminary determination on necessity.

1. How important is the regulatory goal?

The case-law suggests that protection of human health is important to the highest degree. (*European Communities – Asbestos*; *Brazil – Retreaded tyres*)

2. To what extent does the measure contribute to achievement of the regulatory goal?

It is not necessary to prove that the measure achieves the regulatory goal. Rather, a respondent must prove a genuine relationship of ends and means in that the measure brings about a material contribution to achievement of the goal. This contribution can be assessed in quantitative or qualitative terms.

3. How trade-restrictive is the measure?

The panel will consider how the measure violates the GATT and whether this results in a complete ban on importation or some less trade-restrictive outcome.

Step 3. Are less trade-restrictive measures reasonably available?

1. Are the purported alternatives less trade-restrictive?
2. Do the purported alternatives achieve the respondent's risk tolerance or chosen level of protection?
3. Are the purported alternatives true alternatives, or are they actually complementary measures?
4. Are the purported alternatives reasonably available to the Member in question?

Step 4. Is the measure 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 upon trade?

1. Do reasons given for discrimination in application of the measure bear a rational connection to the policy goal or go against that goal?
2. Does a lack of connection between application of the measure and its objective suggest that the measure is applied as a disguised restriction on trade?

(ii) SPS Agreement

To date, no WTO disputes have arisen under the SPS Agreement concerning tobacco control measures. The SPS Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. The definition of sanitary and phytosanitary measures is limited in such a way that the SPS Agreement will apply only to a very narrow range of tobacco control measures. More specifically, the SPS Agreement is likely only to apply to measures concerning foods and beverages, such as nicotine-infused foods and nicotine-infused beverages, but not to other tobacco products.

Because the SPS Agreement applies to such a limited range of tobacco control measures, it will not be discussed in detail here. Nonetheless, there are some important points to note about the Agreement. Article 2.2 establishes a requirement that all SPS measures be applied only to the extent necessary, in this instance, to protect human life or health. Unlike Article XX(b) of the GATT, however, this is an obligation applied to all SPS measures, and not an exception to be invoked when a violation has occurred. Article 2.2 also obliges WTO Members to ensure that SPS measures are based on scientific principles and not maintained without sufficient scientific evidence, except as provided for in Article 5.7 (discussed below).

The necessity requirement in Article 2.2 is also complemented by Article 3, which governs harmonization. Article 3.1 obliges WTO Members to base SPS measures on international standards, guide-

lines or recommendations where they exist, except as otherwise provided in the Agreement.[3] Measures conforming to such instruments are deemed necessary to protect human health and presumed to be consistent with the SPS Agreement (Article 3.2) and the GATT. The applicable international standards, guidelines and recommendations are those of specific bodies listed in Annex A, the most relevant of which is the Codex Alimentarius Commission.[4] At the time of writing, however, there are no relevant instruments for purposes of regulating nicotine-infused foods or beverages.

Article 5.1 of the SPS Agreement obliges WTO Members to base SPS measures on a risk assessment. Under Article 5.7, this is not required where relevant scientific evidence is insufficient. In such a situation, a WTO Member may provisionally adopt SPS measures on the basis of available pertinent information, including information provided by WHO. However, Members doing so must seek to obtain additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

Article 7 of the SPS Agreement also sets out a number of transparency requirements that oblige WTO Members to notify one another of the implementation of SPS measures. In conjunction with the SPS Committee, these notification requirements provide a forum for the discussion of SPS measures prior to domestic implementation.

(iii) TBT Agreement

The TBT Agreement applies to technical regulations that do not fall within the scope of the SPS Agreement. The phrase "technical regulation" is defined in Annex 1.1 of the TBT Agreement. The essence of a technical regulation is that it is a mandatory requirement that lays down product characteristics. Technical regulations can prescribe that a product should take a particular form, or prohibit a product from taking a particular form. In the tobacco control context, technical regulations include measures such as packaging and labelling measures and product regulations, such as restrictions on flavoured tobacco products.[5]

There have been relatively few cases decided under the TBT Agreement. The one case concerning tobacco control is *United States – Clove Cigarettes*, a dispute discussed below.

Article 2.1 obliges WTO Members to ensure that technical regulations do not result in less favourable treatment for imported products than for like domestic products and that technical regulations do not result in less favourable treatment for products from the territory of one WTO Member than for like products from the territory of another WTO Member or any other country. Although this provision resembles Articles I and III of the GATT, Article 2.1 differs in that there is no health exception to fall back on in the event of violation. Nonetheless, as the below discussion of *United States – Clove Cigarettes* highlights, Article 2.1 is interpreted in a manner sensitive to the right to regulate.

Article 2.2 of the TBT Agreement establishes a requirement that WTO Members ensure all technical regulations are not more trade-restrictive than necessary to achieve a legitimate objective, such as the protection of human health. This is an obligation applicable to all technical regulations and not an exception to be invoked if another provision is violated. As in the SPS Agreement, necessity is determined partly by reference to relevant international standards. In this respect, Article 2.4 obliges WTO Members to use relevant international standards as the basis for technical regulations except where use of these standards would be an ineffective or inappropriate means for fulfilment of the legitimate objectives pursued. Additionally, Article 2.5 creates a rebuttable presumption that health measures in accordance with international standards are necessary for the purposes of Article 2.2.

Unlike the SPS Agreement, the TBT Agreement does not limit standard-setting to specific international standards or bodies such as the Codex Alimentarius Commission. The TBT Agreement (Annex 1) defines the term "standard" as a:

3 In this respect, Article 3.3 qualifies the obligation in Article 3.1.

4 SPS Agreement, Annex A(3). In addition to the specific agencies, the SPS Committee may identify other individual standards for the purposes of the Agreement, although no such relevant standards have been identified for the purposes of nicotine-infused water or nicotine-infused foods.

5 For the definition of technical regulations, see TBT Agreement, Annex 1.1. See also Appellate Body Report, *European Commission – Asbestos*, para. 67.

> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

It remains to be seen whether guidelines, such as the guidelines on implementation of Articles 9, 10 and 11 of the WHO FCTC would be international standards. Although the Panel in *United States – Clove Cigarettes* drew upon the WHO FCTC extensively, neither disputant asked the Panel to consider whether partial guidelines for Articles 9 and 10 constitute international standards for purposes of the TBT Agreement.

Finally, Article 2.9 of the TBT Agreement creates notification obligations where a WTO Member implements a technical regulation and that regulation is not in accordance with a relevant international standard, or where no relevant international standard exists. These notification obligations only apply if a technical regulation may have a significant effect on trade of other Members. The terms of Article 2.9.1 – 2.9.4 require a member, *inter alia,* to publish a notice, notify other WTO Members, provide particulars of the proposed regulation upon request, allow a reasonable time for comments and take those comments into account. These processes are intended to give other WTO Members the opportunity to comment while changes may still be made to the technical regulation. This dialogue is conducted partly through meetings of the TBT Committee.

(iv) TRIPS Agreement

Tobacco companies often rely on the TRIPS Agreement in lobbying governments. TRIPS establishes minimum standards for the protection of intellectual property rights, including trademarks. The Agreement applies to all trademarks and is relevant to tobacco packaging and labelling laws.

Before describing the basic obligations in respect of trademark protection, it is worth noting that Articles 7 and 8 of TRIPS establish the objectives and principles of the Agreement. Article 8 recognizes that WTO Members may adopt measures necessary to protect public health, provided that those measures comply with the terms of TRIPS. This provision does not establish an exception to the Agreement. Rather, Article 8 establishes a principle to be used in interpreting the substantive provisions of TRIPS. In short, the substantive obligations of TRIPS include "flexibilities". In accordance with these flexibilities, WTO Members have significant discretion in the way they implement TRIPS in domestic law. This concept is examined below in the discussion of the Doha Declaration on the TRIPS Agreement and Public Health.

Article 15 of TRIPS obliges WTO Members to protect trademarks through their registration. However, Members may deny registration on a number of grounds, including the grounds that a trademark is of such a nature as to mislead the public.[6] For example, in the tobacco context, it is permissible for a WTO Member to deny registration of a misleading trademark containing terms such as "light" or "mild" that suggest a product may be less harmful than other products *(36)*.

Under TRIPS, the right conferred by ownership of a trademark is a right to prevent third parties from using in the course of trade identical signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion (Article 16(1)). More specifically, TRIPS does not confer on a trademark owner the right to use a trademark in the course of trade *(37)*. The right is a negative right which excludes others from use. This is important because a variety of tobacco control measures limit the use of trademarks. For example, use of trademarks is limited where States prohibit:

- the use of tobacco logos or brands on products other than tobacco products (brand-stretching);
- the use of misleading descriptors such as "light" and "mild"; or
- tobacco advertising, sponsorship or promotion.

6 Article 15(2) of TRIPS enshrines the right to deny registration on the grounds permitted under the Paris Convention for the Protection of Industrial Property. Article 6*quinquies* B(iii) of that Convention provides that Parties may refuse registration on the basis that a mark is misleading.

Against this general backdrop, Article 20 of TRIPS is the most relevant provision. Article 20 provides that "[t]he use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings." Tobacco companies often argue that Article 20 prevents measures such as plain packaging and bans on misleading descriptors that are also trademarks. However, it is not clear that the provision applies to measures purely limiting use of a trademark and, in any case, the provision only prohibits unjustifiable encumbrances. This latter point is important because the flexibilities inherent in TRIPS suggest that measures necessary to protect human health are justifiable and therefore lawful.

In their Requests for Consultations with Australia concerning plain packaging of tobacco products, both Ukraine and Honduras have invoked a number of provisions of TRIPS, including Article 20.[38] These are the first WTO disputes under TRIPS concerning a tobacco control measure.

(v) GATS

Some tobacco control measures affect trade in services. For example, restrictions on advertising, sponsorship and promotion could affect advertising services. Similarly, restrictions on the sale of tobacco products through remote means such as the Internet, and licensing measures that limit participation in the tobacco industry, could affect trade in retail or distribution services.

The GATS applies to measures by WTO Members affecting trade in services. For purposes of the GATS, trade in services may be supplied through one of the four following modes:

- cross-border supply (where a service is supplied from the territory of one Member to the territory of another);
- consumption abroad (where a consumer from one Member consumes a service in the territory of another Member);
- commercial presence (where a supplier provides a service through a commercial presence in the territory of another WTO Member); and
- presence of natural persons (where a service is supplied by a service supplier of one Member through presence of natural persons of a Member in the territory of another Member).

Unlike the other WTO covered agreements described above, GATS obligations are partly dependent on each WTO Member's willingness to make specific commitments. Some obligations bind all WTO Members. For example, Article II of GATS establishes a most-favoured-nation obligation binding all WTO Members.

Other obligations bind WTO Members only to the extent that a Member has made specific commitments in respect of a particular service sector and mode of supply. The specific commitments made under the GATS differ from one Member to another. In many instances, a Member's schedule of specific commitments will also be qualified by carve-outs that exclude certain regulatory measures. The obligations of greatest relevance include national treatment (non-discrimination) under Article XVII and market access under Article XVI. Article VI also establishes obligations concerning domestic regulation of the supply of services, e.g. through licensing requirements and other approval procedures where Members have made specific commitments.

The concept of non-discrimination, explained above in the context of the GATT, is similar in principle under the GATS (although it applies to services and service suppliers). On the other hand, the market access obligations in Article XVI of the GATS go much further than Article XI:1 of the GATT, which was also explained earlier. Article XVI of the GATS prohibits a range of restrictions on market access, such as limitations on the number of service suppliers, limitations on the total value of services supplied and limitations on the total number of service operations. This provision is also interpreted in a broad manner. Quantitative-type measures, including complete prohibition of the supply of a service, fall within the scope of the provision, whereas regulation of a qualitative character does not *(39)*. However, the difference between quantitative measures and qualitative regulation is often difficult to identify.

Article XIV of the GATS sets out general exceptions to the obligations described above. This provision is similar to Article XX of the GATT and

there is an exception equivalent to that in GATT Article XX(b), found in GATS Article XIV(b). This provision is interpreted in much the same manner as Article XX(b) of the GATT. Thus, even where a measure is inconsistent with a GATS prohibition, exceptions similar to those in Article XX of the GATT provide wide-ranging protection for WTO Members implementing measures for the protection of human health.

In the event that a tobacco control measure results in violation of a Member's specific commitments (a scenario that is yet to occur), the Member implementing the measure may renegotiate its specific commitments, provided that it compensates other WTO Members where a commitment is withdrawn (GATS, Article XXI:2). In ongoing or future GATS negotiations, WTO Members could also consider whether to include specific carve-outs in their schedules in respect of tobacco control measures that might affect trade in services.

Ongoing negotiations for further liberalization under the GATS could also result in changes to the substantive obligations set out in the text of the Agreement. For example, a number of Members have proposed that provisions governing domestic regulation in Article VI should incorporate a requirement that regulations be necessary to achieve a legitimate objective, such as the protection of health.[7] This could affect measures such as the licensing of entities involved in the tobacco industry by imposing new rules that govern these types of measures. Accordingly, health authorities should consider the implications of ongoing GATS negotiations.

(vi) Remedies and standing to bring a claim under WTO law

Where a WTO Member is found to be in violation of a WTO covered agreement, a panel will recommend that the Member in question should bring the measure into conformity with the Agreement.[8] If it is impracticable to comply with the recommendation of the Dispute Settlement Body immediately, a reasonable period of time to comply will be given.[9] If, after the expiry of that reasonable period of time, a Member has still not implemented the rulings, the complainant may obtain authorization to suspend concessions (WTO obligations owed by the complainant to the respondent) from that point forward.[10] The Dispute Settlement Body will authorize the suspension of concessions only at a level equivalent to the extent to which the complainant's benefits under the Agreement are nullified or impaired as a consequence of the initial violation.

Although WTO Members are under a general obligation to comply with their treaty obligations in good faith,[11] the consequences of violation are an important consideration in the policy-making process. There is no independent enforcement mechanism, meaning that enforcement turns on diplomatic considerations as much as on legal analysis. In addition, the fact that remedies such as the suspension of concessions apply only in a prospective fashion (from the point of authorization forward), limits the risks to which a Member is exposed in implementing a measure.

(vii) Recent WTO disputes relevant to tobacco control

Since 2001, there have been a number of WTO disputes involving tobacco products. *Dominican Republic – Importation and Sale of Cigarettes* concerned measures implemented to address illicit trade. *Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines*, concerned Customs valuation of cigarettes and affects the Thai tobacco tax regime but is not a direct challenge to the autonomy of Members to implement tobacco taxes. *United States – Clove Cigarettes* concerns measures restricting flavoured tobacco products and is a direct challenge to the legitimacy of a tobacco control measure. Additionally, if the Ukrainian and Honduran requests for consultations with Australia concerning plain packaging lead to establishment of a panel, those requests could be seen as a direct challenge to the legitimacy of another, distinct tobacco control measure.

7 For further information, see http://www.wto.org/english/tratop_e/serv_e/s_negs_e.htm (accessed 27 February 2012).
8 See Article 19(1) of the Dispute Settlement Understanding.
9 See Article 21(3) of the Dispute Settlement Understanding.
10 See Articles 22(1) and 22(2) of the Dispute Settlement Understanding.
11 In this respect, see Article 26 of the Vienna Convention on the Law of Treaties, where the principle of *pacta sunt servanda* is codified.

Dominican Republic – Importation and Internal Sale of Cigarettes

In this dispute, Honduras brought a claim against the Dominican Republic concerning a requirement that tax stamps be affixed to cigarettes at the point of importation in the Dominican Republic. This requirement meant that imported products had to be unpacked and stamped on importation, which increased the cost of production and undermined the capacity of foreign manufacturers to control how their products were presented. In contrast, domestic manufacturers could comply with the stamping requirement at the point of manufacture. It was held that this measure resulted in less favourable treatment for imported cigarettes under Article III:4 of the GATT *(40)*.

However, another Honduran claim was rejected under Article III:4. Honduras argued that an import-bonding requirement (designed to secure payment of taxes) was less favourable to imported products because the greater market share of imported goods meant that higher bonds had to be paid by importers than by domestic producers who had a smaller market share (and lower tax liability). In this context, the Panel found that the fact that an importer held the majority market share of an adversely affected good did not mean that a measure was necessarily less favourable to imported goods. As such, this second claim under Article III:4 failed *(41)*.

In its defence, the Dominican Republic invoked Article XX(d) of the GATT, which permits measures necessary to secure compliance with laws or regulations (such as tax laws) where those laws are themselves not inconsistent with the GATT. Honduras argued that less restrictive means existed, such as providing secure stamps for exporters so that the stamps could be affixed under supervision of an agent of the Dominican Republic at the point of production. The Dominican Republic failed to satisfy its burden of showing that this would not be a reasonably available alternative measure *(42)*.

The implications of this dispute for tobacco control measures with the primary purpose of protecting human health are minimal. The outcome of the dispute is more relevant to measures to address illicit trade in tobacco products. The dispute suggests that WTO Members should be careful to ensure that measures targeting specific points in the supply chain are necessary to secure compliance with tax or other laws.

Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines

In this dispute, the Philippines brought a claim against Thailand concerning Thailand's treatment of Philip Morris cigarettes imported from the Philippines *(43)*. The claim did not bring into question the legitimacy of Thailand's tobacco control measures, but concerned measures administering the Thai tobacco tax system.

Some of the claims related to the process of Customs valuation, which occurs when a good is imported. If tariffs and other taxes are based on the value of a good (i.e. *ad valorem* taxes), the Customs valuation forms the basis for determining the taxes due. The Philippines alleged that Thailand was overvaluing cigarettes imported from its territory, resulting in the payment of tariffs and taxes at a higher rate than was due. Thai Customs had rejected the transaction value of the cigarettes (the price at which the imported cigarettes were purchased) as the basis for valuation. Thailand argued that the exporter and importer, both of which are Philip Morris companies, are related parties and that the transaction value was lower than the true value of the imported cigarettes. The Panel agreed with the Philippines, finding that Thailand's Customs authorities had violated a number of procedural obligations governing how imported goods should be valued.

Other claims related to the administration of the Thai tobacco tax system. One claim related to the calculation of the tax base for purposes of Thailand's value-added tax. It was found that Thailand had departed from its general methodology for the calculation of the tax base in respect of imported cigarettes on a number of occasions. The Panel found that the effect of these departures was to increase the amount of tax due on imported cigarettes, but not on domestic cigarettes, resulting in a violation of Article III:2 of the GATT *(44)*.

The Philippines also took issue with Thai laws imposing value-added tax on resellers for the sale of imported cigarettes, but not for domestic cigarettes. Whereas domestic cigarettes qualified for an automatic

exemption, a reseller was forced to apply for a rebate of the tax in respect of sales of imported cigarettes. The Philippines argued that this violated Article III:2 of the GATT because imported cigarettes were taxed more heavily than domestic cigarettes. The Panel agreed, finding that the procedural obligation to apply for a rebate created a risk of discrimination that was sufficient to violate Article III:2 of the GATT *(45)*. In this respect, there was a risk that a reseller might not be granted the rebate if adequate documentation could not be provided. The Panel also found that the additional procedural burden of having to apply for a rebate resulted in violation of Article III:4 of the GATT. In this respect, the Panel found that the less favourable treatment of imported products was based on their foreign origin *(46)*.

Thailand sought to argue that these measures were necessary to secure compliance with tax laws under Article XX(d) of the GATT. However, the Panel ruled that the administrative requirements in question were not compliant with Article III:2 of the GATT and, therefore, Article XX(d) could not be invoked. This aspect of the Panel's decision was reversed by the Appellate Body, although the Appellate Body ultimately held that Thailand had not substantiated its defence under Article XX(d) *(47)*.

In the context of tobacco control, this outcome is likely to affect the price of imported cigarettes in Thailand by pushing that price down. The dispute also raises questions about the ability of WTO Members to conduct customs valuations when transactions between related parties are concerned. However, the broader implications of the dispute for tobacco control appear to be minimal. The outcome of the dispute appears to be quite specific to the way in which the Thai laws in question were implemented. Additionally, questions of customs valuation are less likely to be significant if a domestic tobacco tax regime utilizes specific taxes primarily, as compared with *ad valorem* taxes.

United States – Clove Cigarettes[12]

In *United States – Clove Cigarettes*, Indonesia brought a claim against the United States concerning a law that prohibits cigarettes containing a constituent that is a characterizing flavour of tobacco or tobacco smoke, other than menthol or tobacco *(48)*. Among other things, Indonesia argued that the law treats Indonesian clove cigarettes less favourably than like menthol cigarettes of United States origin, in violation of Article 2.1 of the TBT Agreement and Article III:4 of the GATT. Indonesia also argued that the measure is not necessary to achieve a legitimate objective, such as protection of human life or health, and that accordingly, the measure results in violation of Article 2.2 of the TBT Agreement, and is not defensible under Article XX(b) of the GATT 1994.

The United States argued that the measure is non-discriminatory and that the law draws a distinction between clove cigarettes and menthol cigarettes on health grounds (rather than based on the origin of the products). More specifically, the US argued that clove cigarettes are a niche product that is used disproportionately by youth, whereas menthol cigarettes are attractive to youth and adult smokers in similar proportions, and are smoked by tens of millions of adults in the United States on a regular basis. After the United States had made its first and second written submissions to the panel, the Tobacco Products Scientific Advisory Committee (TPSAC) issued a report concluding that the availability of menthol cigarettes increases initiation among youth *(49)*.

The United States had also argued that a regulatory distinction was drawn between clove and menthol cigarettes because the extent of menthol consumption in the United States means that prohibiting menthol could create significant risks of illicit trade as well as problems for the United States health system (given the addictive character of nicotine).

As noted above, Article III:4 of the GATT 1994 also establishes a principle of non-discrimination with respect to internal regulation.

12 The summary of this dispute is adapted from *Tobacco product regulation and the WTO*: US – Clove Cigarettes [briefing paper 12 September 2011]. Washington, DC, O'Neill Institute for National and Global Health Law, 2011 and *Tobacco product regulation and the WTO*: Appellate Body Report, US – Clove Cigarettes (available athttp://www.law.georgetown.edu/oneillinstitute/documents/O%27Neill%20Briefing_TobaccoProductRegulation.pdf, accessed 11 April 2012).

Three requirements must be met for a violation of Article III:4 to be established. A measure must be a law, regulation or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution or use of a good. Secondly, the imported and domestic goods in question must be considered like. Finally, the imported products in question must be accorded treatment less favourable than that accorded to the like domestic products. The limited case-law applying the TBT Agreement meant that the Panel had to draw some initial conclusions of law relating to the way Article 2.1 applies. In doing so, the Panel compared the TBT Agreement with the GATT 1994 and drew upon the case-law of the latter agreement.

Although the elements of Articles 2.1 and III:4 are similar, the Panel concluded that a different approach to Article 2.1 should be taken. Under Article III:4, whether products are like turns on the extent to which they are in a competitive relationship. In contrast, the Panel concluded that likeness analysis under Article 2.1 should be permeated by the regulatory objective pursued *(50)*. Put another way, the Panel sought to determine whether the products were like in terms of their effect on youth smoking (the risk the United States was seeking to address).

On the facts, the Panel concluded that clove and menthol cigarettes are like in terms of the regulatory objective pursued. The panel found that each type of cigarette imparts a characterizing flavour that reduces the harshness of tobacco, and that each is attractive to youth *(51)*. In drawing this conclusion, the panel determined that evidence presented by both parties concerning the tastes and habits of youth smokers in the United States could not be relied upon for purposes of determining market share *(52)*. Rather than engaging with the evidence presented on questions of market share, to determine whether the products are like the panel drew on the TPSAC report, on the work of a WHO scientific advisory committee and on the WHO FCTC partial guidelines for Articles 9 and 10.

The Panel also drew some conclusions about how the less favourable treatment standard applies under Article 2.1. The Panel stated that it was not sufficient for Indonesia to demonstrate that the measure affected competition between imported clove and domestic menthol cigarettes to the detriment of imported clove cigarettes. Indonesia also had to demonstrate that the adverse effects on clove cigarettes were related to the foreign origin of the product *(53)*. The Panel emphasized that less favourable treatment is not established by merely showing that some imported products are treated less favourably than some domestic like product *(54)*. Nonetheless, on the facts, the Panel concluded that the less favourable treatment requirement was met. The Panel noted that the vast majority of Indonesian exports of cigarettes to the United States were prohibited *(55)*. Because the Panel had already concluded that the exemption of menthol was not based on menthol posing different risks to human health from clove, the United States was forced to rely on the argument that the differential treatment of clove and menthol was based on the risk of illicit trade and risks to the United States health system, rather than on the foreign origin of clove. The Panel rejected this argument and concluded that the purpose of Article 2.1 would be defeated "if Members were allowed to remove their domestic products from the application of those same regulations to avoid potential costs that it might otherwise incur" *(56)*.

The Panel also addressed Indonesian arguments under Article 2.2 of the TBT Agreement. As with Article 2.1, the limited case-law on Article 2.2 meant that the Panel had to draw some preliminary conclusions of law. The Panel noted that the approach to analysing Article XX(b) of the GATT is relevant to Article 2.2 *(57)*.

Firstly, the Panel examined whether Indonesia had demonstrated that the ban on clove cigarettes exceeds the level of protection sought by the United States. The Panel concluded that Indonesia had not brought sufficient evidence to establish the level of protection actually pursued by the United States *(58)*. On this basis, there was not sufficient evidence for the Panel to conclude that the measure exceeded the level of protection pursued.

Secondly, the Panel examined whether Indonesia had demonstrated that the ban on clove cigarettes makes no material contribution to the objective of reducing youth smoking. In rejecting Indonesia's argument, one issue the Panel considered is whether young people smoke

clove cigarettes in insignificant numbers. The evidence brought by the United States and Indonesia on this issue conflicted. The United States evidence suggested that young people smoke clove cigarettes at higher rates than was suggested in evidence presented by Indonesia. In evaluating the evidence, the Panel stated that "the survey evidence before the Panel is susceptible to different interpretations. However, even if we accept Indonesia's numbers, these numbers do not show that an insignificant number of youth smoke clove cigarettes" *(59)*.

The Panel also considered whether the scientific evidence supports Indonesia's argument that banning clove cigarettes will do little to deter young people from smoking. In rejecting Indonesia's argument, the Panel concluded that "this is a case in which the measure actually represents at least the majority view, and potentially the unanimous view" *(60)*. After citing the relevant scientific evidence, the Panel also stated that the WHO FCTC partial guidelines on implementation of Articles 9 and 10 reinforced its understanding. The Panel quoted from the partial guidelines to the effect that they draw on the best available scientific evidence and the experience of Parties, before noting that they "show a growing consensus within the international community to strengthen tobacco-control policies through regulation of the content of tobacco products, including additives that increase the attractiveness and palatability of cigarettes" *(61)*.

Thirdly, the Panel considered whether Indonesia had demonstrated that there are less trade-restrictive alternative measures that would make an equivalent contribution to achievement of the objective at the level of protection sought by the United States. In this respect, the Panel concluded that Indonesia had merely listed a number of tobacco control measures as alternatives, but had not demonstrated that these measures would make an equivalent contribution to achieving the level of protection pursued by the United States *(62)*. The Panel also noted that many tobacco control measures are already in place in the United States, suggesting that these measures may be complementary rather than alternative measures *(63)*. Finally, the Panel noted that "prohibiting the sale of flavoured cigarettes is actually one of the measures that has been recommended in the WHO [FCTC] partial guidelines" *(64)*.

In summary, the Panel concluded that Indonesia had not established that the United States measure was more trade-restrictive than necessary to protect human health under Article 2.2.

The United States appealed the findings of the panel on discrimination under Article 2.1 of the TBT Agreement and on other procedural issues that are not addressed in this paper. Indonesia did not appeal the panel's findings with respect to Article 2.2. The Appellate Body rejected the US appeal concerning Article 2.1, thereby upholding the panel's finding that the law in question is discriminatory.

With respect to likeness, the Appellate Body followed the approach adopted under the GATT and stressed that a determination of likeness under Article 2.1 is "a determination about the nature and extent of a competitive relationship between and among the products at issue."[65] Hence, the Appellate Body rejected the panel's earlier approach of determining whether the products were like in terms of the regulatory objective pursued. In doing so, the Appellate Body reinforced the approach developed in *EC – Asbestos* whereby divergent risks posed by products are relevant only to determining competitiveness of those products. That is, the fact that products pose divergent risks to health will not in and of itself mean that they are not like products.

In its discussion of like products, the Appellate Body made some observations relevant to whether tobacco products in different product categories will ordinarily be considered like products. First, the Appellate Body recognized that satisfying an addiction to nicotine is one end use shared by clove and menthol cigarettes. Second, in discussing the relevance of consumers' tastes and habits the Appellate Body noted that it is not necessary to demonstrate that products are substitutable for all consumers. Rather, if products are highly substitutable for some consumers but not for others, this may be sufficient to show likeness.[66] For example, the fact that one product category is particularly attractive to children may not be significant to likeness if children use that product category interchangeably with another category of tobacco products.

On the facts, the Appellate Body upheld the panel's finding that clove and menthol cigarettes are like for purposes of this dispute.[67]

With respect to the less favorable treatment element, the Appellate Body elaborated a test that seeks to balance the right to regulate with the obligation not to discriminate.[68] The Appellate Body emphasized that the less favorable treatment element of Article 2.1 is not established by mere detriment to some imported products.[69] In this respect, the Appellate Body stated that "Article 2.1 should not be interpreted as prohibiting any detrimental impact on competitive opportunities for imports in cases where such detrimental impact on imports stems exclusively from legitimate regulatory distinctions."[70] To determine whether this is the case panels will need to scrutinize "the design, architecture, revealing structure, operation and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed".[71]

In light of this test, the Appellate Body upheld the panel's finding that the law results in less favorable treatment contrary to Article 2.1. The Appellate Body noted that the prohibited products consist primarily of clove cigarettes from Indonesia whereas the permitted products consist primarily of domestically produced menthol cigarettes.[72] In addition, the Appellate Body stated that it was not persuaded that the detrimental impact on competitive opportunities for imported cigarettes stems from a legitimate regulatory distinction.[73] The Appellate Body relied on the panel's findings that both menthol and clove mask the harshness of tobacco and that "menthol cigarettes have the same product characteristic that, from the perspective of the stated objective of Section 907(a)(1)(A), justified the prohibition of clove cigarettes."[74] The Appellate Body also rejected the argument that risks posed to the United States health system and in terms of illicit trade (if menthol were to be banned) constitute grounds for a legitimate regulatory distinction between clove and menthol cigarettes. Specifically, the Appellate Body stated "it is not clear that the risks that the United States claims to minimize by allowing menthol cigarettes to remain in the market would materialize if menthol cigarettes were to be banned, insofar as regular cigarettes would remain in the market."[75]

The implications of this dispute for tobacco control are mixed. On the one hand:

- The outcome of the dispute binds only the United States and Indonesia.
- The outcome was fact specific in that the dispute was decided on grounds specific to the partial form of regulation implemented by the United States and not on the grounds that prohibiting a specific category of tobacco product is more trade restrictive than necessary to protect human health. Accordingly, the outcome does not prevent other WTO Members from implementing non-discriminatory tobacco product regulations.
- The panel's analysis under Article 2.2 suggests that it will often be difficult for a complainant to meet its burden of proving that another Member's measure is more trade restrictive than necessary to protect human health.
- The panel report made extensive use of the WHO Framework Convention on Tobacco Control and its Partial Guidelines for Implementation of Articles 9 and 10 in the analysis.
- The Appellate Body sought to elaborate a test under Article 2.1 balancing the right to regulate with the obligations of non-discrimination.

On the other hand, the approach to likeness adopted by the Appellate Body suggests that tobacco products will ordinarily be considered like. Hence, for product regulations that fall hardest on imported products the question will be whether the effect on the competitive opportunities of those imported products stems exclusively from legitimate regulatory distinctions.

(viii) Free trade agreements and customs unions

Although the WTO Agreement is the central multilateral instrument governing international trade, free trade agreements are becoming increasingly common. Free trade agreements are usually bilateral or regional in character, and require the elimination of practically all restrictive regulations of commerce (such as tariffs) between the territories involved.[13] In this way, free trade agreements can grant prefer-

13 See GATT Article XXIV:8(b) for a more detailed definition.

ential treatment to goods that originate in the territory of the parties because those goods may enter tariff-free or subject to lower tariffs than goods from the territory of other WTO Members.

Free trade agreements usually set out rules governing non-tariff barriers to trade that are similar to those in the WTO covered agreements. However, in some instances, free trade agreements impose tighter restrictions on domestic regulation. This is seen most often in respect of intellectual property rights. Some free trade agreements incorporate so-called TRIPS-plus provisions, which impose additional requirements for the protection of intellectual property rights that limit the flexibility of Contracting Parties to address issues such as access to essential medicines. Often, free trade agreements also incorporate rules governing the protection of foreign investments, an issue discussed in the next section of this paper.

Customs unions are a deeper form of economic integration between States. Customs unions involve the formation of a single customs territory between two or more States. As with free trade agreements, substantially all restrictive regulations of commerce are eliminated for trade between the territories involved. In addition, the territories of a customs union apply substantially the same regulations (such as tariffs) to the importation of goods from territories not forming a part of the union.[14] The European Union is one prominent example of a customs union.

The risk that liberalization will stimulate demand for tobacco products also applies in the context of concluding a free trade agreement or forming a customs union. Similarly, the risk that an agreement will limit a State's regulatory autonomy also applies. This risk is apparent in a claim filed by Philip Morris against Norway.

Norway is a party to the EEA Agreement, a free trade agreement which extends parts of European Union law governing the free movement of goods to Norway. Philip Morris Norway has lodged a claim with the Oslo District Court, arguing that Norwegian bans on point-of-sale display violate Norway's obligations. The Oslo District Court requested an advisory opinion from the European Free Trade Association (EFTA) Court, which has competence to advise on implementation of the EEA Agreement. In essence, the two questions before the EFTA Court were (1) whether a point-of-sale display ban constitutes a measure having equivalent effect to a quantitative restriction on the free movement of goods and (2) if so, whether a ban would be suitable and necessary for purposes of protecting public health.

On the first question, the EFTA Court concluded that "a visual display ban ... constitutes a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 11 EEA if, in fact, the ban affects the marketing of products imported from other EEA States to a greater degree than that of imported products which were, until recently, produced in Norway". On the second question, the EFTA Court concluded that it is for the national court to "identify the aims which the legislation at issue is actually intended to pursue and to decide whether the public health objective of reducing tobacco use by the public in general can be achieved by measures less restrictive than a visual display ban on tobacco products".

Although the outcome of this claim remains to be seen, it provides an example of ways in which agreements outside the realm of the WTO are also relevant to tobacco control.

(ix) Steps policy-makers can take to protect tobacco control measures

In light of the discussion above, there are some steps policy-makers can take in order to minimize the risk of non-compliance with WTO law. The most obvious step is to seek assistance from a lawyer with expertise in WTO law during the development of new tobacco control measures. This assistance might come from within the government or from external sources. Beyond this, there are specific steps that may minimize the risk of discrimination and maximize the possibility that the necessity of a measure will be established.

With respect to provisions governing discrimination, it is prudent to gather up-to-date information on the composition of the domestic tobacco market. Such information could be used to identify how a proposed measure is likely to affect imported as compared to domestic to-

14 See GATT Article XXIV:8(a) for a more detailed definition.

bacco products. Most importantly, where a proposed tobacco control measure may treat products differently from one another it is prudent to ensure that there are legitimate regulatory reasons for drawing the distinctions in question. If this is not the case, and the effect of the measure falls hardest on imported products, the measure might be considered discriminatory.

With respect to the necessity test, there are a number of steps policy-makers can take to maximize the chances of tobacco control measures being considered necessary. Firstly, policy-makers should take particular care in how they articulate the regulatory goals underlying a tobacco control measure. Framing regulatory goals in qualitative terms and articulating the particular role of a particular measure within the broader quantitative goal of reducing the prevalence of tobacco use may enhance the prospect of a tobacco control measure being considered necessary. Secondly, identifying how a particular measure complements other tobacco control measures in place or under implementation may maximize the possibility of those other measures being considered complementary rather than alternatives. Thirdly, identifying how tobacco control measures implement the WHO FCTC may maximise the role of the WHO FCTC in the event of a WTO dispute. Finally, identifying WHO FCTC guidelines as relevant international standards when notifying other WTO Members of the implementation of a technical regulation under the TBT Agreement may enhance the role played by those guidelines in discussion of TBT issues and in TBT disputes.

2. INTERNATIONAL INVESTMENT LAW

Since 2001, the field of international investment law has grown significantly, as the proliferation of international investment agreements has gathered pace. These agreements have taken the form of bilateral investment treaties and investment chapters in free trade agreements. More importantly, however, the number of disputes arising under international investment agreements has increased since 2001, as foreign investors have turned to international arbitration, rather than foreign courts, as a means of dispute settlement.

The tobacco industry has long asserted that various tobacco control measures would violate international investment agreements, requiring governments to compensate the industry. The classic example can be found in Carla Hills' submission to the Canadian Standing Committee on Health in respect of plain packaging. In addition to arguing that the measure would violate WTO covered agreements, such as TRIPS, Hills argued that plain packaging would constitute expropriation of industry property under the investment chapter of the North American Free Trade Agreement (NAFTA) *(76)*. More recently, Philip Morris Products (Switzerland) and other companies filed a Request for Arbitration *(77)* with the International Centre for Settlement of Investment Disputes (ICSID) against Uruguay, pursuant to a bilateral investment treaty between Switzerland and Uruguay *(78)*.The request concerns Uruguayan tobacco packaging measures and seeks arbitration before the ICSID, which is based at the World Bank in Washington, DC. Philip Morris has also brought a claim under the bilateral investment treaty between Australia and Hong Kong concerning plain packaging measures that the Australian Government intends to implement. Before outlining these disputes in further detail, it is worth identifying some of the standard features of international investment agreements.

Although it is not always the case, most international investment agreements make provision for investor-State dispute settlement. This gives a foreign investor standing to bring a claim against a State for violation of the international investment agreement and to seek compensation. For example, the bilateral investment treaty between Switzerland and Uruguay permits Swiss nationals with an investment in Uruguay to enforce the bilateral investment treaty through arbitration with Uruguay. This can be contrasted with the WTO system, where only WTO Members have standing to bring a claim.

Some features of international investment agreements are similar to trade agreements. For example, international investment agreements usually include provisions governing national treatment and most-favoured-nation treatment that seek to prevent discrimination between investors and investments *(79)*. In other respects, international investment agreements offer protection for investors well be-

yond that offered in trade agreements. Pertinent examples are found in the obligation of States to pay compensation for expropriation of investments and in the obligation to provide investors and investments with fair and equitable treatment.

(i) Expropriation and measures equivalent thereto

Although specific agreements differ in their terms, it is common for international investment agreements to provide that investments of nationals or companies of either contracting party shall not be expropriated, nationalized or subjected to measures having equivalent effect in the territory of the other contracting party, except for a public purpose, on a non-discriminatory basis and against compensation.

Under these types of clauses, expropriation of the property of a national of a contracting party, whether direct or indirect, is prohibited entirely unless it is for a public purpose and on a non-discriminatory basis. Where expropriation occurs and it is non-discriminatory and for a public purpose, compensation must nonetheless be paid.

Typically, tobacco control measures do not involve the direct expropriation or nationalization of the property of a tobacco company, because there is no direct transfer of property from tobacco companies to the State *(80,81)*. As such, the most pertinent issue concerns what is meant by indirect expropriation or measures equivalent to expropriation.

In order for an indirect expropriation to occur, there must be some degree of interference with property rights. Although the exact degree of interference required has not been established by the case-law, in recent years tribunals have viewed indirect expropriation as requiring a taking that is "a substantially complete deprivation of the economic use and enjoyment of rights to the property, or of identifiable distinct parts thereof (i.e. it approaches total impairment)" *(82)*. Interference with an investment is necessary for an indirect expropriation to occur but, as a general rule, interference alone is not recognized as sufficient to constitute expropriation. As one tribunal put it:

> To distinguish between a compensable expropriation and a non-compensable regulation by a host State the following factors (usually in combination) may be taken into account: whether the measure is within the recognized police powers of the host State; the (public) purpose and effect of the measure; whether the measure is discriminatory; the proportionality between the means employed and the aim sought to be realized; and the bona fide nature of the measure *(83,84)*.

Although it is beyond the scope of this section to explain how all of these factors are applied, it is worth explaining what is meant by the police powers of a State, and also to touch on the concept of an investor's legitimate expectations.

With respect to the recognized police powers of the host State, it is well recognized that there is a range of regulatory activity that falls outside the bounds of indirect expropriation. As one NAFTA tribunal put it:

> not all government regulatory activity that makes it difficult or impossible for an investor to carry out a particular business, change in the law or change in the application of existing laws that makes it uneconomical to continue a particular business, is an expropriation under Article 1110. Governments, in their exercise of regulatory power, frequently change their laws and regulations in response to changing economic circumstances or changing political, economic or social considerations. Those changes may well make certain activities less profitable or even uneconomic to continue *(85)*.

This passage is consistent with the long established principle that the State may act within its sovereign police powers, which include the power to protect health, without incurring an obligation to compensate an investor for expropriation, so long as the State's conduct is not discriminatory and is not designed to cause a foreign investor to abandon property to the State or sell it at a distress price *(86,87)*. This view holds either that police powers constitute an exception to the obligation to pay compensation, or that a legitimate exercise of police powers means that a measure is not expropriatory in character. Under this view, whether a measure is implemented for a public purpose is distinct from whether that measure has an expropriatory character.

Another factor for consideration is the extent to which a foreign investor had a legitimate expectation that the value of its property would not be lost in whole or in part by the regulatory activity of the State *(88)*. As one tribunal has put it:

> as a matter of general international law, a non–discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, inter alios, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation *(89)*.

The harmful character of tobacco products and the near-universal ratification of the WHO FCTC suggest that it is reasonable for tobacco companies to expect the implementation of tobacco control measures, a factor weighing against the idea that such measures are compensable expropriation.

(ii) Fair and equitable treatment

An obligation to ensure that investments are afforded fair and equitable treatment is common to most international investment agreements. A variety of different formulations of this concept exist, making it difficult to generalize about the specific requirements of this standard of treatment *(90)*. Some formulations of the concept appear to set out a standalone treaty obligation that could apply to a wide range of conduct, whereas other formulations of the concept are limited to the international minimum standard of treatment required by customary international law.

Notwithstanding the difficulty in generalizing about the content of the fair and equitable treatment standard, it is possible to identify a variety of circumstances in which a violation of this standard may be found. These include:

- failure to provide a transparent and stable environment and to observe an investor's legitimate expectations;
- arbitrary, discriminatory or unreasonable treatment;
- denial of due process or procedural fairness;
- bad faith; or
- government coercion and harassment.

Where clauses governing fair and equitable treatment are formulated in a manner that links them to the international minimum standard and to customary international law, it is generally difficult for an investor to establish a violation of that standard. For example, after reviewing the authorities, the tribunal in *Glamis Gold v United States* stated that, "an act must be sufficiently egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons—so as to fall below accepted international standards" *(91)*. Equally, some tribunals have taken a more liberal approach, concluding that customary international law may be violated by acts that are merely unfair, inequitable or unreasonable *(92)*. Although recent case-law tends to suggest a trend towards a strict standard, such as that identified in *Glamis*, inconsistencies in the case-law mean that it is often difficult to identify the applicable standard with much certainty.

(iii) Recent cases relevant to tobacco control

Philip Morris Products (Switzerland) v Uruguay

As was noted earlier, the Request for Arbitration filed by Philip Morris Products (Switzerland) against Uruguay is a contemporary example of an international investment dispute relevant to tobacco control.

The Request for Arbitration takes issue with the following three aspects of Uruguay's tobacco packaging laws:

- the fact that Uruguayan law requires that tobacco products bear warnings covering 80% of the surface of a pack;
- the images used in mandatory health warnings, which the claimants allege are designed to shock and repulse rather than warn consumers of the actual effects of smoking; and
- a prohibition on the presentation of a single brand in multiple forms (the so-called single presentation requirement), where those forms are misleading about the health consequences of consumption, and in particular, the implementation of this prohibition in

such a way as to constitute a de facto single presentation per brand requirement.

The claimants allege that the measures violate the following three obligations under the Switzerland – Uruguay bilateral investment treaty:

- not to obstruct the management, use, enjoyment, growth or sale of investments through unreasonable or discriminatory measures (Article 3(1));
- to refrain from acts of expropriation except for a public purpose and upon payment of compensation (Article 5(1)); and
- to provide fair and equitable treatment for the claimants' investments (Article 3(2)).

In addition, the claimants argue that a so-called umbrella clause (a clause requiring Uruguay to respect commitments it has made with regard to the investments of Swiss nationals) has been violated. The claimants argue that the commitments referred to include the WTO covered agreements and that Uruguay's measures violate the TRIPS Agreement. Some would argue this is an attempt to circumvent the fact that the claimants do not have standing to bring a claim under WTO law.

It remains to be seen what the outcome of this claim will be. Although it is beyond the scope of this paper to examine the issues in detail, it is worth emphasizing that the discussion above about expropriation and fair and equitable treatment suggests that States generally have a significant degree of regulatory autonomy. There may be exceptions to this conclusion, e.g. where some specific representation has been made to a tobacco company in order to attract investment. There may also be some uncertainty produced by inconsistencies in the case-law. Nonetheless, the weight of the case-law, and State practice in implementing tobacco control measures, suggest that States may implement bona fide public health measures, including tobacco control measures, without having to pay compensation under an international investment agreement.

Philip Morris Asia Limited v Australia

In November 2011, Philip Morris Asia Limited served a Notice of Arbitration on the Commonwealth of Australia *(93)*. The Notice of Arbitration challenges plain packaging requirements in the Tobacco Plain Packaging Act 2011 (Cth) under the bilateral investment treaty between Australia and Hong Kong *(94)*.

The Tobacco Plain Packaging Act requires that tobacco products sold in Australia should be sold in plain packaging. The law implements the guidelines for the implementation of Articles 11 and 13 of the WHO FCTC and, in essence, restricts branding on product packaging to the display of brand and variant names in standardized font styles and sizes. The remainder of a pack's surface is to be taken up by health warnings required by law and a plain background.

Philip Morris Asia Limited alleges that Australia's plain packaging law violates obligations concerning expropriation of investments, fair and equitable treatment, non-impairment of investments, the provision of full protection and security for investments and an obligation to observe commitments which Australia has entered into with regard to investments of Hong Kong SAR investors *(95)*. These arguments are substantially similar to those raised by Philip Morris in its claim against Uruguay.

The Australian Government has responded to the Notice of Arbitration, indicating that Australia intends to contest the jurisdiction of the tribunal, as well as the merits of the claim. Notably, Australia has pointed out that Philip Morris Asia Limited only acquired an indirect interest in the relevant Australian subsidiary after the Australian Government had announced its decision to implement plain packaging. In this respect, an ownership interest was transferred from a Swiss company to Philip Morris Asia Limited. Given that Australia does not have an international investment agreement with Switzerland, it is possible that the transfer was made for the very purpose of bringing a claim under the bilateral investment treaty between Australia and Hong Kong.

Australia has also pointed out that PM Asia can have no grounds for complaint when PM Asia made a decision to acquire an indirect inter-

est in the Australian subsidiary *after* the Government had announced its decision to implement plain packaging, and then did exactly what it said it was going to do.

Grand River Enterprises Six Nations v United States of America

In January 2011, a decision was handed down in an international investment dispute under NAFTA that is peripherally related to tobacco control *(96)*. The dispute concerned implementation of the Master Settlement Agreement, which is a 1998 agreement between tobacco manufacturers and a number of states of the United States. The Master Settlement Agreement settled litigation and required those tobacco manufacturers that are parties to pay compensation to States that are parties. In order to minimize the adverse impact of the Master Settlement Agreement on the competitiveness of participating companies, nonparticipating companies were subjected to separate legislative requirements. These requirements were the subject of the claims.

The claimants are of Canadian nationality and are participants in the tobacco industry in the United States. The claimants made a number of arguments concerning the legislative requirements to which they were subjected. The Tribunal dismissed the majority of the claims for jurisdictional reasons. The outcome of the claims falling within the Tribunal's jurisdiction is not directly relevant to tobacco control, because the model of tobacco control offered by the Master Settlement Agreement is not a common one. Nonetheless, the Tribunal did reach a number of conclusions that may have broader implications for tobacco control.

In discussing the legitimate expectations of one of the claimants, the Tribunal noted that "trade in tobacco products has historically been the subject of close and extensive regulation by US states, a circumstance that should have been known to the Claimant from his extensive past experience in the tobacco business. An investor entering an area traditionally subject to extensive regulation must do so with awareness of the regulatory situation" *(97)*. This passage suggests that, in the absence of some representation by government to the contrary which induces a particular investment, tobacco companies are unlikely to have a legitimate expectation that they can avoid new regulation.

With respect to expropriation, the Tribunal emphasized that Article 1110 of NAFTA concerns expropriation of an investment, not part of an investment. The Tribunal stated that "expropriation must involve the deprivation of all, or a very great measure, of a claimant's property interests" *(98)*. Because the claimant continued to run a successful enterprise, the Tribunal concluded that expropriation was not established. If this rationale were applied more broadly, limited restrictions, such as those relating to the use of trademarks on packaging, would also be unlikely to constitute expropriation solely on the basis that the interference with property interests would not be sufficient. That is, it would not even be necessary to consider the regulatory character of the measure or the police powers of the State.

Feldman Karpa v Mexico

The 2002 award in *Feldman Karpa v Mexico (99)* is another NAFTA dispute concerning the tobacco industry, but peripheral to tobacco control. The claimant was a United States national who conducted a grey-market export business in Mexico. The claimant purchased cigarettes from bulk retailers and sold them abroad. The claimant argued that he was entitled under Mexican law to rebates for taxes paid at the point of purchase in Mexico for cigarettes that were subsequently exported, but had been denied those rebates on some occasions. The claimant argued that this denial amounted to expropriation of his investment and that, when his treatment was compared with the treatment of a Mexican firm operating in like circumstances, Mexico had failed to comply with its national treatment obligations.

The Tribunal rejected the expropriation claim partly on the basis that the claimant continued to run a successful business. However, a majority of the Tribunal did find, on the specific facts of this case, that Mexico had breached its national treatment obligation by providing less favourable treatment to the claimant as compared with a Mexican firm operating in like circumstances. The systemic implications of this case for the relationship between tobacco control and international investment law would appear to be minimal, because the less favourable treatment was specific to the facts of the case.

(iv) Protecting policy space: steps policy-makers can take to protect public health measures

There are a number of different ways in which policy-makers can protect their ability to implement tobacco control measures under international investment agreements. These include ensuring that specific commitments to refrain from regulation are not made to the tobacco industry, monitoring the acceptance of foreign direct investment by the tobacco industry, ensuring that new international investment agreements clarify key concepts like expropriation and fair and equitable treatment and, where possible, clarifying the application of existing international investment agreements.

Ensuring that commitments are not made to the tobacco industry

If an investor has a legitimate expectation that a host State will refrain from regulation or conduct of a particular type, this can be relevant to whether expropriation has occurred and to whether a foreign investor has been treated fairly and equitably. Commitments made by government to the tobacco industry can, therefore, make legitimate tobacco control measures susceptible to challenge under international investment agreements.

For example, when partially privatizing its national tobacco monopoly, one country entered into an agreement with the purchaser (a foreign investor) to the effect that tobacco taxes would not be increased for a period of 30 years. In the event of an increase, the Government is liable under the agreement to pay compensation to the investor. This agreement has undermined the ability of the Government to implement tobacco tax reform by altering the political and budgetary implications of reform.

Monitoring the acceptance of foreign direct investment by the tobacco industry

Some international investment agreements draw a distinction between the way a host State can treat an investment upon entry to the State and the way it treats an investment once it is established in the territory of the host State. For example, it is arguable that some agreements do not govern the establishment of investments at all, meaning that they only apply to State conduct after an investment has been admitted.

Other international investment agreements govern the way a State can treat an investment both pre- and post-establishment. Some of these agreements include clauses that permit a host State to refuse to accept a foreign investment on public health grounds or on the basis that an investment is contrary to domestic law. For example, Article 2(1) of the Switzerland – Uruguay bilateral investment treaty governs promotion and admittance of investments. The provision states:[15]

> (1) To the extent that it is possible, each Contracting Party shall encourage investments by investors of the other Contracting Party within its territory, and shall admit such investments in accordance with its legislation. The Contracting Parties mutually recognize each other's right to not authorize economic activities for reasons of safety, order, health or public morality, as well as activities reserved by law for its own investors.

In accordance with this provision, Uruguay has a broad authority to refuse to admit investments from Swiss nationals for reasons relating to the protection of health. On the other hand, Uruguay's authority to regulate once an investment is established is not stated explicitly in the bilateral investment treaty. It is possible that this clause will be interpreted to apply also to regulation of the type in question, but this is not entirely clear.

Accordingly, governments can minimize the risks posed by international investment agreements by monitoring foreign direct investment in the tobacco industry and refusing to accept inappropriate investment where they have the power to do so. For example, governments could refuse to register trademarks that make a misleading suggestion that a particular tobacco product is less harmful than another. When a foreign investor registers a trademark in a host State, the host

15 Unofficial translation into English.

State could be taken to have accepted that trademark as an investment. Under a clause such as Article 2(1) of the Uruguay – Switzerland bilateral investment treaty, a host State would be within its rights to refuse registration of a tobacco trademark that is misleading. By doing so, the host State would minimize the risk that a tobacco company could bring a claim of the type brought against Uruguay.

Ensuring that new international investment agreements clarify key concepts

There is an emerging trend in international investment agreements to clarify key concepts such as expropriation and fair and equitable treatment. Almost invariably, these clarifications reinforce domestic regulatory autonomy and the ability of governments to protect health. Accordingly, health authorities should monitor the negotiation of international investment agreements and seek to ensure that these agreements do not reduce the scope for tobacco control.

Good examples of language clarifying an agreement can be found in Chapter 11 of the Free Trade Agreement between the Association of South East Asian Nations (ASEAN), Australia and New Zealand of 2009 *(100)*. Article 9 of the Agreement governs expropriation and compensation. The most relevant part of the provision states:

> 1. A Party shall not expropriate or nationalise a covered investment either directly or through measures equivalent to expropriation or nationalisation (expropriation), except:
>
> (a) for a public purpose;
>
> (b) in a nondiscriminatory manner;
>
> (c) on payment of prompt, adequate, and effective compensation; and
>
> (d) in accordance with due process of law.

An annex to this provision clarifies the effect of Article 9. The annex states:

> 1. An action or a series of related actions by a Party cannot constitute an expropriation unless it interferes with a tangible or intangible property right or property interest in a covered investment.
>
> 2. Article 9.1 (Expropriation and Compensation) of Chapter 11 (Investment) addresses two situations:
>
> (a) the first situation is direct expropriation, where a covered investment is nationalised or otherwise directly expropriated through formal transfer of title or outright seizure; and
>
> (b) the second situation is where an action or series of related actions by a Party has an effect equivalent to direct expropriation without formal transfer of title or outright seizure.
>
> 3. The determination of whether an action or series of related actions by a Party, in a specific fact situation, constitutes an expropriation of the type referred to in Paragraph 2(b) requires a case-by-case, fact-based inquiry that considers, among other factors:
>
> (a) the economic impact of the government action, although the fact that an action or series of related actions by a Party has an adverse effect on the economic value of an investment, standing alone, does not establish that such an expropriation has occurred;
>
> (b) whether the government action breaches the government's prior binding written commitment to the investor whether by contract, licence or other legal document; and
>
> (c) the character of the government action, including, its objective and whether the action is disproportionate to the public purpose
>
> 4. Non-discriminatory regulatory actions by a Party that are designed and applied to achieve legitimate public welfare objectives, such as the protection of public health, safety, and the environment do not constitute expropriation of the type referred to in Paragraph 2(b).

This annex, and particularly paragraph 4, clarify that health measures would constitute expropriation in a very limited range of circumstances for purposes of the Agreement. The wording could be considered to represent model language on the issue.

The ASEAN – Australia – New Zealand Free Trade Agreement also clarifies the concepts of fair and equitable treatment for purposes of that Agreement. Article 6 of Chapter 11 governs the treatment of investment. The provision states:

1. Each Party shall accord to covered investments fair and equitable treatment and full protection and security.

2. For greater certainty: [16]

(a) fair and equitable treatment requires each Party not to deny justice in any legal or administrative proceedings;

(b) full protection and security requires each Party to take such measures as may be reasonably necessary to ensure the protection and security of the covered investment; and

(c) the concepts of "fair and equitable treatment" and "full protection and security" do not require treatment in addition to or beyond that which is required under customary international law, and do not create additional substantive rights.

3. A determination that there has been a breach of another provision of this Agreement, or of a separate international agreement, does not establish that there has been a breach of this Article.

The clarifications found in Article 6 confirm that the vague notion of fair and equitable treatment does not require a higher standard than the international minimum standard found in customary international law. This standard was discussed earlier, and it will be recalled that it is only in rare circumstances that a government will be considered to have violated the standard. Thus, the clarification found in Article 6 could also be considered to be model language designed to preserve policy space for host States.

A further option would be to exclude investment in the tobacco sector entirely from the scope of an international investment agreement. This would not be unusual, because many agreements include carve-outs for specific industries. For example, Article 1108 of the NAFTA governs reservations and exceptions and, at the time NAFTA was concluded, permitted Parties to carve out specific sectors, subsectors or activities.

16 [Footnote numbered 6 in the original] In the case of Indonesia, only Paragraph 2(a) and (b) shall apply where Indonesia is the Party according treatment under this Article.

Clarifying existing agreements

In addition to clarifying agreements while they are being negotiated, some States have clarified agreements after their entry into force. For example, Canada, Mexico and the United States clarified the concept of fair and equitable treatment under NAFTA after the Agreement was already in force *(101)*. Similarly, Singapore and the United States exchanged side letters clarifying aspects of the investment chapter of the Singapore – United States free trade agreement.[17] With all parties consenting, States concerned about the extent of their autonomy under existing international investment agreements could do the same. By taking this approach, States would minimize the uncertainty that stems from the vague standards often found in agreements and from the fact that different tribunals have taken inconsistent approaches to application of those standards.

3. THE ENTRY INTO FORCE OF THE WHO FCTC

Without question, the entry into force of the WHO FCTC *(102)* is the most important normative development since 2001 concerning the relationship between trade, investment and tobacco control. This international treaty creates international legal obligations to regulate tobacco. In some instances, the Convention also recognizes the rights of Parties under international law to implement tobacco control measures.

This section describes the basic structure and features of the WHO FCTC and its relevance to the relationship between trade, investment and tobacco control. In a legal sense, the WHO FCTC has at least three implications specific to the trade and investment context. Firstly, Article 5.3 of the Convention has implications for the way in which Parties interact with the tobacco industry. These implications are relevant not only to health officials, but also to other government officials working on trade, finance and investment policies. Secondly, the WHO FCTC and its guidelines may be used in the interpretation of international trade and investment agreements in the context of tobacco control measures. Thirdly, the WHO FCTC also provides some

17 See side letters to that Agreement, available at http://www.fta.gov.sg/fta_ussfta.asp?hl=13 (accessed 28 February 2012).

protection for tobacco control measures in the event of a conflict with a trade or investment agreement.

(i) WHO FCTC

The WHO FCTC is the first treaty concluded under Article 19 of the Constitution of WHO. The Convention was adopted by the World Health Assembly in 2003 and entered into force in 2005. With over 170 Parties, the Convention is one of the most widely adopted treaties in the United Nations system, and has more Parties than the WTO has Members.

Article 3 describes the objective of the WHO FCTC and its protocols as being:

> to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

The WHO FCTC obliges Parties to implement a range of tobacco control measures. Prominent among these are measures to reduce demand such as price and tax measures (Article 6), measures protecting individuals from exposure to tobacco smoke (Article 8), measures to regulate the contents of tobacco products and product disclosures (Articles 9 and 10), packaging and labelling measures (Article 11), measures relating to education, communication, training and public awareness (Article 12), restrictions on tobacco advertising, promotion and sponsorship (Article 13) and measures concerning tobacco dependence and cessation (Article 14). Measures relating to reduction of the supply of tobacco products are also prominent and include measures to reduce illicit trade in tobacco products (Article 15), measures relating to sales to and by minors (Article 16) and the provision of support for alternative livelihoods for tobacco growers (Article 17).

As a framework convention, the text of the WHO FCTC lays out a broad framework of obligations and rights that is supplemented by other instruments. At the time of writing, the Parties are negotiating an optional protocol to the Convention concerning illicit trade in tobacco products. Parties have also adopted guidelines for the implementation of Articles 5.3, 8, 11, 12, 13 and 14 of the Convention, as well as partial guidelines for Articles 9 and 10. Under the law of treaties, the legal status of the guidelines is governed by their terms. It is clear from these terms that the guidelines are not binding standalone legal obligations. However, under the law of treaties some parts of the guidelines may be considered subsequent agreements of the Parties, to be used in interpretation of the Convention's core obligations. In other instances, the guidelines may be recommendations and reflect best practices in tobacco control. It is not the purpose of this paper to comment on the legal status of the guidelines under the law of treaties and therefore, the issue is not discussed further here.

The foreword to the Convention describes it as a response to the globalization of the tobacco epidemic, which was facilitated through processes such as trade liberalization. This is true in both an indirect and a direct sense. In an indirect sense, the WHO FCTC functions as something of a counterweight to other factors that facilitate the spread of tobacco consumption from developed to developing countries. By obliging the Parties to implement tobacco control measures, the Convention counteracts other forces that have stimulated tobacco consumption. In a more direct sense, the Convention should play a role in the way trade and investment policy is set in the tobacco context. As described below, the Convention is also a significant development affecting trade and investment law in the context of tobacco control.

(ii) Implications of Article 5.3 of the WHO FCTC

Article 5.3 of the FCTC provides that "[i]n setting and implementing their public health policies in respect of 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 the implementation of this provision were adopted by

the third session of the Conference of the Parties in 2008. The aim of the guidelines is to assist Parties in meeting their legal obligations under Article 5.3 *(103)*.

One of the central principles of the guidelines is that "[b]ecause their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses." The guidelines also recommend that Parties should not give preferential treatment to the tobacco industry. In this respect, the guidelines state:

> 28. Some governments encourage investments by the tobacco industry, even to the extent of subsidizing them with financial incentives, such as providing partial or complete exemption from taxes otherwise mandated by law.
>
> 29. Without prejudice to their sovereign right to determine and establish their economic, financial and taxation policies, Parties should respect their commitments for tobacco control.
>
> Recommendations
>
> 7.1 Parties should not grant incentives, privileges or benefits to the tobacco industry to establish or run their businesses.
>
> 7.2 Parties that do not have a State-owned tobacco industry should not invest in the tobacco industry and related ventures. Parties with a State-owned tobacco industry should ensure that any investment in the tobacco industry does not prevent them from fully implementing the WHO Framework Convention on Tobacco Control.
>
> 7.3 Parties should not provide any preferential tax exemption to the tobacco industry.

These guidelines are particularly relevant in the context of international investment law. It will be recalled that it was recommended earlier in this paper that States should avoid making specific commitments to the tobacco industry in order to minimize the legal risk that the industry will have a legitimate expectation that it is entitled to special treatment. These guidelines reinforce this conclusion in light of the history of tobacco industry conduct.

The principles underlying these guidelines are also relevant to trade ministries. Trade ministries should take account of the guidelines when dealing with industry lobbying concerning market access abroad. This means that trade ministries should consider the guidelines before negotiating agreements with the tobacco industry's interests in mind and should consider the guidelines before initiating disputes at the international level. Put another way, the guidelines suggest that trade ministries should consider the implications for public health of representing tobacco industry interests abroad.

(iii) Uses of the WHO FCTC in interpretation of trade and investment agreements

It is an established principle of international law that treaties should not be interpreted in isolation from one another *(104)*.[18] Accordingly, in the context of disputes involving tobacco control measures, the WHO FCTC and its guidelines may be used in interpreting international trade and investment agreements *(105)*.

One way in which the WHO FCTC might be used in a trade or investment dispute is as evidence of a fact in dispute. For example, in the context of necessity analysis under WTO law, the Convention or its guidelines might constitute evidence of the:

- existence of certain risks to health (or of a consensus that such risks exist)
- regulatory goal underlying a measure
- contribution a measure makes to achievement of a State's regulatory goal and
- importance of the regulatory goal pursued.

The WHO FCTC and its guidelines could also be used in the application of trade and investment rules to specific tobacco control measures. For example, the fact that a measure is compelled or encouraged by the Convention or its guidelines favours the conclusion that the measure is necessary and proportional to the health risks that a State may be seeking to address. This might also affect other legal questions, such as whether a foreign investor had legitimate expectations that it could avoid regulation of the type in dispute.

18 See also Vienna Convention, Article 31(3)(c).

It is also possible that WHO FCTC guidelines could constitute international standards for purposes of the TBT Agreement.[19] This would depend on whether the WHO FCTC Conference of the Parties, or the WHO itself, is recognized as an international standards organization and whether the guidelines themselves constitute international standards. The case-law does not yet clarify this matter. In *United States – Tuna*, a recent dispute under the TBT Agreement, the panel gave a wide definition to these terms, finding that a resolution of the Member States of the Agreement on the International Dolphin Conservation Program constitutes an international standard *(106)*. Following this authority, WHO FCTC guidelines may constitute international standards for the purposes of the TBT Agreement. However, at the time of writing, this aspect of the Panel's report is under appeal. If WHO FCTC guidelines were recognized as international standards, measures in accordance with the guidelines would be presumed not to create an unnecessary obstacle to international trade.

The fact that the WHO FCTC and its guidelines may be used in the ways described above is important because it is likely to heighten the sensitivity of WTO panels and investment arbitrators to the concerns underlying tobacco control measures. This was certainly the case in *United States – Clove Cigarettes* (discussed above), in that the Panel drew upon the WHO FCTC and its guidelines to confirm its interpretation of the law in a number of respects.

(iv) Conflicts between the WHO FCTC and trade and investment agreements

Where the WHO FCTC and a trade or investment agreement govern the same subject matter, there is also a risk that the agreements will conflict. Where a conflict arises, one treaty may prevail over the other to the extent of that conflict. The question of which treaty prevails is governed first by the terms of the treaties in question and secondly by customary international law.

Article 2.2 of the WHO FCTC governs the relationship between the Convention and other treaties concluded later in time, stating:

> The provisions of the Convention and its protocols shall in no way affect the right of Parties to enter into bilateral or multilateral agreements, including regional or subregional agreements, on issues relevant or additional to the Convention and its protocols, provided that such agreements are compatible with their obligations under the Convention and its protocols. The Parties concerned shall communicate such agreements to the Conference of the Parties through the Secretariat.

By providing that subsequent agreements must be compatible with the Convention, Article 2.2 gives priority to the WHO FCTC in the event of conflict with treaties concluded later in time *(107)*. However, this clause does not govern treaties concluded earlier than the WHO FCTC, such as the WTO Agreement and many international investment agreements. Assuming the absence of wording governing conflicts in these treaties, which is ordinarily the case, conflicts are governed by customary international law. This custom is reflected in Article 30 of the Vienna Convention. In effect, customary international law gives priority to the treaty concluded later in time. Accordingly, customary international law gives the WHO FCTC priority in the event of conflicts with treaties concluded earlier and Article 2.2 of the Convention gives it priority in the event of conflict with treaties concluded later in time.

The apparent protection afforded to the WHO FCTC by these rules is qualified by the fact that conflicts can only arise where three prerequisites are met. There must be an overlap of parties and subject matter, and these overlaps must occur at the relevant point in time.

The requirement that there be an overlap of parties means that a conflict between treaties can only arise between States parties to both treaties. The rationale for this is that a treaty cannot govern relations between two States where one State has not consented to application

19 The term "standard" is defined in Annex 1 of the TBT Agreement as a "[d]ocument approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

of both treaties by becoming a party to both. For example, in the trade law context, a conflict could not arise between the WHO FCTC and the WTO Agreement in respect of a claim brought by a WTO Member that is not a Party to the WHO FCTC. Similarly, in the international investment law context, it is only where both States parties to an international investment agreement are Parties to the WHO FCTC that a conflict could arise.

The question whether two treaties govern the same subject matter concerns whether those treaties actually conflict with one another. One view is that "a conflict in the strict sense of incompatibility arises only where a party to the two treaties cannot simultaneously comply with its obligations under both treaties" *(108)*. Under this view, an obligation under the WHO FCTC could conflict with a prohibition under another treaty. However, a right in a treaty such as the WHO FCTC would give way to an obligation in a treaty such as the WTO Agreement because both treaties could be complied with if a State elects not to exercise its right (in this example, a right to control tobacco). Another view is that the concept of conflict is much broader and that the common intentions of the States in question, as reflected in the treaties, is the controlling issue *(109)*. Although the case-law tends to favour the narrow view, the broader view is gaining acceptance *(110,111)*. This view would recognize a conflict between a right set out in the WHO FCTC and a prohibition in another treaty.

The question of which treaty was concluded prior to the other can also be complex. For example, if the States in question were not both parties to a treaty from the date of its entry into force, the date of ratification is a more appropriate date to use. This causes problems where States have ratified treaties in a different order to one another because the treaties cannot be considered earlier or later for purposes of relations between the States in question *(112)*. For example, one State may ratify the WHO FCTC before acceding to the WTO Agreement, whereas another State may undertake obligations in the opposite order.

In summary, rules governing conflicts between treaties may provide some protection for measures implementing the WHO FCTC, in the rare event that those measures violate WTO law. However, the protection afforded under the rules governing conflicts is qualified because conflicts are not likely to arise often *(113)*.

4. OTHER NORMATIVE DEVELOPMENTS CONCERNING TRADE AND HEALTH

In addition to the WHO FCTC, there have been a number of other normative developments specific to the relationship between trade and health. In late 2001, the Ministerial Council of the WTO issued the Doha Declaration on the TRIPS Agreement and Public Health. In 2006, the World Health Assembly passed a resolution on trade and health, which stressed the need for greater coordination in the development of trade and health policies. In 2010, the fourth session of the Conference of the Parties to the WHO FCTC unanimously adopted the Punta del Este Declaration on implementation of the Convention. This section gives a brief explanation of these instruments and their implications. The instruments are given in full in an annex to this paper.

(i) The Doha Declaration on the TRIPS Agreement and Public Health

The Ministerial Conference of the WTO adopted the Doha Declaration in 2001 (reproduced in Annex 1 of this paper) in response to concerns about the implications of the TRIPS Agreement for access to essential medicines.

One purpose of the Declaration was to clarify application of the TRIPS Agreement, particularly in respect of the compulsory licensing of patents and parallel importing of pharmaceuticals. Because these issues are not central to tobacco control, they will not be explained further here, except to say that the Doha Declaration clarified the flexibilities available to WTO Members under TRIPS in respect of these issues. In doing so, the declaration also clarified the relationship between TRIPS and public health more generally. The Ministerial Conference stated:

> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement

can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

The objectives and principles of TRIPS are set out in Articles 7 and 8 of the Agreement, the relevant parts of which state:

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Thus, the Doha Declaration confirms the use of provisions such as Articles 7 and 8 in interpreting the substantive obligations found in TRIPS. In the tobacco control context, the general interpretive guidance to TRIPS offered by the Doha Declaration is significant because it reinforces the right of WTO Members to regulate tobacco products in a manner that affects use of trademarks. This interpretive guidance is reiterated in the Punta del Este declaration.

(ii) Resolution WHA59.26 on international trade and health

Resolution WHA59.26 of 2006 (reproduced in Annex 1 of this paper) recognized the demand for information on the possible implications of international trade and trade agreements for health and health policy. The resolution urged WHO Member States to promote a multi- stakeholder dialogue at the national level, take action to address the outcomes of that dialogue, use coordination mechanisms across relevant ministries, create constructive relationships across the public and private sector and continue to develop capacity to address the challenges that trade and trade agreements pose for health. The resolution also requested the Director-General to provide support to Member States in their efforts to frame coherent policies to address the relationship between trade and health, respond to requests for support in terms of capacity building and coordinate activities with other competent international organizations.

In contrast to the Doha Declaration, the focus of this resolution was not on the legal question of the regulatory autonomy States have under trade agreements. Rather, the resolution addressed problems of policy incoherence. In the tobacco control context, these problems are reflected in the risk that trade liberalization and foreign direct investment in the tobacco sector may indirectly stimulate demand for tobacco products. The challenges of coordinating policies so as to maximize the potential economic benefits of trade while also protecting against negative health impacts are discussed in Part IV of this paper.

(iii) The Punta del Este Declaration on Implementation of the WHO FCTC

Following the Request for Arbitration filed against Uruguay, which was described earlier, the fourth session of the Conference of the Par-

ties to the WHO FCTC issued the Punta del Este Declaration in 2010 (decision FCTC/COP4(5), reproduced in Annex 1 of this paper). In its preamble, the Declaration recalls the right to the highest attainable standard of health and the determination of the Parties to the WHO FCTC to give priority to their right to protect health. The preamble also recognizes that "measures to protect public health, including measures implementing the WHO FCTC and its guidelines fall within the power of sovereign States to regulate in the public interest" and recalls a number of provisions in WTO law that affirm the regulatory autonomy of WTO Members.

The instrument declares both the commitment of Parties to implement the WHO FCTC and their legal authority to do so within the boundaries set by agreements such as the WTO covered agreements. In the latter respect, the Declaration emphasizes the principles and objectives underlying the TRIPS Agreement, as set out in Articles 7 and 8 of that Agreement. The instrument declares that "Parties may adopt measures to protect public health, including regulating the exercise of intellectual property rights in accordance with national public health policies, provided that such measures are consistent with the TRIPS Agreement". This Declaration, like Article 8, recognizes the flexibilities inherent in TRIPS that permit measures to protect health. That is, the provisions governing protection of intellectual property rights such as trademarks leave significant scope for health measures.

The legal status of the Declaration is not entirely clear. In the context of WTO law, the instrument does not have any formal legal effect. Under the WTO Agreement (Article IX:2), only the Ministerial Conference of the WTO and the General Council have the power to issue authoritative interpretations of the WTO covered agreements.

Under international law more generally, there are two roles the Declaration could play. One interpretation is that the instrument declares or clarifies customary international law, particularly in respect of the sovereign powers of States to regulate in the public interest. This could be relevant to claims for expropriation or claims relating to fair and equitable treatment that are linked to the standards of treatment required in customary international law. Another interpretation is that the Declaration constitutes a subsequent agreement of the parties to an international investment agreement (where both are Parties to the WHO FCTC), and on this basis be used in interpretation of the agreement. A further alternative is that the Declaration will be viewed as a political instrument that has no formal legal status. It is not possible to predict which of these approaches an arbitral tribunal might take.

III. TOBACCO INDUSTRY EXPLOITATION OF TRADE AND INVESTMENT AGREEMENTS

In their 2001 paper, Bettcher et al. identified how the tobacco industry viewed trade agreements as a means of improving access to foreign markets for imported tobacco products *(114)*. Today, there are at least four primary ways in which trade and investment agreements open up foreign markets to the tobacco industry. Trade and investment agreements can facilitate market access:

- by lowering tariffs;
- through the removal of non-tariff barriers to trade, such as monopolies and regulatory measures;
- by providing a set of legal rules for the tobacco industry to refer to in attempts to resist regulation; and
- through foreign direct investment, which may increase access to the market in which an investment is made as well as access to other markets having preferential trading arrangements with the host State.

This section provides some contemporary case-studies to illustrate how the industry seeks to exploit trade and investment agreements. The case-studies draw upon documents prepared by tobacco companies and other groups that represent their interests. The section is

divided into two parts. Part 1 sets out some examples of the way the industry uses agreements to gain access. Part 2 provides some contemporary examples of the way the industry draws on trade and investment agreements in attempts to resist regulation.

A. Tobacco industry use of trade and investment agreements to access foreign markets

Trade agreements open up and liberalize markets when they require a foreign State to reduce tariffs on the importation of tobacco products. Lower tariffs reduce the costs associated with importing products, thereby increasing the competitiveness of imported products in terms of price. Thus, the tobacco industry has often lobbied trade officials in the hope that these officials would push for lower tariffs on tobacco products in the territory of trading partners. For example, during China's accession to WTO, British American Tobacco lobbied European Union and United States authorities to urge China to lower tariffs on tobacco products as a part of its accession agreement *(115)*.

Trade agreements also require the removal of some non-tariff barriers to trade. For example, in China's WTO accession negotiations, British American Tobacco lobbied European Union and United States authorities to call for the removal of a distribution monopoly and special licensing requirements for the sale of imported tobacco products *(116)*. The fact that trade agreements address non-tariff barriers to trade also creates a window for the industry to lobby trade officials on common tobacco control measures that would not violate the agreements in question. For example, when the office of the United States Trade Representative (USTR) urged Japan to open up its market to United States cigarettes in the 1980s, it also urged the country not to restrict tobacco advertising *(117)*. British American Tobacco also lobbied European Union and United States trade authorities on this point in the context of China's WTO accession *(118)*.

International trade and investment agreements may also facilitate foreign direct investment, which provides another means for tobacco companies to access a foreign market. Where tariffs on importation of tobacco products remain high, companies may choose to invest directly in a market by locating a manufacturing facility in that market. This circumvents the barriers put in place by tariffs, and makes an investor's products more competitive (in terms of price) in the country hosting the investment. Foreign direct investment can also make an investor's products more competitive in foreign markets with which the host State has preferential trading arrangements, e.g. by virtue of a regional trade agreement or free trade agreement.

1. CASE-STUDY: THE TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS

At the time of writing, a number of Asia-Pacific Economic Cooperation (APEC) Member States are negotiating a new trade and investment agreement, known as the Trans-Pacific Partnership (TPP).[20] In 2009, the United States Trade Representative published a request for comments concerning the proposed agreement. A response by PMI provides some insight into the way the company still lobbies governments with a view to improving market access and limiting regulation abroad. In its general comments, PMI shows its support for trade and investment liberalization by stating:

> As a company heavily engaged in international trade on a constant basis, PMI supports bilateral, plurilateral, and multilateral negotiations that promote freer trade in goods, services and investment; encourage uniform rules of origin; foster harmonization of legitimate, science-based regulations; increase the efficiency of moving goods, services and investment across national borders; and protect investor and intellectual property rights *(119)*.

In its submission, PMI also makes a number of specific comments concerning the coverage of the Trans-Pacific Partnership, restrictions on the use of trademarks and investor protection.

With respect to the coverage of the Partnership, Philip Morris argues that the agreement should be comprehensive and lead to the com-

20 Brunei, Chile, New Zealand and Singapore are already parties to an agreement. Australia, Malaysia, Peru, the United States and Viet Nam are negotiating to join the group on new terms.

plete elimination of tariffs on all goods. The subtext to this submission is that, if they chose to do so, Partnership countries could negotiate an agreement that does not require any additional reductions in tariffs on tobacco products. In order to avoid this possibility, PMI argues that longer phase-out periods and temporary special safeguards can be used as means of mitigating the impact of obligations to remove tariffs on sensitive products (such as tobacco products).

With respect to the protection of trademark rights, PMI states that it:

> is becoming increasingly concerned about government-sponsored initiatives that would effectively cancel or expropriate valuable trademark rights. PMI supports the inclusion of a comprehensive "TRIPs-plus" intellectual property chapter that includes a high standard of protection for trademarks and patents.

The submission details an example of this concern by identifying legislative initiatives in Australia to implement plain packaging of tobacco products, a measure recommended in the guidelines for the implementation of Articles 11 and 13 of the WHO FCTC. PMI argues that:

> by imposing severe restrictions – restrictions tantamount to expropriation – on the use of long-held and extremely valuable intellectual property rights, plain packaging would unduly limit the freedom of commercial speech, significantly restrict competition and breach Australia's obligations under the WTO TRIPs Agreement.[footnote omitted] Given, on the one hand, the lack of evidence that plain packaging will achieve its intended public health objectives [footnote omitted] and, on the other hand, the wide range of effective measures to reduce smoking incidence, plain packaging is neither an appropriate nor proportionate step to address smoking related issues. [footnote omitted]

In essence, PMI submits that the United States Trade Representative should seek strong provisions governing intellectual property in the Trans-Pacific Partnership in order to prevent initiatives such as plain packaging.

With respect to investor protection, PMI argues that the Partnership should include a strong investment chapter, including investor-State dispute settlement permitting foreign investors to bring claims before international arbitral tribunals. In essence, PMI is seeking the inclusion of provisions similar to those that it is invoking in its complaint against Uruguay before the International Centre for Settlement of Investment Disputes. This would expand the ability of the company to bring complaints of this type in countries such as Australia.[21]

Subsequent to the PMI submissions, in April 2011, the Australian Government issued a trade policy statement. It took a step back from investor-State dispute settlement and expressed the Government's intention to avoid agreements that would limit Australia's regulatory autonomy, stating:

> The Gillard Government supports the principle of national treatment – that foreign and domestic businesses are treated equally under the law. However, the Government does not support provisions that would confer greater legal rights on foreign businesses than those available to domestic businesses. Nor will the Government support provisions that would constrain the ability of Australian governments to make laws on social, environmental and economic matters in circumstances where those laws do not discriminate between domestic and foreign businesses. The Government has not and will not accept provisions that limit its capacity to put health warnings or plain packaging requirements on tobacco products or its ability to continue the Pharmaceutical Benefits Scheme.
>
> In the past, Australian Governments have sought the inclusion of investor-State dispute resolution procedures in trade agreements with developing countries at the behest of Australian businesses. The Gillard Government will discontinue this practice. If Australian businesses are concerned about sovereign risk in Australian trading partner countries, they will need to make their own assessments about whether they want to commit to investing in those countries *(120)*.

21 Australia has free trade agreements with investment chapters and bilateral investment treaties with a number of Trans-Pacific Partnership countries. However, Australia's free trade agreement with the United States includes an investment chapter that does not permit investor-State dispute settlement.

Although the Australian Government's position suggests that PMI's lobbying of the United States Trade Representative is unlikely to be successful in respect of plain packaging, the submission concerning the Trans-Pacific Partnership provides a contemporary example of the types of outcome that the tobacco industry pursues through trade and investment agreements. These outcomes include tariff reductions abroad, increased protection of tobacco industry trademarks and the right to bring claims before international arbitral tribunals with a view to resisting regulation. Alongside this strategy, Philip Morris has since brought a claim against Australia under the bilateral investment treaty between Australia and the Hong Kong.

2. USE OF FOREIGN DIRECT INVESTMENT AND STRATEGIC LOCATIONS TO IMPROVE MARKET ACCESS IN ASIA

International investment agreements and free trade agreements can create incentives for foreign investment. In the tobacco context, these agreements can be used to gain improved access to markets in a way not possible from a company's home country. These agreements can also be used for purposes of creating staging points for international litigation.

Preferential trade agreements, such as free trade agreements, offer favourable market access to participating countries. Under the GATT, WTO Members have bound tariff rates that cannot be exceeded. However, WTO Members are also permitted to enter into regional or bilateral agreements. These agreements liberalize substantially all trade between participants, meaning that substantially all tariffs are eliminated between those countries participating in a regional or bilateral agreement. The participating countries receive improved access to one another's markets, primarily in the form of lower tariffs. Goods from the participating countries are likely to receive preferential access in the sense that tariffs for goods from the territory of a participating country will be lower than from the territory of other WTO Members that do not have a similar agreement with the importing country (assuming that the importing country does not apply a tariff rate lower than the tariff ceiling in its bound commitment).

The production of Philip Morris cigarettes in the Philippines by Philip Morris Philippines Manufacturing Inc. (PMPMI) is an example of the way preferential trade agreements can be used to access foreign markets. The Philippines and Thailand are both members of ASEAN and participants in the ASEAN Free Trade Area. Under the WTO Agreement, Thailand is permitted to maintain tariffs on the importation of tobacco products, including cigarettes. At present, Thailand applies an *ad valorem* tariff of 60% for cigarettes from the territory of WTO Members. However, pursuant to agreements governing AFTA, Thailand charges no tariff on the importation of cigarettes from original AFTA Members and charges a 5% *ad valorem* tariff on the importation of cigarettes from new Members *(121)*. Accordingly, cigarettes from the Philippines are treated preferentially when compared with cigarettes from the territory of other States that lack a similar arrangement with Thailand. As discussed above, trade theory would suggest that this preferential access is likely to lower prices, increase competition and stimulate consumption in countries such as Thailand.

Another possible implication of foreign direct investment of the type undertaken in the Philippines is that it will undermine domestic tobacco control efforts by changing the political economy of tobacco control. For example, in 2003 President Arroyo claimed that the inauguration of a PMPMI production facility in the Philippines was proof of investor confidence in her Government *(122)*. Through this claim, the Government of the Philippines linked its success in terms of attracting foreign direct investment directly to the success of PMPMI. Subsequently, the Government of the Philippines supported Philip Morris by bringing the abovementioned WTO claim against Thailand in *Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines*.

This dispute also reflects the way foreign direct investment and preferential trade arrangements through free trade agreements may create a staging point for international litigation. More specifically, foreign direct investment of this type can create an incentive for a Government to bring an international claim on behalf of a tobacco company where such an incentive may not previously have existed. Similarly, in the context of investor-State dispute settlement, Philip

Morris has located its assets strategically so as to take advantage of the investment treaties to which states are parties. For example, the Australian Government has argued that Philip Morris (Asia) Ltd only acquired a stake in its Australian subsidiary after it was announced that the Government intended to implement plain packaging. The argument advanced by Australia is that Philip Morris did so for the purpose of bringing the claim in question *(123)*.

B. Tobacco industry invocation of trade and investment agreements in attempts to resist regulation

Tobacco companies often rely on international trade and investment agreements in attempts to resist domestic regulation. For example, the industry argues that many tobacco control measures violate WTO Members' legal obligations and that some measures require the payment of compensation under international investment law.

As the analysis in Part II demonstrated, actual trade or investment law disputes have been quite rare in the context of tobacco control measures that are designed to protect public health. One reason for this is that tobacco companies themselves have no standing to bring WTO claims and will only be able to bring investment claims in limited circumstances where there is jurisdiction under a relevant treaty. Another possible reason is that testing industry arguments in international dispute resolution carries a risk for the industry that those arguments will be dismissed, undermining their use in lobbying.

That said, there has been some litigation. The Philip Morris (Switzerland) claim against Uruguay is one example. However, even this dispute could be viewed as an attempt to convince a government to roll back tobacco control measures. Two aspects of the Request for Arbitration filed by Philip Morris (Switzerland) et al. suggest that the central goal is the softening of tobacco control measures rather than the pursuit of compensation. Firstly, the Request for Arbitration was filed only a few days before President Tabaré Vázquez, a vocal supporter of tobacco control, left office. The timing suggested that the claimants were testing the political commitment to tobacco control of the new Uruguayan Government. Secondly, the primary remedy sought in the Request for Arbitration is an order for the removal of the tobacco control measures rather than compensation.

The incentive for the industry to use international trade or investment agreements in lobbying or litigation is also high where potentially trend-setting measures are at issue. For example, by requiring pack warnings to cover 80% of the surface of a pack and implementing the single presentation requirement, Uruguay went further than any other country had gone before. Thus, the arbitration involving Uruguay could be seen as a means of dissuading other countries from implementing similarly strong measures or delaying such action. The same could be said in the context of plain packaging given that Australia is the first state to implement the measure.

In the case of established measures, there is likely to be less doubt about whether they are lawful. For example, the industry often argues that prohibiting descriptors such as "light" and "mild", which are misleading when used in conjunction with tobacco products, violates the TRIPS Agreement because the descriptors are also registered trademarks. For example, Japan Tobacco International has often argued that prohibiting use of the brand "Mild 7" would violate TRIPS. However, many countries have implemented such measures, giving regulators comfort as they prohibit misleading use of these terms. In a sense, there is strength in numbers, because the fact that many countries have implemented a measure may reinforce the necessity or proportionality of the measure.

The way in which the industry has targeted new potentially trend-setting measures can also be illustrated by case-studies of Australia's move to plain packaging and Canada's experience with restrictions on flavoured tobacco products.

1. CASE-STUDY: AUSTRALIA'S MOVE TO PLAIN PACKAGING

The Australian Government has passed legislation that will require tobacco products to be packaged in plain packaging from December

2012. Under the Tobacco Plain Packaging Act 2011 (Cth), all tobacco products manufactured or packaged in Australia for domestic consumption from 1 October 2012 will be required to be in plain packaging. All tobacco products sold in Australia will be required to be sold in plain packaging by 1 December 2012. The legislation will prohibit tobacco industry logos, brand imagery, colours and promotional text other than brand and variant names in a standard colour, position, font style and size; it will also restrict the use of branding and logos on tobacco products. This initiative provides a useful case-study of the way the tobacco industry invokes trade and investment agreements in its attempts to resist regulation.

The first stage of tobacco industry lobbying occurred in the context of an Australian Preventative Health Taskforce report, which examined, among other things, Australia's regulation of tobacco products. The taskforce, which was composed of expert public health practitioners, was lobbied by the tobacco industry, including on the lawfulness of plain packaging.

The second phase of lobbying came before the Australian Government announced that it would implement plain packaging, when an independent senator introduced the Plain Tobacco Packaging (Removing Branding from Cigarette Packs) Bill 2009 to the Australian Parliament. This bill was referred for a parliamentary inquiry and members of the public were permitted to make submissions. These submissions show the way the tobacco industry rallies chambers of commerce and similar industry groups, libertarian-leaning think tanks, law firms, academics and associations of intellectual property lawyers in its defence. The submissions also illustrate how the industry and its defenders use legal arguments that are selective at best, and at times misleading. These arguments appear to be designed to overwhelm public health policy-makers, who may have limited capacity to engage in legal analysis of international trade and investment law.

Tobacco industry lobbying moved into a new phase after the Australian Government committed publicly to the introduction of plain packaging. The Government released an exposure draft of the legislation and solicited public comments relating to that draft. Australia also notified other WTO Members of its intention to implement the legislation, triggering discussions in the TBT Committee and TRIPS Council.

(i) Rallying sympathetic actors to the cause

The Australian Parliament held two separate inquiries into the plain packaging legislation in 2011. Both inquiries received submissions from a wide variety of sources *(124)*. In the specific context of international trade and investment law, Philip Morris Limited presented documents prepared by law firms and academics. British American Tobacco Australia and Imperial Tobacco Australia Limited chose to address the trade and investment law issues in their own respective submissions.

In the first inquiry, at least four submissions on international trade and investment law were received from bodies devoted to libertarian causes or the protection of free enterprise, many of which are based in Washington, DC. Industry groups based in the United States and other countries, associations of intellectual property lawyers and a foreign government made other submissions.

In the first inquiry, 17 submissions argued that Australia would violate either international trade or international investment laws if it were to implement plain packaging. Although the focus of this discussion is on tobacco industry tactics, it is also worth noting that a number of submissions argued the contrary view that plain packaging is lawful under Australia's international commitments.

(ii) Selective use of legal authorities

It is not the purpose of this paper to address in detail the legal merits of the submissions made *(125,126)*. Nonetheless, the submissions do not reflect impartial attempts to weigh the legal issues and advise on the merits. Rather, legal authorities are used in a selective manner, with authorities favourable to the industry's interests being cited and unfavourable authorities being ignored. This use of law in industry lobbying is well documented. For example, Physicians for a Smoke-Free Canada have documented the way tobacco industry documents reveal the industry's own impression that agreements such as TRIPS

do not offer protection from measures such as plain packaging and how, despite this, the industry has made assertions to the contrary in its lobbying *(127)*.

With few exceptions, the submissions made to the Australian Government which opposed the plain packaging measure neglect to mention key principles that confirm the extent of Australia's regulatory autonomy. These principles include the following:

- trademark rights (as provided for under international law) are negative rights that permit a right-holder to exclude third parties from use of a trademark in certain circumstances, but are not a positive right to use of a registered trademark;
- the TRIPS Agreement contains flexibilities that permit WTO Members to regulate in the public interest, as recognized in the Doha Declaration;
- Article 8 of the TRIPS Agreement sets out the principles to be used in interpretation of the Agreement, including the principle that WTO Members may adopt measures necessary to protect public health; and
- that there is a distinction under international investment agreements between indirect expropriation and non-compensable government regulation, such as exercise of police powers.

(iii) Lobbying in the TBT Committee and TRIPS Council

At the time of writing, a number of WTO Members have taken up arguments made by the tobacco industry and presented them either in the WTO TRIPS Council or the TBT Committee. At the meeting of the TRIPS Council on 7 June 2011, the Dominican Republic expressed concern that plain packaging would violate Article 20 of the TRIPS Agreement. The Dominican Republic was supported by a number of WTO Members, including some that are Parties to the WHO FCTC *(128)*. These sentiments were again expressed at the meetings of the TRIPS Council on 24-25 October 2011 and 28-29 February 2012 *(129)*.

Similar arguments were made in the TBT Committee meetings of 15–16 June 2011 and 10-11 November 2011, where a number of WTO Members suggested that plain packaging is more trade-restrictive than necessary to achieve Australia's objective. It is quite clear from the minutes of the June meeting that Members were taking issue with plain packaging per se, and not with anything specific to Australia's implementation of plain packaging *(130)*.

The objections to plain packaging made in the TRIPS Council and TBT Committee are largely similar in substance to those raised by tobacco companies in their submissions to the Australian Government. Of importance from the perspective of WTO law is the Dominican Republic's argument that there is not sufficient scientific evidence to suggest that plain packaging will be an effective means of tobacco control *(131)*.

Australia responded to this concern by highlighting the fact that the measure had been recommended by a committee of Australia's leading public health experts and by pointing to peer-reviewed experimental research suggesting that the measure would be an effective means of achieving the objectives pursued *(132)*. The Australian plain packaging measure has received support from a number of WTO Members including Norway, Canada, Uruguay and New Zealand.

WHO was also represented at the TBT Committee meeting, as was the Convention Secretariat of the WHO FCTC. WHO explained the impact of tobacco on public health and highlighted WHO FCTC provisions and guidelines addressing plain packaging. WHO also stressed that peer-reviewed research suggests that plain packaging "would increase the impact of health warnings, reduce false and misleading messages that deceive customers into believing that some tobacco products were safer than others, and reduce the attractiveness of products to segments of the population specifically targeted by tobacco companies" *(133)*.

As was noted above, Ukraine and Honduras have each made a formal Request for Consultations with Australia, which is the first step in WTO dispute settlement.

2. CASE-STUDY: CANADA'S EXPERIENCE WITH RESTRICTIONS ON FLAVOURED TOBACCO PRODUCTS

Canada's experience with the imposition of restrictions on flavoured tobacco products provides another example of attempts by the tobac-

co industry to resist regulation through the invocation of international trade and investment agreements. This case-study also highlights how the industry rallies sympathetic actors to its cause. In addition, the case-study illustrates how international trade and investment law arguments can spill over into WHO FCTC activities.

In 2009, the Canadian Parliament passed an Act to Amend the Tobacco Act, which is also known as the Cracking Down on Tobacco Marketing Aimed at Youth Act. The Act came into force in July 2010. Among other things, the Act prohibits use of specific additives, including some flavours in cigarettes, little cigars and blunt wraps. This prohibition includes flavourings that are used to enhance the taste of American-style blended cigarettes that incorporate burley, which form less than 1% of the Canadian tobacco market. As is the case with measures implemented in the United States, there is an exemption for menthol-flavoured products. Health Canada has argued that menthol-flavoured cigarettes are already established in the market, and that the new measure is targeted at new products designed to entice children to initiate tobacco use *(134)*.

International trade and investment laws have been referred to in political debates at three levels. Firstly, various entities lobbied the Canadian Government before enactment of the Act, arguing that it would result in violation of Canada's international trade and investment commitments. These entities included tobacco companies, foreign governments and elected officials in other countries *(135)*.

Secondly, the legislation was discussed in the TBT Committee. It will be recalled from the earlier discussion of the TBT Agreement that the TBT Committee provides a forum for discussion of technical regulations. In this context, WTO Members have questioned the scientific basis for the Canadian measures and have asserted that the measures are more trade-restrictive than necessary to achieve Canada's regulatory goal *(136)*. Objections have been raised primarily by countries where burley is grown. At the time of writing, the discussions in the TBT Committee appear to be continuing, although no WTO Member has filed a formal request for consultations with Canada, which is the first step in dispute settlement.

Thirdly, controversy over the Canadian measures was reflected in negotiations during the fourth session of the Conference of the Parties to the WHO FCTC. At this session, the Parties adopted partial guidelines for the implementation of Articles 9 and 10 of the Convention. One issue considered in these negotiations was the guidance which should be given in respect of the regulation of flavourings in tobacco products. The draft guidelines presented to the Conference of the Parties suggested that Parties should either prohibit or restrict ingredients that may be used to increase palatability, including flavouring substances. During discussion of the passage, at least one Party drew upon international trade law in arguing against inclusion of the provision.

For its part, Canada has maintained the measures and argued that they comply with WTO law. Canada's actions provide an example for other States in a number of respects. The Government was prepared to answer the arguments raised in industry lobbying because it had taken legal advice prior to enactment of the legislation. The Canadian Government was also well placed to identify how the measure would affect imported and domestic products because the Government compiles basic information about the make-up of the market. The Government was thus able to determine that American-style blended cigarettes made up less than 1% of the domestic market.

The Canadian experience of restricting flavoured tobacco products, like the Australian experience with plain packaging, is continuing. Both episodes illustrate the lengths to which the industry will go in resisting new tobacco control measures as well as the way it uses trade and investment law in doing so.

IV. CHALLENGES FOR TOBACCO CONTROL POSED BY TRADE AND INVESTMENT AGREEMENTS

As discussed earlier, trade and investment agreements pose two general risks for tobacco control. One risk is that trade and investment in the tobacco sector will lead to demand stimulation and associated increases in morbidity and mortality. At the domestic level, this risk creates a challenge of policy coordination and coherence. Another risk discussed earlier was the risk that trade and investment agreements will restrict domestic regulatory autonomy. At the domestic level, there are various challenges created by this risk, including ensuring that legal capacity is sufficient to analyse the legal issues and ensuring that political will is not eroded by spurious claims. These challenges, and some of the approaches adopted to address them, are examined below.

A. Challenges in policy coordination

Governments face challenges in coordinating their public health policies with their trade and investment policies. While one government department may be pursuing a strong tobacco control policy, another

may be preparing to liberalize trade in tobacco, accept foreign direct investment in the tobacco sector or even promote the export of tobacco products. The general difficulties of policy coordination and coherence are well established at the international level *(137)*. This is also true in the context of trade and health, as is reflected in resolution WHA59.26, described earlier, and in a body of academic literature *(138)*. Ultimately, failure to coordinate policies makes it difficult to maximize the potential economic benefits of trade and investment while protecting against negative health impacts.

The fact that trade negotiations are usually shielded from public view while they are under way is a central challenge for policy coordination. The primary justification given for this secrecy is that it insulates governments from the protectionist demands of their local industries *(139)*. One criticism of this approach is that it undermines the democratic legitimacy of the trade regime and makes it difficult for civil society to have an input into what may be important public policy choices. Another more critical perspective on the status quo is that it actually has the reverse effect of that intended because it privileges a group of "insiders", including powerful industry groups which have access to government and elected officials, to the exclusion of a broader cross-section of society.

Another challenge for policy coordination lies in the barriers that exist between the health community, on the one hand, and the trade and investment communities, on the other. As a general rule, health officials have limited capacity to engage with trade and investment officials on questions of trade policy. Similarly, it is not common for trade or investment officials to have training in public health, limiting their capacity to identify the potential implications of their actions for public health. These gaps among policy-makers are most evident in the way in which some WTO Members have objected to tobacco control measures at the WTO, despite their support for the same measures in the WHO FCTC context.

In the tobacco control context, examples of failure to coordinate trade and investment policy with health policies could include the following actions by governments:

- opposing adoption of tobacco control measures that have been endorsed in other international forums, such as the by WHO FCTC Conference of the Parties;
- lowering tariffs on tobacco products without using other measures, such as taxes, to negate the impact of lower tariffs on prices;
- making specific commitments to foreign investors that could undermine the ability of the government to implement its public health agenda; and
- entering international investment agreements that fail to clarify the meaning of key provisions, such as those invoked by Philip Morris against Uruguay.

There is no perfect approach to policy coordination that works in all circumstances. The most prominent approach is the Sustainability Impact Assessment model used by the European Commission *(140)*. This approach uses external experts to conduct *ex ante* impact assessments of the economic, social and environmental implications of a potential trade agreement. The assessments examine the potential impact on European Union countries as well as on trading partners. Equally, some commentators have been critical of this process, arguing that tobacco companies have sought to ensure it is business oriented.[141]

Other commentators have called for broader changes that would build health engagement and capacity and assert health goals in trade policy. These proposals would require efforts by a variety of actors (including governments) to strengthen the evidence base on the links between trade and health. These proposals also suggest that governments should ensure that health representatives are involved in trade policy-making, e.g. through inclusion in trade delegations and the development of interdepartmental committees *(142)*.

Others still have called not so much for policy coordination, but for the assertion of health interests over economic interests, through the exclusion of tobacco products from the scope of trade agreements. This approach has, however, been criticized on the basis that it would undermine economic efficiency, protect the tobacco industries of developed countries and permit discriminatory regulatory measures in the absence of a health rationale justifying discrimination *(143,144)*.

It is not the purpose of this paper to evaluate the merits of different approaches to enhancing policy coherence. Nonetheless, it is possible to observe that the tobacco control community must monitor and engage with trade and investment policy in order to meet the challenges posed for public health.

B. Legal capacity constraints and the erosion of political will

It is well established that many countries, particularly developing countries, have very limited internal capacity in the areas of international trade and investment law. These capacity constraints limit the ability of governments to identify their international trade and investment obligations as they apply to public health measures.

A number of negative consequences may flow from legal capacity constraints. These include industry arguments appearing more credible in the eyes of government than they may actually be, and increased costs associated with tobacco control because of legal fees. These consequences may affect the political will necessary for the implementation of public health measures. For example, the prospect of litigation alters the cost–benefit analysis of implementing a tobacco control measure by increasing the up-front costs in terms of legal fees and time spent by government officials. Financial and other risks associated with losing a claim also increase the potential cost of a government policy. It also stands to reason that, wherever the legal risks associated with a tobacco control measure are significant in the policy choices a government makes, the capacity to assess those risks will be important.

A number of different approaches are used to address the limited trade law capacity of governments. The WTO Secretariat has provided extensive trade-related technical assistance to developing and least-developed countries *(145)*. Similarly, the United Nations Conference on Trade and Development has provided significant support for developing countries on international investment issues. Some WTO Members have also established the Advisory Centre on WTO Law, which provides advice and representation for developing countries and least-developed-countries *(146)*. Retaining private counsel is another approach used by some States. For example, since becoming a WTO Member in 2001, China has often retained private counsel and required them to collaborate with domestic lawyers in an attempt both to remedy limited capacity and to ensure that domestic legal capacity is built up *(147)*.

However, there are limitations on the successes of capacity building. Capacity building can be more difficult in the context of international investment law because the field lacks a unifying multilateral regime like the WTO. Internal capacity building in respect of trade and health may also be of limited interest to governments managing small economies where trade policy is not a priority. Additionally, even where trade and investment law capacity is strong, the fact that domestic trade and investment lawyers are not ordinarily familiar with the rationales underlying tobacco control measures, or the policy choices involved, may undermine their ability to give sound advice.

These limitations suggest that the merits of new initiatives may be worth exploring. One approach is to follow a capacity-building model and attempt to ensure that States have some standing capacity to address the issues. In this context, initiatives worth exploring might include training public health lawyers on the interaction of trade law with health, and sensitizing trade and investment lawyers to tobacco control and public health issues. Another approach would be to create a mechanism that provides information and assistance to States on a case-by-case basis.

V. CONCLUDING COMMENTS

A great deal has happened since Bettcher et al. published their important 2001 paper. Empirical and descriptive studies have tended to confirm that trade liberalization and foreign direct investment may pose risks for tobacco control. More notably, however, significant normative developments have helped to clarify the extent of domestic regulatory autonomy under international trade and investment agreements. WTO case-law, the entry into force of the WHO FCTC, trends in international investment law and declarations by international bodies have all given support to the conclusion that States have a broad authority to engage in tobacco control under international law.

However, as States have developed stricter tobacco control laws, their authority has begun to be tested. At the time of writing, there are a number of international disputes under way. Ukraine and Honduras have requested consultations at the WTO with Australia concerning plain packaging. Philip Morris (Switzerland) et al. have brought an international investment claim against Uruguay in respect of tobacco packaging measures. Philip Morris (Asia) has brought a claim against Australia concerning plain packaging. Similarly, Philip Morris (Nor-

way) has brought a claim in Norwegian courts that invokes a trade agreement in respect of bans on the display of tobacco products at the point of sale.

These disputes suggest that the tobacco industry will use international trade and investment agreements to resist new regulatory developments that enhance tobacco control. In this context, policy coordination and legal capacity are becoming increasingly important because the failure to protect against these kinds of challenges and to defend them when they arise could result in setbacks for public health.

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ANNEX 1 – KEY DOCUMENTS

Resolution WHA59.26 International trade and health

The Fifty-ninth World Health Assembly,

Having considered the report on international trade and health;[22]
Recalling resolutions WHA 52.19, WHA 53.14, WHA 56.23, WHA 56.27, WHA 57.14 and WHA57.19;

Recognizing the demand for information on the possible implications of international trade and trade agreements for health and health policy at national, regional and global levels;

Mindful of the need for all relevant ministries, including those of health, trade, commerce, finance and foreign affairs, to work together constructively in order to ensure that the interests of trade and health are appropriately balanced and coordinated,

1. URGES Member States:

(1) to promote multi-stakeholder dialogue at national level to consider the interplay between international trade and health;

(2) to adopt, where necessary, policies, laws and regulations that deal with issues identified in that dialogue, and to take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health, considering, where appropriate, using their inherent flexibilities;

(3) to apply or establish, where necessary, coordination mechanisms involving ministries of finance, health, and trade, and other relevant institutions, to address public-health related aspects of international trade;

22 Document A59/15.

(4) to create constructive and interactive relationships across the public and private sectors for the purpose of generating coherence in national trade and health policies;

(5) to continue to develop capacity at national level to track and analyse the potential opportunities and challenges of trade and trade agreements for health-sector performance and health outcomes;

2. REQUESTS the Director-General:

(1) to provide support to Member States, at their request and in collaboration with the competent international organizations, in their efforts to frame coherent policies to address the relationship between trade and health;

(2) to respond to Member States' requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health and to address relevant issues through policies and legislation that take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health;

(3) to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors at regional and global levels, including generating and sharing evidence on the relationship between trade and health;

(4) to report to the Sixty-first World Health Assembly, through the Executive Board, on progress made in implementing this resolution.

(Ninth plenary meeting, 27 May 2006 – Committee A, sixth report)

FCTC/COP4(5) Punta del Este Declaration on the Implementation of the WHO Framework Convention on Tobacco Control

Recalling the preamble of the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being;

Recalling the preamble of the WHO Framework Convention on Tobacco Control (WHO FCTC), which states that the Parties to the Convention are determined to give priority to their right to protect public health, due to the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke;

Recognizing that the spread of the tobacco epidemic is a global problem with serious consequences for public health and that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability affecting all segments of the population in every country in the world, particularly the younger population;

Recognizing that measures to protect public health, including measures implementing the WHO FCTC and its guidelines fall within the power of sovereign States to regulate in the public interest, which includes public health;

Taking into account the fact that Article 5.3 of the WHO FCTC states that: "in setting and implementing their public health policies in respect of tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law";

Recalling Article XX (b) of The General Agreement on Tariffs and Trade (GATT 1947) which states that nothing in the agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures necessary to protect human health, subject to the requirement that such measures 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;

Recalling Article 2.2 of the Agreement on Technical Barriers to Trade, which states that Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade and for this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective,

such as the protection of human health or safety, taking account of the risks non-fulfilment would create;

Recalling Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations;

Recalling Article 8 of the TRIPS Agreement, which states that Members may adopt measures necessary to protect public health provided that such measures are consistent with the provisions of the said Agreement;

Recalling paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health which states that: "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, it can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health";

Recalling also that paragraph 5(a) of the said Declaration recognizes in the light of paragraph 4 that: "while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include, (...) in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular in its objectives and principles",

The Parties to the WHO Framework Convention on Tobacco Control declare:

1. The firm commitment to prioritize the implementation of health measures designed to control tobacco consumption in their respective jurisdictions.

2. Their concern regarding actions taken by the tobacco industry that seek to subvert and undermine government policies on tobacco control.

3. The need to exchange information on the activities of the tobacco industry, at a national or international level, which interfere with the implementation of public health policies in respect of tobacco control.

4. That in the light of the provisions contained in Articles 7 and 8 of the TRIPS Agreement and in the Doha Declaration, Parties may adopt measures to protect public health, including regulating the exercise of intellectual property rights in accordance with national public health policies, provided that such measures are consistent with the TRIPS Agreement.

5. That Parties have the right to define and implement national public health policies pursuant to compliance with conventions and commitments under WHO, particularly with the WHO FCTC.

6. The need to urge the United Nations Ad Hoc Interagency Task Force on Tobacco Control to support multisectoral and interagency coordination for the strengthening of the implementation of the WHO FCTC within the whole United Nations system.

7. The need to include the topic "challenges to tobacco control" in the agenda of the summit on non-communicable diseases, which will be organized by the United Nations in 2011.

8. The need to urge all countries that have not done so, to ratify the WHO FCTC and implement its provisions and take measures recommended in its guidelines.

(Sixth plenary meeting, 18 November 2010)

FCTC/COP4(18) Cooperation between the Convention Secretariat and the World Trade Organization

The Conference of the Parties,

Recalling the preamble to the WHO Framework Convention on Tobacco Control (WHO FCTC), which states that Parties to the Convention are "determined to give priority to their right to protect public health";

Having considered the report by the Convention Secretariat on cooperation with international organizations and bodies for strengthening implementation of the Convention (document FCTC/COP/4/17);

Welcoming progress made in establishing cooperative relations with international organizations towards implementation of the Convention, particularly activities related to achievement of the Millennium Development Goals and other aspects of the global development agenda;

Recalling that the Fifty-ninth World Health Assembly noted the need for all relevant ministries, including those of health, trade, commerce, finance and foreign affairs, to work together constructively in order to ensure that the interests of trade and health are appropriately balanced and coordinated, and requested the Director-General to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors at regional and global levels (resolution WHA59.26);

Recalling that the joint 2002 study by WHO and the World Trade Organization (WTO) Secretariat on WTO agreements and public health1 recognizes that health and trade policy-makers can benefit from closer cooperation to ensure coherence between their different areas of responsibilities;

Mindful that closer cooperation with the WTO specifically on tobacco-control issues would support Parties to the WHO FCTC in implementing the Convention;

Recalling that WHO has observer status in the WTO Technical Barriers to Trade Committee and that it has ad hoc observer status in the TRIPS and GATS Councils,

1. REQUESTS the Convention Secretariat to invite WHO to develop, in consultation with the Convention Secretariat and appropriate international organizations or bodies, a comprehensive report for presentation to the fifth session of the Conference of the Parties that explores options for cooperation with the WTO on trade-related tobacco-control issues as a means of strengthening implementation of the Convention, and that makes recommendations on the feasibility of implementing the identified options;

2. REQUESTS the Convention Secretariat to:

(1) cooperate with the WTO Secretariat with the aim of information sharing on trade-related tobacco control issues;

(2) monitor trade disputes regarding WHO FCTC-related tobacco control measures and other trade-related issues of relevance to the implementation of the Convention;

(3) facilitate information sharing on trade-related issues between Parties to the WHO FCTC, by creating links between Parties having similar problems;

(4) to communicate regularly with the relevant WHO offices on tobacco-control issues raised at WTO committees and report on these activities regularly to the Conference of the Parties.

(Tenth plenary meeting, 20 November 2010)

Declaration on the TRIPS Agreement and Public Health (Doha Declaration)

World Trade Organization

WT/MIN(01)/DEC/2
20 November 2001
(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH
Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the most-favoured-nation and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, in respect of pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

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