



# Threats to Tobacco Control Under U.S. Trade and Investment Agreements

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# Threats to Tobacco Control Under U.S. Trade and Investment Agreements

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ASH has a long and successful history of advocacy, education and legal initiatives in the fight against tobacco. ASH uses the powers of science and law to protect health above the interests of the tobacco industry. ASH has fought for health in courts, before legislative bodies and regulatory agencies, as well as international agencies such as the United Nations and the World Health Organization. ASH was formed in 1967 by John F. Banzhaf III, and a distinguished body of physicians, attorneys and other prominent citizens who saw the need for an organization to represent nonsmokers' rights.

701 4th St. NW / Washington, DC 20001 / (202) 659-4310  
*On the web at: <http://ash.org/>*

## **Harrison Institute for Public Law – Georgetown University Law Center**

Contributors to this report include Matthew Porterfield, senior fellow; Robert Stumberg, professor of law; Kathryn Lang, policy analyst (2013-14); and Jung Hwa Song, policy analyst (2013-14). This report reflects the views of the authors and not those of Georgetown University.

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## I. Introduction and Summary

The tobacco industry increasingly uses international trade and investment rules to challenge tobacco control regulations. For example, Philip Morris is using investment treaties to challenge labeling laws in Australia and Uruguay. Several countries, including Honduras and Ukraine, are using World Trade Organization (WTO) rules to challenge Australia's plain packaging law, and Indonesia has already won a WTO dispute with the United States over Congress's ban on clove cigarettes.

This paper examines the potential use of international trade and investment rules to challenge tobacco control regulations in the United States. The rules include those in the WTO agreements as well as regional free trade agreements that are "WTO-plus" – meaning they add broader coverage or stronger trade rules to the WTO baseline. The WTO-plus negotiations on the Trans-Pacific Partnership (TPP) and the Trans-Atlantic Trade and Investment Partnership (TTIP) cover more than half of global GDP.

International dispute forums for trade and investment have broad discretion to interpret the rules. Accordingly, this paper does not reach for definitive conclusions regarding how disputes would be resolved. What we can do is identify when a trade or investment rule covers a U.S. measure and explain how that rule has been or could be used to challenge a tobacco measure. Then we identify options for reducing the threat to tobacco control measures, for example, through a combination of exceptions and exclusions (carve-outs) of tobacco measures. We also discuss legal restraints on U.S. trade policy regarding tobacco under Executive Order 13193.

### Threats to Tobacco Control from Trade and Investment Agreements

#### Rules that Apply to Trade in Goods

*1. National treatment.* One of the central trade rules is "national treatment." It prohibits governments from treating foreign products less favorably than competing domestic products. The WTO's Appellate Body found that the U.S. ban on flavored cigarettes—including clove cigarettes, which are manufactured primarily in Indonesia—violated national treatment. The Appellate Body noted that the ban exempted menthol cigarettes, which are produced primarily in the United States, and as a result, treated clove cigarettes less favorably than a competing domestic product. Similar challenges might be brought against bans on other flavored products such as bidis, which are produced primarily in India.

*2. Necessity requirement.* The WTO's rules on trade in goods also require that product regulations not be more trade restrictive than necessary to fulfill a legitimate objective. This rule has been interpreted to require, among other things, that a law materially contribute to achieving a legitimate objective and that it be the least-trade-restrictive means of achieving the objective. Various types of tobacco control regulations—including restrictions on Internet sale and tobacco packaging—might be challenged under this rule on the grounds that there is not adequate evidence that they

contribute to health objectives or that there are less trade-restrictive means for achieving those objectives.

**3. *Disclosure requirement.*** In the negotiations on the proposed Trans-Pacific Partnership (TPP), the United States reportedly supports a proposal that would prohibit countries from requiring companies to disclose proprietary product formulas—unless there is a “legitimate need” for disclosure. According to one report the prohibition is limited to food products, but earlier reports indicate that the objective is to protect other industries that are concerned about attempts to steal their trade secrets with the help of governments that might join the TPP in future years. If the latter approach is adopted, tobacco companies might be able to challenge state and federal laws requiring the disclosure of tobacco-product ingredients.

### **Rules that Apply to Trade in Services**

Trade agreements also contain provisions that restrict regulations that affect trade in services, including services relevant to tobacco such as packaging, wholesale and retail distribution, and advertising.

**1. *National treatment.*** As with the provisions that apply to trade in goods, trade rules that apply to trade in services also include a national treatment requirement that requires governments to treat foreign service suppliers “no less favorably” than like domestic service providers. Restrictions on wholesale distribution of tobacco products, such as bidis, that are primarily imported might be challenged as denying national treatment to the relevant service suppliers if similar restrictions were not applied to “like” distribution of domestically produced cigarettes.

**2. *Market Access.*** Market access rules prohibit governments from imposing quantitative limits or quotas on services, including bans, which are considered “zero quotas.” Bans on tobacco-related services, such as sale of tobacco products over the Internet, might be challenged under market access rules.

**3. *Necessity requirement.*** Some regional trade agreements include a rule stating that regulations affecting services must “not be more burdensome than necessary to ensure the quality of the service.” Necessity rules could be used to challenge tobacco control laws such as bans on Internet sales that are intended to prevent underage smokers. Such bans are not related to the “quality of the service” of retail tobacco sales and therefore are arguably more burdensome than necessary.

### **Regulatory Coherence Requirements**

Negotiators hope to include chapters in both the TPP and TTIP addressing “regulatory coherence,” which refers to procedures for promoting compatibility among the regulatory standards and procedures both within and among different countries. Given the limited information that has been disclosed, it is difficult to assess how these rules might affect tobacco control measures. However, they might be used to undermine

regulation of emerging issues such as electronic cigarettes.

### **Intellectual Property Protections**

The Ukraine and several other countries are currently challenging Australia's plain packaging law on the grounds that it violates protections for trademarks provided under the WTO's Agreement on Trade Related Aspects of Intellectual Property (TRIPS). If this argument works, tobacco companies might use it to challenge less stringent warnings in other countries, including those being developed by the U.S. Food and Drug Administration. Australia's likely defense is that TRIPS protects against third-party use, but it does not provide a right to use a trademark. But in the TPP negotiations, the United States has proposed—for the first time—a right to use geographical names for products that are not produced in the place indicated by the name. Tobacco companies or countries might use this rule to challenge packaging and advertising restrictions on tobacco brands such as Marlboro, Winston, and Salem.

### **Foreign Investor Rights**

Investment rules permit foreign investors, including tobacco companies, to directly sue countries and seek monetary compensation for regulations that adversely affect their investments. Philip Morris is using investment rules contained in bilateral investment treaties (BITs) to challenge tobacco-packaging laws in Australia and Uruguay. Using BITs or the investment chapter of free trade agreements (FTAs), similar challenges could be brought against tobacco regulations in the United States.

**1. Expropriation.** Philip Morris is arguing that limits imposed by Uruguay and Australia on use of its trademarks and graphic warnings on cigarette packages constitute indirect expropriations of its intellectual property and related investments. Tobacco companies might use a similar argument against cigarette warning labels being developed by the FDA.

**2. Fair and equitable treatment.** Philip Morris is also arguing that Australia and Uruguay violate its right under international investment treaties to “fair and equitable treatment” (FET). Philip Morris contends that FET includes both a right not to have its “legitimate expectations” frustrated by new tobacco regulations and a requirement that countries must demonstrate that the benefits of new tobacco regulations outweigh the burden they impose on tobacco companies. A number of tobacco control measures in the United States (existing and proposed) might be challenged on FET grounds. These include flavored product bans, Internet sales bans, and restrictions on packaging. Regarding the latter, Philip Morris argues that graphic warning labels as proposed by Uruguay and Australia (similar to proposed FDA labels) violate FET—independent of “plain” presentation of trademarks.

**3. National treatment.** Like trade agreements, investment agreements also contain national treatment rules that require governments to treat foreign investors and investments no less favorably than domestic investors and investments. These provisions

might be used to challenge tobacco regulations that disproportionately affect foreign producers of tobacco products. For example, if a proposed BIT between the United States and India is completed, an Indian producer of bidis (hand-rolled cigarettes) might invoke the BIT’s national treatment provision to challenge U.S. bans on bidis.

The trade and investment rules that threaten U.S. tobacco controls can be understood as three layers. The first layer includes rules that are already part of the WTO baseline. These rules are presently available for countries that might want to challenge U.S. tobacco measures, as Indonesia recently has done.

The second layer includes the WTO-plus trade rules that the United States and other countries are proposing in negotiations to create the TPP and the TTIP. The third layer is also WTO-plus. It includes the proposed expansion in the TPP and TTIP of foreign investor rights that would benefit new countries and investors that are not now covered by U.S. investment treaties or FTAs. The following chart summarizes these layers.

<b>Threats to U.S. Tobacco Controls</b>			
<b>Measure</b>	<b>WTO baseline</b>	<b>WTO-Plus: Trade Rules</b>	<b>WTO-Plus: ISDS</b>
<b>State Law</b>			
Flavored product bans	■	■	■
Internet sales	■	■	■
Product disclosure		■	■
<b>Federal Law</b>			
Flavored cigarette ban	■	■	■
Packaging requirements	■	■	■
Product disclosure		■	■
Reformulation approval		■	■
Regulation of e-cigarettes		■	■

### **Restraints on U.S. Trade Policy on Tobacco under Executive Order 13193**

Executive Order 13193 prohibits the United States from pursuing trade policies that either (1) “promote the sale or export of tobacco or tobacco products,” or (2) seek “the reduction or removal” of nondiscriminatory restrictions on marketing by foreign governments. Proposed elements of both the TPP and TTIP arguably violate these restrictions.

### **Options for Reducing the Threat**

Tobacco control advocates could address the threat posed by trade and investment agreements by participating in the U.S. trade policy process and promoting safeguards for tobacco control measures.



## **Participation in the U.S. Trade Policy Process**

Tobacco-control stakeholders have several options for participating in the U.S. trade policy process, including the formal advisory system, state-level oversight committees, and the Congressional oversight process.

## **Legal Safeguards in Future Agreements**

There are three principal approaches that could be taken to safeguard tobacco control laws under trade and investment agreements: exclusions, exceptions, and reservations.

*An exclusion* (or “carve-out”) is the strongest approach. It would simply exclude tobacco, tobacco control laws, or both, from coverage under an agreement.

*An exception* may be asserted as an affirmative defense if a measure is found to violate an agreement. To date, exceptions do not apply to important chapters of U.S. free trade agreements, for example, intellectual property and investment. The standard exception for measures necessary to protect health would operate only after a trade or investment panel takes jurisdiction over a tobacco control measure. It would require the United States to litigate seven legal tests in order to determine whether a particular tobacco control measure is permissible.

*A reservation* enables countries to exclude designated measures or categories of measures from certain provisions of a trade agreement. U.S. trade agreements typically do not permit reservations to be taken from some of the most important rules—including “fair and equitable treatment” and intellectual property rules—that the tobacco industry has been using to challenge tobacco control laws.

In August 2013, the U.S. Trade Representative (USTR) proposed language in the TPP, that would merely indicate that the TPP’s health exception “applies” to tobacco control measures. A WTO dispute panel has already described the health connection as “self-evident.” The most serious shortcoming is that the TPP health exception would not apply to the most important investment and IP rules, as noted above. The USTR’s proposal would also require TPP countries to consult one another before one could challenge a tobacco control measure under the agreement. However, consultation is already required in the dispute settlement process.

In contrast to the U.S. proposals, Malaysia has proposed a full carve-out of tobacco control measures from all chapters of the TPP. In October 2014, USTR began to vet the idea of a *partial* carve-out that would exclude tobacco measures from investment disputes.

## **Legal Safeguards for Existing Trade Agreements**

In addition to including protections for tobacco control in future agreements, safeguards could also be incorporated into existing trade and investment agreements through either *amendments* or formal *interpretations*.

## II. Trade and Investment Agreements

The universe of international trade and investment rules has changed dramatically over the last several decades. The United States has continued to negotiate trade and investment agreements—long after completion of the baseline agreements of the World Trade Organization (WTO) in 1995. These agreements are often referred to as “WTO-plus” because they expand coverage, trade rules, and investor rights in comparison to the WTO agreements. They include bilateral and regional free trade agreements (FTAs) and bilateral investment treaties (BITs). The United States is negotiating two major agreements (Pacific and Atlantic) that would encompass well over half of global GDP. Current trade and investment obligations threaten tobacco-control measures, and negotiating WTO-plus agreements without protecting tobacco control would increase the risk of international litigation.

### A. Multilateral Agreements under the WTO

The 1947 General Agreement on Tariffs and Trade (“GATT”) established the centerpiece of the global trade regime that, in 1995, became the WTO.<sup>1</sup> Parties to the GATT agreed to limit measures that impeded free trade in goods, including tariffs, taxes, quotas and subsidies. Since then, the subjects of WTO agreements and negotiations have expanded to cover intellectual property, services, and domestic regulatory authority. In addition to the growth of the substantive scope of the WTO’s rules, its membership has also expanded through the years from 23 original GATT signatories to 159 current WTO members.<sup>2</sup> Many of these countries are major tobacco exporters, centers of tobacco trade, and home to subsidiaries of U.S. tobacco companies.

Several of these WTO agreements pose threats to tobacco-control measures in the United States. These include the GATT (covering tariff and non-tariff barriers to trade in goods), the General Agreement on Trade in Services (“GATS”) (covering barriers to trade in the service sector), the Agreement on Technical Barriers to Trade (“TBT”) (covering technical regulations concerning products), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) (setting minimum standards for protection of intellectual property).<sup>3</sup>

When one member (the “complainant”) alleges that another (the “respondent”) has violated one of these agreements by enacting a particular tobacco-control measure, the dispute is settled using the WTO’s dispute settlement mechanism. This mechanism resolves disputes arising between two countries (i.e., “state-to-state” disputes) concerning

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<sup>1</sup> MICHAEL J. TREBILCOCK, UNDERSTANDING TRADE LAW 11 (2011) [hereinafter UNDERSTANDING TRADE LAW].

<sup>2</sup> *Understanding the WTO: Organization: Members and Observers*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited Oct. 31, 2013).

<sup>3</sup> *Legal Texts: the WTO Agreements*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/docs\\_e/legal\\_e/ursum\\_e.htm#nAgreement](http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement) (last visited Oct. 31, 2013).

compliance with WTO obligations.<sup>4</sup> The procedure begins with consultation between the members and progresses to a dispute settlement panel if the parties cannot reach an agreement. The panel assesses the facts and determines how WTO law applies to the dispute. If a country appeals the panel's determination, the WTO Appellate Body considers the dispute. The Appellate Body reviews questions of law and renders its decision in a "report."<sup>5</sup> The panel or Appellate Body report is adopted by the WTO membership—acting collectively as the "Dispute Settlement Body"—unless *all* WTO members agree by consensus to reject the report.<sup>6</sup>

If a respondent country does not modify a law that has been found to violate a WTO rule, the Dispute Settlement Body can authorize the complainant country to impose trade sanctions on the respondent.<sup>7</sup> The sanctions may take the form of tariffs imposed on imports of products from the losing country or suspension of rights (e.g., protection of patents) under other WTO agreements in a process known as "cross-sectoral retaliation."<sup>8</sup> Trade sanctions must be "equivalent to the level of the nullification or impairment."<sup>9</sup> In other words, the complainant country must establish an absolute dollar value of a violation. In practical terms, this means that even if they win a trade dispute, small-volume exporters may have limited leverage against large-market economies like the United States.

## **B. Regional and Bilateral Agreements Outside the WTO Framework**

In the past decade, negotiators have found it difficult to reach agreements within the WTO framework, as evidenced by their inability to complete the Doha Round of negotiations that was launched in 2001.<sup>10</sup> The WTO generally operates by consensus, which is difficult to achieve among 159 geographically, economically, and culturally diverse members. Given the impasse in the WTO, many countries have sought to further liberalize trade by forming agreements outside of the WTO framework.<sup>11</sup>

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<sup>4</sup> Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Understanding of Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, art. 1, [hereinafter DSU] *available at* [http://www.wto.org/english/tratop\\_e/dispu\\_e/dsu\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm).

<sup>5</sup> DSU art. 17.14.

<sup>6</sup> DSU, art. 16.

<sup>7</sup> *See generally* DSU, Article 22.

<sup>8</sup> *See id.*, Article 21.3(b) and (c).

<sup>9</sup> DSU, art. 22(4).

<sup>10</sup> The Doha Round, currently in its thirteenth year of negotiation, was initially intended to further open markets in both goods and services while also providing rules that would bolster developing countries' economies, but on November 26, 2013, Roberto Azevedo, the Director-General of the WTO, expressed that he was "worried... that a once-in-a-generation opportunity may have slipped our grasp." John Heilprin, *Talks on Global Free Trade Deal Collapse in Geneva*, ASSOCIATED PRESS, Nov. 26, 2013, *available at* <http://www.bigstory.ap.org/article/wto-chief-says-no-chance-global-trade-deal>.

<sup>11</sup> *See* SIMON LESTER, BRYAN MERCURIO & ARWEL DAVIES, *WORLD TRADE LAW: TEXTS, MATERIALS AND COMMENTARY* 59 (2d ed., 2012) [hereinafter "WORLD TRADE LAW"]. Countries completed the last successful round of GATT negotiations, the Uruguay Round, in 1995. There, they created the World Trade Organization, under which parties unified all prior GATT agreements would be unified, expanded the global trading system to cover trade sectors beyond trade in goods, and agreed to settle all

The United States has entered into many bilateral and regional trade and investment agreements outside the auspices of the WTO.<sup>12</sup> These agreements have allowed the United States to pursue trade rules and sector commitments that have been impossible to achieve under the WTO negotiating framework. Such “WTO-plus” provisions vary among agreements but typically include obligations regarding regulation of services, intellectual property, and foreign investment.<sup>13</sup> All of these provisions might create vulnerabilities for certain types of tobacco-control measures.

The United States has already entered into over a dozen WTO-plus FTAs<sup>14</sup> and is likely to enter into several more in the next decade. Examples of agreements containing WTO-plus provisions include the North American Free Trade Agreement (“NAFTA”) and the recently enacted United States-Korea Free Trade Agreement. Most of these agreements contain state-to-state dispute settlement procedures similar to those of the WTO,<sup>15</sup> which allow one country to suspend its obligations (impose trade sanctions) if another country violates the agreement.<sup>16</sup>

The United States has entered into BITs with forty-two countries.<sup>17</sup> BITs contain rules that set the standard of treatment that the parties to the treaty must give to each other’s investors and investments.<sup>18</sup> If the United States enacts certain new tobacco-

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subsequent disputes arising under WTO agreements. By contrast, leaders have described negotiations at the current Doha Round, begun in 2001, as being at an “impasse” and at serious risk of failure. Jane Perlez and Joe Cochrane, *Pacific Rim Leaders Urge New Focus on Global Trade Talks*, THE NEW YORK TIMES, Oct. 8, 2013, available at [http://www.nytimes.com/2013/10/09/world/asia/asia-pacific-economic-cooperation-summit.html?\\_r=0](http://www.nytimes.com/2013/10/09/world/asia/asia-pacific-economic-cooperation-summit.html?_r=0).

<sup>12</sup> Lorand Bartels, Introduction, *Regional Trade Agreements and the WTO Legal System*, 1. <http://0-www.oxfordscholarship.com.gull.georgetown.edu/view/10.1093/acprof:oso/9780199206995.001.0001/acprof-9780199206995-chapter-1>

<sup>13</sup> See *Regional Trade Agreements: Scope of RTAs*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/tratop\\_e/region\\_e/scope\\_rta\\_e.htm](http://www.wto.org/english/tratop_e/region_e/scope_rta_e.htm). This type of agreement usually also includes provisions relating to domestic standards, customs administration, competition, the environment and labor, but these provisions are not likely to affect tobacco control in the United States. See *id.*

<sup>14</sup> *Trade and Related Agreements Database*, UNITED STATES OFFICE OF TRADE AGREEMENTS NEGOTIATION AND COMPLIANCE, [http://tcc.export.gov/Trade\\_Agreements/All\\_Trade\\_Agreements/index.asp](http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/index.asp) (last accessed Mar. 23, 2014).

<sup>15</sup> See Claude Chase, Alan Yanovich, Jo-Ann Crawford, and Pamela Ugaz, *Mapping of Dispute Settlement Mechanisms in Regional Trade Agreements – Innovative or Variations on a Theme?* World Trade Org. Econ. Research and Statistics Div., Staff Working Paper, ERSD-2013-07, 14 (2013), available at [http://www.wto.org/english/res\\_e/reser\\_e/ersd201307\\_e.pdf](http://www.wto.org/english/res_e/reser_e/ersd201307_e.pdf).

<sup>16</sup> E.g. United States-Korea Free Trade Agreement art. 22.13., U.S.-Kor., effective Mar. 15, 2012, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text> [hereinafter U.S.-Kor. FTA].

<sup>17</sup> *Bilateral Investment Treaties*, UNITED STATES OFFICE OF TRADE AGREEMENTS NEGOTIATIONS AND COMPLIANCE, [http://tcc.export.gov/Trade\\_Agreements/Bilateral\\_Investment\\_Treaties/index.asp](http://tcc.export.gov/Trade_Agreements/Bilateral_Investment_Treaties/index.asp) (last visited Mar. 23, 2014).

<sup>18</sup> *Trade Guide: Bilateral Investment Treaties*, UNITED STATES OFFICE OF TRADE AGREEMENTS NEGOTIATIONS AND COMPLIANCE,

control measures, tobacco companies might assert—as they have with other countries—that the measures violate U.S. BIT obligations. BITs are particularly dangerous in these situations because they give investors the right to directly challenge the United States in an arbitration proceeding, which allows investors to bypass the U.S. judicial system.<sup>19</sup> Investors can initiate BIT claims without involving the investor’s home government. These disputes are known as “investor-state” disputes. The investment chapters of some bilateral and regional FTAs also typically include investor-state dispute settlement (ISDS) procedures.<sup>20</sup> Rather than use retaliatory trade sanctions, the principal remedy in investor-state disputes is the awarding of monetary damages.

### C. Proposed New Regional and Bilateral Trade and Investment Agreements

The United States is negotiating several agreements that could build upon the current baseline of trade and investment rules in ways that increase the vulnerabilities of tobacco-control measures. These agreements include the Trans-Pacific Partnership Agreement (“TPP”), the Transatlantic Trade and Investment Partnership (“TTIP”), the United States-China BIT, and the United States-India BIT.

The TPP, which negotiators had planned to complete before the end of 2013, would cover more than 40 percent of global GDP.<sup>21</sup> Negotiators have hailed it as a “21<sup>st</sup> century” trade agreement that will serve as a model for trade and investment negotiations in the future.<sup>22</sup> Substantively, the TPP is expected to expand trade and investment rules beyond what is contained in current agreements; many of its provisions will be WTO-plus and will provide investors with broader protections than they enjoy under the current

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[http://tcc.export.gov/Trade\\_Agreements/All\\_Trade\\_Agreements/exp\\_002699.asp#P77\\_2877](http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_002699.asp#P77_2877) (last visited Mar. 23, 2014).

<sup>19</sup> See *Trade Guide: Bilateral Investment Treaties*, UNITED STATES OFFICE OF TRADE AGREEMENTS NEGOTIATIONS AND COMPLIANCE, [http://tcc.export.gov/Trade\\_Agreements/All\\_Trade\\_Agreements/exp\\_002699.asp#P77\\_2877](http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_002699.asp#P77_2877) (last visited Mar. 23, 2014).

<sup>20</sup> Despite the fact that FTAs and BITs often provide similar protections, the United States rarely has a problem of redundancy or conflict between the two types of treaties because it rarely enters into FTA investment agreements in places where it already has an operating BIT. In cases of overlap, the United States has suspended conflicting or redundant portions of its BIT. See *Morocco Bilateral Investment Treaty*, UNITED STATES OFFICE OF TRADE AGREEMENTS NEGOTIATIONS AND COMPLIANCE, [http://tcc.export.gov/Trade\\_Agreements/All\\_Trade\\_Agreements/exp\\_005864.asp](http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_005864.asp) (last visited Mar. 23, 2014) (providing an example of the domestic legal mechanisms that the United States employs to nullify conflicting portions of a BIT and FTA).

<sup>21</sup> U.S. Dep’t of State Bureau of Public Affairs, *Fact Sheet: The Trans-Pacific Partnership: Building on U.S. Economic and Strategic Partnerships in the Asia-Pacific* (Sep. 5, 2013), <http://www.state.gov/r/pa/pl/2013/214166.htm>.

<sup>22</sup> Press Release, United States Trade Representative, Remarks by Ambassador Ron Kirk at the Washington International Trade Association (Dec. 15, 2009), available at <http://www.ustr.gov/about-us/press-office/speeches/transcripts/2009/december/remarks-ambassador-ron-kirk-washington-inte>; see also Press Release, The White House Office of the Press Sec’y, Trans-Pacific Partnership Leaders Statement (Oct. 8, 2013), available at <http://www.whitehouse.gov/the-press-office/2013/10/08/trans-pacific-partnership-leaders-statement>.

baseline of investment agreements.<sup>23</sup> Both the size and influence of the TPP's novel provisions could have a significant impact on tobacco control.

In addition to the TPP, the United States is currently negotiating the TTIP, the United States-China BIT, and the United States-India BIT. The TTIP will be an agreement between the United States and the European Union that covers nearly half of global GDP.<sup>24</sup> Like the TPP, the TTIP will contain both trade and investment terms that will expand upon the baseline of WTO and investment agreement obligations. The BITs with China and India will similarly expand on current investment obligations with regard to two of the United States' largest trading partners.<sup>25</sup> China and India are major tobacco exporters and investors, and Indian tobacco products were the first that the U.S. FDA blocked from import under new regulatory authority.<sup>26</sup> All of these agreements could pose significant threats to tobacco-control measures in the United States and should be more closely analyzed as their specific provisions become known.

### III. Vulnerable Domestic Tobacco Control Measures

The agreements discussed in part II impose obligations that tobacco companies or tobacco-friendly countries could use to challenge certain tobacco control measures, both federal and state-level, in the United States. This part describes the measures at risk; part IV discusses the various legal theories under which they are vulnerable.

#### A. Federal Law

##### 1. Tobacco-control laws

In 1964, the Surgeon General of the United States linked smoking to cancer, prompting Congress to pass the Federal Cigarette Labeling and Advertising Act in the following year.<sup>27</sup> That legislation established the ubiquitous "Surgeon General's Warning" found on tobacco packaging today.<sup>28</sup> In 1970, President Richard Nixon signed

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<sup>23</sup> Robert Stumberg, *Safeguards for Tobacco Control: Options for the TPPA*, 39 AM. J.L. & MED. 382, 385 (2013).

<sup>24</sup> Delegation of the European Union to the U.S., *Transatlantic Trade and Investment Partnership (TTIP): Creating Jobs, Boosting Exports, and Investing in the Economy of Tomorrow* (2013), available at [http://www.euintheus.org/wp-content/uploads/2013/07/TTIP\\_Publication\\_85x11in\\_High\\_res.pdf](http://www.euintheus.org/wp-content/uploads/2013/07/TTIP_Publication_85x11in_High_res.pdf)

<sup>25</sup> See *India Puts Conditions for Bilateral Investment Treaty with US*, ECON. TIMES (Jul. 23, 2013), [http://articles.economictimes.indiatimes.com/2013-07-23/news/40749425\\_1\\_investment-treaty-protection-agreement-bilateral-investment-promotion](http://articles.economictimes.indiatimes.com/2013-07-23/news/40749425_1_investment-treaty-protection-agreement-bilateral-investment-promotion).

<sup>26</sup> *US FDA starts to stamp out Indian bidis*, TIMES OF INDIA (February 23, 2014), available at <http://timesofindia.indiatimes.com/business/india-business/US-FDA-starts-to-stamp-out-Indian-bidis/pmarticleshow/30875571.cms?prtpage=1> (viewed June 30, 2014).

<sup>27</sup> See Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 HEALTH LAWYER 13 (2010); Roseann B. Termini, Esq., *Life Sciences Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods and Dietary Supplements* 508 (4<sup>th</sup> ed. 2010).

<sup>28</sup> Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 HEALTH LAWYER 13 (2010); Roseann B. Termini, Esq., *Life Sciences Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods and Dietary Supplements* 508 (4<sup>th</sup> ed. 2010).

the Public Health Cigarette Smoking Act, banning television and radio cigarette advertisements and requiring all cigarette packaging to include a label that said, “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.”<sup>29</sup> After the Federal Trade Commission (FTC) found that the mandated warning labels had little impact on public awareness, Congress passed the Comprehensive Smoking Education Act of 1984, which required more specific and emphatic health warnings to be printed on all cigarette packages and advertisements.<sup>30</sup> The new warning stated that smoking caused cancer, heart disease, and emphysema; it warned pregnant women that smoking caused serious harm to the fetus; and it reminded users that cigarette smoke contained carbon monoxide.<sup>31</sup> By the mid-1980s, scientific evidence revealed that smokeless tobacco also caused oral cancer and nicotine addiction, among other ailments.<sup>32</sup> In response, Congress passed the Comprehensive Smokeless Tobacco Health Education Act of 1986, which required three rotating warning labels to be displayed on smokeless tobacco advertisements and packaging.<sup>33</sup>

While these legislative efforts did advance the U.S. tobacco control regime, it was not until 2009 that a federal agency was given the power to regulate the tobacco industry.<sup>34</sup> The Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) granted the FDA express authority to regulate the advertising, promotion, and use of tobacco products.<sup>35</sup> The Tobacco Control Act required approval of labeling and advertising of tobacco products, banned cigarettes with flavorings other than menthol and tobacco, prohibited the distribution of free tobacco samples, and banned tobacco

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<sup>29</sup> Public Health Cigarette Smoking Act of 1969, 84 Stat. 87 (1970).

<sup>30</sup> Comprehensive Smoking Education Act, 98 Stat. 2200 (1984). *See also*, 2000 Surgeon General’s Report: Reducing Tobacco Use, Centers for Disease Control and Prevention, *available at* [http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data\\_statistics/sgr/sgr\\_2000/highlights/highlight\\_labels.htm](http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_2000/highlights/highlight_labels.htm).

<sup>31</sup> Comprehensive Smoking Education Act, 98 Stat. 2200 (1984). *See also*, 2000 Surgeon General’s Report: Reducing Tobacco Use, Centers for Disease Control and Prevention, *available at* [http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data\\_statistics/sgr/sgr\\_2000/highlights/highlight\\_labels.htm](http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_2000/highlights/highlight_labels.htm).

<sup>32</sup> 2000 Surgeon General’s Report: Reducing Tobacco Use, Centers for Disease Control and Prevention, *available at* [http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data\\_statistics/sgr/sgr\\_2000/highlights/highlight\\_labels.htm](http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_2000/highlights/highlight_labels.htm).

<sup>33</sup> Comprehensive Smokeless Tobacco Act, 15 U.S.C. § 4402. *See also*, 2000 Surgeon General’s Report: Reducing Tobacco Use, Centers for Disease Control and Prevention, *available at* [http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data\\_statistics/sgr/sgr\\_2000/highlights/highlight\\_labels.htm](http://web.archive.org/web/20070427165525/http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_2000/highlights/highlight_labels.htm).

<sup>34</sup> Prior to the enactment of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) in 2009, the Food and Drug Administration (FDA) lacked the power to regulate tobacco unless manufacturers made specific health claims. *See* Public Health Law Center at William Mitchell College of Law, *Federal Regulation of Tobacco*, *available at* <http://publichealthlawcenter.org/topics/tobacco-control/federal-regulation-tobacco>.

<sup>35</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009). For an overview of the Tobacco Control Act, *see* Overview of the Family Smoking Prevention and Tobacco Control Act: Consumer fact sheet, U.S. Food and Drug Administration, *available at* <http://www.fda.gov/tobaccoproducts/guidancecomplianceinformation/ucm246129.htm>.

companies' sponsorship of events.<sup>36</sup> The Act also required tobacco companies to disclose ingredients (including all smoke constituents) contained in new products as well as any changes to existing tobacco products.<sup>37</sup> The FDA also required face-to-face sales of cigarettes, thus banning vending machines, except in adult-only facilities "where no person younger than 18 years of age is present, or permitted to enter, at any time."<sup>38</sup>

In addition to granting the FDA regulatory authority, the Tobacco Control Act directed the Secretary of Health and Human Services to issue regulations mandating larger, more graphic health warnings on packaging for cigarettes and other tobacco products. The FDA cited the government's "substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use."<sup>39</sup> The FDA stated that by "clearly and effectively convey[ing] the negative health consequences of smoking," the new warnings would prevent nonsmokers from "initiating cigarette use" and encourage current smokers to quit.<sup>40</sup> Five tobacco companies, however, challenged this rule.<sup>41</sup> In a 2-1 decision, the court of appeals affirmed the district court's ruling in favor of the tobacco companies and vacated the rule on the grounds that it violated the right to commercial speech under the First Amendment.<sup>42</sup> The FDA decided not to seek further review and instead is working to develop new packaging regulations.<sup>43</sup>

On March 31, 2010, President Obama signed the Prevent All Cigarette Trafficking Act to regulate online and mail-order sales of tobacco products.<sup>44</sup> The Act bans delivery of tobacco products through the United States Postal Service and requires age verification

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<sup>36</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

<sup>37</sup> Family Smoking Prevention and Tobacco Control Act, 123 Stat. 1776-1858, Sec. 904 (2009).

<sup>38</sup> This rule caused vending machines to be banned in most establishments, including bars in which a minor under the age of 18 may enter if accompanied by an adult (even if the minor cannot drink).

<sup>39</sup> Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,525 (Nov. 12, 2010).

<sup>40</sup> Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,526 (Nov. 12, 2010).

<sup>41</sup> *R. J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration*, No. 11-1482 (D.D.C.), *on appeal*, No 11-5332 (D.C.Cir.).

<sup>42</sup> *R. J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration*, No. 11-1482 (D.D.C.), *on appeal*, No 11-5332 (D.C.Cir.).

<sup>43</sup> According to U.S. Food and Drug Administration spokeswoman Jennifer Haliski, "FDA will undertake research to support a new rulemaking consistent with the Tobacco Control Act...FDA will need to conduct more research and propose new rulemaking to be able to implement graphic health warning labels." See Steven Reinberg, *U.S. Supreme Court Rejects Challenge to New Cigarette Labeling*, HEALTH DAY (April 22, 2013), <http://consumer.healthday.com/public-health-information-30/food-and-drug-administration-news-315/u-s-supreme-court-rejects-challenge-to-new-cigarette-labeling-675670.html>. See also Dr. Harold K. Koh, *A Steadfast Commitment to End the Tobacco Epidemic*, HUFFINGTON POST (March 19, 2013), [http://www.huffingtonpost.com/dr-howard-k-koh/a-steadfast-commitment-to\\_b\\_2901521.html](http://www.huffingtonpost.com/dr-howard-k-koh/a-steadfast-commitment-to_b_2901521.html).

<sup>44</sup> Prevent All Cigarette Trafficking (PACT) Act, Pub. L. 111-154, 124 Stat. 1087 (Mar. 31, 2010).



upon both purchase and delivery. It requires all taxes on tobacco products to be paid and documented and authorizes higher penalties and stricter enforcement of the law.

## 2. Tariffs

The United States does not use tariffs on imported tobacco as an element of its tobacco control policy, so this paper discusses them only briefly. Although the United States' bound rates are not high, they add a significant margin to tobacco costs. For example, U.S. tariffs range as high as \$1.50 per kilogram plus 3.2% on cigarettes and \$5.48 per kilogram on unprocessed tobacco leaf (WTO bound rates).<sup>45</sup>

Any tax on tobacco can reduce its level of consumption. As shown in *Pricing Policy*, a 2014 report by the Center for Public Health Systems Analysis at Washington University in St. Louis,<sup>46</sup> tobacco consumption is highly sensitive to prices, and prices are highly sensitive to taxes. The retail price of cigarettes varies widely among states due in part to wide variation in the cumulative level of federal, state, and local excise taxes.

In this multi-layered tax environment, it is not likely that a reduction in tariffs on some tobacco products (or their contents) will be matched by a reciprocal increase in tobacco taxes at all of these levels of government. As a result, tobacco companies would realize a net windfall in revenue (for exports) or in cost (for imports). Tobacco companies would be in a position to apply this windfall to discounts, coupons, advertising, or other marketing strategies. While not a central part of the United States' tobacco control program, the tariff reductions in the TPP and TTIP are likely to provide windfall revenue to tobacco companies and have adverse consequences for tobacco use.

## B. State Law

Despite its far-reaching federal jurisdiction, the Tobacco Control Act preserved significant authority for state and local governments to address tobacco's health risks.<sup>47</sup> It did not preempt any "measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age."<sup>48</sup> Instead, it recognized a role for states to enact more restrictive tobacco control measures tailored to the needs of their jurisdictions.

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<sup>45</sup> World Trade Organization, WTO Tariff Analysis Online, <http://tariffdata.wto.org/> (last accessed February 28, 2012).

<sup>46</sup> *Pricing Policy: a Tobacco Control Guide*, CENTER FOR PUBLIC HEALTH SYSTEMS ANALYSIS AT WASHINGTON UNIVERSITY IN ST. LOUIS (Winter 2014), <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-pricing-policy-WashU-2014.pdf> (last visited Mar. 22, 2014). See Public Health Law Center at William Mitchell College of Law, *Taxation and Product Pricing*, available at <http://publichealthlawcenter.org/topics/tobacco-control/taxation-and-product-pricing>.

<sup>47</sup> Leslie Zellers and Ian McLaughlin, *State and Local Policy as a Tool to Complement and Supplement the FDA Law*, 2 HASTINGS SCI. & TECH. L.J. 117, 118 (2010).

<sup>48</sup> Family Smoking Prevention and Tobacco Control Act § 916(a)(1) (codified as 21 U.S.C. § 387p).

By 2007, state and local governments had passed more than 1,600 anti-smoking laws, many of which go further than the Tobacco Control Act.<sup>49</sup> States also remain free to adopt “best practices” policies, including tax increases, smoke-free laws, sales restrictions, or increased funding for tobacco prevention programs.<sup>50</sup> A brief overview of the at-risk categories of state-level tobacco-control regulation follows.

## 1. Electronic Cigarettes

Electronic cigarettes, or e-cigarettes, contain no tobacco but deliver nicotine and other chemicals through a battery-heated vapor that, unlike cigarette smoke, does not contain carcinogenic tar.<sup>51</sup> Tobacco companies expect that e-cigarettes sales will mitigate the losses from sharply declining cigarette sales in the United States. According to one analyst, the e-cigarette market is expected to grow from \$2 to \$10 billion by 2017.<sup>52</sup>

Thus far, a number of states and large cities have only restricted the sale of e-cigarettes to keep them from minors.<sup>53</sup> Many states are conducting research to study whether there is a need to develop more restrictive e-cigarette regulations, but they have had limited information on which to base their decisions.<sup>54</sup> To take but one example, it is

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<sup>49</sup> Clayton Mosher & Scott Akins, *DRUGS AND DRUG POLICY* 297 (2007). For instance, the Tobacco Control Act prohibited self-service tobacco displays but made an exception for adult-only facilities. Family Smoking Prevention and Tobacco Control Act § 102 (incorporating by reference 61 Fed. Reg. 44615-44618). California, however, has retained its law eliminating that exception for adult-only facilities and prohibiting all self-service displays of cigarettes. Stop Tobacco Access to Kids Enforcement (STAKE) Act § 22062(b)(1)(A).

<sup>50</sup> Federal Regulation of Tobacco: Impact on State and Local Authority, Tobacco Control Legal Consortium, July 2009, available at <http://publichealthlawcenter.org/sites/default/files/fda-1.pdf>

<sup>51</sup> Jean-Francoise Etter, Chris Bullen, Andreas D. Flouris, Murray Laugesen, Thomas Eissenberg, *Electronic nicotine delivery systems: a research agenda*, 20 *TOBACCO CONTROL* 243 (2011).

<sup>52</sup> Marina Lopes, *E-cigarettes: a burning question for regulators*, Reuters, Dec. 11, 2013, <http://www.reuters.com/article/2013/12/11/us-usa-ecigarettes-idUSBRE9BA0ZT20131211>.

<sup>53</sup> Five states and the District of Columbia have already included e-cigarettes in anti-smoking bans or moved to restrict where they can be used. Last year, New York City passed an ordinance applying traditional anti-smoking rules to e-cigarettes. See *Electronic Cigarettes – Law in New York City*, The Official Website of the City of New York, available at <http://www1.nyc.gov/nyc-resources/service/1591/electronic-cigarettes-law-in-new-york-city>. Chicago recently moved to prohibit vaping in bars, restaurants and most indoor public places. See *City Council Approves Ordinance to Regulate E-Cigarettes as Tobacco Products*, The City of Chicago’s Official Site, available at <http://www.cityofchicago.org/city/en/depts/cdph/provdrs/boh/news/2014/jan/city-council-approves-ordinance-to-regulate-e-cigarettes-as-toba.html>. See Leslie Zellers and Ian McLaughlin, *State and Local Policy as a Tool to Complement and Supplement the FDA Law*, 2 *HASTINGS SCI. & TECH. L.J.* 117, 120 (2010).

<sup>54</sup> Most of the restrictions on e-cigarettes are happening at the local level. Several cities, including New York, Boston, Chicago, and Los Angeles have prohibited the use of e-cigarettes in smoke-free zones, where cigarette use is also banned. See *E-cigarettes banned in workplaces in Boston, and city prohibits sales to minors*, BOSTON.COM (December 1, 2011); available at <http://www.boston.com/2011/12/01/ecigs/eI6HXuVTwWDRgDAEZMB5yM/story.html>; *City ban on indoor e-cigarette use goes into effect*, CHICAGO TRIBUNE (April 30, 2014), available at [http://articles.chicagotribune.com/2014-04-30/news/ct-e-cigarette-indoor-ban-met-20140430\\_1\\_e-cigarettes-e-cigarette-users-e-cigarette-smoking](http://articles.chicagotribune.com/2014-04-30/news/ct-e-cigarette-indoor-ban-met-20140430_1_e-cigarettes-e-cigarette-users-e-cigarette-smoking); *Los Angeles moves to ban e-cigarettes, joining NY*,

difficult to evaluate the safety of e-cigarettes because manufacturers are not required to disclose the ingredients of the vapor that users and those in their close vicinity inhale.<sup>55</sup>

The National Association of Attorneys General (NAAG) has asked the FDA to immediately regulate the sale and advertising of e-cigarettes as “tobacco products” under the Tobacco Control Act, as they are products made or derived from tobacco.<sup>56</sup>

The FDA has also pointed out that there is sparse research regarding either the long-term safety of e-cigarettes or their efficacy as a potential smoking cessation tool.<sup>57</sup> The FDA has proposed to begin a process for regulating e-cigarettes, the first stage of which is to announce that it “deems” e-cigarettes to be a tobacco product. The FDA’s scope of regulation includes components and parts of e-cigarettes as a whole tobacco product, but not accessories. As of this writing (June 2014), the FDA was seeking public comments on its proposal to deem e-cigarettes a tobacco product.<sup>58</sup>

## 2. Flavored Tobacco Products

States may also regulate flavored tobacco products other than cigarettes. Flavored small cigars, sometimes called flavored cigarillos, are illegal to sell in New York City, Providence, Rhode Island, and the state of Maine.<sup>59</sup> As with flavored cigarettes, flavored small cigars may also attract under-aged smokers.<sup>60</sup> A recent study by the Centers for Disease Control and Prevention revealed that nearly one in twelve high school seniors

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others, Reuters (Mar. 4, 2014), available at <http://www.reuters.com/article/2014/03/05/us-usa-e-cigarettes-california-idUSBREA2324920140305>

<sup>55</sup> Americans for Non-Smokers’ Rights, Electronic Cigarettes, <http://no-smoke.org/learnmore.php?id=645>.

<sup>56</sup> National Association of Attorneys General, AGs urge FDA to regulate sale and advertising of e-cigarettes (September 24, 2013), <http://www.naag.org/ags-urge-fda-to-regulate-sale-and-advertising-of-e-cigarettes.php>.

<sup>57</sup> *E-Cigarette Policy: The FDA Should Promptly Exercise Regulatory Authority Over E-Cigarettes*, LEGACY FOR HEALTH (January 2014), [http://www.legacyforhealth.org/content/download/3962/56088/version/1/file/LEG-Policy\\_Statement-ECigarette-JAN2014.pdf](http://www.legacyforhealth.org/content/download/3962/56088/version/1/file/LEG-Policy_Statement-ECigarette-JAN2014.pdf).

<sup>58</sup> Department Of Health And Human Services, Food and Drug Administration, 21 CFR Parts 1100, 1140, and 1143 [Docket No. FDA–2014–N–0189] RIN 0910–AG38, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 FR 23142, 23152-23153 (April 24, 2014).

<sup>59</sup> Deborah Kotz, *Teens smoking flavored little cigars despite laws banning sale to minors*, Boston Globe, Oct. 23, 2013, <http://www.boston.com/lifestyle/health/blogs/daily-dose/2013/10/22/teens-smoking-flavored-little-cigars-despite-laws-banning-sale-minors/6t8QKBWUsaoyufkdxLKoJ/blog.html>; see also, *Flavored Cigars Popular With Youth, Study Finds*, Associated Press, Oct. 22, 2013, [http://www.nytimes.com/2013/10/23/us/flavored-cigars-popular-with-youth-study-finds.html?\\_r=0](http://www.nytimes.com/2013/10/23/us/flavored-cigars-popular-with-youth-study-finds.html?_r=0).

<sup>60</sup> Legacy for Health, *Flavored Tobacco Continues to Play a Role in Tobacco Use Among Young Adults*, Apr. 3, 2013, <http://www.legacyforhealth.org/newsroom/press-releases/flavored-tobacco-continues-to-play-a-role-in-tobacco-use-among-young-adults>.

smoke sweet-flavored little cigars,<sup>61</sup> and more than forty percent of middle- and high-school students who smoke report using flavored little cigars or flavored cigarettes.<sup>62</sup>

Bidis are another type of flavored tobacco product with broad appeal to youths. Produced primarily in India, bidis are hand-rolled cigarettes with high tobacco content that are frequently sold in flavors such as cherry or chocolate.<sup>63</sup> Their candy-flavored offerings and resemblance to marijuana “joints” are believed to entice under-aged smokers. Illinois, New York, Vermont, and West Virginia have banned the sale of bidis.<sup>64</sup> In all, seven states ban flavored tobacco products.

In early 2014 the FDA blocked import of several brands of bidis from India in the first-ever exercise of its new regulatory authority. The basis for blocking imports was the failure of the Indian manufacturer to provide information that the FDA requires to establish that a tobacco product is substantially equivalent (SE) to a “predicate tobacco product.”<sup>65</sup>

### **3. Internet Sales of Tobacco Products**

States have also gone further than the federal government’s ban on U.S. Postal Service deliveries of tobacco products, which is designed to restrict youths’ access to tobacco products. For example, Washington State made it illegal to order or sell most tobacco products by telephone, mail order, or through the Internet, for shipping directly to Washington consumers using *any* parcel service.<sup>66</sup> Of the 27 states that regulate Internet sales, 12 states ban Internet sales.

### **4. Vending Machine Bans**

As discussed above, the Tobacco Control Act banned vending machine sales of cigarettes and smokeless tobacco products except for adult-only facilities where no

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<sup>61</sup> *Flavored Cigars Popular With Youth, Study Finds*, Associated Press, Oct. 22, 2013, [http://www.nytimes.com/2013/10/23/us/flavored-cigars-popular-with-youth-study-finds.html?\\_r=0](http://www.nytimes.com/2013/10/23/us/flavored-cigars-popular-with-youth-study-finds.html?_r=0).

<sup>62</sup> Centers for Disease Control and Prevention, *More than 40 percent of middle and high schoolers who smoke use flavored little cigars or flavored cigarettes*, Oct. 22, 2013, [http://www.cdc.gov/media/releases/2013/p1022-flavored-cigarettes.html?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=more-than-40-percent-of-middle-and-high-schoolers-who-smoke-use-flavored-little-cigars-or-flavored-cigarettes](http://www.cdc.gov/media/releases/2013/p1022-flavored-cigarettes.html?utm_source=rss&utm_medium=rss&utm_campaign=more-than-40-percent-of-middle-and-high-schoolers-who-smoke-use-flavored-little-cigars-or-flavored-cigarettes)

<sup>63</sup> Centers for Disease Control and Prevention, *Fact Sheet on Bidis and Kreteks*, July 9, 2013, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/bidis\\_kreteks/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/bidis_kreteks/)

<sup>64</sup> See VT STAT. ANN. TIT. 7, § 1003(e) (2000), 720 ILL. COMP. STAT. 685/4 (a-5) & 685/5 (2001), W. VA. CODE § 16-9A-9 (2001), N.Y. [PUB. HEALTH] LAW § 1399-LL (2000).

<sup>65</sup> *FDA issues first orders to stop sale, distribution of tobacco products*, FDA News Release (Feb 21, 2014); *US FDA starts to stamp out Indian bidis*, TIMES OF INDIA (February 23, 2014), available at <http://timesofindia.indiatimes.com/business/india-business/US-FDA-starts-to-stamp-out-Indian-bidis/pmarticleshow/30875571.cms?prtpage=1> (viewed June 30, 2014).

<sup>66</sup> WA Code, [RCW 70.155.140](http://leg.wa.gov/RCW/070/155/140).

minors are permitted to enter. Idaho has completely banned all vending machines selling tobacco products or e-cigarettes.<sup>67</sup>

## **5. Product Disclosure Laws**

Six states have passed product disclosure laws that go beyond the federal standard. In Minnesota, for example, tobacco product manufacturers must submit an annual report of certain substances for each brand of tobacco product.<sup>68</sup>

The following list summarizes the state and federal laws that are at risk of trade or investment litigation, as explained in part IV.

### ***State laws***

- Flavored product bans
- Internet sales
- Product disclosure

### ***Federal laws***

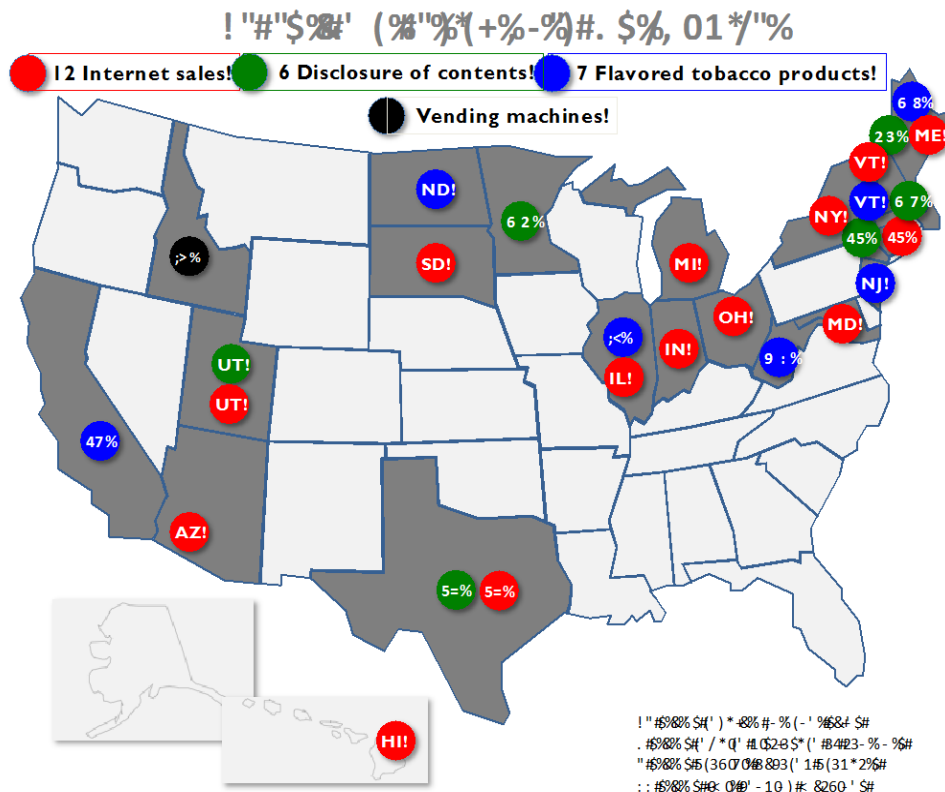
- Flavored cigarette ban
- Packaging requirements
- Product disclosure
- Reformulation approval
- Regulation of e-cigarettes

The following chart shows the geographic distribution of state laws at risk of trade conflict.

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<sup>67</sup> IDAHO CODE §39-5706 (2012).

<sup>68</sup> MINN. STAT. § 461.17 (1997).



Each of these federal and state measures could come under attack under one or several of the agreements discussed in part II. Part IV explains how the various agreements operate to threaten tobacco control measures in the United States.

#### IV. Threats to Tobacco Control in Trade and Investment Agreements

Potential threats to the tobacco control measures discussed in part III generally fall into several categories: (A) rules that apply to trade in goods, (B) rules that apply to trade in services, (C) regulatory coherence requirements, (D) intellectual property protections, and (E) foreign investor rights. This part describes the relevant investment or trade rules for each of these categories, then explain how the rules could threaten tobacco-control measures.

The trade and investment rules that threaten U.S. tobacco controls can be understood as three layers. The first layer is the WTO baseline. These rules are presently available for countries that might want to challenge U.S. tobacco measures, as Indonesia recently has done.

The second layer is WTO-plus trade rules that the United States is negotiating in the TPP and the TTIP. The third layer is also WTO-plus. It is the expansion of foreign investor rights in the TPP and TTIP that would benefit new countries and investors that

are not now covered by U.S. investment treaties or FTAs. The following chart summarizes these layers.

### Threats to U.S. Tobacco Controls

Measure	WTO baseline (state-to-state disputes)	WTO-Plus: Trade Rules (state-to-state disputes)	WTO-Plus: ISDS (investor-state disputes)
<b>State Law</b>			
Flavored product bans	■	■	■
Internet sales	■	■	■
Product disclosure		■	■
<b>Federal Law</b>			
Flavored cigarette ban	■	■	■
Packaging requirements	■	■	■
Product disclosure		■	■
Reformulation approval		■	■
Regulation of e-cigarettes		■	■

#### A. Rules that Apply to Trade in Goods

The foundational trade agreement governing trade in goods is the GATT. One of the central provisions of the GATT is the “national treatment” rule, which prohibits governments from treating imported products less favorably than competing domestic products.<sup>69</sup>

A measure’s violation of the GATT national treatment rule may nonetheless be excused if it satisfies the criteria for one of the GATT’s several general exceptions.<sup>70</sup> One exception is for measures necessary to protect human life or health.<sup>71</sup> This exception has the potential to protect tobacco-control measures from challenges under the GATT.

<sup>69</sup> See GATT art. III. One straightforward example of treatment prohibited by the GATT is a law that imposes a 50% tax on imported cell phones and only a 5% tax on domestically produced cell phones. For more complicated cases, the legal determination as to whether a country has violated national treatment is similar under the GATT and the TBT. The national treatment obligation is discussed with greater detail in context of the TBT, which is more relevant to the discussion of the agreements’ effects on tobacco control. See part IV.A.2.i., *supra*.

<sup>70</sup> See Appellate Body Report, *U.S. – Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 187, WT/DS58/AB/R (Oct. 12, 1998), available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/58abr.pdf](http://www.wto.org/english/tratop_e/dispu_e/58abr.pdf). Although the WTO DSB found that the United States’ regulations requiring specific equipment to be used in harvesting shrimp so as to avoid harm to sea turtles did violate the GATT national treatment obligation, it was nevertheless a permissible regulation under the GATT exception for measures necessary to protect “exhaustible natural resources.” GATT art. XX(g).

<sup>71</sup> GATT, art. XX(b).

The Technical Barriers to Trade Agreement (TBT Agreement) also contains rules that apply to trade in goods.<sup>72</sup> This agreement also imposes a national treatment obligation<sup>73</sup> but is more specific in its application. It applies to “technical regulations” concerning products, which are defined as mandatory “product characteristics or their related processes and production methods, including the applicable administrative provisions.”<sup>74</sup> In addition to the national treatment obligation, the TBT Agreement contains a “necessity” requirement that prohibits technical regulations that are more restrictive than necessary to accomplish a legitimate government objective.<sup>75</sup> Unlike the GATT, the TBT Agreement contains no general exceptions.<sup>76</sup>

The TPP and the TTIP are expected to incorporate the national treatment and necessity rules of the TBT Agreement, and they could impose new WTO-plus obligations regarding product regulation. For example, Malaysia has reportedly tabled a proposal that would prohibit governments from requiring companies to disclose proprietary formulas before allowing those companies to market their products.<sup>77</sup> The specific rules relating to trade in goods are discussed below; they include (1) national treatment, (2) a necessity requirement, and (3) a disclosure prohibition.

## 1. National Treatment

The WTO’s Appellate Body ruled that the U.S. ban on flavored cigarettes under the 2009 Tobacco Control Act<sup>78</sup> violates the national treatment provision of the TBT Agreement.<sup>79</sup> In *US – Clove Cigarettes*, Indonesia asserted that the United States violated the TBT Agreement by enacting a measure that prohibited flavored cigarettes.<sup>80</sup> Indonesia’s cigarette exports to the United States were almost exclusively clove-flavored cigarettes, which the new law banned. However, menthol cigarettes, which are produced primarily in the United States, were excluded from the ban. Based on this difference in treatment, Indonesia alleged that the law violated the TBT Agreement’s national treatment obligation.

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<sup>72</sup> Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1868 U.N.T.S. 120 [hereinafter TBT Agreement].

<sup>73</sup> TBT Agreement, art. 2.1.

<sup>74</sup> TBT Agreement, annex 1.

<sup>75</sup> TBT Agreement, art. 2.2.

<sup>76</sup> The TBT Agreement does contain a clause in its preamble that alludes to countries’ retained right to protect human life; however, this was not specifically written as an exception to the agreement and is not considered to protect domestic regulations as strongly as the GATT exceptions do.

<sup>77</sup> *U.S. Backs Malaysian TPP Proposal Aiming to Protect Product Formulas*, INSIDE U.S. TRADE, Jan. 9, 2013, at 31.

<sup>78</sup> 21 U.S.C.A. § 387g(a)(1)(A).

<sup>79</sup> Appellate Body Report, *U.S. – Measures Affecting the Production and Sales of Clove Cigarettes*, ¶ 298, WT/DS406/AB/R (Apr. 4, 2012) [hereinafter “*US-Clove Cigarettes*”] available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/406abr\\_e.pdf](http://www.wto.org/english/tratop_e/dispu_e/406abr_e.pdf).

<sup>80</sup> See *US-Clove Cigarettes*, ¶ 2.



TBT Article 2.1 contains the national treatment obligation and states that “products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.”<sup>81</sup> A measure will be found to violate national treatment if it (1) distinguishes between foreign and domestic competing products, or “like products,” and (2) treats the foreign product less favorably than the domestic “like product.” Even if a measure is found to violate the national treatment requirement, it may nevertheless be permissible under the TBT Agreement if the defending country can prove that the difference in treatment between the foreign and domestic products “stems exclusively from a legitimate regulatory distinction rather than reflecting discrimination against the group of imported products.”<sup>82</sup>

The Appellate Body indicated that determining whether two products are “like” focuses on “the nature and extent of a competitive relationship between and among the products at issue.”<sup>83</sup> Accordingly, although clove cigarettes and menthol cigarettes have different physical characteristics and appeal to different types of consumers, they were “like products” because they compete for some tobacco smokers.<sup>84</sup> The Appellate Body did not announce a specific threshold level of competition that would make two products “like” under the TBT Agreement. This uncertainty could generate future litigation over regulations that affect different portions of the tobacco market.

The Appellate Body noted that clove cigarettes as a group were produced primarily in Indonesia, while menthol cigarettes as a group were produced primarily in the United States.<sup>85</sup> Although neither group of products was entirely domestic or foreign, the partial flavor ban treated the foreign group less favorably than the domestic group and therefore violated the second prong of the National Treatment test.<sup>86</sup>

Finally, the Appellate Body found that the United States failed to meet its burden of showing that the distinction contained in the measure stemmed exclusively from a legitimate regulatory purpose. The United States had attempted to justify its exemption for menthol-flavored cigarettes by arguing that the exemption would avoid the costs associated with large numbers of menthol smokers experiencing withdrawal symptoms.<sup>87</sup> The Appellate Body rejected this justification and stated that it was unclear that these risks would in fact materialize.<sup>88</sup> The United States has sharply criticized this finding as the WTO’s “substituting its own judgment—instead of that of the regulator—with regard

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<sup>81</sup> TBT Agreement, art. 2:1.

<sup>82</sup> *US-Clove Cigarettes*, ¶ 182.

<sup>83</sup> *US-Clove Cigarettes*, ¶ 120.

<sup>84</sup> See WORLDTRADELAW.NET, *Dispute Settlement Commentary: Appellate Body Report: United States – Measures Affecting the Production and Sale of Clove Cigarettes*, 7-9 (Aug. 18, 2012).

<sup>85</sup> *US-Clove Cigarettes*, ¶ 224.

<sup>86</sup> *US-Clove Cigarettes*, ¶ 226.

<sup>87</sup> *US-Clove Cigarettes*, ¶ 216.

<sup>88</sup> *US-Clove Cigarettes*, ¶ 225.

to whether additional regulations should be adopted in the face of potential harms.”<sup>89</sup> The United States continues to allow menthol cigarettes while banning other flavored cigarettes, despite the WTO’s ruling.<sup>90</sup> It does so in the face of likely trade sanctions.

The combination of the loose, competition-based likeness test and the strict test establishing that a regulation was enacted exclusively for a legitimate government purpose are likely to invite future litigation over tobacco-control measures. The onus is low for challengers to establish a *prima facie* violation of National Treatment, while it is high for the United States to establish a defense. To illustrate, consider that the Appellate Body would likely classify two types of cigarettes with different levels of appeal to children and adolescents as “like products” based only on their competitive relationship. If a country sought to more aggressively regulate the type that is more appealing to children, as some jurisdictions do by tightly regulating bidis,<sup>91</sup> the Appellate Body would most likely find that the country discriminates between “like products.” One product’s greater appeal to children would not render the two products unlike. If the more attractive type happened to be a foreign product, the country being challenged would then have to prove that its regulation stemmed *exclusively* from a legitimate regulatory purpose. As one observer has noted, this would be difficult to prove in *any* case, even our seemingly legitimate example, because “domestic policy is driven by the art of the possible. Regulatory changes affecting small numbers of people are often more politically feasible than those affecting large numbers.”<sup>92</sup> Rarely do all of the parties necessary to enact a law or regulation do so for a singly unified purpose, yet this seems to be what the Appellate Body now requires.

Certain flavored products, like cloves in *US – Clove Cigarettes*, are primarily produced abroad. Bidis, for example, are primarily imported from India.<sup>93</sup> Since all tobacco products are, on some level, competitors, countries might challenge bidi bans or flavoring bans on the theory that they afford less favorable treatment to foreign “like products,” in violation of both the GATT and the TBT Agreement.

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<sup>89</sup> *Statements by the United States at the April 24, 2012, DSB Meeting*, ¶ 4.A, [geneva.usmission.gov/2012/04/25/statements-by-the-united-states-at-the-april-24-2012-dsb-meeting/](http://geneva.usmission.gov/2012/04/25/statements-by-the-united-states-at-the-april-24-2012-dsb-meeting/).

<sup>90</sup> The United States has neither repealed the ban on flavored cigarettes nor extended it to cover menthol cigarettes. Instead, it has taken some steps to explore the feasibility of banning menthol cigarettes. Jamie Strawbridge, *U.S. Implementation of Adverse WTO Rulings: A Closer Look at the Tuna-Dolphin, COOL, and Clove Cigarettes Cases*, AMERICAN SOC. OF INT’L LAW (Oct. 30, 2013), <http://www.asil.org/insights/volume/17/issue/23/us-implementation-adverse-wto-rulings-closer-look-tuna-dolphin-cool-and>. The United States maintains that it has complied with the WTO ruling, and it is currently disputing with Indonesia the procedures by which Indonesia might be able to implement retaliatory trade measures. *U.S., Indonesia Clove Cigarette Fight Raises Key DSU Issues In WTO*, Inside U.S. Trade (Sep. 5, 2013), <http://0-insidetrade.com.gull.georgetown.edu/Inside-US-Trade/Inside-U.S.-Trade-09/06/2013/us-indonesia-clove-cigarette-fight-raises-key-dsu-issues-in-wto/menu-id-710.html>.

<sup>91</sup> See Part II, *supra*.

<sup>92</sup> See Todd Tucker, ‘One of These Things Is Not Like the Other’: Likeness and Detrimental Impacts in *US – Clove Cigarettes*, 5 TDM J. 3, 5 (2012).

<sup>93</sup> *Fact Sheet on Bidis and Kreteks*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Jul. 9, 2013), [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/bidis\\_kreteks/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/bidis_kreteks/).

## 2. Necessity Requirement

Article 2.2 of the TBT Agreement requires that “technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective.”<sup>94</sup> While the panel in *US – Clove Cigarettes* found that the ban on clove cigarettes did not violate the necessity test of Article 2.2, the test it used is instructive. To be permissible, a measure must (1) pursue a legitimate objective, (2) not be broader than necessary to achieve that objective, (3) make a material contribution to that objective, and (4) be the least restrictive measure capable of achieving that objective.<sup>95</sup> For the fourth prong, the burden is on the challenging country to identify a less trade-restrictive measure.

In *US-Clove Cigarettes*, Indonesia also alleged that the clove ban violated Article 2.2. The panel in *US-Clove Cigarettes* found that the flavor ban did not violate this article because (1) the ban pursued the legitimate objective of reducing youth smoking, (2) it was not overly broad, (3) it made a material contribution to the U.S. objective, and (4) Indonesia had not met its burden of identifying a less restrictive alternative measure that would be capable of fulfilling the U.S. objective.<sup>96</sup>

Although the flavor ban survived scrutiny under Article 2.2, the four-part test applied under this provision invites future litigation over the necessity of tobacco-control measures due to its complexity and subjectivity.<sup>97</sup> The most vulnerable tobacco-control measures—both at risk of litigation and at risk of losing a trade dispute—are those that have either not been clearly shown (e.g., by scientific experiments) to advance their legitimate purpose, or those that, while possibly advancing their legitimate purpose, impose additional burdens that do not themselves advance the purpose. These characteristics create vulnerabilities under prongs 2, 3, and 4 of the necessity test.

Vulnerable measures under TBT Article 2.2 could include the following:

- bans and restrictions on Internet retail sale of tobacco,
- required disclosure of tobacco product contents,
- required FDA approval of formula changes, and
- regulation of packaging and contents of e-cigarettes as “tobacco products.”

Measures from all four of these categories are vulnerable to the arguments that they are broader than necessary to achieve the objective (prong 2), that they do not make a material contribution to that objective (prong 3), or that a less-restrictive measure would

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<sup>94</sup> TBT Agreement, art. 2.2.

<sup>95</sup> See Panel Report, *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 7.430 to 7.431, WT/DS406/R (Sep. 2, 2011).

<sup>96</sup> Panel Report, *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 7.430 to 7.431, WT/DS406/R (Sep. 2, 2011).

<sup>97</sup> For example, there is no clear metric capable of measuring whether or not a tobacco control measure contributes “materially,” or whether one hypothetical alternative would be less restrictive than the existing measure.

be capable of achieving the same objective (prong 4). Internet retail restrictions and e-cigarette regulation are particularly vulnerable.

Bans and restrictions on Internet retail sales do contribute to the legitimate purpose of reducing underage access to tobacco products, but they place high burdens on Internet retailers. These burdens might prompt a challenging country to argue either that the restrictions exceed the level of protection sought by the United States (prong 2), or to suggest an alternate method of preventing underage access that does not place as high a burden on Internet retailers (prong 4).

E-cigarette regulation is also vulnerable under prong 3 and potentially under prong 1, since it is not yet clear whether a connection exists between e-cigarette use and smoking or whether e-cigarettes themselves pose significant health risks.<sup>98</sup>

Regardless of the precise theory of attack or the specific tobacco-control measure that is targeted, a trade panel's inquiry into these issues would be intensively fact-based, as it was in the *US –Clove Cigarettes* case. This makes any dispute settlement proceeding addressing Article 2.2 time-consuming, expensive, and difficult to use as precedent in future cases.<sup>99</sup> This continued uncertainty could encourage more litigation under this Article.

### 3. Disclosure Prohibition

In the TPP negotiations, the United States reportedly supports a Malaysian proposal that would prohibit a country from requiring that companies disclose proprietary formulas—unless there is a “legitimate need” for disclosure—as a precondition to entering the country's market.<sup>100</sup> According to USTR, this proposal complements U.S. proposals for enforcement of trade secrets, including criminal penalties for theft of trade secrets.<sup>101</sup>

According to one report, the proposed prohibition is limited to food products.<sup>102</sup> But earlier reports state that the objective is also to protect chemical, pharmaceutical or other industries concerned about attempts to steal their trade secrets with the help of governments, particularly those that might join the TPP in future years.<sup>103</sup> If this approach is adopted, tobacco companies might be able to challenge state and federal laws requiring the disclosure of the ingredients of tobacco products.<sup>104</sup>

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<sup>98</sup> See part II, *supra*.

<sup>99</sup> See Panel Report *United States-Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/R (Sep. 2, 2011) 98-126.

<sup>100</sup> *U.S. Backs Malaysian TPP Proposal Aiming to Protect Product Formulas*, INSIDE U.S. TRADE, Jan. 9, 2013, at 31.

<sup>101</sup> *Id.*

<sup>102</sup> *Civil Society Groups Air Worries About Malaysian TPP Formula Proposal*, INSIDE U.S. TRADE (March 8, 2013).

<sup>103</sup> *U.S. Backs Malaysian TPP Proposal Aiming to Protect Product Formulas*, INSIDE U.S. TRADE, Jan. 9, 2013, at 31.

<sup>104</sup> See part III, *supra*.

## B. Rules that Apply to Trade in Services

The WTO's General Agreement on Trade in Services ("GATS") imposes obligations on countries with respect to any measure that affects trade in services in agreed-upon sectors, including rules on market access and national treatment.<sup>105</sup> Every sale of a tobacco product involves related services such as packaging, wholesale and retail distribution, advertising, etc.<sup>106</sup> Tobacco-control measures that negatively affect sales could have similar consequences for these services, thereby creating GATS vulnerabilities.

The TPP and TTIP are expected to include chapters on cross-border services that will build upon the GATS rules by adding a necessity test for domestic regulations.<sup>107</sup>

Furthermore, while the GATS is a "positive-list" agreement, meaning that countries must affirmatively list sectors that the agreement will govern, the TPP and TTIP will likely be "negative-list" agreements. This means that countries must specifically take a reservation to exclude a sector or type of measure that they do not wish to include.<sup>108</sup> The United States, however, has already made commitments under GATS in service sectors relevant to tobacco control, including advertising, packaging, and both wholesale and retail distribution services.<sup>109</sup> So for the United States, tobacco measures that affect trade in these sectors are already exposed to trade litigation.

The specific rules relating to trade in services include (1) national treatment, (2) market access, and (3) a necessity requirement. Before discussing these rules, it is important to note that the true risks that services rules present may be broader than

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<sup>105</sup> General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization art. 1, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 284 (1999), 1869 U.N.T.S. 183, 33 I.L.M. 1167 (1994) [hereinafter GATS]

<sup>106</sup> See JANE KELSEY, INTERNATIONAL TRADE LAW AND TOBACCO CONTROL: TRADE AND INVESTMENT LAW ISSUES RELATING TO PROPOSED TOBACCO CONTROL POLICIES TO ACHIEVE AN EFFECTIVELY SMOKEFREE NEW ZEALAND BY 2025, 36 (2012).

<sup>107</sup> Notwithstanding the "cross-border" name of these chapters, they are likely to apply some rules (market access, domestic regulation, and transparency) to measures that regulate purely domestic services by subsidiaries of foreign holding companies. Cross-border services is mode 1 in the GATS lexicon; the other three modes of supply covered under GATS are: (2) Consumption abroad; (3) Commercial presence; and (4) Presence of natural persons. GATS, art. 1.2 (Scope and Definition). Article 12.1.3(a) of the United States – Korea FTA provides, "Articles 12.4 [Market Access], 12.7 [Domestic Regulation], and 12.8 [Transparency] shall also apply to measures adopted or maintained by a Party affecting the *supply of a service in its territory by a covered investment*." United States-Korea Free Trade Agreement, U.S.-Kor., ch. 12, art. 12.1.3(a), *effective* Mar. 15, 2012, Office of the U.S. Trade Representative, <http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text> [hereinafter U.S.-Kor. FTA] (emphasis added).

<sup>108</sup> See *Stumberg, supra*, at 391; IAN FERGUSSON & BRUCE VAUGHN, CONG. RESEARCH SERV., R40502, THE TRANS-PACIFIC PARTNERSHIP AGREEMENT 7 (2011).

<sup>109</sup> See WTO, Schedules of commitments and lists of Article II exemptions, [http://www.wto.org/english/tratop\\_e/serv\\_e/serv\\_commitments\\_e.htm](http://www.wto.org/english/tratop_e/serv_e/serv_commitments_e.htm).

outlined here. The services rules have the potential to have extremely broad coverage; even measures that do not directly regulate the provision of services across borders must meet the GATS requirements if they *affect* a particular service.<sup>110</sup> The WTO's Appellate Body has yet to clearly define the test for what constitutes an effect, which invites litigation on marginal measures, even if they do not directly regulate tobacco products.<sup>111</sup> The TPP is expected to replicate the broad language and substantive rules of GATS. The TPP may also include a necessity test for domestic regulation of services, which several countries have called for in negotiations over service-sector obligations in other agreements.<sup>112</sup> This would not only increase the risk of litigation but also make it harder for the United States to defend its tobacco-control measures.

## 1. National Treatment

The national treatment provision in GATS requires each WTO member to “accord to services and service suppliers of any other Member, in respect of all measures affecting the supply of services, treatment no less favourable than it accords to its own like services and service suppliers.”<sup>113</sup> Essentially, governments may not impede the ability of foreign service suppliers to compete with “like” domestic suppliers in covered service sectors.<sup>114</sup> This obligation bears close resemblance to the national treatment rules of the GATT and the TBT Agreement. Like disputes arising under those agreements,<sup>115</sup> GATS national treatment disputes often involve the critical determination of whether two services or service suppliers are “like.” The WTO has yet to announce a clear test that allows governments to predict whether it will consider two services to be “like” services. As with the “like product” analysis under GATT, national treatment under GATS is likely to depend on the existence of a competitive relationship between the relevant service suppliers.<sup>116</sup>

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<sup>110</sup> See Appellate Body Report, *European Communities-Regime for the Importation, Sale and Distribution of Bananas*, ¶ 220, WT/DS27/AB/R (Nov. 26, 2008) [hereinafter “EC-Bananas”](finding that the language of GATS Art. I:1 indicates that GATS has a “broad scope of application,” and measures directly governing tariffs leveraged on bananas could nevertheless be challenged under GATS). See also WORLD TRADE LAW, at 640.

<sup>111</sup> See Panagiotis Delimitis, *Due Process and Good Regulation Embedded in the GATS*, 10 J. Int'l Econ. Law 13, 21 (2006).

<sup>112</sup> See N.Z., *Necessity Test*; Communication from Australia, Chile, Hong Kong, China, New Zealand and the Separate Customs Territory of Taiwan, Kinmen and Matsu, *Article VI:4 Disciplines – Proposal for Draft Text*, JOB(06)/193 (June 19, 2006) (produced by the Working Party on Domestic Regulation, World Trade Organization).

<sup>113</sup> GATS art. XVII:1.

<sup>114</sup> WORLD TRADE LAW, at 265-66.

<sup>115</sup> See discussion, *infra* part IV.A.2.i.

<sup>116</sup> See Mireille Cossy, *Determining Likeness Under the GATS: Squaring the Circle?*, World Trade Organization Economic Research and Statistics Division, Staff Working Paper No. ERSD-2006-08, available at [http://www.wto.org/english/res\\_e/reser\\_e/ersd200608\\_e.pdf](http://www.wto.org/english/res_e/reser_e/ersd200608_e.pdf). The Appellate Body did, however, state in *EC-Bananas III* that previous panel interpretations of the GATT would be relevant in rendering decisions based upon analogous parts of the GATS. Thus, we can expect the inquiry into likeness between services to resemble the inquiry into likeness between goods. See Guojun Li, *National Treatment Under the General Agreement on Trade in Services*, 6 Cambridge Student L. Rev. 74, 75 (2010).

### ***a. Flavor Bans and Bidi Bans***

Although flavor bans and bidi bans are measures directed at goods, they potentially affect the services of packaging, transport, bulk storage and retail, among others, and are therefore covered by GATS.<sup>117</sup> A country could allege that a ban violates national treatment by arguing that it distinguishes between “like” products and, by extension, “like” services. Both likeness inquiries would be resolved largely based on the nature and extent of a competitive relationship between menthol and clove-flavored cigarettes, as with the Appellate Body’s likeness analysis in *US-Clove Cigarettes*.<sup>118</sup> Just as clove-flavored cigarettes compete with menthol-flavored cigarettes in that case, flavored tobacco products and bidis compete, on some level, with other tobacco products. A government could therefore argue that the bans discriminate against “like” products and, by extension, the “like” services related to those products. Whether in GATS or a future trade agreement, an obligation of nondiscrimination among “like” services could create a risk to flavored tobacco bans and bidi bans.

### ***b. Bans and Restrictions on Internet Retail Sales and Vending Machine Sales***

It is unclear whether Internet, vending machine, and face-to-face retail sales of tobacco products might all be considered “like” services. Since they are alternative means by which a consumer might purchase tobacco, Internet retailers and vending machine owners could argue that these bans and restrictions discriminate against “like” service suppliers. Thus, the national treatment obligation in the services sector creates a basis for challenging Internet retail sales restrictions and bans, so long as the Internet and vending machine suppliers are foreign.

## **2. Market Access**

GATS prohibits the imposition of quotas on covered service sectors.<sup>119</sup> The WTO Appellate Body has found that bans are a type of quota and therefore violate the GATS agreement in covered sectors.<sup>120</sup> Hence, a tobacco-control measure that has the effect of banning a particular type of service might be challenged under the GATS market access requirements.

### ***a. Flavor Bans and Bidi Bans***

Just as in the nondiscrimination context, flavor bans and bidi bans might affect market access for services including packaging, advertising, and wholesale and retail

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<sup>117</sup> See Stumberg, *supra*, at 382, 390.

<sup>118</sup> See Appellate Body Report, *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 120, WT/DS406/AB/R (Apr. 4, 2012) [hereinafter *US-Clove Cigarettes*]

<sup>119</sup> GATS Art. XVI:2.

<sup>120</sup> See Appellate Body Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶ 223, WT/DS285/AB/R (Apr. 20, 2005) [hereinafter *US-Gambling*].

distribution. Countries wishing to challenge these product bans might argue that they impose an impermissible ban on the services associated with the products.

### ***b. Bans and Restrictions on Internet Retail Sales and Vending Machine Sales***

Challenging governments might argue that these laws either forbidding or significantly restricting the retail sale of tobacco products over the Internet or through vending machines constitute a ban on Internet retail or vending machine sales services, thereby violating market access requirements.

### ***c. Regulation of E-Cigarettes as Tobacco Products***

Regulating e-cigarettes as tobacco products could result in bans on many advertising services associated with e-cigarettes. A government could therefore allege that such measures impose impermissible bans on these advertising services.

## **3. Necessity Requirement**

Several U.S. trade agreements contain language requiring the federal and state governments to “endeavor to ensure” that domestic regulations applying to services are “not more burdensome than necessary to ensure the quality of the service.”<sup>121</sup> Other TPP countries are advocates for stronger necessity language (without the “endeavor” clause) that they use in their regional FTAs.<sup>122</sup> Thus, it is possible that the TTP or TTIP will include necessity provisions applicable to regulation of services. The language of these provisions resembles the TBT necessity requirement, discussed above.

Obligations like these place on governments the burden not only of proving that their tobacco control measures are “necessary,” but also that they are necessary to “ensure the quality of the service” that they affect. Such a requirement would invite litigation for

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<sup>121</sup> See, e.g., United States-Peru Free Trade Agreement, U.S.-Peru, Apr. 12, 2006, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text> [hereinafter U.S.-Peru FTA], art. 11.7(2) (“[E]ach Party shall endeavor to ensure . . . that [qualifications, technical standards, and licensing] measures are: . . . (b) not more burdensome than necessary to ensure the quality of the service”) (emphasis added). See also GATS art. VI:4 (directing WTO Members to develop rules to ensure, inter alia, that technical standards and licensing requirements are “not more burdensome than necessary to ensure the quality of the service.”)

<sup>122</sup> See, e.g., Trans-Pacific Strategic Economic Partnership, Brunei-Chile-N.Z.-Sing.-Chile, art. 12.10.2(b), July 18, 2005, N.Z. Ministry of Foreign Affairs & Trade, <http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/index.php> (“[E]ach party shall ensure that [an authorizing, licensing or qualification measure] . . . is not more burdensome than necessary to ensure the quality of the service”) (emphasis added); New Zealand-Malaysia Free Trade Agreement, N.Z.-Malay., § 8.18.2(b), Oct. 26, 2009, N.Z. Ministry of Foreign Affairs & Trade, <http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Malaysia/index.php> - text. Compare U.S.-Kor. FTA, supra note 47, art. 12.7, (relating to domestic regulation but containing no necessity language), with Agreement Establishing the ASEAN-Australia-New Zealand Free Trade Area, ASEAN-Austl.-N.Z., art. 10.2.2, Jan. 1, 2010, N.Z. Ministry of Foreign Affairs & Trade, <http://www.asean.fta.govt.nz/preamble/> (pertaining to domestic regulation and including necessity language that depends on the outcome of WTO negotiations).



almost any type of tobacco-control measure, including flavor bans, bidi bans, Internet retail sales bans and restrictions, packaging requirements, and regulation of e-cigarettes as “tobacco products,” as none of them are designed to ensure the quality of services associated with the production and provision of tobacco products. For example, restrictions on online tobacco retail are designed to prevent underage smokers from accessing tobacco products; they are not intended to improve this retail service.

### C. Regulatory Coherence Requirements

Regulatory coherence generally refers to a set of procedures that coordinate covered domestic regulations with international trade agreements. A regulatory coherence chapter would theoretically work with other trade agreement chapters to help harmonize future domestic regulations to make them “coherent” with trade liberalization.<sup>123</sup> According to a United States-European Union working group report, the goal of the regulatory coherence chapter in TTIP will be to make standards and regulations compatible “while achieving the levels of health, safety, and environmental protection that each side deems appropriate.”<sup>124</sup>

The TPP and TTIP are the first trade agreements to dedicate a full chapter to regulatory coherence, which indicates that there may be a trend toward more explicit regulatory coherence provisions in future trade negotiations. TTIP negotiators from the United States and European Union have “acknowledged that regulatory issues—cooperation and coherence—will be the most important and the most challenging for the trade negotiators.”<sup>125</sup>

Although little information is available about the proposed regulatory coherence provisions, this part discusses the contents of two leaked documents from the TPP and TTIP and concludes with a brief discussion of their potential application to e-cigarettes.

#### 1. TPP Regulatory Coherence Provisions

The draft TPP chapter applies principally to federal regulatory measures, and with regard to state and local laws, it indicates only that parties should “maintain communication” with relevant sub-national governmental bodies as feasible and appropriate.<sup>126</sup>

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<sup>123</sup> See Stumberg, *supra*, at 382, 393.

<sup>124</sup> *Final Report*, HIGH LEVEL WORKING GROUP ON JOBS AND GROWTH (February 11, 2013), available at [http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc\\_150519.pdf](http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf).

<sup>125</sup> *Resolution on Regulatory Coherence in the Transatlantic Trade and Investment Partnership*, TRANSATLANTIC CONSUMER DIALOGUE Doc. No. 16/13 (December 2013), available at <http://test.tacd.org/wp-content/uploads/2014/01/TACD-TTIP-Resolution-on-Regulatory-Coherence-in-the-Transatlantic-Trade-and-Investment-Partnership.pdf>.

<sup>126</sup> See Trans-Pacific Partnership—Regulatory Coherence, art. X.2.3 (March 4, 2010) (“Regulatory Coherence Draft”), available at <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificRegulatoryCoherence.pdf>.

The draft chapter does not define “regulatory coherence,” stating only that “TPP countries should discuss further the appropriate scope for a definition of regulatory coherence.”<sup>127</sup> Despite the apparent lack of consensus on a definition, the 2011 leaked draft is more explicit than any other trade agreement in laying out requirements for the mechanisms and procedures by which governments should evaluate domestic regulations. It does not appear, however, to impose new, substantive restrictions on domestic law. Using hortatory language, the TPP draft chapter proposes that each country “shall endeavor to ensure that it has a process or mechanism to facilitate central coordination and review of certain new regulatory measures, and should consider establishing and maintaining a national coordinating body for this purpose.”<sup>128</sup> The TPP draft chapter also encourages regulatory authorities to conduct “regulatory impact assessments”—including cost-benefit analyses—for proposed regulatory measures.<sup>129</sup>

The tobacco industry supports cost-benefit analysis as necessary for “harmonization of legitimate, science-based regulations.”<sup>130</sup> Legal critics of the industry describe cost-benefit analysis as a highly subjective exercise that the tobacco industry uses to generate evidence for litigation against tobacco control measures.<sup>131</sup> Public health scientists have stridently criticized the FDA’s cost-benefit studies of tobacco warning labels. Some assert that the FDA has grossly under-estimated the costs of tobacco use,<sup>132</sup> while others assert that the FDA has grossly over-estimated the benefits—including the “lost pleasure” that addicted smokers experience when they stop smoking.<sup>133</sup> Their critique of the rational consumer choice aspect of cost-benefit analysis is specific to tobacco as an addictive product:

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<sup>127</sup> Regulatory Coherence Draft, art. X.1.

<sup>128</sup> Regulatory Coherence Draft, art. X.2.1.

<sup>129</sup> Regulatory Coherence Draft, art. X.3.

<sup>130</sup> Philip Morris International, Submission of Philip Morris International in Response to the Request for Comments Concerning the Proposed Trans-Pacific Partnership Trade Agreement (January 22, 2010).

<sup>131</sup> See, e.g., JANE KELSEY, INTERNATIONAL TRADE AND INVESTMENT LAW ISSUES RELATING TO NEW ZEALAND’S PROPOSED TOBACCO CONTROL POLICIES TO ACHIEVE AN EFFECTIVELY SMOKEFREE NEW ZEALAND BY 2025, § 3.7.2 Regulatory Coherence (2012); Claudio M. Radaelli, *Evidence Based Policy and Political Control: What Does Regulatory Impact Tell Us?*, Paper to the European Consortium for Political Research, University of Rennes, France (April 2008); Fiona Haines and David gurney, *The Shadows of the Law: Contemporary Approaches to Regulation and the Problem of Regulatory Conflict*, 25 LAW AND POLICY 353-380 (October 2003); M. Scollo et al., *Review of the quality of studies on the economic effects of smoke-free policies on the hospitality industry*, 12 TOBACCO CONTROL 13–20 (2003), cited in World Health Organization, *Tobacco Industry Interference with Tobacco Control* 18 (2008).

<sup>132</sup> Jidong Huang, Frank J Chaloupka, and Geoffrey T Fong, *Cigarette graphic warning labels and smoking prevalence in Canada: a critical examination and reformulation of the FDA regulatory impact analysis*, TOBACCO CONTROL, TC Online First, published on November 11, 2013 as 10.1136/tobaccocontrol-2013-051170 (2013), available at <http://tobaccocontrol.bmj.com/content/early/2013/11/11/tobaccocontrol-2013-051170.full.pdf+html>.

<sup>133</sup> Anna V. Song, Paul Brown, and Stanton A. Glantz, *When Health Policy and Empirical Evidence Collide: The Case of Cigarette Package Warning Labels and Economic Consumer Surplus*, 104 Am. J. Public Health e42-e51, available at <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301737?&> (viewed May 6, 2014).

[E]mpirical evidence from psychological cognitive science and behavioral economics demonstrates that the assumptions of rational choice are inconsistent with complex multidimensional decisions, particularly smoking. Rational choice does not account for the roles of emotions, misperceptions, optimistic bias, regret, and cognitive inefficiency that are germane to smoking, particularly because most smokers begin smoking in their youth.<sup>134</sup>

In his commentary on this study, Legacy Professor Stanton Glantz observes, “By so radically underestimating benefits and overstating costs, the FDA's own analysis ... is making it particularly difficult to justify *any* regulation designed to protect public health.” By imbedding cost-benefit analysis in the TPP, U.S. trade policy would reinforce the bias of regulatory impact assessments.<sup>135</sup>

The draft TPP regulatory coherence chapter also sets out various provisions regarding a committee with TPP country representatives. This committee would convene to consider issues arising from the implementation and execution of the regulatory coherence chapter as well as identify future priorities and cooperative opportunities related to regulatory coherence obligations.<sup>136</sup> The inaugural meeting of this committee will “establish mechanisms to ensure meaningful opportunities for interested persons to provide views on approaches to enhance regulatory coherence through the Agreement.”<sup>137</sup> Article X.5 is the only mandatory provision, which calls for each country to report to this Committee “relevant information regarding the national process or mechanism established pursuant to Article X.2.1” and identify a contact point for the country’s implementation of the processes.<sup>138</sup>

The draft chapter indicates that the obligation under Draft Article X.2.1 to have “processes or mechanisms to facilitate central coordination and review of certain new regulatory measures” would be the only provision of the chapter subject to the TPP’s dispute settlement procedures.<sup>139</sup> In order to bring a claim under this provision, a country would need to demonstrate that another country violated that obligation and that such a

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<sup>134</sup> Id.

<sup>135</sup> Stanton Glantz, FDA puts economic theory over empirical evidence in its cost-benefit analysis; undermines sensible public health regulation, blog post, Center for Tobacco Control, Research & Education (December 12, 2013), available at <https://tobacco.ucsf.edu/fda-puts-economic-theory-over-empirical-evidence-its-cost-benefit-analysis-undermines-sensible-publi> (viewed May 6, 2014).

<sup>136</sup> Regulatory Coherence Draft, art. X.5.1.

<sup>137</sup> Regulatory Coherence Draft, art. X.6.

<sup>138</sup> Jane Kelsey, *Preliminary Analysis on the Draft TPP Chapter on Domestic Coherence* (Oct. 23, 2011), available at [http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific\\_RegCoherenceMemo.pdf](http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific_RegCoherenceMemo.pdf).

<sup>139</sup> Regulatory Coherence Draft art. X.8. The availability of the TPP’s dispute settlement procedures to enforce this provision, however, is arguably incompatible with the hortatory language used in Article X.2.1: (“each Party shall *endeavor to ensure* that it has a process or mechanism to facilitate central coordination and review of certain new regulatory measures . . . at the central level of government . . .”) (emphasis added).

violation adversely affected trade and investment among TPP countries.<sup>140</sup> The TPP draft chapter also states that no country will be required to disclose confidential information that could undercut its competitive position or that is otherwise exempted or prohibited from disclosure by law.<sup>141</sup>

Without specifically referencing TPP obligations, the White House has already communicated that it will pursue greater international coordination of regulatory activities. In the run-up to the Dallas TPP negotiations, President Obama issued an executive order identifying a preexisting regulatory working group to “serve as a forum to discuss, coordinate, and develop a common understanding among agencies” regarding “international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions,” “efforts across the Federal Government to support significant, cross-cutting international regulatory cooperation activities,” as well as “the promotion of good regulatory practices internationally.”<sup>142</sup>

## 2. TTIP Regulatory Coherence Provisions

A paper leaked from the European Commission indicates that in addition to regulatory impact assessment, the TTIP will insert *trade impact* assessment into the regulatory coherence chapter: The TTIP “should cover, in principle, any planned and existing regulatory measures of general application with significant (potential or actual) impact” on international trade.<sup>143</sup> According to this paper, the trade impact assessment would apply to any European Union legislation and implementing measures, as well as U.S. legislation and agency rulings.<sup>144</sup> In the case of any overlap between the regulatory coherence chapter and other chapters, the provisions of the Technical Barriers to Trade

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<sup>140</sup> Regulatory Coherence Draft, art. X.8.

<sup>141</sup> Regulatory Coherence Draft, art. X.9.

<sup>142</sup> Exec. Order No. 13,609, 77 Fed. Reg. 87 (Mar. 1, 2012), <http://www.whitehouse.gov/the-press-office/2012/05/01/executive-order-promoting-international-regulatory-cooperation>. Administrator of the White House Office of Information and Regulatory Affairs Cass Sunstein pointed out that the executive order “[would] build on work that is already under way.” Cass Sunstein, *Reducing Red Tape: Regulatory Reform Goes International*, Office of Mgmt. and Budget, Mar. 1, 2012, <http://www.whitehouse.gov/blog/2012/05/01/reducing-red-tape-regulatory-reform-goes-international>. He further emphasized the interagency group identified by the President, “while insisting on those priorities and prerogatives...[could] eliminate pointless red tape.” *Id.* He also insisted in a Wall Street Journal op-ed that the executive order would eliminate “unnecessary differences in countries’ regulatory requirements [that] can cost money, compromising economic growth and job creation.” Cass Sunstein, *The White House vs. Red Tape*, Wall Street Journal, May 1, 2012, [http://www.ftc.gov/sites/default/files/documents/public\\_events/enforceable-codes-conduct-protecting-consumers-across-borders/sunstein-executive-order.pdf](http://www.ftc.gov/sites/default/files/documents/public_events/enforceable-codes-conduct-protecting-consumers-across-borders/sunstein-executive-order.pdf).

<sup>143</sup> *TTIP: Cross-cutting disciplines and Institutional provisions*, European Commission Position Paper, section 1 (December 2, 2012), available at <http://corporateeurope.org/sites/default/files/ttip-regulatory-coherence-2-12-2013.pdf> (“European Commission Position Paper”).

<sup>144</sup> *TTIP: Cross-cutting disciplines and Institutional provisions*, European Commission Position Paper, section 1 (December 2, 2012), available at <http://corporateeurope.org/sites/default/files/ttip-regulatory-coherence-2-12-2013.pdf>.

(TBT), Sanitary and Phytosanitary Measures (SPS),<sup>145</sup> Financial Services, and Sustainable Development chapters would prevail.<sup>146</sup>

Media reports thus far have indicated that United States and European Union negotiators have not reached a consensus on the scope of application of the regulatory coherence provisions in the TTIP. European Union negotiators have called for increasing regulatory coherence in specific sectors, such as automobiles, pharmaceuticals, and chemicals,<sup>147</sup> while U.S. negotiators have pushed for “horizontal” rules that apply across a broad range of sectors, particularly regarding transparency of EU rule-making procedures.<sup>148</sup> Although horizontal obligations are a top priority, the Office of the United States Trade Representative (USTR) has indicated that this is not an “either-or” proposition.<sup>149</sup>

The European position paper also emphasizes the need for increased coordination between parties while maintaining the right to regulate “without unnecessary restrictions.”<sup>150</sup> Parties should, however, update one another “at least twice a year” on regulatory and legislative initiatives with potentially significant trade impact, as well as share this information with stakeholders.<sup>151</sup> With stakeholder input, United States regulators and EU commissioners should conduct impact assessments to evaluate proposed regulatory measures and exchange data with the other Party, if requested.<sup>152</sup> The TTIP regulatory coherence chapter would create a committee that would give “interested persons” convenient, timely access to information regarding “measures of general application” covered by the regulatory coherence chapter.<sup>153</sup> The chapter would also create the “Regulatory Cooperation Council” to report biannually on planned and ongoing regulatory cooperation as well as to consider ways to increase regulatory cooperation for future and existing regulatory measures.<sup>154</sup>

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<sup>145</sup> The Sanitary and Phytosanitary Measures (SPS) agreement is a World Trade Organization treaty that oversees member-states’ application of food safety and animal and plant health regulations. See *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, WORLD TRADE ORGANIZATION, (April 5, 2014, 5:43 PM), [http://www.wto.org/english/tratop\\_e/sps\\_e/spsund\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm).

<sup>146</sup> *TTIP: Cross-cutting disciplines and Institutional provisions*, European Commission Position Paper, section 2 (December 2, 2012), available at <http://corporateeurope.org/sites/default/files/ttip-regulatory-coherence-2-12-2013.pdf>.

<sup>147</sup> *U.S., EU Agree in Principle to Seek Long-Term Regulatory Mechanism*, INSIDE U.S. TRADE, November 21, 2013.

<sup>148</sup> *U.S., EU Negotiators Out of Sync on TTIP Regulatory Cooperation Approach*, INSIDE U.S. TRADE, September 27, 2013.

<sup>149</sup> *Id.*

<sup>150</sup> *TTIP: Cross-cutting disciplines and Institutional provisions*, European Commission Position Paper, section 2 (December 2, 2012), available at <http://corporateeurope.org/sites/default/files/ttip-regulatory-coherence-2-12-2013.pdf>.

<sup>151</sup> *Id.*, section 3.

<sup>152</sup> *Id.*, section 5.

<sup>153</sup> *Id.*, section 6.

<sup>154</sup> *Id.*, section 7.

### 3. Regulatory Coherence Provisions and E-Cigarette Regulations

Because no existing international trade agreement has included a regulatory coherence chapter, it is difficult to predict how it would apply to tobacco control laws in practice or influence an international dispute over tobacco regulation.

If a regulatory coherence chapter is incorporated in the TPP or TTIP, a sensitive area to monitor for potential conflict is e-cigarette regulation, which varies broadly around the world—from no regulations to outright bans on e-cigarettes.<sup>155</sup> The United Kingdom’s regulatory agency recently decided to regulate e-cigarettes as medical products because their use is comparable to that of other nicotine replacement products, like patches or gum.<sup>156</sup> In the United States, however, the FDA has not classified them as medical devices or drugs due to insufficient research on their health effects.<sup>157</sup> The White House Office of Management and Budget has been reviewing a proposal to regulate e-cigarettes and other tobacco products since October 1, 2013.<sup>158</sup> Meanwhile, some U.S. cities and states have regulated e-cigarettes like traditional cigarettes rather than medical products.<sup>159</sup> And as noted above, the National Association of Attorneys General asked the FDA to regulate e-cigarettes as a tobacco product under the 2009 Tobacco Control Act.

If the FDA finalizes federal regulations governing e-cigarettes, the leaked TPP and TTIP regulatory coherence provisions suggest that the regulation would be subject to a regulatory impact assessment and a trade impact assessment.<sup>160</sup> With stakeholder input, the impact assessment would need to consider the policy objective, the need to regulate the product, and the existence of alternative measures.<sup>161</sup> For the regulatory assessment, both the TPP and TTIP would call for the FDA to draw from scientific data supporting the regulation and its policy objective.<sup>162</sup> Available scientific data on e-cigarettes,

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<sup>155</sup> Jean-Francoise Etter, Chris Bullen, Andreas D. Flouris, Murray Laugesen, Thomas Eissenberg, *Electronic nicotine delivery systems: a research agenda*, 20 TOBACCO CONTROL 243 (2011).

<sup>156</sup> Medicines and Healthcare Products Regulatory Agency, *Nicotine Containing Products* (April 5, 2014, 5:35 PM), <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Nicotinecontainingproducts/index.htm>

<sup>157</sup> U.S. Food and Drug Administration, *Electronic Cigarettes* (April 5, 2014, 5:35 PM), available at <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>.

<sup>158</sup> Harold P. Wimmer, *Are e-cigarettes dangerous*, CNN, Jan. 7, 2014, [http://www.cnn.com/2014/01/06/opinion/wimmer-ecigarette-danger/index.html?hpt=hp\\_c2](http://www.cnn.com/2014/01/06/opinion/wimmer-ecigarette-danger/index.html?hpt=hp_c2)

<sup>159</sup> See discussion under III. Vulnerable Domestic Tobacco Control Measures, B. State Law, 1. Electronic Cigarettes.

<sup>160</sup> Regulatory Coherence Draft art. X.3; European Commission Position paper, section 5.

<sup>161</sup> Regulatory Coherence Draft art. X.3.1.b(1)-(3); European Commission Position paper, section 5.

<sup>162</sup> TPP Regulatory Coherence Draft art. X.3.1.b(4) states that the decisions should be based on “the best reasonably obtainable scientific, technical, economic, and other information within the boundaries of the authorities, mandates, and resources of the particular regulatory authority.” Similarly, section 5 of the European Commission position paper on TTIP states that “both sides will exchange, upon request, information on underlying assumptions, scientific evidence and data as well as methodology applied.”

however, are limited, and it is difficult to predict when additional data will become available.<sup>163</sup>

## D. Intellectual Property Protections

The WTO's Agreement on Trade Related Aspects of Intellectual Property ("TRIPS") is the current baseline for commitments with respect to intellectual property.<sup>164</sup> In addition to imposing national treatment requirements similar to those found in agreements governing trade in goods and services, TRIPS also establishes minimum standards of protection for intellectual property that countries must incorporate into their domestic legal systems.<sup>165</sup> Several of these standards protect the registration and use of trademarks.<sup>166</sup> These standards currently form a basis for the WTO challenges to Australia's plain packaging law,<sup>167</sup> which business associations have described as "mandated trademark destruction."<sup>168</sup> In addition, the United States has proposed additional protections in the intellectual property chapter of the TPP that would grant producers new rights to use names associated with geographical places (such as parmesan and feta cheese) so long as they do not reflect the products' true places of origin. These rules and their implications for tobacco control are described below.

### 1. Protections for Trademarks

Several countries have initiated WTO dispute-settlement proceedings against Australia, arguing that Australia's plain packaging law violates TRIPS commitments.<sup>169</sup> These TRIPS commitments include: (1) the requirement that any visually perceptible sign capable of distinguishing among goods and products be eligible for registration as a trademark,<sup>170</sup> (2) the prohibition on obstacles to registration based on the nature of the product,<sup>171</sup> (3) the prohibition against unjustifiably encumbering trademarks' use with

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<sup>163</sup> American Lung Association Statement on E-Cigarettes, American Lung Association, *available at* <http://www.lung.org/stop-smoking/tobacco-control-advocacy/federal/e-cigarettes.html>.

<sup>164</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C [hereinafter TRIPS].

<sup>165</sup> WORLD TRADE LAW, at 41.

<sup>166</sup> TRIPS, arts. 15-20.

<sup>167</sup> The law forbids the inclusion of trademarks on the retail packaging of tobacco products and requires that packaging be of "drab dark brown" color and include graphic warning labels. Australia Plain Packaging Act, sec. 18-20. The producer's name may only appear in one line of text at the bottom of the product carton. *Id.* sec. 21.

<sup>168</sup> Press Release, Nat'l Foreign Trade Council, US Business Groups Issue Statement Expressing Deep Concern Following Announcement by the New Zealand Government of a Public Consultation to Review the Mandated Destruction of Trademarks and Branding in the Tobacco Sector (Apr. 20, 2012), <http://www.nftc.org/newsflash/newsflash.asp?Mode=View&id=236&articleid=3466&category=All>.

<sup>169</sup> *See e.g.*, Request for Consultations by the Ukraine, *Australia—Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS434/11 (Aug. 17, 2012).

<sup>170</sup> TRIPS Agreement, art. 15.1.

<sup>171</sup> TRIPS Agreement, art. 15.4.

special requirements,<sup>172</sup> and (4) the requirement that trademark holders be given the right to exclude others from using their trademarks.<sup>173</sup> The complaining countries argue that Australia's law violates these commitments by (1) failing to give effect to tobacco companies' right to register their trademarks because these marks cannot be affixed to their products, (2) making the nature of the product an obstacle to effective registration of the tobacco companies' trademarks, (3) implementing "special requirements" in the form of standardized appearance and form of packaging that prevent consumers from using trademarks to distinguish among goods and (4) preventing tobacco companies from enjoying the "right" associated with owning a trademark.<sup>174</sup>

Although it is unclear how the WTO's Dispute Settlement Body will rule on any of these issues, similar arguments could form the basis of future challenges to packaging regulations in the United States. An example of an at-risk measure is the graphic warning requirement for cigarette packages that the FDA is currently re-formulating.<sup>175</sup> If the FDA succeeds in drafting the warning so as to not run afoul of the First Amendment, the tobacco industry might still invoke international intellectual property protections to attack these warning requirements.

## 2. Protections for Indicators of Geographical Areas

TRIPS requires governments to protect certain geographical indications "where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."<sup>176</sup> Certain governments, including the United States, have criticized the strong protection TRIPS gives to geographical origin names.<sup>177</sup> Thus, the United States has proposed a WTO-plus rule in the intellectual property chapter of the TPP that would require each Party to "permit the use, and... allow the registration of signs or indications that identify goods other than wines or spirits, and that reference a geographical area that is not the place of origin of the goods."<sup>178</sup> While this language is intended to protect U.S. producers of products generally associated with a particular region (for example, "Swiss" cheese that is not really Swiss in origin),<sup>179</sup> the tobacco

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<sup>172</sup> TRIPS Agreement, art. 20.

<sup>173</sup> TRIPS Agreement, art. 20.

<sup>174</sup> Request for Consultations by Ukraine, *Australia - Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Relating to Tobacco and Plain Packaging*, WT/DS434/1 (Mar. 15, 2014), available at [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S006.aspx?Query=\(@Symbol=%20wt/ds434/1%20or%20wt/ds434/1/\\*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds434/1%20or%20wt/ds434/1/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#).

<sup>175</sup> See part III.A.1, *supra*.

<sup>176</sup> TRIPS Agreement, art. 22.1.

<sup>177</sup> See WORLD TRADE LAW, at 60.

<sup>178</sup> Draft Trans-Pacific Partnership Agreement, Intellectual Property Chapter, art. QQ.D.14 (Aug. 30, 2013), available at <https://wikileaks.org/tpp/#start>.

<sup>179</sup> See *Business Coalition Draft Paper Reveals New IPR Strategy For TPP*, INSIDE U.S. TRADE, DEC. 2, 2010.



industry could also take advantage of this affirmative right to use particular types of signs and indications.

An obligation to permit the use of geographical areas could cover product names like Marlboro, Winston, and Salem, and it might motivate tobacco companies to develop new geographical product names. If federal or state regulators in the United States attempt to restrict the use of tobacco trademarks, whether in packaging, advertising, or marketing, another TPP country might challenge the restriction by alleging that it violates the obligation to protect use of geographical names. In addition, the commitment to permit the use of geographical indicators could also be raised in investor-state disputes, which is discussed in part IV.E below.

## E. Foreign Investor Rights

In addition to the trade obligations discussed above, many agreements, including BITs and the investment chapters of FTAs, contain investment rules. Many of these rules pose risks to tobacco-control measures, and they are directly enforceable by foreign investors. The threat posed by these investment agreements is demonstrated by two ongoing investment claims brought by Philip Morris against tobacco control laws in Uruguay and Australia. Philip Morris claims that the laws violate two investment rules: expropriation and fair and equitable treatment.<sup>180</sup> Other investor challenges have invoked a third type of investment rule, national treatment. This part discusses how these investor protection rules could threaten U.S. tobacco-control laws.

### 1. Expropriation

International investment rules contained in BITs and the investment chapters of FTAs typically require governments to compensate investors for both direct and indirect expropriations.<sup>181</sup> Direct expropriation occurs when a host country seizes a foreign-owned property.<sup>182</sup> Indirect expropriation occurs when a host country regulates a foreign investment in a manner that deprives the investor of control or substantial value of the investment, even in the absence of a physical appropriation.<sup>183</sup> The rules against indirect expropriation create vulnerabilities for cigarette packaging laws, as well as bans on flavored tobacco, bidis, Internet sales, and cigarette vending machines.

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<sup>180</sup> Philip Morris v. Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration (Feb. 19, 2010), available at <http://italaw.com/documents/PMI-UruguayNoA.pdf> (hereafter, PMI v. Uruguay, Request for Arbitration); Philip Morris Asia Ltd. v. Austl., UNCITRAL, PCA Case No. 2012-12, Written Notification of Claim (Jun. 27, 2011), available at <http://www.italaw.com/sites/default/files/case-documents/ita0664.pdf>. (hereafter, PMA v. Australia, Written Notification of Claim)

<sup>181</sup> See, e.g., 2012 Model U.S. BIT Article 6.1: “Neither Party may expropriate or nationalize a covered investment either directly or indirectly through measures equivalent to expropriation or nationalization (“expropriation”) except: (a) for a public purpose; (b) in a non-discriminatory manner; (c) on payment of prompt, adequate, and effective compensation; and (d) in accordance with due process of law...”

<sup>182</sup> Andrew D. Mitchell and Sebastian M. Wurzberger, *Boxed In? Australia’s Plain Tobacco Packaging Initiative and International Investment Law*, 27 ARBITRATION INT’L 623, 634 (2011).

<sup>183</sup> UNCTAD Series on issues in international investment agreements, Taking of Property 4, 41 (2000).

### *a. Cigarette Packaging Laws*

In February 2010, Philip Morris instituted an investor-state dispute settlement proceeding seeking compensation for Uruguay's new tobacco packaging regulations, which restricted branding on cigarette packages and required health warnings and graphic pictograms showing the health consequences of smoking.<sup>184</sup> In addition, Uruguay's law included a "single presentation" requirement limiting tobacco companies to selling just one product variety under each of their brands.<sup>185</sup> "[T]he combined effect" of the requirements, Philip Morris argued, decreased its sales, deprived it of its intellectual property rights, and therefore "amount[ed] to an indirect expropriation of the Claimant's remaining trademarks."<sup>186</sup>

In 2011, Philip Morris brought a similar investor-state claim against Australia, arguing that Australia's plain packaging legislation amounted to an expropriation of its investments. The legislation states that, as of December 2012, all cigarettes were to be sold in generic, green packages displaying pictograms of cigarette-related diseases.<sup>187</sup> Within one hour of the Australian parliament's passing of the act, Philip Morris submitted a claim arguing that the legislation violated its rights under the Australia-Hong Kong BIT and constituted a "substantial deprivation of the intellectual property and goodwill."<sup>188</sup> Philip Morris argues that Australia's law expropriates by depriving it of its intellectual property and decreasing the value of the shares of its Australian subsidiary.<sup>189</sup>

Similar arguments might be used to challenge restrictions on cigarette packaging in the United States, including new warning labels that the FDA is developing under the 2009 Tobacco Control Act. As of this writing, the FDA is revising its proposed

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<sup>184</sup> PMI v. Uruguay, Request for Arbitration, *supra*.

<sup>185</sup> PMI v. Uruguay, Request for Arbitration, *supra*, at ¶ 3.

<sup>186</sup> PMI v. Uruguay, Request for Arbitration, *supra*, at ¶ 82.

<sup>187</sup> *Cigarette Plain Packaging Laws Pass Parliament*, Australian Broadcasting Corporation (Nov. 21, 2011, 2:15PM), available at <http://www.abc.net.au/news/2011-11-21/cig-plain-packaging-laws-pass/3684374>.

<sup>188</sup> Philip Morris Asia Ltd. v. Australia, UNCITRAL, PCA Case. No. 2012-12, Notice of Arbitration (Nov. 21, 2011) available at <http://www.italaw.com/sites/default/files/case-documents/ita0665.pdf>. Although Australia excluded ISDS from its 2004 FTA with the US, Phillip Morris International was able to circumvent that exclusion through its subsidiary, Philip Morris Asia. The Australia case shows how tobacco companies may choose from a variety of BITs and trade agreements to select a forum that best suits their potential claims. Philip Morris took legal action against Australia "less than an hour after Parliament passed legislation banning all logos from cigarette packages." See *Philip Morris sues Australia over new tobacco law*, ASSOCIATED PRESS (Nov. 21, 2011), available at <http://finance.yahoo.com/news/Philip-Morris-sues-Australia-apf-3549611349.html>.

<sup>189</sup> See Philip Morris Asia Ltd. v. Australia, UNCITRAL, PCA Case. No. 2012-12, Notice of Arbitration, ¶ 7.3 (Nov. 21, 2011) available at <http://www.italaw.com/sites/default/files/case-documents/ita0665.pdf>. See also *FTR Holdings S.A. (Switzerland) v. Oriental Republic of Uruguay*, ICSID case no. ARB/10/7, Request for Arbitration, ¶ 82-83 (February 19, 2010), available at <http://www.italaw.com/sites/default/files/case-documents/ita0343.pdf> (asserting that Uruguay's cigarette packaging regulations expropriate Philip Morris's intellectual property rights).

regulations after tobacco companies successfully challenged its first final rule on First Amendment grounds.<sup>190</sup>

The FDA's proposed graphic warnings replicate the approach of Australia and several dozen other countries in terms of pictures that depict tobacco-related diseases. As required by the Tobacco Control Act, the FDA pictures would cover the top 50% of the pack and 20% of print advertisements.<sup>191</sup> This is less than Australia's coverage of 75% of the front and 90% of the back.<sup>192</sup> Unlike Australia's "plain" format, the proposed FDA regulations did not require presentation of a company's brand name in standard font with a monochrome background.<sup>193</sup>

Even if the FDA's second final rule is limited to large graphic warning labels,<sup>194</sup> it would be within the grasp of PMI's legal arguments. In its claim against Australia, PMI asserts that the graphic warning alone "is tantamount to plain packaging."<sup>195</sup> PMI argues that graphic warnings and plain packaging "jointly and severally" deprive the company "of the intellectual property and the commercial utility of its Brands; this is the central purpose of the legislation."<sup>196</sup> And PMI goes out of its way to state that, "For the avoidance of doubt, [its claim] encompasses the GHW [Graphic Health Warning] regulation (or any other extension of current regulations concerning graphic health warnings) ..."<sup>197</sup>

When PMI challenged Uruguay's graphic warnings in 2010, a dispute that is ongoing, it described the pictures as "highly shocking images that are designed to evoke emotions of repulsion and disgust, even horror, and effectively operate so as to undermine and indeed destroy the good will associated with ... legally protected trademarks."<sup>198</sup> The pictures used by Uruguay, Australia, and the FDA are analogous depictions of tobacco-

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<sup>190</sup> In June 2011, the FDA published a rule requiring that graphic warnings cover fifty percent of the front and back of cigarette packages sold in the U.S. and twenty percent of cigarette advertisements. Final Rule, Department Of Health and Human Services, Food And Drug Administration, 21 CFR Part 1141 [Docket No. Fda-2010-N-0568], Rin 0910-Ag41, Required Warnings For Cigarette Packages and Advertisements, 76 FR 36628 (June 22, 2011); 15 U.S.C. § 1333(a)(2) and (b)(2). (hereafter, FDA Final Rule of 2011) The United States Court of Appeals for the D.C. Circuit upheld the district court's finding that the graphic warning requirement unconstitutionally limited the tobacco companies right to exercise commercial speech. See CNN Health, *FDA changes course on graphic warning labels for cigarettes* (March 20, 2013), available at <http://www.cnn.com/2013/03/19/health/fda-graphic-tobacco-warnings/> (viewed July 14, 2014); Reynolds Tobacco Co. v. United States Food & Drug Admin., 696 F.3d 1205 (D.C. Cir. 2012). If the FDA issues a new rule on graphic health warnings, it will likely be challenged by tobacco companies.

<sup>191</sup> 15 U.S.C. § 1333(a)(2) and (b)(2).

<sup>192</sup> PMA v. Australia, Written Notification of Claim, *supra*, at ¶¶ 7, 16.

<sup>193</sup> See generally FDA Final Rule of 2011.

<sup>194</sup> For the status of FDA proposals, see FDA, Cigarette Health Warnings, <http://www.fda.gov/TobaccoProducts/Labeling/Labeling/CigaretteWarningLabels/default.htm> (viewed July 14, 2014).

<sup>195</sup> Id. at ¶ 16.

<sup>196</sup> Id. at ¶ 33.

<sup>197</sup> Id. at ¶ 47.

<sup>198</sup> PMI v. Uruguay, Request for Arbitration, *supra*, at ¶ 42.

related diseases including, for example, cancer of the mouth, a tracheotomy, heart surgery, and extracted lungs.<sup>199</sup>

Considering their success using First Amendment arguments in U.S. courts, tobacco companies have no need at this time to challenge FDA regulations based on trade or investment agreements. But for future reference, PMI has deployed arguments against graphic warnings that apply to regulations being considered by the United States.

### ***b. Flavored Tobacco Product Bans***

A tobacco company might argue that a ban on flavored tobacco products (such as the Tobacco Control Act's ban on flavored tobacco products) expropriates its investment. Some tobacco products, such as cigarillos or bidis, are most popular in flavored form.

As Philip Morris did with respect to restrictions on brands, a tobacco company might argue that a ban on flavored tobacco products deprives manufacturers of the use, control, value, or reasonably expected benefits of their investments related to selling these products in the United States.

### ***c. Internet Sales Bans***

Some foreign tobacco manufacturers may use the Internet to sell their products to consumers located in the United States. If a foreign tobacco manufacturer sells a substantial portion of its products on the Internet, an Internet sales ban or restriction might significantly interfere with that manufacturer's ability to do business and, therefore, provide a basis for a claim of expropriation.

## **2. Fair and Equitable Treatment**

Tribunals have interpreted fair and equitable treatment ("FET") to require governments to maintain a "stable and predictable regulatory environment" and to make decisions in a consistent and transparent manner that aligns with the "legitimate expectations" of foreign investors.<sup>200</sup> If a regulatory measure adversely affects a foreign investor's legitimate expectations, a tribunal could find an FET violation, even if the adverse effect does not reach the quantum threshold of an indirect expropriation.<sup>201</sup>

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<sup>199</sup> See, e.g., *See the new cigarette warning labels*, CNN HEALTH (June 21, 2012), available at <http://www.cnn.com/2011/HEALTH/06/21/cigarette.labels.gallery/> (viewed July 14, 2014). Compare, e.g., *Australians Face Gangrene Photos as Tobacco Brands Vanish*, BLOOMBERG NEWS (December 2, 2013), available at <http://www.businessweek.com/news/2012-12-02/australians-face-gangrene-photos-as-tobacco-brands-vanish> (viewed July 14, 2014); *Big Tobacco vs. Little Uruguay*, FINANCIAL TIMES, beyondbrics blog (July 3, 2013) available at <http://blogs.ft.com/beyond-brics/2013/07/03/big-tobacco-vs-little-uruguay/> (viewed July 14, 2014).

<sup>200</sup> Matthew C. Porterfield, *State Practice and the (Purported) Obligation under Customary International Law to Provide Compensation for Regulatory Expropriations*, 37 N.C. J. INT'L L. & COM. REG. 159, 166-67 (2011), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1969838](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1969838).

<sup>201</sup> Matthew C. Porterfield, *State Practice and the (Purported) Obligation under Customary International*

Philip Morris argues that Uruguay’s tobacco-labeling law violates its right to fair and equitable treatment under the Switzerland-Uruguay BIT by frustrating its “legitimate expectations” concerning its investment in Uruguay.<sup>202</sup> Philip Morris also claims that Uruguay’s tobacco labeling law violates FET because it is inconsistent with Uruguay’s obligations regarding intellectual property under the TRIPs.<sup>203</sup>

In its FET claim against Australia, Philip Morris is making a slightly different argument. In that dispute, Philip Morris asserts that FET requires “a balancing of the investor’s legitimate and reasonable expectations on the one hand and the host State’s legitimate regulatory interests on the other.”<sup>204</sup> Philip Morris argues that Australia’s plain packaging law fails to satisfy this standard because it “has no demonstrable ability to improve public health” and “effective alternative measures are available.”<sup>205</sup> Philip Morris further suggests that the plain packaging law violates FET because its “claimed public health benefits . . . are entirely disproportionate to its harm . . .”<sup>206</sup> Philip Morris thus offers several different theories for finding violations of FET, including the following: (1) interference with an investor’s “legitimate expectations,” (2) violation of another obligation under international law, (3) lack of evidence that the measure contributes to its purported objectives, (4) lack of proportionality between a measure’s benefits and the harms it causes to investors, and (5) availability of less burdensome regulatory alternatives.

U.S. tobacco control laws that are vulnerable to a FET claim include bidi and flavored tobacco product bans, Internet sales bans, and packaging restrictions. Packaging restrictions are more complex than outright bans on products or modes of distribution. As noted above (part III.E.1.a), the FDA is rewriting its regulations on graphic warnings in response to the tobacco industry’s successful challenge of the FDA’s first final rule on First Amendment grounds. The expropriation arguments that PMI is making against graphic warning requirements in its claims against Uruguay and Australia (quoted above) also apply with respect to FET. In its Uruguay claim, PMI argues—apart from the size of the graphic warning—that the pictures themselves violate FET:

... pictograms specifically designed to associate Claimant’s products and their trademarks with offensive and repulsive imagery are neither necessary nor justified to warn consumers of the health risks associated

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*Law to Provide Compensation for Regulatory Expropriations*, 37 N.C. J. INT’L L. & COM. REG. 159, 168 (2011), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1969838](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1969838).

<sup>202</sup> FTR Holdings S.A. (Switzerland) v. Oriental Republic of Uruguay, ICSID case no. ARB/10/7, Request for Arbitration, ¶ 84 (February 19, 2010), available at <http://www.italaw.com/sites/default/files/case-documents/ita0343.pdf>. Philip Morris also claims that Uruguay’s tobacco labeling law violates FET because it is inconsistent with Uruguay’s obligations regarding intellectual property under the TRIPs. FTR Holdings S.A. (Switzerland) v. Oriental Republic of Uruguay, ICSID case no. ARB/10/7, Request for Arbitration, ¶ 85 (February 19, 2010), available at <http://www.italaw.com/sites/default/files/case-documents/ita0343.pdf>.

<sup>203</sup> PMI v. Uruguay, Request for Arbitration, *supra*, at ¶¶ 76, 81, 85, 86.

<sup>204</sup> PMA v. Australia, Notice of Arbitration, *supra*, at ¶ 7.6.

<sup>205</sup> PMA v. Australia, Notice of Arbitration, *supra*, at ¶ 7.7.

<sup>206</sup> PMA v. Australia, Notice of Arbitration, *supra*, at ¶ 7.8.

with smoking [...] —a goal that can be reached without denigrating the Claimants’ products and without destroying their legally protected trademarks and the goodwill associated with such trademarks.”<sup>207</sup>

**a. Bidi and Flavored Tobacco Product Bans**

Growing awareness of the health risks associated with bidis may lead more states to ban or restrict their sale. Producers of bidis might argue that a bidi ban (or a broad ban on flavored tobacco products, which would include flavored bidis) violates FET because investors in flavored tobacco products have expended capital to distribute their products in the United States and may have a “legitimate expectation” to be able to continue doing so. Foreign tobacco companies could also argue that a bidi ban violates FET because its public health benefits have not been demonstrated. If Philip Morris’ theory regarding proportionality of benefits and harms to investors prevails, foreign bidi manufacturers might also argue that the harm they suffer from a ban is disproportionate to the public health benefits.

**b. Packaging Restrictions**

Philip Morris argues that Uruguay’s restrictions on cigarette packaging were unfair and inequitable because Uruguay’s restrictions “failed to maintain a stable and predictable regulatory framework consistent with Philip Morris’ legitimate expectations.”<sup>208</sup> Uruguay’s requirements did not exist prior to Philip Morris’ entry into the country’s market, and Philip Morris claims that it did not anticipate such regulatory changes. New regulations of cigarette packaging by the FDA might encounter a similar legal challenge.

**c. Internet Sales Bans**

Some states have banned Internet sales of tobacco because the availability of tobacco products online may facilitate purchase by youths. A foreign tobacco manufacturer may argue that banning Internet sales is not a legitimate response to such a public policy concern because youths are as likely to purchase tobacco through retail stores or vending machines, perhaps through adult intermediaries, and so the measure may not contribute to its objective of reducing smoking by youths or provide the least burdensome method of reducing underage access to tobacco. Alternatively, a foreign distributor might argue that, even if there were evidence that an Internet sales ban could reduce youth smoking rates, the resulting harm to foreign brands (not otherwise available in retail stores) would be disproportionate to its public health benefits.

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<sup>207</sup> PMI v. Uruguay, Request for Arbitration, *supra*, at ¶¶ 81.

<sup>208</sup> FTR Holdings S.A. (Switzerland) v. Oriental Republic of Uruguay, ICSID case no. ARB/10/7, Request for Arbitration, ¶ 84 (February 19, 2010), available at <http://www.italaw.com/sites/default/files/case-documents/ita0343.pdf>.

### 3. National Treatment

National treatment is a standard provision in most BITs and FTA investment chapters—similar to national treatment of trade in goods and services. For investment, it requires a host country to treat foreign investors no less favorably than its domestic investors “in like circumstances.”<sup>209</sup> The first step of the national treatment analysis requires a determination of whether a foreign investor and a domestic investor are in a similar situation, or “like circumstances.”<sup>210</sup> The second step is to determine whether the foreign investor has been treated at least as favorably as the domestic investor. National treatment rules protect foreign investors from both overt discrimination and facially neutral regulatory distinctions that have a discriminatory impact (e.g., a ban on a certain method of production that is only used in foreign countries).

If a country loses a trade dispute on national treatment grounds—as the United States did in *Clove Cigarettes*—it should not be surprised if an investment dispute follows on the heels of the trade dispute. For example, shortly after Canada lost a WTO dispute regarding renewable energy policies, a U.S. investor cited the WTO ruling in its investment dispute over failure to provide national treatment under the same policies.<sup>211</sup>

To follow this pattern, a tobacco company would need to be established in a country with which the United States has a BIT or FTA investment chapter. For example, if United States-India BIT negotiations succeed,<sup>212</sup> an Indian bidi manufacturer might follow Indonesia’s example in the clove cigarettes dispute and argue that a facially neutral ban on flavored tobacco products disproportionately affects bidis and, therefore, amounts to *de facto* discrimination against bidi manufacturers, who are predominantly Indian. Under the first step of the test, an Indian manufacturer producing bidis would presumably be considered in “like circumstances” to a domestic cigarette manufacturer.

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<sup>209</sup> Catherine Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law*, Organisation for Economic Co-operation and Development (OECD) Working Papers on International Investment Number 2004/3 (Sept. 2004), available at <http://www.oecd.org/investment/internationalinvestmentagreements/33776498.pdf>. See, e.g., North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289, Art. 1102 (1993). Article 1102 (1) NAFTA reads: “Each Party shall accord to investors of another Party treatment no less favorable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.”

<sup>210</sup> Rudolf Dolzer, *National Treatment: New Developments*, Symposium co-organized by the Organisation for Economic Co-operation and Development (OECD), International Centre for Settlement of Investment Disputes (ICSID), and United Nations Conference on Trade and Development “Making the Most of International Investment Agreements: A Common Agenda,” Dec. 12, 2005, available at <http://www.oecd.org/investment/internationalinvestmentagreements/36055356.pdf>. A finding of “like circumstances” does not necessarily mean that the investors must be in the same business (e.g., the exporting of cigarettes.)

<sup>211</sup> The U.S. investor, Mesa Power, cites the WTO ruling in support of its national treatment claim under NAFTA’s investment chapter. See *Mesa Power Group v. Canada*, Memorial of the Investor, ¶¶ 283-286 (November 20, 2013).

<sup>212</sup> Ashish Goel and Harish Goel, *India-US bilateral investment treaty going nowhere*, East Asia Forum (Aug. 31, 2013), available at <http://www.eastasiaforum.org/2013/08/31/india-us-bilateral-investment-treaty-going-nowhere/>.

The foreseeable argument would be that a ban on bidis in the United States would subject Indian bidi manufacturers to less favorable treatment than domestic cigarette manufacturers, and therefore, the ban violates national treatment.

## F. Cumulative Effects of the Multiple Threats to Tobacco-Control Measures

In addition to the discrete risks to tobacco control posed by each trade and investment rule discussed above, it is important to note that many tobacco-control measures are potentially vulnerable under multiple trade or investment rules. The overall risk posed by these overlapping threats is greater than the sum of its parts; multiple legal vulnerabilities give rise to multiple potential arguments tobacco companies could use to challenge a tobacco-control measure before different trade and investment fora, creating the potential need for the United States to defend the same measure, at a significant cost, multiple times. The overlapping threats are illustrated in the chart below.

**Cumulative effect:  
Potential Threats to U.S. Tobacco Control Measures**

Measure	Goods			I.P.	Services			Reg. Coherence	Investment		
	Nat'l Treat	Neces-sity	Disclo-sure Prohib	Right to use trade mark	Nat'l Treat	Market Access	Neces-sity		Nat'l Treat	Expro	Fair & Equit. Treat
<b>State law</b>											
Flavored tobacco ban	■	■			■	■	+	+	±	±	±
Internet sales ban	■	■			■	■	+	+	±	±	±
Product disclosure prohib			■				+	+			
<b>Federal law</b>											
Flavored cigarette ban	■	■			■	■	+	+	±	±	±
Packaging requirements		■		+			+	+		±	±
Reformulation approval		■					+	+			±
Product disclosure prohib		■	■				+	+			
Reg. of e-cigarettes		■				■	+	+			±

**Key to potential legal conflicts**

■	WTO baseline rule
+	WTO-plus trade rule – TPP & TTIP
±	WTO-plus coverage of investors and countries – TPP & TTIP

## V. Restraints on U.S. Trade Policy Regarding Tobacco under Executive Order 13193

The United States has entered into trade and investment agreements that could undermine its domestic tobacco-control efforts. It has done so in the face of two legal provisions that prohibit federal agencies from using trade policy to promote the export of tobacco products or to undermine nondiscriminatory restrictions by foreign governments on tobacco marketing. The first provision is Section 2(a) (“Tobacco Trade Policy”) of Executive Order 13193, signed by President Clinton on January 18, 2001, which states that —



[i]n the implementation of international trade policy, executive departments and agencies shall not promote the sale or export of tobacco or tobacco products, or seek the reduction or removal of foreign government restrictions on the marketing and advertising of such products, provided that such restrictions are applied equally to all tobacco or tobacco products of the same type.

The second provision is “the Doggett Amendment,” which, since 1997, the U.S. Congress has adopted in annual appropriations legislation. It imposes similar prohibitions with regard to the agencies funded through that Act, including USTR, which has primary responsibility for negotiating trade agreements on behalf of the United States.<sup>213</sup>

Executive Order 13193 and the Doggett Amendment prohibit USTR from pursuing two categories of trade policies, those that either: (1) promote “the sale or export of tobacco or tobacco products,” or (2) seek “the reduction or removal” of nondiscriminatory restrictions by foreign governments on tobacco marketing. As discussed below in part IV.B, several current or proposed U.S. trade agreements could violate one or both of these prohibitions.

## **VI. Options for Reducing the Threats**

There are a variety of approaches that tobacco control stakeholders could pursue to reduce the threat to tobacco control regulations posed by international trade and investment rules. Options include participating in the trade policy *process* to ensure that USTR does not negotiate agreements that threaten tobacco control measures and promoting *substantive* legal mechanisms that would protect tobacco control measures from challenge under both new and existing trade and investment agreements.

### **A. Participation in the U.S. Trade Policy Process**

Stakeholders have several options for engaging with USTR on tobacco control, including the formal U.S. trade policy advisory system, state-level oversight, and Congressional advocacy.

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<sup>213</sup> See Consolidated Appropriations Act, 2014, Pub. L. No. 113-76, Div. B, § 509 available at <http://beta.congress.gov/113/bills/hr3547/BILLS-113hr3547enr.pdf>:

None of the funds provided by this Act shall be available to promote the sale or export of tobacco or tobacco products, or to seek the reduction or removal by any foreign country of restrictions on the marketing of tobacco or tobacco products, except for restrictions which are not applied equally to all tobacco or tobacco products of the same type.

## 1. The Trade Policy Advisory System

Congress has established a system of advisory committees to ensure that the United States' trade policy represents the national interest.<sup>214</sup> These committees could be encouraged to advise USTR to protect tobacco control laws from challenge under trade and investment agreements. Potential committees that could be approached include the Agricultural Policy Advisory Committee, the Intergovernmental Policy Advisory Committee (which represents the interest of state and local governments in trade policy), and the recently established Public Interest Trade Advisory Committee.

## 2. State and Local Governments and Organizations

State and local governments can also participate in the U.S. trade policy process, both through national associations of state and local officials and through individual states. For example, the National Association of Attorneys General recently sent a letter, signed by the attorneys general of forty-five states, to the U.S. Trade Representative requesting that tobacco control measures be carved out from trade agreements.<sup>215</sup> Other national associations that could engage in the debate over trade and tobacco include the National Governors Association, the National Conference of State Legislatures, and the National League of Cities. Several states also have trade oversight committees that have encouraged USTR to exclude tobacco from trade agreements. These include the Maine Citizen Trade Policy Commission<sup>216</sup> and the Vermont Commission on International Trade and State Sovereignty.<sup>217</sup>

## 3. Congressional Oversight

Congressional committees with jurisdiction over either trade agreements (the Senate Finance Committee and the House Ways and Means Committee) or public health (including the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce) could hold oversight hearings on the use of trade and investment rules to challenge tobacco regulations. Congress could also use trade promotion authority legislation to direct USTR to protect tobacco control measures under future trade agreements.

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<sup>214</sup> See Office of the United States Trade Representative, *Advisory Committees*, available at <http://www.ustr.gov/about-us/intergovernmental-affairs/advisory-committees>.

<sup>215</sup> See National Association of Attorneys General Letter to Ambassador Michael Froman (February 14, 2014), available at <http://www.naag.org/assets/files/pdf/signons/2014-02-05%20TPP%20Final%20Letter1.pdf>. The letter was also signed by the attorneys general of the District of Columbia, Guam, and the Northern Mariana Islands.

<sup>216</sup> See Letter from Maine Citizen Trade Policy Commission to Ambassador Michael Froman (August 22, 2013), available at <http://www.maine.gov/legis/opla/CTPC%20Froman%20letter%208-22-13.pdf>.

<sup>217</sup> See Letter from Vermont Commission on International Trade and State Sovereignty to Ambassador Ron Kirk (July 25, 2012), available at <https://leg2.vermont.gov/sites/legislature/Committees/CTFWG/VTCITSS/ITSSRC/2012%20Document/Letter%20to%20Ambassador%20Kirk%20Regarding%20TPPA%20Tobacco.pdf>.

## B. Legal Safeguards in Future Agreements

There are three main options for protecting tobacco control laws under future trade agreements such as the TPP and TTIP: exclusions, exceptions, and reservations.

### 1. Exclusions

An exclusion, or “carve-out,” is a provision in a trade agreement that limits the scope of the agreement’s application. As noted above, there is growing support from various groups—including the National Association of Attorneys General—for carving tobacco control measures out of trade agreements. This approach would deny trade dispute panels and investment tribunals jurisdiction over challenges to tobacco-control regulations.<sup>218</sup> An exclusion would be the simplest approach that USTR could take to comply with Executive Order 13193 and the Doggett Amendment. A complete tobacco carve-out would avoid the violations.<sup>219</sup>

### 2. Exceptions

An exception is a provision in a trade agreement that may be asserted as an affirmative defense for a measure found both to be covered and to violate a rule of the agreement. Unlike exclusions, exceptions do not preclude trade panels from asserting jurisdiction. Exceptions only apply to certain trade rules. In the WTO, for example, both GATT (Article XX) and GATS (Article XIV) contain a general exception for measures “necessary to protect human . . . life or health.”

Although the health exception provides some degree of protection for tobacco-control measures, it requires litigation of four stages with seven legal tests to determine whether a particular measure is permissible:<sup>220</sup>

*Stage 1* – whether a measure is within the scope of protected health measures.

*Stage 2* – whether a measure is *prima facie* “necessary.” There are three tests for necessity. They “weigh and balance” (a) the importance of values or interests at stake, (b) the contribution of the measure to the objective, and (c) the restrictive effects of the measure on international trade;

*Stage 3* – whether less-restrictive measures are reasonably available; and

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<sup>218</sup> See Stumberg, *supra*, at 402.

<sup>219</sup> A complete carve out tobacco from trade agreements would also avoid violations of Executive Order 13193 and the Doggett amendment that could arise from negotiating tariff reductions on tobacco and tobacco products. See *part V.b.4(b), infra*. There are precedents for excluding tobacco and other products from tariff reduction commitments. Tobacco is not subject to tariff reduction commitments under the U.S. - Jordan Free Trade Agreement, rice is excluded from tariff concessions by South Korea under the U.S. - Korea FTA, and sugar is excluded from tariff concessions by the United States under the U.S. - Australia FTA. See Remy Jurenas *Agriculture in U.S. Free Trade Agreements: Trade with Current and Prospective Partners, Impact, and Issues* at 9 (Congressional Research Service, Updated January 30, 2008) available at <http://www.nationalaglawcenter.org/assets/crs/RL34134.pdf>.

<sup>220</sup> See Stumberg, *supra*, at 402-03.

*Stage 4* – whether the measure satisfies the “chapeau” requirements that a measure cannot constitute “arbitrary or unjustifiable discrimination” or a “disguised restriction” on trade.

As a result of these legal hurdles, it is difficult to predict with any certainty the outcome of a particular dispute. Moreover, some agreements that are being used to challenge tobacco regulations—including the TBT Agreement that Indonesia invoked in its successful WTO challenge to the U.S. ban on flavored cigarettes—do not contain general exceptions.

The practice of the United States in its regional and bilateral free trade agreements is to apply exceptions only to certain chapters, *not* including investment and intellectual property.<sup>221</sup> Some countries, however, have included exceptions that are applicable to investment rules in their free trade agreements.<sup>222</sup>

### **3. Reservations**

The United States could also assert reservations for tobacco-control measures in future agreements. Like exceptions, reservations apply only to certain trade rules, but they operate as exclusions; they do not require litigation with multiple stages to defend the measure.<sup>223</sup> For example, the U.S.–Peru Trade Promotion Agreement permits parties to assert reservations from certain provisions of the chapters on services and investment—including National Treatment, Most Favored Nation Treatment, and Market Access.<sup>224</sup> U.S. trade agreements, however, do not permit countries to take reservations from some of the most important rules that the tobacco industry is using to challenge tobacco control laws—including indirect expropriation, fair and equitable treatment, and intellectual property provisions.

### **4. Proposals for covering tobacco in the TPP**

In May of 2012, USTR proposed a specific exception for tobacco in the TPP, which it described as a “safe harbor” provision.<sup>225</sup> Proposed as part of the general exceptions chapter, it would have “allow[ed] health authorities in TPP governments to adopt regulations that impose origin-neutral, science-based restrictions on specific tobacco

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<sup>221</sup> See, e.g., Free Trade Agreement Between the United States of America and the Republic of Korea, art. 23.1, available at [http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset\\_upload\\_file755\\_12697.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file755_12697.pdf).

<sup>222</sup> See, e.g., Korea-Australia Free Trade Agreement, art. 22.1(3), available at <http://dfat.gov.au/fta/kafta/downloads/KAFTA-chapter-22.pdf>.

<sup>223</sup> See Stumberg, *supra*, at 401.

<sup>224</sup> See U.S.–Peru Trade Promotion Agreement, Chapter 10—Investment, Article 10.13; Chapter 11—Services, Article 11.6, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text>.

<sup>225</sup> Office of the United States Trade Representative, *TPP Tobacco Proposal* (May 18, 2012). The May 2012 tobacco proposal has been removed from USTR’s website, but is available at <http://www.scribd.com/doc/162101394/2013-08-12-TPP-Tobacco-Proposal>.

products/classes in order to safeguard public health . . . while retaining important trade disciplines (national treatment, compensation for expropriations, and transparency) on tobacco measures.”<sup>226</sup> USTR also included two additional elements: (1) a commitment to seeking tariff phase-outs on all tobacco products, and (2) a recognition of the “unique status of tobacco products from a health and regulatory perspective.”

About a year after the U.S. proposal on tobacco (summer of 2013), Malaysia proposed to “carve-out” tobacco control measures from the TPP. This is not a carve-out of tobacco *products*, per se, as some media have reported. Carving out products would affect negotiations to reduce tariffs on tobacco products. Rather, Malaysia is proposing to carve out laws and administrative measures that *regulate* tobacco products and services. Malaysia’s carve-out would exclude those measures from coverage by all of the TPP chapters.<sup>227</sup>

According to media reports, all TPP countries except Japan and Vietnam have indicated support for some kind of tobacco-specific language.<sup>228</sup> Malaysia’s proposal has strong support from the Malaysian Council for Tobacco Control (MCTC), the Southeast Asia Tobacco Control Alliance (SEATCA), 45 state-level attorneys general in the United States, the New York Times editorial board, and numerous public health and medical organizations in the United States (including, among others, the Campaign for Tobacco Free Kids, Action on Smoking and Health, the Center for Policy Analysis on Trade and Health, the American Public Health Association, and the American Academy of Family Physicians).<sup>229</sup>

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<sup>226</sup> *Id.* The safe harbor provision previously proposed by USTR would apparently have applied only to tobacco control “regulations” issued by administrative agencies and would not have protected tobacco control legislation from challenges under trade and investment rules. This approach would be inconsistent with Executive Order 13193 and the Doggett amendment, which prohibit federal agencies from undermining “restrictions” on tobacco advertising and marketing, regardless of which branch of government promulgates them. It is not clear why USTR chose to make this distinction, particularly given that the United States’ legislatively imposed ban on clove cigarettes has been held to violate U.S. obligations under the WTO. *See also* Appellate Body Report, *United States - Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/AB/R (April 4, 2012).

<sup>227</sup> *TPP Countries Will Consult Internally On Tobacco Proposals, Official Says*, INSIDE US TRADE (September 5, 2013); *Malaysia Softens Its Position On SOEs, Tobacco Carveout Language*, INSIDE US TRADE (December 10, 2013).

<sup>228</sup> *E.g., Malaysia Flags Major TPP Outstanding Issues, Says U.S. Needs TPA To Close*, INSIDE US TRADE (February 28, 2014).

<sup>229</sup> *TPP Countries Will Consult Internally On Tobacco Proposals, Official Says*, INSIDE US TRADE (September 5, 2013); National Association of Attorneys General, Letter to Amb. Michael Frohman (February 5, 2014); American Public Health Association, Letter to Amb. Michael Frohman (October 2, 2013); CPATH, American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Physicians (ACP), and American Congress of Obstetricians and Gynecologists (ACOG), Letter to Amb. Frohman (September 11, 2013).

U.S. negotiators initially responded to Malaysia in August of 2013 by (a) reaffirming their commitment to tariff elimination for all tobacco products, (b) proposing to recognize the “unique status” of tobacco, and (c) replace the “safe harbor” proposal with language stating that the TPP’s general exception for measures necessary to protect human health “applies” to tobacco control measures. USTR also proposed language requiring health authorities of the affected TPP Parties to consult before one Party could bring a state-to-state claim regarding a tobacco measure under the TPP.<sup>230</sup>

USTR’s August 2013 proposal was widely criticized by public health advocates.<sup>231</sup> The language indicating that the TPP’s general exception “applies” to tobacco control measures is not legally significant for two reasons. First, the general exception will not apply to investor-state disputes such as the claims being brought by Philip Morris against Uruguay and Australia. Second, there is no debate concerning whether tobacco control measures are health measures. As the WTO panel noted in the clove cigarettes case, “It is self-evident that measures to reduce youth smoking are aimed at the protection of human health ...”<sup>232</sup> The issue is not whether a tobacco measure is a health measure; it is whether the measure would satisfy the subsequent four tests for necessity and the two additional tests under the “chapeau” of the general exception (“arbitrary or unjustifiable discrimination” and “disguised restriction” on trade).<sup>233</sup> In the clove cigarette dispute, the WTO’s Appellate Body applied what it characterized as a comparable standard (under the TBT Agreement) in striking down the U.S. ban on clove cigarettes.<sup>234</sup>

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<sup>230</sup> See USTR, *Fact Sheet: New U.S. Proposal on Tobacco Regulation in the Trans-Pacific Partnership* (August 21, 2013), available at <http://www.ustr.gov/about-us/press-office/fact-sheets/2013/august/fact-sheet-tobacco-and-tpp>.

<sup>231</sup> See, e.g., Michael R. Bloomberg, *Why is Obama Caving on Tobacco?* *New York Times* (Aug. 22, 2013), available at [http://www.nytimes.com/2013/08/23/opinion/why-is-obama-caving-on-tobacco.html?hp&\\_r=1&](http://www.nytimes.com/2013/08/23/opinion/why-is-obama-caving-on-tobacco.html?hp&_r=1&) (describing the Obama Administration’s new proposal for covering tobacco under the TPP as “weak half-measures at best that will not protect American law—and the laws of other countries—from being usurped by the tobacco industry, which is increasingly using trade and investment agreements to challenge domestic tobacco control measures”); Action on Smoking and Health (ASH), *Obama Goes to Bat for Big Tobacco in TPP* (Aug. 19, 2013), available at <http://ash.org/obama-goes-to-bat-for-big-tobacco-in-tpp/>; Action on Smoking and Health (ASH), Center for Policy Analysis on Trade and Health (CPATH), Corporate Accountability International, Human Rights and Tobacco Control Network (HRTCEN), International Association for the Study of Lung Cancer (IASLC), *Smoke Out Tobacco from the TPP—Exclude tobacco from the Trans Pacific Partnership*, available at <http://www.cpath.org/id51.html>; Campaign for Tobacco-Free Kids, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association and American Academy of Pediatrics, *USTR Abandons Plan to Protect Tobacco Control Measures under Trans-Pacific Partnership Trade Agreement* (Aug. 19, 2013), available at [http://www.tobaccofreekids.org/press\\_releases/post/2013\\_08\\_19\\_trade](http://www.tobaccofreekids.org/press_releases/post/2013_08_19_trade).

<sup>232</sup> Panel Report, *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/R (2 Sept. 2011) ¶ 7.347.

<sup>233</sup> See Stumberg, *supra*, at 415.

<sup>234</sup> See Appellate Body Report, *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/AB/R (4 April 2012), para. 96:

The balance set out in the preamble of the *TBT Agreement* between, on the one hand, the desire to avoid creating unnecessary obstacles to international trade and, on the other hand, the recognition of Members' right to regulate, is not, in principle, different from the balance set out in the GATT 1994,

USTR’s proposed consultation requirement would not preclude a Party from proceeding with a dispute and would be largely redundant with the obligation to consult that already exists in U.S. free trade agreements.<sup>235</sup>

After seeing the response to their August 2013 proposal, U.S. negotiators signaled a possible shift in their position about a year later. In October 2014, U.S. negotiators began vetting the idea of a *partial* carve-out—to exclude tobacco measures only from ISDS.<sup>236, 237</sup> Whether a partial carve-out would actually block all private investment claims depends how the carve-out is drafted.<sup>238</sup>

## 5. Compliance with E.O. 13193 and the Doggett Amendment

### a. USTR’s proposal to eliminate tobacco tariffs appears to violate E.O. 13193

As the U.S. position on safeguards for tobacco control has fluctuated, the U.S. commitment to eliminating tariffs on tobacco products has been constant throughout the course of TPP negotiations.

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where obligations such as national treatment in Article III are qualified by the general exceptions provision of Article XX.

<sup>235</sup> See, e.g., United States – Republic of Korea Free Trade Agreement, art. 22.3 (Cooperation) (“The Parties shall endeavor to agree on the interpretation and application of this Agreement, and shall make every attempt through cooperation and consultations to arrive at a mutually satisfactory resolution of any matter that might affect its operation”), and art. 22.7 (Consultation) (“Either Party may request consultations with the other Party with respect to any matter . . . .”), available at [http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset\\_upload\\_file973\\_1272.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file973_1272.pdf).

<sup>236</sup> Krista Hughes, U.S. floats cutting tobacco from part of Pacific trade pact -sources, REUTERS (October 21, 2014); USTR Informally Floats ISDS Tobacco Carveout With Some TPP Countries, INSIDE US TRADE (October 7, 2014); Adam Behsudi, Morning Trade: Tobacco raises TPP concerns, POLITICO, (October 8, 2014).

<sup>237</sup> [This idea \(absent specific language\) drew immediate criticism from businesses and legislators from tobacco-growing states and a broad coalition of national business organizations.](#) Letter to Ambassador Frohman from the American Farm Bureau Federation, American Meat Institute, Corn Refiners Association, Emergency Committee for American Trade National Association of Manufacturers, National Foreign Trade Council, National Oilseed Processors Association, United States Council for International Business, United States Hide, Skin and Leather Association, US-ASEAN Business Council, and the U.S. Chamber of Commerce (October 21, 2014); North Carolina Agribusiness Council, NCAC Warning: Abandoning Tobacco Growers in Trans-Pacific-Partnership Negotiations Would Devastate NC Economy, press release (October 13, 2014); Len Bracken, Trans-Pacific Partnership – Lawmakers Express Concerns on Exclusion Of Tobacco from ISDS in Trans-Pacific Pact, BNA (October 15, 2014).

<sup>238</sup> See part 4.d below. Since no text is available regarding a carve-out from the TPP’s investment chapter, this paper does not address the potential that a carve-out from ISDS could be drafted so as to permit state-to-state challenges or even some investor-state challenges of tobacco control measures. For a helpful discussion of these issues, see Jane Kelsey, *Preliminary Analysis: Why a Tobacco “Exception” from ISDS Won’t Sufficiently Protect Tobacco Control Measures* (Feb. 22, 2014), available at [http://ash.org/blanket-exemption-for-tobacco-in-tpp/](http://ash.org/blanket-exemption-for-tobacco-in-tp/) (viewed October 9, 2014). For an evaluation of multiple alternative safeguards, see Mitchell and Sheargold, *Autonomy of States*, *supra* note 9, text accompanying notes 33-50; see also Stumberg, *supra* note 3, at 436-440.

According to the World Bank, reduced tariffs and other restrictions on tobacco products “tend to introduce greater competition that results in lower prices, greater advertising and promotion, and other activities that stimulate demand,” leading to “increases in cigarette consumption, particularly in the low- and middle-income countries.”<sup>239</sup> USTR’s proposal to use the TPP to eliminate tariffs on tobacco products therefore appears to be inconsistent with the prohibition in Executive Order 13193 on promoting tobacco sales and exports. The full text of that prohibition is:

In the implementation of international trade policy, executive departments and agencies shall not promote the sale or export of tobacco or tobacco products, or seek the reduction or removal of foreign government restrictions on the marketing and advertising of such products, *provided that such restrictions are applied equally to all tobacco or tobacco products of the same type.* (emphasis added)

It has been suggested that the proviso clause at the end means that the prohibition on promoting tobacco products does not apply to reducing tariffs. The reasoning is that tariffs are by nature discriminatory, so if the prohibition only applies to restrictions that apply equally to all tobacco products, then it does not apply to tariffs.<sup>240</sup> This rationale for reducing tobacco tariffs ignores plain semantics. The proviso clause that limits the prohibition applies to “restrictions” on marketing or advertising, the second category of prohibited activity—not the first prohibition on promoting sale of tobacco products.

The syntactical logic of this reading of the provision can be illustrated by eliminating the phrase describing the first category of prohibited activity (promotion) from the text:

In the implementation of international trade policy, executive departments and agencies shall not [. . .] seek the reduction or removal of foreign government *restrictions* on the marketing and advertising of such products, provided that *such restrictions* are applied equally to all tobacco or tobacco products of the same type.

The resulting text is syntactically coherent and logical. Conversely, eliminating the phrase describing the second category of prohibited activity (seeking the reduction or removal of marketing restrictions) results in an incoherent sentence:

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<sup>239</sup> The World Bank, *CURBING THE EPIDEMIC: GOVERNMENTS AND THE ECONOMICS OF TOBACCO CONTROL* (1999) at 14-15, available at <http://go.worldbank.org/USV7H5C800>.

<sup>240</sup> See Simon Lester, *Free Trade and Tobacco: Thank You for Not Smoking (Foreign) Cigarettes* (CATO Institute, August 15, 2012) (arguing that “targeting discriminatory measures is clearly permitted, and tariffs are a classic form of discriminatory measure”), available at <http://www.cato.org/publications/free-trade-bulletin/free-trade-tobacco-thank-you-not-smoking-foreign-cigarettes>. Although USTR has not explained its apparent position that its approach to covering tobacco under trade agreements is consistent with E.O. 13193 and the Doggett Amendment, its Fact Sheet on the new proposal suggests that it may be relying on the language regarding discrimination: “we will continue to press for the elimination of tariffs on U.S. agriculture exports, which, by their very nature, discriminate against American farmers.” See USTR, August 2013 Fact Sheet.



In the implementation of international trade policy, executive departments and agencies shall not promote the sale or export of tobacco or tobacco products [. . .] provided that *such restrictions* are applied equally to all tobacco or tobacco products of the same type.

There is no antecedent to which “such restrictions” can refer. Accordingly, the proviso clause does not apply to the first category of prohibited activities, which means that USTR’s proposal to promote the sale and export of tobacco products by negotiating tariff reductions is inconsistent with the Executive Order.

***b. USTR’s proposal to permit trade and investment challenges appears to violate E.O. 13193***

USTR’s proposal would permit tobacco-control measures to be challenged under trade and investment rules, thereby undermining restrictions on tobacco marketing in violation of the provisions of Executive Order 13193 and the Doggett amendment. Both policies prohibit federal agencies from undermining nondiscriminatory restrictions on tobacco advertising and marketing. Under the TPP’s expropriation and fair and equitable treatments provisions, for example, tobacco companies could challenge tobacco marketing regulations based on an adverse impact on their business *even if the challenged regulations are nondiscriminatory and applied equally to foreign and domestic businesses*, such as the packaging laws that Philip Morris is challenging in Australia and Uruguay.<sup>241</sup>

To summarize, the 2013 U.S. proposal on tobacco in the TPP provides no meaningful safeguard for tobacco measures, and its other elements appear to be inconsistent with the prohibition under Executive Order 13193 and the Doggett amendment on using trade policy to undermine restrictions on the marketing and advertising of tobacco products.

**C. Safeguards for Existing Trade Agreements: Amendments and Interpretations**

Safeguards for tobacco control regulations could be incorporated into existing trade agreements through either amendments or formal interpretations. Under international law, treaties generally may be amended by agreement of the parties.<sup>242</sup> Treaties may also provide for specific procedures for amendments. For example, under Article X of the Agreement Establishing the World Trade Organization, amendments to WTO agreements may be adopted if supported by three-fourth of the members.<sup>243</sup>

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<sup>241</sup> See part IV(E), *supra*. See also Lester, (“some of the intellectual property and investment provisions cited in the plain packaging cases do go beyond nondiscrimination, and could put constraints on nondiscriminatory actions by governments.”)

<sup>242</sup> See Vienna Convention on the Law of Treaties, Article 39.

<sup>243</sup> Agreement Establishing the World Trade Organization, Article X, *available at* [http://www.wto.org/english/docs\\_e/legal\\_e/04-wto.pdf](http://www.wto.org/english/docs_e/legal_e/04-wto.pdf).

Some trade agreements also permit Parties to adopt formal “interpretations” of existing rules. As with amendments, Article IX:2 of the WTO Agreement permits interpretations to be adopted by a vote of three-fourths of the Members.<sup>244</sup> U.S. free trade agreements also typically provide a mechanism for the parties to adopt formal interpretations.<sup>245</sup>

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<sup>244</sup> *See id.*, Art. IX:2 (“[t]his paragraph shall not be used in a manner that would undermine the amendment provisions of Article X.”).

<sup>245</sup> *See, e.g.*, The United States-Peru Trade Promotion Agreement, art. 20.1(3) (providing the Free Trade Commission established under the Agreement with the authority to “issue interpretations of the provisions of this Agreement”).