Title
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Defending strong tobacco packaging and labeling regulations in Uruguay: transnational tobacco control network versus Philip Morris International

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b Campaign for Tobacco Free Kids
c Department of Politics, University of California, Santa Cruz

ABSTRACT

Objective Describe the process of enacting and defending strong tobacco packaging and labeling regulations in Uruguay amidst Philip Morris International (PMI) legal threats and challenges.

Methods Triangulated government legislation, news sources, and interviews with policymakers and health advocates in Uruguay.

Results In 2008 and 2009, the Uruguayan government enacted at the time the world’s largest pictorial health warning labels (HWLs) (80% of front and back of package) and prohibited different packaging or presentations for cigarettes sold under a given brand. Philip Morris International (PMI) threatened to sue Uruguay in international courts if these policies were implemented. The Vazquez Administration maintained the regulations, but a week prior to President Vazquez’s successor, President Mujica, took office on March 1, 2010 PMI announced its intention to file an investment arbitration dispute against Uruguay in the International Centre for the Settlement of Investment Disputes. Initially, the Mujica Administration announced it would weaken the regulations to avoid litigation. In response, local public health groups in Uruguay enlisted former President Vazquez and international health groups and served as brokers to develop a collaboration with the Mujica Administration to defend the regulations. This united front between the Uruguayan government and the transnational tobacco control network paid off when Uruguay defeated PMI’s investment dispute in July 2016.

Conclusion To replicate Uruguay’s success, other countries need to recognize that strong political support, an actively engaged local civil society, and financial and technical support are important factors in overcoming tobacco industry legal threats to defend strong public health regulations.

INTRODUCTION

Since the 1990s the tension between trade and tobacco control has escalated1 as new legal rules concerning intellectual property and foreign investment have enabled investors (including tobacco companies) to challenge domestic public health policies in international trade and investment arbitration courts.2-4 Tobacco companies lobbied states in the General Agreement on Tariffs and Trade (GATT) and World Trade Organization (WTO) to file trade disputes against other member states’ tobacco control policies.3, 6 Subsequently, tobacco companies directly challenged public health policies using investor-state dispute settlement (ISDS) mechanisms in trade and investment agreements7 and used the threat of legal action8 to dissuade governments from implementing tobacco control policies.9

Partially in response to trade challenges, tobacco control advocates formed a transnational tobacco control network, consisting of health advocates, health organizations, academics, lawyers and donors to increase exchanges of information and services.10 This network combines characteristics of global civil society,11 epistemic communities,12, 13 and advocacy networks.14 This network supported the creation of the WHO Framework Convention on Tobacco Control (FCTC)15 and assisted governments in implementing it,16-19 which has accelerated the adoption of tobacco control regulations,20-23 including pictorial health warning labels (HWLs) on cigarette packages.24 The fact that the FCTC does not clearly prioritize health over trade1, 25 forced this network to adapt and combat emerging pressures of trade on tobacco control.

In 2004, Dr. Tabaré Vazquez, an oncologist, was elected president and made reducing tobacco consumption a high priority. Supported by strong local advocates, Uruguay became the first Latin American country to establish 100% smokefree environments in all workplaces and public places,26 prohibit misleading descriptors on cigarette packages, and adopt pictorial health warning labels (HWL) covering 50% of the front and back of the package27 (Table 1). As in other countries,28-30
Philip Morris International’s (PMI) Uruguayan subsidiary Abal Hermanos (Abal) responded to the prohibition by color-coding cigarette packages (e.g., replacing Marlboro Lights with yellow Marlboro packages). In 2008 and 2009, the Uruguayan government responded by implementing the world’s strongest (at the time) tobacco packaging and labeling regulations, requiring pictorial HWLs covering 80% of the front and back of the package\(^{31}\) (Figure 1) and that cigarette brands be sold in a single pack presentation.\(^{32}\) (The single pack presentation permitted only one variant of each cigarette brand which prohibited the color-coding of “light” and “mild”\(^{28-30,33}\) or menthol\(^{33}\) variants.) PMI then threatened and sued Uruguay in domestic and international courts. With strong political support, an actively engaged local civil society and the transnational tobacco control network that provided financial and technical support, Uruguay overcame these legal challenges and defended its regulations, serving as a model for future public health successes.

METHODS

Between August 2014 and June 2016 we reviewed Uruguayan tobacco control legislation (available at https://parlamento.gub.uy/), government and health group reports (https://www.google.com.uy), and newspaper articles (www.elpais.com.uy) using standard snowball searches\(^{34}\) beginning with search terms “advertencias sanitarias,” “el comercio internacional,” “tratado bilateral de inversion,” “propiedad intellectual,” “marcas,” “Philip Morris,” and “Abal Hermanos,” as well as key dates and specific actors. Between November 2014 and July 2015 we attempted to recruit 26 interviewees via email and telephone and 16 agreed to be interviewed (four denied our requests and six never responded after multiple requests). The 16 interviewees included 7 Uruguayan tobacco control advocates, 3 congressmen, 5 Ministry of Health officials, and 1 Ministry of Foreign Relations official. The interviewees agreed to waive their anonymity in accordance with a protocol approved by the University of California, Santa Cruz Committee on Human Research. Results were triangulated and thematically analyzed through standard process tracing frameworks.\(^{35}\)

RESULTS

Abal (PMI) domestic and international legal threats

Between September 2008 and June 2009, Abal sent five letters to the Health Ministry (Table 1) arguing the packaging and labeling regulations were unconstitutional, beyond the executive’s jurisdiction and violated Uruguay’s obligations under two treaties governing trademark and investment rights, the Paris Convention for the Protection of Industrial Property and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).\(^{36-38}\) Abal argued the regulations violated a 1991 Uruguay-Switzerland bilateral investment treaty (BIT) and threatened to file a complaint with the World Bank’s International Centre for Settlement of Investment Disputes (ICSID) seeking compensation for damages.

Vazquez administration’s response to Abal’s first threats (2008-2010)

Despite Abal’s threats, the administration remained firm on the regulations. The Health Ministry recognized trade and investment agreements presented new complexities beyond their expertise and requiring discussions with the Ministries of Economy and Foreign Affairs.\(^{39,40}\) Their support\(^{41}\) for the Health Ministry’s approach to HWLs was necessary since each ministry had different priorities and stakeholders. President Vazquez’s support,\(^{41}\) as well as public support for tobacco control and Uruguay’s international commitments to the FCTC\(^{42}\) were vital to defending the regulations.

Health officials contacted local health groups, the Centro de Investigacion para la Epidemia del Tabaquismo (CIET, Tobacco Epidemic Research Center) and the Sociedad Uruguaya de Tabacología (SUT, Uruguayan Tobacco Society) for information on the regulations’ international legal implications; these organizations asked the US-based Campaign for Tobacco Free Kids (TFK, supported by the Bloomberg Initiative to Reduce
<table>
<thead>
<tr>
<th>Date</th>
<th>Actor</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>31 Oct 2004</td>
<td>X</td>
<td>Tabaré Vazquez is elected president of Uruguay.</td>
</tr>
<tr>
<td>31 May 2005</td>
<td>X</td>
<td>Health Ministry issues health decree N. 35 requiring cigarette packages be sold without misleading descriptors and pictorial HWLs covering 50% of both sides of the package.</td>
</tr>
<tr>
<td>2006-2008</td>
<td>X</td>
<td>Abal Hermanos (PMI) ignores law by continuing to sell color-coded cigarette packages.</td>
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<tr>
<td>6 Mar 2008</td>
<td>X</td>
<td>Congress enacts Law 18.256 to further institutionalize packaging and labeling policies.</td>
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<tr>
<td>18 Aug 2008</td>
<td>X</td>
<td>Health Ministry issues Public Ordinance N. 514 requiring each cigarette brand to have a single presentation.</td>
</tr>
<tr>
<td>10 Sep 2008</td>
<td>X</td>
<td>Abal sends letter to Health Ministry arguing Ordinance N. 514 violates the Uruguayan constitution and their investment rights under international treaties.</td>
</tr>
<tr>
<td>23 Sep 2008</td>
<td>X</td>
<td>Abal sends another letter to Health Ministry arguing Ordinance N. 514 violates treaties.</td>
</tr>
<tr>
<td>26 Dec 2008</td>
<td>X</td>
<td>Abal sends another letter to Health Ministry arguing Ordinance N. 514 violates treaties.</td>
</tr>
<tr>
<td>3 Feb 2009</td>
<td>X</td>
<td>Abal sends another letter to Health Ministry arguing Ordinance N. 514 violates treaties.</td>
</tr>
<tr>
<td>9 Feb 2009</td>
<td>X</td>
<td>Abal files a request in local courts for injunction to suspend Ordinance N. 514.</td>
</tr>
<tr>
<td>14 Feb 2009</td>
<td>X</td>
<td>Ordinance N. 514 comes into effect.</td>
</tr>
<tr>
<td>18 Feb 2009</td>
<td>X</td>
<td>Civil court denies Abal’s request for an injunction on procedural grounds.</td>
</tr>
<tr>
<td>27 Apr 2009</td>
<td>X</td>
<td>Civil court of appeals rejects Abal’s appeal on procedural grounds.</td>
</tr>
<tr>
<td>9 Jun 2009</td>
<td>X</td>
<td>Abal files an annulment action with the Administrative Court seeking the annulment of Article 3 (requiring single brand presentation) and suspension of Ordinance N. 514.</td>
</tr>
<tr>
<td>15 Jun 2009</td>
<td>X</td>
<td>President Vazquez issues executive decree N. 287 to increase pictorial HWLs from covering 50% to 80% of the front and back of the package.</td>
</tr>
<tr>
<td>25 Jun 2009</td>
<td>X</td>
<td>Abal sends threatening letter to Health Ministry arguing Decree N. 287 violates the Uruguayan constitution and their investment rights under international treaties.</td>
</tr>
<tr>
<td>11 Sep 2009</td>
<td>X</td>
<td>Abal files annulment action with the Administrative Court that executive decree N. 287 grants the executive branch unlimited power to impose restrictions on individual rights.</td>
</tr>
<tr>
<td>12 Dec 2009</td>
<td>X</td>
<td>Decree N. 287 comes into effect.</td>
</tr>
<tr>
<td>19 Feb 2010</td>
<td>X</td>
<td>PMI pays a non-refundable fee of $25,000 to file an investment dispute against Uruguay in ICSID under a 1991 Uruguay-Switzerland BIT to challenge the regulations.</td>
</tr>
<tr>
<td>19 Feb 2010</td>
<td>X</td>
<td>Members of local tobacco control organizations CIET and SUT publish opinion-editorials in local newspapers denouncing PMI’s attempt to intimidate the government.</td>
</tr>
<tr>
<td>1 Mar 2010</td>
<td>X</td>
<td>President Mujica enters office as President of Uruguay.</td>
</tr>
<tr>
<td>Mar 2010</td>
<td>X</td>
<td>Local health groups inform international health groups the government’s willingness to defend regulations but that they lack legal and financial capacity to fight PMI.</td>
</tr>
<tr>
<td>26 Mar 2010</td>
<td>X</td>
<td>The ICSID Secretary-General determines PMI’s challenge falls within the jurisdiction of the Centre and registers the investment dispute.</td>
</tr>
<tr>
<td>Apr-Jul 2010</td>
<td>X</td>
<td>PMI privately meets with top government officials about amending the regulations.</td>
</tr>
<tr>
<td>Jun-Jul 2010</td>
<td>X</td>
<td>CIET members learn that PMI is privately negotiating with the government to weaken the regulations and warn against the possibility of weakened regulations in the media.</td>
</tr>
<tr>
<td>29 Jun 2010</td>
<td>X</td>
<td>CIET writes a letter to former President Vazquez informing him that the Mujica government is privately negotiating with PMI to weaken the regulations.</td>
</tr>
<tr>
<td>16 Jul 2010</td>
<td>X</td>
<td>TFK coordinates letter from international groups to President Mujica to offer legal support, requesting the administration not settle with PMI by weakening the regulations.</td>
</tr>
<tr>
<td>22 Jul 2010</td>
<td>X</td>
<td>CIET meets with Senator Lucia Topolanski, President Mujica’s wife, to explain the risks of weakening the regulations. Mujica’s wife suggests speaking directly to the president and in response CIET requests a meeting with President Mujica.</td>
</tr>
<tr>
<td>Date</td>
<td>X</td>
<td>Event Description</td>
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</table>
| 23 Jul 2010|   | Health Ministry announces on the radio the government is going to eliminate Ordinance N. 514 and weaken Decree N. 287 by lowering the size of HWLs from 80% to 65%.  
| 24 Jul 2010| X | Former President Vazquez criticizes Mujica government for weakening the regulations.                                                                                                                                |
| 28 Jul 2010|   | Health groups send letters to petition President Mujica to defend regulations and offer technical assistance.                                                                                                        |
| 30 Jul 2010| X | President Mujica announces on the radio that tobacco companies are powerful enemies but that Uruguay will continue to explore options in maintaining the regulations.   |
| 3 Aug 2010 | X | Former President Vazquez meets with current President Mujica and urges him to accept the help from the international health groups and defend the regulations.      |
| 5 Aug 2010 | X | Officials from the Mujica Administration reach out to CIET and TFK inviting them to a meeting to discuss the international legal ramifications of the regulations. |
| 10 Aug 2010| X | International delegation of lawyers meet with top government officials and communicate that Uruguay has a strong legal case to defend the regulations. TFK offers financial assistance to help defend the regulations against the PMI investment dispute challenge. |
| 27 Aug 2010| X | TFK sends a letter to Uruguayan government to further communicate that there is widespread support from transnational tobacco control network and their commitment of financial support to minimize legal costs of a potential arbitration case against PMI. |
| 29 Sep 2010| X | PAHO Executive Committee unanimously approves a resolution supporting Uruguay’s tobacco control program and critical of PMI arbitration challenge, the first official statement by an international body on the PMI vs. Uruguay dispute. |
| 30 Sep 2010| X | TFK’s legal team meet again with top government officials to further communicate their commitments to generating international support.                                                                                  |
| 4 Oct 2010 | X | Uruguayan Foreign Minister Luis Almagro announces the governments’ intention to pursue the arbitration against PMI and accept financial support from the TFK.       |
| 6 Oct 2010 | X | TFK sends a follow up letter to top government officials to explain their plan to generate positive media coverage of the PMI vs. Uruguay dispute in Uruguay and build public support for Uruguay’s position from other countries and international organizations. |
| 15-20 Nov 2010| X | FCTC Secretariat holds 4th COP meeting in Punta del Este, Uruguay and issues the Punta del Este Declaration, which declares countries can prioritize public health regulations over trade agreements provided they are consistent with the WTO TRIPS agreement. |
| 16 Nov 2010| X | WHO holds press conference to announce it will provide scientific evidence to support regulations and coordinate briefings related to trade and tobacco.       |
| 16 Nov 2010| X | Michael Bloomberg issues a press release and personally calls President Mujica to announce that he (through TFK) will help finance Uruguay’s legal defense against PMI. |
| 15 Mar 2011| X | ICSID arbitration proceedings officially begin.                                                                                                          |
| 23 Sept 2011| X| Uruguayan government files a memorandum challenging ICSID jurisdiction claiming PMI was required under treaty to litigate treaty disputes in domestic courts first. |
| 28 Aug 2012| X| The Administrative Court rejects Abal’s challenge and upholds the Health Ministry’s jurisdiction and authority to implement Decree N. 287.                       |
| 3 Jul 2013| X| ICSID arbitrators denied Uruguay’s motion to dismiss PMI’s legal challenge.                                                                              |
| 28 Jan 2015| X| WHO and FCTC secretariat submit amicus brief to support the Uruguayan regulations.                                                                           |
| 6 Mar 2015| X| PAHO submits an amicus brief to support the Uruguayan regulations.                                                                                          |
| 5 Oct 2015| X| Uruguayan delegates participate in oral hearings on the merits of the case.                                                                                  |
| 8 Jul 2016| X| ICSID rejects PMI’s investment dispute, ruling that PMI has to pay US$7 million of Uruguay’s cost and an additional US$1.5 million for administrative fees and expenses and confirms Uruguay’s sovereign right to implement the regulations. |

Tobacco Use and the Framework Convention Alliance (FCA) for help.

**Political support in the legislature**

In addition to support by the executive branch, there was strong support for the regulations in the Uruguayan congress. Legislators confirmed local tobacco control organizations, CIET and SUT, and President Vazquez changed the culture of tobacco control in Uruguay and achieved strong political consensus for the regulations, assisted by strong public support, and a reduction in hospital admissions following Uruguay’s smokefree law. This assistance proved critical because unlike other countries, congress did not attempt to weaken the regulations.

**Abal’s domestic legal challenge**

After failing to force the Vazquez administration to withdraw the regulations, between 2009 and 2012 Abal unsuccessfully filed two lawsuits to block the single pack presentation on the grounds that the Health Ministry did not have jurisdiction to issue the ordinance and that only congress could restrict Abal’s constitutional rights. Then Abal unsuccessfully sued to block the requirement for the 80% pictorial HWLs, again arguing the Health Ministry did not have authority to issue the decree (Table 1).

**PMI ratchets up threats against new Mujica administration (2010-2015)**

On March 1, 2010, while the domestic legal challenges were pending and a week before new President Mujica took office, PMI filed a request for arbitration with ICSID under the Uruguay-Switzerland BIT. PMI argued the regulations expropriated PMI’s trademark property rights without compensation, the company was not provided fair and equitable treatment under a stable regulatory environment, and was not dealt with properly by Uruguayan courts (Table 2). PMI sought damages which it later quantified as US$25.7 million, and requested the tribunal order Uruguay to suspend the regulations, an unusual request that was later dropped as investor-state disputes usually only award monetary damages. PMI’s statements concerning intellectual property and investment in trade agreements were magnified by front page stories in major Uruguayan newspapers. The ICSID’s Secretary General registered PMI’s challenge as within the jurisdiction of the Centre on March 26, 2010.

**Mujica administration’s response to PMI's second set of threats (2010-2015)**

Mujica’s administration told the media they were “reviewing” the issue. Between April and June 2010 reports surfaced that PMI was privately negotiating an amendment to the regulations with the Ministers of Economy, Foreign Affairs, and Health. While it is unclear what occurred during these private meetings, on July 23, 2010 Health Minister Daniel Olesker announced the regulations would be amended by eliminating the single pack presentation rule and reducing the size of HWLs from 80% to 65%.

**Early mobilization by local health groups in Uruguay**

In February and March 2010, CIET and SUT published opinion-editorials in newspapers denouncing PMI’s attempt to intimidate the government. In March 2010, during a WHO meeting, CIET convened a meeting with TFK and FCA, Uruguayan government officials, and WHO lawyers to request support defending the regulations. After learning about the government’s private negotiations with PMI, CIET alerted the media and met with government officials to argue for maintaining the regulations. CIET wrote former President Vazquez stating changes to the regulations would reverse progress in Uruguay and set a bad precedent for the region. In July, CIET met with Senator Lucia Topolanski, President Mujica’s wife, to explain the risks of weakening the regulations. She told CIET to speak directly with the president. CIET requested a meeting and was eventually invited (together with a delegation of international lawyers) to discuss the regulations in August (Table 1).
Figure 1 Example cigarette package sold in Uruguay with single brand presentation and pictorial HWLs covering 80% front and back of the package. Package reads: “Smoking causes bad breath, stained teeth, and unpleasant odor” [translated by author].

Response from former President Vazquez

On July 24, 2010, a day after Health Minister Olesker announced the government intended to weaken the regulations, the press and CIET contacted former President Vazquez who appeared on television to express disappointment in the Mujica administration and oppose weakening the regulations. Luis Almagro, Minister of Foreign Affairs, responded, telling reporters the government remained committed to fighting tobacco but was uncertain of the regulations’ legality under international trade law.

A few days later, Mujica visited Vazquez to privately discuss PMI’s legal threats and the regulations, when Vazquez reportedly urged Mujica to defend the regulations and seek international support. Mujica reportedly acknowledged that Vazquez made some convincing arguments but that he was still concerned about the legal costs of fighting PMI, and was continuing to evaluate the situation.

International support to the Uruguayan government

CIET requested TFK’s assistance to help the government defend the regulations. In response, TFK wrote President Mujica on July 16, 2010 (a week before the public announcement of the weakened regulations) offering legal support and requesting that his administration not settle with PMI. On July 28, 2010 (four days after the public announcement of the weakened regulations), TFK coordinated a letter signed by several international health groups urging Mujica to defend the regulations. This support and Vazquez’s encouragement helped Mujica reconsider defending both regulations in August 2010.

Bloomberg financial support

On August 10, 2010 the international delegation of lawyers met high level government officials and congressmen to argue against settling. They told the government it had a strong legal case because international law, including the Uruguay-Switzerland BIT, recognized governments’ authority to protect public health. Uruguay’s legal position was strengthened by being a party to the FCTC, which recommends the implementation of strong regulations. With authorization from the Bloomberg Foundation, TFK offered financial assistance to the Uruguayan government to help support Uruguay’s legal defense.

Generating international political support for Uruguay

In late August, TFK reiterated to the Uruguayan government the widespread global support to Uruguay’s case. In September 2010, the Pan American Health Organization (PAHO), the WHO regional office for the Americas,
<table>
<thead>
<tr>
<th>PMI’s claims</th>
<th>Tribunal ruling</th>
<th>Tribunal quotes</th>
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</thead>
<tbody>
<tr>
<td>(1) Regulations expropriate PMI’s property rights without compensation</td>
<td>a.) Regulations did not substantially deprive PMI’s value of investment as a.) PMI could continue selling tobacco in Uruguay and</td>
<td>“as long as sufficient value remains after the Challenged Measures are implemented, there is no expropriation. As confirmed by investment treaty decisions, a partial loss of the profits that the investment would have yielded absent the measure does not confer an expropriatory character on the measure.” [P 286]</td>
</tr>
<tr>
<td></td>
<td>b.) the state can exercise its right to regulate in the public good (police powers)</td>
<td>“Protecting public health has long since been recognized as an essential manifestation of the State’s police powers” [P 291]</td>
</tr>
<tr>
<td></td>
<td>c.) The registration of PMI’s trademarks does not grant them the right to use those trademarks</td>
<td>“The Tribunal notes that there is nothing in the Paris Convention that states expressly that a mark gives a positive right to use” [P 260]</td>
</tr>
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<td></td>
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<td>“nowhere does the TRIPS Agreement, assuming its applicability, provide for a right to use” [P 262]</td>
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<td></td>
<td></td>
<td>“The Claimants [PMI] also argue that a trademark is a property right under Uruguayan law which thus accords a right to use. Again, nothing in their argument supports the conclusion that a trademark grants an inalienable right to use the mark.” [P 266]</td>
</tr>
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<td></td>
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<td>“The Tribunal concludes that under Uruguayan law or international conventions to which Uruguay is a party the trademark holder does not enjoy an absolute right to use, free of regulation, but only an exclusive right to exclude third parties from the market so that only the trademark holder has the possibility to use the trademark in commerce, subject to the State’s regulatory power” [P 271]</td>
</tr>
<tr>
<td>(2) Regulations are arbitrary and not supported by evidence so they do not accord PMI with fair and equitable treatment</td>
<td>Regulations were not arbitrary as they fulfilled Uruguay’s national and international legal obligations for protecting public health under the FCTC</td>
<td>“It should be stressed that the [Challenged Measures] have been adopted in fulfillment of Uruguay’s national and international legal obligations for the protection of public health” [P 302]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“For a country with limited technical and economic resources, such as Uruguay, adhesion to the FCTC … represented an important if not indispensable means for acquiring the scientific knowledge and market experience needed for the proper implementation of its obligations under the FCTC” [P 393]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“in these circumstances there was no requirement for Uruguay to perform additional studies or to gather further evidence in support of the Challenged Measures” [P 396]</td>
</tr>
<tr>
<td>(3) Regulations do not meet PMI’s legitimate expectations of a stable regulatory environment</td>
<td>Given the harmful effects of tobacco, it would be reasonable to expect stronger regulation of tobacco over time</td>
<td>“In light of widely accepted articulations of international concern for the harmful effects of tobacco, the expectation could only have been of progressively more stringent regulation on the sale and use of tobacco products. Nor is it a valid objection to a regulation that it breaks new ground.” [P 430]</td>
</tr>
<tr>
<td>(4) Uruguayan courts have not dealt properly with PMI’s domestic legal challenges and there was a denial of justice</td>
<td>The domestic rulings may appear unusual but investment tribunals should not act as courts of appeal to national courts to find a denial of justice</td>
<td>“In general, when considering procedural improprieties arbitral tribunals have adopted a high threshold for a denial of justice. For a denial of justice to exist under international law there must be “clear evidence of … an outrageous failure of the judicial system’ or a demonstration of “systemic injustice’ …” [P 500]</td>
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became the first inter-governmental health organization to formally support Uruguay.\textsuperscript{61}

PAHO’s Executive Committee passed a resolution which specifically expressed support for Uruguay implementing FCTC recommended policies and urged member states to oppose tobacco industry interference.\textsuperscript{61} PAHO also offered technical support to the Health Ministry, focusing on the Conference of the Parties (COP), the FCTC’s governing body, scheduled to be held in Uruguay in November 2010.

In late September and early October, TFK reiterated its offer of financial and technical support to defend the regulations and develop a communications strategy.\textsuperscript{62} (Table 1). On October 4, 2010, the Foreign Minister held a press conference to announce the government would fight PMI and accepted the financial support provided by Bloomberg though TFK.\textsuperscript{63} From this point on, the Mujica administration took a strong stance against PMI and the investment challenge to ensure the regulations would be protected.

\textit{The 4th Conference of the Parties meeting in Uruguay}

The FCTC COP, which had been scheduled two years earlier, was held in Punta del Este, Uruguay in November, 2010, providing further international support to Uruguay. During the COP, international health groups informed governments and generated international media coverage of PMI’s attempts to intimidate Uruguay.\textsuperscript{87} (Table 1). Uruguay produced and tabled the Punta del Este Declaration, supported by the FCTC Parties attending the COP (except the EU, China, and Japan), declaring the rights of sovereign countries to prioritize public health regulations over trade agreements.\textsuperscript{25} The declaration specifically recognized the Parties’ concern regarding industry attempts to undermine government tobacco control regulations and Parties’ right and commitment to implement the FCTC.\textsuperscript{25} The EU successfully proposed adding the clause, “provided that such measures are consistent with the TRIPS agreement.”\textsuperscript{25}

This international support sent a clear signal that Uruguay was not alone in defending its regulations against PMI. Former President Vazquez and President Mujica addressed the COP, acknowledging the assistance from the transnational tobacco control network and the courage required to defend the regulations.\textsuperscript{25, 88} The WHO held a press conference and announced it would provide scientific evidence supporting the regulations and coordinate briefings related to trade and tobacco control to assist other governments in defending their regulations against legal challenges.\textsuperscript{43}

On November 15, 2010, New York City Mayor Michael Bloomberg announced he had offered $500,000 to help defend Uruguay’s regulations against the investment challenge and personally called President Mujica to offer his support.\textsuperscript{64} This ongoing assistance included legal collaboration with the law firm retained by the Uruguayan government to represent it throughout the ICSID proceedings.

\textbf{PMI investment challenge}

After the ICSID Secretary General registered PMI’s investment dispute on March 26, 2010, the Uruguayan government and PMI spent a year selecting arbitrators for the tribunal, which was constituted in March 2011.\textsuperscript{46} In September 2011, Uruguay filed a memorandum arguing the tribunal did not have jurisdiction to hear the claim as PMI was required under the treaty to litigate in domestic court before seeking arbitration,\textsuperscript{46} which the arbitrators denied in 2013.\textsuperscript{46} The next two years each party presented their arguments to the tribunal, which reviewed the case. In January and March 2015, the WHO and FCTC Secretariat\textsuperscript{66} and PAHO\textsuperscript{67} presented separate amicus briefs expanding on the scientific evidence and public health justification for the regulations. President Tabaré Vazquez, reelected in 2014 and resuming office in March 2015, appointed a new team to coordinate the legal defense for the oral hearings on the merits of the case held in Washington, DC in October 2015.

In July 2016, ICSID rejected PMI’s claims and ruled Uruguay had the sovereign right to protect public health.\textsuperscript{89} ICSID ruled the regulations did not substantially deprive PMI’s value of investment, were not arbitrary, were reasonable and expected regulations, and were handled properly in Uruguayan domestic courts\textsuperscript{46} (Table 2). The tribunal noted PMI’s total costs were US$16.9 million while Uruguay’s total costs were US$10.3 million and ruled PMI had to pay US$7 million of Uruguay’s cost and an
additional US$1.5 million for “all of the fees and expenses of the Tribunal and ICSID’s administrative fees and expenses,” leaving the government to pay $3.3 million. Bloomberg through TFK funded $1.5 million of the $3.3 million legal defense.

**DISCUSSION**

The Uruguayan case illustrates how strong political support, an actively engaged local civil society, and international financial and technical support are important factors in overcoming tobacco industry legal threats to defend public health policies.90, 91

**Strong political support**

The Vazquez and Mujica administrations demonstrated strong political commitments to tobacco control and ensuring the regulations were protected. President Vázquez’s leadership and prioritizing tobacco control helped alter the culture of tobacco control in Uruguay, demonstrating the importance of political champions in advancing tobacco control measures. Uruguay’s Health Ministry established supportive communication with the Ministry of Foreign Affairs, illustrating the importance of developing interagency alliances and a whole-of-government approach to implement the FCTC and resolve differences at the intersection of health and trade.

**Active engagement by local civil society**

Similar to successful tobacco control advocacy efforts in other countries, local civil society groups developed close relationships with government officials, provided evidence-based information to policymakers, and closely monitored swift government actions and industry activity to advance tobacco control in Uruguay. When the Mujica administration considered weakening the regulations to avoid an expensive legal battle with PMI (whose 2010 annual net revenues exceeded $64 billion versus Uruguay’s $32 billion GDP54) local health groups mobilized support from former President Vazquez and international health groups to produce a strong united response to support defending the regulations.

**Support by the transnational tobacco control network**

The united front between local and international health organizations demonstrates the value of the transnational tobacco control network in combating tobacco industry interference and supporting FCTC implementation,13, 95, 96 especially in low and middle-income countries.19, 20, 80 Even though international health organizations could have responded sooner to the government’s legal concerns, organizations such as TFK, WHO, and PAHO have become more knowledgeable about trade and investment issues. Advocacy networks and epistemic communities have continuously improved the links between science and advocacy to advance tobacco control policy;13, 14, 95, 97 the Uruguay case highlights how this network strengthened the links between trade and tobacco control to combat emerging pressures of trade on health. The network recognized the importance of legal precedents in tobacco control,98 contributing to their decision to support Uruguay’s regulations as a global tobacco control issue.

**International financial and technical support**

Bloomberg’s financial contributions highlight that trade and investment disputes create substantial burdens for small and financially vulnerable countries, which can be strong incentives for governments to settle these lawsuits. As a result, international organizations have focused more attention and resources towards this growing concern, especially in low and middle-income countries. In particular, in March 2015 Bloomberg and Bill Gates launched a $4 million “anti-tobacco trade litigation fund” to assist countries in drafting legislation “to avoid legal challenges and potential trade disputes,” and if challenges arise to provide funds for actual litigation defense expenses.99

**Domestic and international legal implications**

PMI’s losses to Uruguay in domestic and international courts are the latest in a string of losses at the national and international level. Constitutional courts upheld strong tobacco control policies in fourteen countries.17, 19, 94, 100 In particular, the Australian,101 UK,102 and Indian103 High Courts upheld strong packaging and
labelling policies, concluding similarly to the 2016 ICSID Uruguay ruling, that the registration of tobacco company trademarks did not prevent governments from restricting their use and imposing such restrictions was not expropriating their intellectual property rights. The EU Court of Justice also upheld the EU Tobacco Products Directive that grants the authority for each EU member to implement plain packaging and an arbitration tribunal dismissed as an ‘abuse of rights’ a BIT investment challenge filed by PMI against Australia’s plain packaging law on jurisdictional grounds.

PMI’s loss to Uruguay in ICSID, along with other defeats, provides greater legal clarity surrounding a country’s sovereign right to implement public health regulations. While there is no binding precedent in international arbitration law, the broader value of each award can contribute to the development and understanding of investment treaty law vis-a-vis tobacco control. By highlighting the importance of the FCTC in justifying evidence-based tobacco control measures, ICSID’s ruling should assist other countries, including New Zealand, Canada, Norway, South Africa, Malaysia, Turkey, India, Panama, Brazil, Ecuador and Chile, which, as of February 2017, were implementing or had announced plans to introduce similar tobacco packaging and labelling regulations.

A more direct way to minimize the tobacco industry’s ability to threaten governments would be eliminating the application of ISDS mechanisms in relation to tobacco (and public health more broadly) in trade and investment agreements. Without the ISDS mechanism in the Uruguay-Switzerland BIT, PMI would have had to convince a WTO member to challenge Uruguay’s regulations. Forced to lobby WTO member states to file trade disputes can also backfire; after tobacco companies paid the fees for the Ukraine government to challenge Uruguay’s plain packaging policy, health advocates convinced the new government to withdraw the claim because Ukraine had no tobacco trade with Australia. Ten months after Australia announced the plain packaging proposal, PMI moved ownership of its Australian operations from Switzerland to Hong Kong to challenge Australia’s plain packaging policy under a 1993 Australia-Hong Kong BIT. This treaty shopping also failed when the investment dispute was rejected on jurisdictional grounds.

LIMITATIONS

Top government officials in the president’s office and the Ministry of Foreign Affairs declined requests to be interviewed for this study, limiting the complete understanding of how the Mujica administration responded to tobacco industry legal threats. To protect attorney-client privileges policymakers in the Health Ministry and Foreign Affairs Ministry could not discuss legal advice given to the President surrounding the PMI investment challenge against Uruguay.

CONCLUSION

To replicate Uruguay’s success, other countries need to recognize that strong political support, an actively engaged local civil society, and financial and technical support are important factors in overcoming tobacco industry legal threats to defend strong public health regulations. Uruguay’s historic legal victory should provide legal clarity for other countries interested in implementing similar tobacco packaging and labeling regulations.

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**Ethics Approval** This study was conducted with the approval of the UCSC Committee on Human Research.

### WHAT THIS PAPER ADDS

**What is already known on this subject?**
- Tobacco companies have threatened governments over their packaging and labeling laws with international investment lawsuits since the 1980s.

**What important gaps in knowledge exist on this topic?**
- Historically, some countries have dropped or delayed strong packaging and labeling rules in the face of industry legal threats, but Uruguay, a small middle-income country successfully resisted these threats with strong political leadership and support from the transnational tobacco control network.

**What does this study add?**
- This is the first case study of how a tobacco company tried using investor protection provisions in an international trade and investment treaty in order to intimidate a government into withdrawing, weakening, or delaying progressive tobacco packaging and labeling regulations. Uruguay illustrates how strong political will at the national level with support from the transnational tobacco control network helped a small and financially vulnerable country confront the tobacco industry in an international investment dispute to defend its public health regulations.

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