nies expand across the globe, technology transfer to affiliates in developing countries can be expected to become more common, provided that IPRs, particularly patent rights, are sufficiently strong in those countries.

To the extent that the calls to curtail patent rights on clean technologies stem from a theoretical belief that an exclusionary right must necessarily be a barrier to technology transfer or from an assumption that the pharmaceutical analogy applies to technology transfer for clean technologies, those views must yield in the face of hard evidence to the contrary. As explained by Barton (2007), for example, and as discussed above, the pharmaceutical analogy is not applicable to the role of IPRs in transferring clean technologies to developing countries since there is competition within and between various clean technologies, unlike the situation for pharmaceuticals where there may be no substitute for a patented drug.[57] Should some future clean technology depend upon a unique chemical compound for which there is no substitute, and should a patent on that compound be enforced in a way that prevents the technology from being available in developing countries, the *existing* compulsory licensing provisions of Article 31 of the TRIPS agreement are available to address that situation. The existing compulsory licensing provisions of Article 31 are flexible, contain no subject matter restrictions, and are fully available for clean technologies; the primary procedural requirement is to engage in negotiations with the patent owner.[58] As such, no restructuring of the existing compulsory licensing provisions of Article 31 are needed to provide a special status for clean technologies as has been proposed. In addition, considering that recent studies show that IPRs are not a barrier to the transfer of clean technologies to developing countries and instead likely facilitate such technology transfer, excluding clean technologies from patenting and/or revoking existing patents on clean technologies in developing countries is not only unwarranted but would also run a risk of actually thwarting that technology transfer.

57 See Barton, "Intellectual Property and Access to Clean Energy Technologies", *supra* note 32, at p. x.

58 See Bollyky, "Intellectual Property Rights", *supra* note 3, at p. 5; Khor, "Climate and Trade Relation", *supra* note 3, at pp. 33–34.

## Lifestyle Risks

*This section discusses the regulation of "lifestyle risks", a term that can apply to both substances and behaviours. Lifestyle risks take place along the line of "abstinence – consumption – abuse – addiction". This can concern substances such as food, alcohol or drugs, as well as behaviours such as gambling or sports. The section also addresses the question of the appropriate point of equilibrium between free choice and state intervention (regulation), as well as the question of when risks can be considered to be acceptable or tolerable. In line with the interdisciplinary scope of the journal, the section aims at updating readers on both the regulatory and the scientific developments in the field. It analyses legislative initiatives and judicial decisions and at the same time it provides insight into recent empirical studies on lifestyle risks.*

### *Philip Morris v. Uruguay:* The Punta del Este Declaration on the Implementation of the WHO Framework Convention on Tobacco Control

*Benn McGrady**

*In November 2010, 171 Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC) unanimously adopted the Punta del Este Declaration on implementation of the Convention.*[1] *The Declaration follows the filing of an international investment claim against Uruguay by Philip Morris Products (Switzerland) and related companies. The Declaration reaffirms the commitment of the 171 WHO FCTC Parties to implementation of the Convention and addresses the relationship between the WHO FCTC and international trade and investment agreements, particularly in the context of intellectual property rights. This article outlines the Request for Arbitration, sets out the Declaration and the broader normative context in which it arose before touching briefly on the implications of the Declaration.*

* O'Neill Institute for National and Global Health Law, Georgetown University, Washington, USA.

1 Punta del Este Declaration on the Implementation of the WHO Framework Convention on Tobacco Control, Conference of the Parties to the WHO Framework Convention on Tobacco Control, fourth session, Punta del Este, Uruguay, 6 December 2010, FCTC/COP/4/DIV/6.

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## I. Introduction

In February 2010, Philip Morris Products (Switzerland) and related companies filed a Request for Arbitration with the International Centre for Settlement of Investment Disputes (ICSID).[2] The request sought to institute arbitral proceedings in accordance with the ICSID Convention and pursuant to a bilateral investment treaty (BIT) between Switzerland and Uruguay. The Request for Arbitration took issue with the following three aspects of Uruguay's tobacco packaging laws:

- the fact that Uruguayan law requires that tobacco products bear warnings covering 80% of the surface of a pack;
- the images used in mandatory health warnings, which the claimants allege are designed to shock and repulse rather than warn consumers of the actual effects of smoking; and
- a prohibition on misleading packaging, and more specifically, the implementation of this prohibition in such a way as to constitute a de facto single presentation per brand requirement.

The claimants allege that the measures violate the following four obligations under the Switzerland – Uruguay BIT:

1. not to obstruct the management, use, enjoyment, growth or sale of investments through unreasonable or discriminatory measures (Article 3(1));
2. to refrain from acts of expropriation except for a public purpose and upon payment of compensation (Article 5(1));
3. to provide fair and equitable treatment to the claimants' investments (Article 3(2)); and
4. to respect commitments made by Uruguay to investors (Article 11).

From the Request for Arbitration, it appears possible that the claimants may argue that all three measures violate each of Articles 3(1), 3(2) and 5(1). The claim relating to Article 11 of the Switzerland – Uruguay BIT may also relate to all three measures.

With respect to the size of the pack warnings, the central claim appears to be that Uruguay has gone too far. The claimants appear to accept that warnings covering 50% of the pack are reasonable, but that warnings covering 80% are not.

With respect to the graphic images used in the warnings, the Request for Arbitration appears to suggest that it is unlawful for governments to seek to discourage tobacco consumption and that the proper role of government under the investment treaty is merely to correct market failures, such as by providing information to consumers. The success of such an argument would have wide-ranging implications for tobacco control given that measures such as tax measures and advertising restrictions often have the stated aim of discouraging consumption.

In the case of Uruguay's laws governing misleading packaging, the central concern is that a variety of Philip Morris brands can no longer be sold under their previous branding. For example, the effect of the law is that Philip Morris can only sell one form of Marlboro and not a variety of different forms. Since a bilateral investment treaty is not a general guarantee permitting a foreign investor to engage in misleading conduct, the essence of the claim must be that the prohibited brands are not in fact misleading.

Each of these arguments also relates to the use of intellectual property because tobacco industry trademarks form the central investment that the claimants allege to have been interfered with unlawfully. The claim relating to Article 11 of the Switzerland – Uruguay BIT also seeks to invoke the law of the World Trade Organization (WTO) through an umbrella clause. More specifically, the claimants argue that Uruguay's obligation to respect its commitments under Article 11 includes commitments made under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and that Uruguay is in violation of those commitments.

Although tobacco companies such as Philip Morris International often draw on international investment agreements in attempts to resist regulation, this is the first public claim of this type before an international arbitral tribunal. Thus, the claim has symbolic implications in terms of the allocation of regulatory authority. The claim seeks to override the decisions of domestic health authorities, thereby suggesting a vertical shift in authority from the domestic to the international level. The constitution of an ICSID tribunal also represents a horizontal shift in authority at the international level from the WHO Framework

2 *FTR Holdings SA (Switzerland), Philip Morris Products SA (Switzerland) and Abal Hermanos SA (Uruguay) v. Oriental Republic of Uruguay,* Request for Arbitration, Under the Rules of the International Centre for Settlement of Investment Disputes, 19 February 2010.

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

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

1. The firm commitment to prioritize the implementation of health measures designed to control tobacco consumption in their respective jurisdictions.
2. Their concern regarding actions taken by the tobacco industry that seek to subvert and undermine government policies on tobacco control.
3. The need to exchange information on the activities of the tobacco industry, at a national or international level, which interfere with the implementation of public health policies with respect to tobacco control.
4. That in the light of the provisions contained in Articles 7 and 8 of the TRIPS Agreement and in the Doha Declaration, Parties may adopt measures to protect public health, including regulating the exercise of intellectual property rights in accordance with national public health policies, provided that such measures are consistent with the TRIPS Agreement.
5. That Parties have the right to define and implement national public health policies pursuant to compliance with conventions and commitments under WHO, particularly with the WHO FCTC.
6. The need to urge the United Nations Ad Hoc Interagency Task Force on Tobacco Control to support multisectoral and interagency coordination for the strengthening of the implementation of the WHO FCTC within the whole United Nations system.
7. The need to include the topic "challenges to tobacco control" in the agenda of the summit on non-communicable diseases, which will be organized by the United Nations in 2011.
8. The need to urge all countries that have not done so, to ratify the WHO FCTC and implement its provisions and take measures recommended in its guidelines.

*(Sixth plenary meeting, 18 November 2010)*

## III. The normative context of the Uruguayan measures

The Uruguayan measures implement various provisions of the WHO FCTC and its guidelines. These provisions place the Punta del Este Declaration in context. The WHO FCTC obliges Parties, including Uruguay, to prohibit misleading packaging or advertising and to require the attachment of health warnings to product packaging. The Convention also permits Parties to require health warnings of the size required by Uruguay and permits the use of pictograms on health warnings.

Article 4 of the WHO FCTC establishes the guiding principles of the Convention. Of most relevance is Article 4.1, which states that:

Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke.

Article 11 of the WHO FCTC governs packaging and labeling of tobacco products:

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:
   (a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and
   (b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use,

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and may include other appropriate messages. These warnings and messages:
(i) shall be approved by the competent national authority,
(ii) shall be rotating,
(iii) shall be large, clear, visible and legible,
(iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,
(v) may be in the form of or include pictures or pictograms.

2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.
3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.
4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

In November 2008, the third session of the Conference of Parties to the WHO FCTC adopted Guidelines for Implementation of Article 11.[4] The guidelines "are intended to assist Parties in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labeling measures."[5] The guidelines reiterate Article 4.1 of the Convention, stating:

*Globally, many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality due to tobacco use and exposure to tobacco smoke. Well designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means to increase public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption. Effective health warnings and messages and other tobacco product packaging and labelling measures are key components of a comprehensive, integrated approach to tobacco control.*

Article 13 of the FCTC governs tobacco advertising, promotion and sponsorship. The most relevant parts of Article 13 state:

2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
...
4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:
(a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
(b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;

Guidelines for Implementation of Article 13 were also adopted unanimously by the third session of the Conference of Parties to the WHO FCTC. These guidelines identify several means of promoting tobacco products that may be regarded as misleading. In addition to the use of terms, descriptors, trademarks, figurative or other signs, the guidelines refer to emblems, marketing images, logos and colors.[6] A footnote to the relevant passage states that "[t]hese phrases are taken from Article 11.1(a) of the Convention, with the addition of the word "color", which the working group recognizes can be used to convey a misleading

4 WHO Framework Convention on Tobacco Control, Guidelines for Implementation: Article 5.3, Article 8, Article 11, Article 13, World Health Organization, Geneva 2009.

5 WHO FCTC Guidelines for Implementation of Article 11, para. 1.

6 WHO FCTC Guidelines for Implementation of Article 13, para. 39.

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impression about the characteristics, health effects or hazards of tobacco products."[7]

The misleading character of terms such as "low tar", "light", "ultra-light", and "mild" stems partly from the fact that consumers addicted to nicotine consume tobacco products so as to service their addiction. This means that consumers take larger puffs, inhale deeper and smoke more of these types of cigarettes. In this sense, the machines used to test for tar and nicotine content do not replicate human behavior. In addition, small holes in the filters of "low tar", "light", "ultra light" and "mild" cigarettes undermine the accuracy of machine testing used to quantify tar and nicotine. Emissions escape through these holes when products are machine tested. However, the holes are partially blocked by a smoker's fingers or lips when a cigarette is smoked. This suggests that the measurement of tar and nicotine levels is fundamentally inaccurate and that the descriptors in question are misleading.[8]

Colors may also be misleading, as recognized in Guidelines to Article 13. In some instances, the misleading character of colors can flow from their association with misleading descriptors. As misleading descriptors were being banned around the world tobacco companies began to re-brand their products. For example:

- Marlboro Light products became Marlboro Gold;
- Marlboro Ultra Lights became Marlboro Silver;
- Marlboro Menthol Milds became Marlboro Blue; and
- Marlboro Menthol is sold in a green colored pack.

The use of colors as a means of distinguishing between variants within brand families has led to the argument that restrictions on misleading descriptors have been circumvented by the use of colors. More specifically, it is argued that re-branding of this type prolongs the misleading conduct.

Guidelines for Implementation of Article 13 also recommend that Parties restrict the use of product packaging to a greater degree than the measures implemented by Uruguay. The guidelines recognize that "[p]ackaging is an important element of advertising and promotion."[9] The guidelines further state:

*The effect of advertising or promotion on packaging can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products.*[10]

The guidelines then make the following recommendation:

*Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive.*[11]

In summary, Uruguay is compelled by the WHO FCTC to require the attachment of health warnings and messages taking up at least 30 % of the principal display areas. The WHO FCTC also encourages Parties to use larger warnings, and Uruguay has done so but has not regulated packaging to the full extent contemplated in WHO FCTC guidelines. Uruguay is also bound by Articles 11 and 13 of the FCTC to prohibit misleading packaging. Accordingly, the Request for Arbitration challenges Uruguay's implementation of the WHO FCTC and in so doing, challenges the WHO FCTC indirectly.

## IV. Implications of the Declaration

As a political document, the Punta del Este Declaration reinforces the flexibilities available to states when regulating product packaging as well as the regulatory freedom that they enjoy under international trade and investment law. The Declaration affirms the power of sovereign states to regulate in the public interest and recognizes that WHO FCTC

7 WHO FCTC Guidelines for Implementation of Article 13, para. 39, fn 7.

8 See, for example, Lynne Kozlowski, Richard O'Connor, "Cigarette Filter Ventilation is a Defective Design because of Misleading Taste, Bigger Puffs, and Blocked Vents", 11(Suppl I) *Tobacco Control* (2002), i40 – i50.

9 WHO FCTC Guidelines for Implementation of Article 13, para. 15.

10 WHO FCTC Guidelines for Implementation of Article 13, para. 16.

11 WHO FCTC Guidelines for Implementation of Article 13, para. 17.

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measures fall within this realm. This type of political statement is likely to give domestic authorities comfort in the face of industry arguments that established tobacco packaging measures violate international trade and investment agreements.

As a legal instrument, it remains to be seen what the effect of the Declaration will be. Parties to the WHO FCTC did not express their understanding of the status of the Declaration in its text or during negotiations. In the context of WTO law, the instrument is likely to be viewed purely as a political instrument because under the WTO Agreement, only the Ministerial Conference of the WTO and the General Council have the power to issue authoritative interpretations of the WTO covered agreements.[12] In the context of international investment law, the issue is less clear. In this context, the instrument could be construed as a Declaration of customary international law, particularly with respect to the sovereign powers of states to regulate in the public interest. Alternatively, the Declaration might be viewed as a subsequent agreement of the parties to an international investment agreement, and on this basis be used in interpretation of the agreement.[13]

The Declaration comes at a time when the appropriateness of investor state arbitration is increasingly being called into question. It can be argued that claims such as that made by Philip Morris are unlikely to arise in systems where only states have standing. States tend to view the issues in a systemic manner and seek to avoid actions contrary to the public interest. It can also be argued that there are few checks at the international level that prevent an investor from bringing spurious or opportunistic claims in a context where many developing countries have limited capacity to defend investment claims and limited funding to retain outside counsel. These arguments suggest that the Philip Morris claim poses a very public challenge not only to global tobacco control, but also to the legitimacy of international investment arbitration.

12 Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 4 (1999), 33 I.L.M. 1144 (1994), Article IX:2.

13 Although, this is doubtful in the *Philip Morris v. Uruguay* dispute because Switzerland is not a WHO FCTC Party.

# Pharmaceuticals

*This section updates readers on the latest developments in pharmaceutical law, giving information on legislation and case law on various matters (such as clinical and pre-clinical trials, drug approval and marketing authorisation, the role of regulatory agencies) and providing analysis on how and to what extent they might affect health and security of the individual as well as in industry.*

## Reverse Payment Settlements in the Pharmaceutical Sector: A European Perspective

*Pier Luigi Parcu* and Maria Alessandra Rossi***

On 17 January 2011, the European Commission launched , a monitoring exercise of patent settlements in the pharmaceutical sector for the second time after the Pharmaceutical sector inquiry of 2009. As was the case for the first monitoring exercise launched in January 2010, a number of pharmaceutical companies were asked to submit copies of their patent settlement agreements concluded in the European Economic Area (EEA), together with any relevant annex, amendment or related agreement.

The rationale for the monitoring exercise derives from some of the findings of the Pharmaceutical Sector Inquiry, which had highlighted the possibility that some of the agreements reached by originators and generics to settle IP-related disputes (generally believed to be efficiency-enhancing tools to save money on litigation costs), may in fact turn out to have anticompetitive effects on the market. This is particularly the case for so-called "reverse payment agreements". These are settlements that involve a payment (in direct or indirect form) flowing in a direction that intuitively appears "reverse", as money is paid by the patent holder (the originator) to the alleged infringer – a generic firm. The main concern with regard to these agreements is that they imply a restriction of access to the market by one or more generic firms, agreed upon by the incumbent and the potential entrant, with clear negative implications in terms of prices paid by consumers.

* Florence School of Regulation, European University Institute (Florence) and Studio Economico Parcu and Associates (Rome).

** Department of Economics, University of Siena. Corresponding Author: <alessandra.rossi@unisi.it>.

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