

# International investment agreements and public health: neutralizing a threat through treaty drafting

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**Abstract** The high profile investment claims filed by Philip Morris challenging Uruguayan and Australian measures that restrict advertising and logos on tobacco packaging awakened the public health community to the existence and potential detrimental impact of international investment agreements (IIAs). More recently, Eli Lilly challenged Canada's invalidation of a pharmaceutical patent under an IIA. All of the cases claim that the intellectual property rights of the investor were infringed. As a result of these cases, many commentators and activists view IIAs as a threat to public health and have lobbied against their inclusion in ongoing trade negotiations. This article does not argue against IIAs. Instead, it seeks to demonstrate how more sophisticated treaty drafting can neutralize the threat to public health. In this regard, the article seeks to engage members of the public health community as campaigners not against IIAs but as advocates of better treaty drafting to ensure that IIAs do not infringe upon the right of a nation to take non-discriminatory measures for the promotion and protection of the health of their populations.

Abstracts in **عربي**, **中文**, **Français**, **Русский** and **Español** at the end of each article.

## Introduction

International investment agreements (IIAs) are treaties negotiated by two or more States to create rights for individual investors and obligations for governments. With no multilateral investment agreement, IIAs were initially concluded as stand-alone treaties but are increasingly negotiated as part of comprehensive bilateral or regional free trade agreements. Most IIAs provide for investor–state dispute settlement, which grants investors the right to challenge laws and measures of the host government in front of an arbitral tribunal.

Although IIAs date back to 1959, it is only in the past 20 years that investors have begun filing claims for monetary damages directly against governments. Such claims have for some time related to measures ostensibly taken by the host government for the promotion or protection of the environment, but it is only recently that claims have been based on the argument that health-related measures are inconsistent with a treaty commitment. Three of these claims have garnered worldwide attention – two of them, filed by tobacco manufacturer Philip Morris, challenged restrictions on the advertising and packaging of cigarettes (which, in part, implement the World Health Organization's Framework Convention on Tobacco Control) in Uruguay and Australia, respectively,<sup>1,2</sup> while the third was filed by pharmaceutical company Eli Lilly, alleging that in invalidating several pharmaceutical patents the Canadian court violated the investment chapter of the North American Free Trade Agreement.<sup>3</sup> All of the claims directly relate to the alleged infringement of investor intellectual property rights, with trademarks being the relevant right in the Philip Morris claims and patents in Eli Lilly's claim. No decision has been reached with respect to either claim yet.

Investors have rarely linked intellectual property rights to IIAs and these are the first prominent claims regarding intellectual property rights in investor–state dispute settlement. These cases are a useful reminder – or perhaps a wake-up

call – that intellectual property rights are indeed included in IIAs and that such provisions could affect the ability of host governments to promote and regulate public health.

Since these cases were filed, numerous public health commentators and activists have demonized IIAs for being detrimental to public health. This article is not a call for the rejection of IIAs or of investor–state dispute settlement. Both have proven to be useful in attracting needed foreign investment, particularly in developing countries where potential investors may not have faith in the local legal system or host government.<sup>4,5</sup> Instead, the article aims to inform the debate by highlighting the importance of treaty language. There are currently over 3000 IIAs in existence, and while it is easy for commentators to make sweeping statements, all treaties are not created equally. In fact, substantial differences exist that could determine to a large degree whether health-related measures are deemed to be compliant or inconsistent with the relevant IIA.

International investment agreements contain dozens of host state obligations and investor protections, but this article will focus on the one having the most relevance and importance to potential claims relating to health measures – expropriation. Expropriation is relevant to public health insofar as it could apply to everything from the invalidation of a patent, the issuance of a compulsory license for a life-saving pharmaceutical, or measures that limit or revoke intellectual property rights, such as the regulation of tobacco advertising on cigarette packaging.

Following a brief explanation of why intellectual property rights fall within the scope of IIAs, the article will use expropriation as an example of how more sophisticated drafting can lessen the potentially harmful effect of IIAs. It is the hope of this author that by raising these issues with the public health community, another voice will be added to those calling for better treaty drafting to ensure that non-discriminatory health-related measures are never held to be inconsistent with treaty obligations.

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## Intellectual property rights as an investment

Protections granted in IIAs only attach to “covered investments.” Individuals or companies are covered “investors” only if their investment falls within the scope of the relevant IIA. In almost all IIAs, intellectual property rights are explicitly included in the definition of “investment”. The United States–Korea Free Trade Agreement (Article 11.28) provides a representative definition repeated in many IIAs: an “investment” includes “every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk”.<sup>6</sup> This broad definition is followed with specific forms the investment could take and include, *inter alia*, “intellectual property rights” and “other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens, and pledges”.<sup>6</sup> Other IIAs do not explicitly provide for intellectual property rights within the scope of an “investment,” but intellectual property rights nevertheless remain a covered investment either through provisions protecting investor “returns” (which in the context of intellectual property rights would include royalties and fees) or through the definition of an “asset”.<sup>7</sup> It is therefore clear that intellectual property rights are a covered investment in IIAs.

## Treaty language to safeguard public health

Expropriation is generally allowed at international law as long as it is: for a public purpose; in a non-discriminatory manner; on payment of prompt, adequate and effective compensation; and in accordance with due process of law.<sup>8</sup> International investment agreements provide protection against both direct and indirect expropriations not in accordance with the above criteria. Direct expropriations include measures that deprive the investor of ownership rights in the investment/property (i.e. transferring title from one party to another), whereas indirect expropriations occur when a measure or series of measures erode and effectively deprive

the investor of the use and enjoyment of the investment and/or of rights of ownership, even though actual property rights remain with him. To be actionable the governmental measures normally must result in a “substantial” or “radical” deprivation of the “use and enjoyment” of the investment of a lasting or permanent nature,<sup>9</sup> although partial or temporary deprivations do occasionally rise to the level of an expropriation.<sup>10,11</sup> Importantly, seemingly legitimate regulatory measures can be deemed an expropriation, as the tribunal in *Feldman v. Mexico* made clear when it stated: “No one can seriously doubt that in some circumstances governmental activity can be a violation of [the expropriation provision in the North American Free Trade Agreement].”<sup>12</sup> Similarly, the tribunal in *ADC v. Hungary* stated:

“...the inherent right to regulate ... is not unlimited and must have its boundaries. ... [W]hen a State enters into a bilateral investment treaty like the one in this case, it becomes bound by it and the investment-protection obligations it undertook therein must be honoured rather than be ignored by a later argument of the State’s right to regulate.”<sup>13</sup>

In most health-related cases, the claim would likely be that a measure has resulted in an indirect expropriation – i.e. that the measure did not directly take ownership of the intellectual property but that there has been a substantial deprivation of the use and enjoyment of ownership. For instance, Philip Morris is claiming that the restrictions on cigarette advertising curtail its rights and destroy the value of its investment so severely, that the measures are tantamount to indirect expropriation.

The line between a legitimate regulatory measure and an indirect expropriation is a fine one and each case must be decided on an individual basis.<sup>14</sup> Unfortunately, most IIAs provide no further guidance. The fate of a governmental regulation is therefore left to a tribunal of three members who determine whether the measure meets the criteria of a vague provision. Arbitration tribunals are usually composed of experts in commercial law – as opposed to public or health law – and have generally proven to be pro-investor and inconsistent in the application of standards.<sup>15–17</sup>

The uncertainty can be illustrated through the example of the issuance of a compulsory licence. While Article 28 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) grants an owner the right to prevent third parties from “making, using, offering for sale, selling, or importing” the protected product, the right is not absolute. One key health-related exception is the compulsory licence. Article 31 of the TRIPS agreement allows a government to authorize a third party to “use” intellectual property rights without the consent of the owner, provided that certain (mainly) procedural requirements are met.

A compulsory license therefore allows a third party to use and exploit the intellectual property right without the consent of the rights owner, which can detract from or limit the benefits to the rights holder. In this regard, a compulsory license taken in the public interest, without discrimination and in a manner consistent with Article 31 of the TRIPS agreement, could still be deemed an illegal expropriation of an investor’s investment. Such an outcome, however undesirable, is a real possibility since the scope of expropriation in most IIAs is exceptionally wide.

To inject more certainty into the process, the United States and a handful of other countries began negotiating textual guidance for IIAs that provides an interpretive framework to lead an arbitration tribunal. The guidance states that factors relevant to the determination of whether a regulation rises to the level of an expropriation include: (i) the extent to which the government action interferes with distinct, reasonable investment-backed expectations; (ii) the character of the government action and (iii) whether there is adverse economic impact, although such impact is not in itself sufficient to prove the claim.<sup>18,19</sup> Language of this kind is helpful to governments instituting non-discriminatory measures in the pursuit of better public health outcomes, as it requires tribunals to weigh and balance the nature and potential impact of all three factors. In this regard, neither firm government action nor economic impact will automatically outweigh health-related measures. However, the provision is only of limited assistance insofar as the language employed is fairly vague and provides no direction

as to how the factors should be weighed and balanced.

Subsequent agreements negotiated by the United States and other countries utilize additional language in a more direct attempt to limit the impact of the expropriation clause on intellectual property rights and health by providing that:

“This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights to the extent that such issuance, revocation, limitation or creation is consistent with [TRIPS].”<sup>19–22</sup>

With the addition of this clause, IIAs have for the first time recognized the potential for overlapping and inconsistent commitments in international economic treaties. The insertion of such a provision is intended to avoid the situation in which a compulsory licence is issued or a measure is taken to limit or revoke intellectual property rights in accordance with TRIPS but is found to be inconsistent with the IIA. However, the clause is also problematic, as it explicitly brings TRIPS into any interpretation of the relevant provision. This is a dangerous addition to IIAs because arbitration tribunals that may or may not have expertise in WTO law and jurisprudence will now be called upon to interpret whether a host state’s measure is consistent with TRIPS.

Even more recently, the United States has gone further and employed even more powerful language in an attempt to limit an overbroad interpretation of IIA protections relating to public health and other domestic priorities:

“Except in rare circumstances, such as, for example, when an action or a series of actions is extremely severe or disproportionate in light of its purpose or effect, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, the environment, and real estate price stabilization (through, for example, measures to improve the housing conditions for low-income households), do not constitute indirect expropriations.”<sup>19,22</sup>

This clause is also included in paragraph 4(b) of Annex 12-C of the leaked

draft version of the controversial Trans-Pacific Partnership Agreement, which signals the intent of the United States and eleven other negotiating partners to continue carving out exceptions to the expropriation provision. While again no panacea, this language moves beyond the explicit conditional carve-outs tied to TRIPS quoted above and sends a strong signal of the intent of the negotiating parties that legitimate health (and other) measures should not constitute indirect expropriations. In fact, such a clause “significantly narrows and constrains any potential claim for indirect expropriation” based on a compulsory licence or any limitation, revocation or creation of intellectual property rights.<sup>23</sup>

Although the health community would undoubtedly rather that IIAs explicitly exclude health-related measures from the scope of the treaties, such desires are mere fancy and actually undesirable. Due process demands that claimants have the right to challenge governmental measures. The health community should not be afraid, as the provision is a clear indication that the parties do not wish to see legitimate, non-discriminatory measures taken in the interests of public health fall afoul of an IIA.

An alternate approach used by a handful of countries is to insert a clause modelled on Article XIV of the WTO’s General Agreement on Trade in Services providing an exhaustive list of exceptions to the substantive treaty obligations, as long as the measures – including those that are “necessary to protect human, animal or plant life or health” – are not applied in an arbitrary or unjustifiable manner and are not a disguised restriction on investors and investments.<sup>21</sup> Such a provision *borrow*s language from the WTO Agreement but does not *directly reference* it. In this regard, it is very different from the first example provided. Only a handful of IIAs provide for a general exception clause, but this approach also appears to be a promising step towards limiting the applicability of investment protections to public-health-related measures. That being said, such clauses only provide a defence against a claim and are not a magic bullet; the “necessity” of a measure must be demonstrated, and whether a measure is arbitrary, unjustifiable or a disguised restriction on investors or investment will certainly be argued in a case. Here, arbitration tribunals can

draw upon the rich jurisprudence of the WTO in interpreting the equivalent exception clauses in its agreements. The bar can be high, but at least this clause is recognition that life and health can trump substantive IIA obligations.

Unfortunately, some agreements limit the scope of the applicability of such clauses by excluding their application to expropriation (and another obligation known as fair and equitable treatment).<sup>24</sup> Such an exclusion nullifies any effect the clause could have had on the legality of issues such as compulsory licensing of medicines and limitations to intellectual property rights on public health grounds (i.e. regulations pertaining to mandatory cigarette labelling).

Ideally, parties negotiating IIAs will eventually combine the two approaches and include both health-specific limitation clauses and a general exception clause. Moreover, parties could include pro-health (and probably pro-environment) language in the preamble, in the introductory provisions to the treaty, or both. Such a combination would provide additional reassurance to governments desiring to take pro-active, non-discriminatory health-related measures that they will not fall afoul of any treaty obligations.

## Conclusion

Every IIA contains an expropriation clause whose potential use by intellectual property rights holders to fight against measures taken in the interests of public health is a real threat. Most treaties provide wide scope for the provision and arbitral tribunals are notoriously pro-investor. The emergence of clauses limiting the applicability of expropriation when public health and other domestic priorities are concerned is welcome – as are other efforts, such as the negotiation of special provisions relating to tobacco in the Trans-Pacific Partnership.<sup>6</sup>

For the first time treaty drafters are attempting to take note of and neutralize potential conflicts between investment and public health. These changes have the potential to radically alter the course of investment agreements in the future, the effect of which cannot be overstated. Unfortunately, these efforts have been criticized by many in the public health community for not going far enough. Although far from perfect, limitation clauses should be

viewed as first steps on a path towards safeguarding non-discriminatory health measures.

The relevant treaties applying to Philip Morris' claims against Uruguay and Australia are rather old and neither contains a limitation clause, while the North American Free Trade Agreement similarly fails to include any health-specific limitations to expropriation. This will make it more difficult for Australia and Uruguay to defend their tobacco packaging measures designed to curtail the uptake of smoking, and for Canada to defend its interpretation of the criteria required for the patentability of an invention.<sup>23,25-27</sup> Moreover, international investment arbitration is not based on a system of precedents. Hence tribunals are not bound by prior interpretations or decisions. This has resulted in several

cases of inconsistent decisions based on the same facts.<sup>28-33</sup> The addition of clear provisions that limit treaty obligations will go some way in safeguarding against such inconsistent decisions when a non-discriminatory health measure is at issue.

Re-negotiating more than 3000 treaties would be practically impossible, but bilateral and regional free trade agreements containing IIAs continue to proliferate at an astonishing rate. Furthermore, with the European Union recently acquiring competence over investment matters – i.e. European Union treaties will replace those negotiated by individual member states – opportunity exists for large numbers of treaties to be redesigned to include limitation clauses such as those we have described. The potential therefore exists for a system

providing greater uniformity and consistency.

International investment agreements need not pose a threat to legitimate health measures. The addition of limitation clauses such as those being negotiated into the most recent IIAs provide an additional hurdle for the claimant and more comfort for countries taking measures to protect and promote public health. With appropriate drafting, provisions can be negotiated into future IIAs to effectively neutralize the threat to public health. The efforts of those countries negotiating pro-health limitation clauses should be applauded and further dissemination and refinement of such clauses should be encouraged by the public health community. ■

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## ملخص

### اتفاقات الاستثمار الدولية والصحة العمومية: القضاء على التهديد من خلال صياغة معاهدة

جماعات ضغط لإدراجها في المفاوضات التجارية الجارية. ولا تعارض هذه المقالة اتفاقات الاستثمار الدولية. ولكنها تسعى، بدلا من ذلك، إلى توضيح كيفية معادلة التهديد على الصحة العمومية عن طريق صياغة معاهدة أكثر تطوراً. وفي هذا الخصوص، تسعى المقالة إلى إشراك أفراد مجتمع الصحة العمومية في الحملات ليس بصفة مناهضين لاتفاقات الاستثمار الدولية ولكن كمناصرين لصياغة معاهدة أفضل بغية ضمان عدم انتهاك اتفاقات الاستثمار الدولية حق أي دولة في اتخاذ تدابير غير تمييزية لتعزيز صحة سكانها وحمايتهم.

نبهت مطالبات الاستثمار البارزة، التي قدمتها فيليب موريس للاعتراض على تدابير أورغواي وأستراليا التي تقيد الإعلانات والشعارات على عبوات التبغ، مجتمع الصحة العمومية إلى وجود اتفاقات استثمار دولية وأثرها الضار المحتمل. وفي الآونة الأخيرة، اعترضت شركة إيلي ليلي على إبطال كندا لبراءة اختراع صيدلانية بموجب أحد اتفاقات الاستثمار الدولية. وتزعم جميع الدعاوى أنه تم انتهاك حقوق الملكية الفكرية للمستثمر. ونتيجة لهذه الدعاوى، ينظر الكثير من المعلقين والناشطين إلى اتفاقات الاستثمار الدولية باعتبارها تهديداً للصحة العمومية وشكلوا

## 摘要

国际投资协定和公共卫生：通过条约起草来消除威胁  
菲利普莫里斯公司 (Philip Morris) 提交的投资求偿备受瞩目，其向乌拉圭和澳大利亚限制烟草包装上广告和商标的措施发起挑战，这唤醒公众卫生界对国际投资协议 (IIA) 现有和潜在有害影响的关注。最近，礼来制药公司依据 IIA 对加拿大宣告药物专利无效提出抗辩。所有这些案例都宣称投资者的知识产权受到侵犯。这些案例让许多评论家和活动家将 IIA 视为公众

健康的威胁，游说反对将其纳入正在进行的贸易谈判。本文并不反对 IIA。相反，本文寻求证明更为巧妙的条约起草可以如何化解对公众健康的威胁。在此方面，本文试图让公共卫生界人士不要反对 IIA，而是倡导通过更好的条约起草确保 IIA 不会侵犯各国采取非歧视性的措施促进和保护其人群健康的权利。

## Résumé

### Accords internationaux d'investissement et santé publique: neutralisation d'une menace par la rédaction de traités

Les plaintes en matière d'investissement très médiatisées, qui ont été déposées par Philip Morris contre les mesures australiennes et uruguayennes restreignant la publicité et les logos sur les emballages des produits à base de tabac, ont sensibilisé la communauté de la santé publique à l'existence et à l'impact potentiellement négatif des accords internationaux d'investissement (AII). Plus récemment, Eli Lilly a contesté l'invalidation par le Canada d'un brevet pharmaceutique en vertu d'un AII. Tous ces cas soutiennent que les droits de propriété

intellectuelle de l'investisseur ont été bafoués. En raison de ces cas, de nombreux commentateurs et activistes considèrent ces AII comme des menaces pour la santé publique et ont fait pression pour qu'ils ne soient pas inclus dans les négociations commerciales en cours. Cet article ne plaide pas contre les AII. Il cherche plutôt à démontrer de quelle manière la rédaction de traités plus sophistiqués peut neutraliser la menace sur la santé publique. À cet égard, l'article vise à amener les membres de la communauté de la santé publique à faire campagne non pas contre les

All, mais en tant qu'avocats d'une meilleure rédaction des traités, afin de s'assurer que ces All n'empiètent pas sur le droit d'une nation à prendre

des mesures non discriminatoires pour la promotion et la protection de la santé de ses populations.

## Резюме

### Международные инвестиционные соглашения и общественное здравоохранение: нейтрализация угрозы путем улучшенной разработки договоров

Громкие инвестиционные претензии компании Philip Morris к мерам, предпринятым правительствами Уругвая и Австралии, ограничивающим рекламу и логотипы компаний-изготовителей на упаковках табачных изделий, привели к осознанию организациями общественного здравоохранения факта существования и потенциального вредного воздействия международных инвестиционных соглашений (МИС). Не так давно компания Eli Lilly оспорило решение о признании недействительным в Канаде фармацевтического патента, действующего на основе МИС. Во всех этих случаях утверждается о нарушении прав интеллектуальной собственности инвестора. В результате этих случаев многие обозреватели и активные

участники процесса рассматривают МИС как угрозу для здоровья населения и активно выступают против их включения в текущие торговые переговоры. Авторы данной статьи не выступают против МИС. Напротив, в ней показывается, как более продуманная разработка договоров может нейтрализовать угрозу для здоровья населения. В этой связи, авторы статьи стремятся привлечь организации общественного здравоохранения не в качестве участников кампании против МИС, а в качестве сторонников более продуманной разработки торговых соглашений, обеспечивающих неущемление со стороны МИС прав наций на принятие недискриминационных мер с целью улучшения и охраны здоровья населения.

## Resumen

### Los acuerdos internacionales de inversión y la salud pública: neutralizar una amenaza a través de la redacción de tratados

Las demandas por inversiones de alto perfil presentadas por Philip Morris frente a las medidas uruguayas y australianas que restringen la publicidad y logotipos en el empaquetado de tabaco abrieron los ojos al sector de salud pública acerca de la existencia y el posible impacto negativo de los acuerdos internacionales de inversión (All). Más recientemente, Eli Lilly desafió la invalidación de Canadá de una patente farmacéutica con arreglo a un All. Todos estos casos demandan la violación de los derechos de propiedad intelectual de los inversores. Es por ello que muchos comentaristas y activistas consideran los All una amenaza para la sanidad pública y han presionado en contra para

evitar que sean incluidos en las negociaciones comerciales en curso. El presente artículo no argumenta en contra de los All, sino que busca demostrar cómo es posible neutralizar la amenaza para la salud pública a través de una redacción de tratados más compleja. En este sentido, el artículo pretende involucrar a los miembros del sector sanitario público como activistas, no en contra de los All, sino como defensores de una redacción de tratados mejorada que garantice que los All no infringen el derecho de una nación a tomar medidas no discriminatorias para la promoción y protección de la salud de sus poblaciones.

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