INTRODUCTION

Although it is unclear whether and when the Transatlantic Trade and Investment Partnership (TTIP) will be concluded, it has the potential to be the most significant international economic agreement of this century. It is currently being negotiated by two of the world’s top economic powerhouses which combined together represent nearly half of all GDP worldwide, namely the EU and the US.¹ In addition to its free trade provisions, the TTIP is also expected to feature an investment chapter. While the EU as an institution is a newcomer to the international investment law scene, it has the potential to be a key player given the longstanding traditions of its Member States for concluding International Investment Agreements (IIA)² and the collective power they now enjoy at the negotiating table. However, concerns about including investor-state dispute settlement (ISDS) provisions in the EU’s IIAs were expressed shortly after the Lisbon Treaty came into force³ and ISDS has also proven to be one of the most contentious issues in the TTIP negotiations. Specific concerns have been expressed about the risk of regulatory chill.⁴ Advocates of this theory argue that ISDS

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² IIAs include Bilateral Investment Treaties (BIT) as well as other agreements which govern cross-border investment protection, such as Free Trade Agreements (FTA) featuring an investment chapter.
restricts the freedom of governments to implement policies and legislation due to the possibility that private companies may take them to an international investment tribunal.⁵

Even though the alleged risk of regulatory chill concerns a number of areas, this paper will examine the issue from an intellectual property (IP) law perspective. This is important as while IP rights were hardly ever targeted by ISDS claims in the past, this is no longer the case. Claimants have recently begun using ISDS as a vehicle for challenging compliance with IP law and, as a result, IP has moved to the centre of ISDS discourse. This study will first provide a brief overview of ISDS in order to explain why it is an essential element of modern IIAs and why ISDS or similar provisions are likely to be included in the TTIP. It will then analyse the regulatory chill theory and the potential threat to policy space posed by the inclusion of ISDS in the TTIP with reference to some of the most controversial ISDS disputes involving IP law.

**INVESTOR-STATE DISPUTE SETTLEMENT**

While the substantive provisions of an IIA determine whether a certain measure breaches international investment law, procedural clauses such as ISDS regulate the enforcement aspects of the case.⁶

**History**

The original aim of ISDS was to guarantee security to private investors in developing countries considered risky as their legal systems were less advanced or members of the judiciary were not completely independent from the government. Prior to ISDS, investment disputes were highly politicised as they involved direct confrontation between sovereign states.⁷ Since governments are cautious about initiating proceedings against each other due to political considerations,⁸ this necessitated the development of a de-politicised dispute settlement mechanism independent of the diplomatic ties between countries.⁹ ISDS thus came into being to ensure that substantive rights can be enforced directly before an international dispute settlement tribunal.⁴

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⁵ Ibid.
tribunal\textsuperscript{10} and resolved two key deficiencies which plagued dispute settlement at the time: the unreliability of diplomatic protection and the inadequate effectiveness of domestic remedies.\textsuperscript{11} Nowadays, the usage of IIAs including ISDS provisions has expanded and is no longer confined to agreements between a developed and a developing country.\textsuperscript{12} For example, ISDS was included in KAFTA\textsuperscript{13} and is expected to be included in the TTIP.

**Role and inclusion in the TTIP**

IIAs provide a legal framework for the protection of foreign investment by offering certainty and predictability.\textsuperscript{14} Such protection includes, *inter alia*, fair and equitable treatment, non-discrimination and adequate redress in the case of expropriation. ISDS plays a key role in ensuring that investors can enforce these rights reliably. Apart from the protection it provides to investors, ISDS is also an important tool for stimulating foreign investment.\textsuperscript{15} This is a key reason why ISDS or a similar mechanism is expected to be included in the TTIP.

The Investment Court System recently proposed to be included in the TTIP appears to be very similar to traditional ISDS, although it is based on a permanent, court-like model and provides a number of improvements such as increased transparency, safeguards for governments and special provisions for small and medium-sized companies.\textsuperscript{16} It is also reportedly faster, more cost efficient and, unlike traditional arbitration, allows appeals. While the ICS is likely to be a considerable improvement on conventional ISDS, given its enhanced democratic legitimacy and accountability, the two models are not inherently different as they are based on the same fundamental principles. The ICS could therefore be regarded as a modernised enforcement mechanism which addresses many of the concerns which have arisen in the past rather than a radically different system of investment dispute settlement.

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Compensation

Compensation awarded to investors in ISDS cases is confined to monetary damages and tribunals cannot force states to alter or abandon their policies. However, while tribunals cannot theoretically compel a state to change a certain measure against their will, the pressure they can put on a government is tremendous. As the amount awarded may be extremely high, it could be argued that this may effectively lead to policy changes. This assertion is directly relevant to the regulatory chill theory which will be examined below.

REGULATORY CHILL

What are the concerns?

Perhaps the most fiercely criticised aspect of the inclusion of ISDS in the TTIP is the possibility of regulatory chill. Advocates of the regulatory chill theory argue that ISDS makes governments hesitant or reluctant to pass legislation and regulatory measures in order to avoid litigation before an investment tribunal. More specifically, it is claimed that the prospect of paying compensation as well as potential reputational damage may discourage a government from enacting various social measures. Others have opposed such claims, arguing that the “literature supporting the contention that regulatory chill does exist is largely anecdotal and has not been adequately substantiated”. For example, Schill has argued that “investment treaties neither obstruct nor chill state regulation” and Soloway has dismissed claims that NAFTA is causing regulatory chill by highlighting the high amount of legislation in allegedly affected areas in Canada at the time. While regulatory chill has been associated

18 Although regulatory chill is not purely an ISDS issue and can be attributed to the entire international investment protection system, it is also commonly invoked as an argument specifically against ISDS; see, for instance, Australian Government, Department of Foreign Affairs and Trade, “Gillard Government Trade Policy Statement: Trading our way to More Jobs and Prosperity” (2014), http://www.acci.asn.au/getattachment/b9d3cfae-fc0c-4c2a-a3df-3f58228daff6d/Gillard-Government-Trade-Policy-Statement.aspx [Accessed October 3 2016].
20 J. Coe Jr and N. Rubins, ”Regulatory expropriation and the Tecmed case: Context and contributions” in T. Weiler (eds), International Investment Law and Arbitration: Leading cases from the ICSID, NAFTA, bilateral treaties and customary international law (Cameron May, 2005) 599.
with cases challenging both legislation and administrative measures, the vast majority of ISDS claims have been brought against the latter category.\(^{26}\)

The explicit inclusion of IP rights in the Commission’s draft text on the TTIP’s investment chapter\(^ {27}\) indicates that IP law is an area likely to be affected by this issue. In the IP context, it is argued that regulatory chill “freezes IP policy and subordinates national welfare interests to the private expectations of a single foreign actor… [and] undermines the capacity of intellectual property law and policy to respond to dynamic shifts in the national or global technological frontier”.\(^ {28}\) Such claims, especially if substantiated, are particularly worrisome as IP is an area which has to be flexible enough to respond to constant technological and societal developments. Being unable to respond to such changes may not only stifle the implementation of more progressive IP legislation but it could also affect other areas such as health and environmental protection, as it will be explored below.

**Defining and assessing regulatory chill**

The problem with either proving or disproving the regulatory chill theory is that its exact meaning is arguably far from clear;\(^ {29}\) moreover, the chilling effect is very difficult to measure in practice.\(^ {30}\) Tienhaara has offered the following working definition:

> In some circumstances, governments will respond to a high (perceived) threat of investment arbitration by failing to enact or enforce bona fide regulatory measures (or by modifying measures to such an extent that their original intent is undermined or their effectiveness is severely diminished).\(^ {31}\)

Although this is a satisfactory and reasonably clear formulation, it could be argued that it is rather broad as it is evident that an actual threat is not required; a perceived threat will suffice. On the other hand, this could be seen as a fair expansion of the definition as the mere belief

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\(^{29}\) Soloway (2003) 1.


\(^{31}\) Ibid, 610.
that there might be ISDS litigation could determine whether a certain measure is abandoned or amended.\textsuperscript{32}

Regulatory chill has been further divided into different categories.\textsuperscript{33} \textit{Anticipatory chill} refers to legislators or regulatory bodies being cautious of potential disputes before they even start drafting policy changes; \textit{specific response chill} occurs when a specific measure is stopped once the decision-making body is made aware of the possibility of ISDS; \textit{precedential chill} involves situations where legislators or regulatory entities change a certain measure once a dispute has been resolved due to fear of new claims based on the pre-modified regulation.

All of these hypothetical scenarios can theoretically reduce a government’s policy space and make it abandon certain measures. However, it could be argued that the reduction of regulatory freedom which the inclusion of ISDS in the TTIP may cause would be negligible when put in context, given that the EU’s Member States have already voluntarily undertaken a variety of obligations which have decreased their sovereignty in return for something else. For example, both EU and ECHR membership limit their policy space to a considerable extent. Conversely, others may legitimately argue that as their regulatory freedom is already significantly reduced with or without ISDS in the TTIP, no further limitations should be imposed.

While the regulatory chill theory may intuitively seem convincing, it must be tested empirically.\textsuperscript{34} Unfortunately, this is a difficult task as a significant part of the government’s policy-making process is confidential and thus hard to assess. What is more, governments are likely to avoid publicly admitting that they have been dissuaded from making desired policy changes due to a threat of being sued by a private foreign investor.\textsuperscript{35} Such a confession is likely to undermine their credibility in the eyes of the public. Nevertheless, some government officials have made statements which have been interpreted by advocates of the regulatory chill theory as confirming it. For example, a legal advisor for the Sri Lankan Government expressly acknowledged the possibility of regulatory chill,\textsuperscript{36} although no specific examples were given. Additionally, Van Harten recently conducted confidential interviews with a

\textsuperscript{32} The inclusion of \textit{bona fide} serves to filter out measures enacted solely with protectionism and discrimination in mind which would be illegitimate in any event.

\textsuperscript{33} Tietje and Baetens (2014) 41.


\textsuperscript{35} Tienhaara (2011) 609.

number of government officials in Canada where the responses confirmed the existence of regulatory chill.\(^{37}\) While such evidence should be taken with a grain of salt considering that ISDS may be used as a scapegoat for officials’ own failures, the potential risk should not be ignored. Further empirical research in this area is necessary and while there are no such studies directly aimed at the relationship between regulatory chill and IP, it would be interesting to see how the governments of Australia and Canada internally responded to *Philip Morris*\(^{38}\) and *Eli Lilly*\(^{39}\) which will be discussed below.

### IP disputes and TTIP implications

Another way to examine the impact of regulatory chill on IP law is to look at the case law in this area. Interestingly, despite the fact that most modern IIAs include intellectual property rights as a type of protected investment, surprisingly few cases have focused on IP measures so far.\(^{40}\) In recent years, rights holders have begun using ISDS as a vehicle for challenging IP legislation and some cases have attracted considerable attention.\(^{41}\) For example, *Philip Morris v Australia* and *Philip Morris v Uruguay*\(^{42}\) concerned plain packaging legislation and trademarks, *Eli Lilly v Canada* focused on patent revocation and *AHS v Niger*\(^{43}\) dealt with unauthorised use of trademarks. Concerns about the impact of ISDS on IP law are therefore no longer merely theoretical. Questions have arisen as to whether IP should be regarded as an “investment” in the first place\(^{44}\) and concerns have also been expressed about an “invasion of sovereignty” resulting from ISDS in the IP context.\(^{45}\) It has been argued that due to the threat of ISDS disputes, governments may be unable to balance IP rights protection against other vital priorities such as public health or environmental law.\(^{46}\) This section will briefly outline


\(^{38}\) *Philip Morris Asia Ltd v Australia*, UNCITRAL, PCA Case. No. 2012-12, Written Notification of Claim (June 27, 2011).

\(^{39}\) *Eli Lilly and Company v The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Notice of Arbitration (September 12, 2013).


\(^{42}\) *Philip Morris Brand Sarl, Philip Morris Products SA and Abal Hermanos SA (Uruguay) v Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Request for Arbitration (February 19, 2010).

\(^{43}\) *AHS Niger and Menzies Middle East and Africa SA v Republic of Niger*, ICSID Case No. ARB/11/11, Award (July 15, 2013).


\(^{46}\) Ibid.
two of the most controversial IP ISDS cases before analysing their wider implications in the context of the TTIP.

**Philip Morris v Australia**

Although *Philip Morris* challenged Australian public health measures, IP was a key issue. In 2012, Australia put in force legislation requiring tobacco products packaging to be coloured in “drab dark brown” and to display graphic health warnings. Crucially, graphic logos representing the brand were also prohibited. The primary purpose of the legislation was to promote public health by reducing the attractiveness of tobacco products. Philip Morris brought ISDS proceedings against Australia under the Australia-Hong Kong BIT, arguing that the legislation “manifestly deprives it of its intellectual property and the commercial utility of its brands”. The company claimed that as they are not allowed to use their trademarks, Australia’s actions were “expropriatory”. Philip Morris argued that Australia violated the BIT by enacting legislation which is incompatible with other international agreements governing IP law, namely the Paris Convention for the Protection of Industrial Property and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In December 2015, the tribunal dismissed Philip Morris’ claims on jurisdictional grounds.

Prior to initiating the dispute the company obtained an Australian subsidiary solely for the purpose of suing Australia under the BIT, which amounted to an abuse of process. The significance of this case is analysed further below.

**Eli Lilly v Canada**

The *Eli Lilly* case was the first IP ISDS dispute filed under the North American Free Trade Agreement (NAFTA). Eli Lilly is a global pharmaceutical company which had the patents for two of its drugs invalidated by Canadian courts on the basis of the “promise doctrine”. This rule requires patent applications to support the claimed inventive promise in order to satisfy the utility standard. If the applicant does not provide evidence of the claimed benefits at the time of applying, the patent could be revoked. In late 2012, Eli Lilly started

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48 Agreement with Hong Kong concerning the Promotion and Protection of Investments [1993] ATS 30.
52 Okediji (2014)
ISDS proceedings against Canada, claiming that the doctrine is “inconsistent with the utility standard embodied in NAFTA Chapter 17, is significantly out of step with the law of utility in Canada’s NAFTA partners, and is a dramatic departure from the standard in Canada when [the patents] were filed”. The company argued that the decision violates the country’s international IP obligations under NAFTA, TRIPS and the Patent Cooperation Treaty. It claimed that the actions of Canada amounted to an indirect expropriation of its IP rights and sought $500 million in damages. The case is still pending as of November 2016.

Analysis and implications for the TTIP

While no ISDS proceedings challenging IP law have been brought against EU Member States yet, Philip Morris and Eli Lilly are indicative of the potential problems which may emerge in Europe following the conclusion of the TTIP. These cases highlight the tensions which may arise between governments pursuing legitimate public policy objectives and private companies which may incur financial losses as a result. The plain packaging dispute is particularly controversial due to the sensitivity of the issues involved and is often used as an example for the reduced regulatory freedom ISDS allegedly causes. Moreover, while Philip Morris was decided on jurisdictional grounds, it is unclear what would have happened if the substance of the company’s claims was examined. Indeed, following the tribunal’s decision, the tobacco company stated that it is “regrettable that the outcome hinged entirely on a procedural issue that Australia chose to advocate instead of confronting head-on the merits of whether plain packaging is legal or even works”. The statement indicates that this is unlikely to be the last attempt for a tobacco company to challenge such legislation and that this may well occur in Europe once the TTIP comes into force, especially considering the recent implementation of legislation on standardised tobacco products packaging in the EU.

Similarly, although Eli Lilly is still pending, it indicates the challenges EU governments may face in the field of patent law and confirms recent tendencies to challenge compliance with international IP obligations via ISDS. What is interesting about this case is that the company is seeking compensation for rights which never existed in the first place as the patents were automatically rendered invalid. Commentators have described Eli Lilly’s claim

55 Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products...
56 Khan (2016) 249.
as a “clear attack on the principle that national courts have the right to determine matters of patent validity under national legislation”\(^{57}\) while others have argued that “intellectual property has long ceased to be primarily a domestic concern”.\(^{58}\) Furthermore, it has been claimed that if Eli Lilly wins, it will “disrupt internationally accepted norms that permit countries to have different standards of protection”.\(^{59}\) Even before Eli Lilly initiated proceedings, one of the largest law firms in the world reportedly suggested that IIAs including ISDS are the new way forward for pharmaceutical companies to protect themselves from the “assault” their patents are facing abroad.\(^{60}\) Moreover, it has been argued that compensation is not the primary objective of Eli Lilly; rather, it is claimed that the company is attempting to change Canadian patent law to fit its own ends.\(^{61}\) While it is difficult to determine whether such claims are true, using ISDS as a tool to force changes to undesirable laws is foreseeable within the theory of regulatory chill. If Eli Lilly is successful, this may encourage any private company opposed to a particular IP measure to attempt to indirectly change the law to fit its own needs.

The implications of these cases are therefore significant. They demonstrate that IP law is an area vulnerable to regulatory chill. Crucially, they also suggest there is a high risk that states participating in the TTIP may become increasingly cautious about reforming their domestic IP laws following its implementation.

**CONCLUSION**

At this stage of the negotiation process, it appears highly likely that ISDS or a similar arbitration mechanism such as the proposed Investment Court System will be incorporated in the final TTIP deal. Although such a dispute-settlement system could provide a number of benefits such as greater protection for foreign investors and increased inward investment flows for participating governments, there are also legitimate concerns about reduced regulatory freedom. While some may argue that the debate on regulatory chill is inconclusive as it is difficult to demonstrate its existence with absolute certainty, this should not be a reason to dismiss or underestimate concerns about the negative impact of ISDS on IP law. As long as there is a potential risk, the dispute settlement provisions in the TTIP must be

\(^{57}\) McDonagh (2015).
\(^{58}\) Okediji (2014) 1122.
\(^{59}\) Ho (2015) 213.
\(^{60}\) Ibid, 220. This statement is problematic as it is questionable which side is really carrying out the alleged “assault” – is it governments pursuing legitimate public policy objectives or private companies which have been adversely affected as a result?
\(^{61}\) Okediji (2014) 1121.
negotiated with great caution in order to ensure that the interests of the participating governments are appropriately safeguarded. Importantly, IP law is a quickly evolving area which has to be flexible enough to enable important policy objectives to be achieved. Cases such as Philip Morris and Eli Lilly demonstrate that this may prove challenging and that the implementation of more progressive, innovative and fair IP legislation might be stifled if such disputes are brought under TTIP.

There are various ways to mitigate the potential risk of regulatory chill on IP law in the context of the TTIP. One way would be to exclude ISDS or similar provisions from the agreement altogether, although this is unlikely to be a viable option considering the current political landscape and the fact that both negotiating sides would like to see such provisions included. Considering that increased protection of IP rights in particular has not been shown to have a profound effect on investment flows in the ISDS context, a more justifiable, subtle and realistic option would be to specifically exclude IP rights from the scope of ISDS in the TTIP. This could be achieved by narrowing down the substantive provisions of the investment chapter and not regarding IP rights as a type of protected investment. Such an approach would be in line with the traditional notion of viewing IP as a system of exclusive rights which is not designed to protect investments per se but what results from that investment. It will also ensure that the room for manoeuvre traditionally provided by TRIPS is respected and governments are still able to freely fine-tune their IP laws without being under the constant threat of ISDS litigation.

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63 McDonagh (2015).