

# 1

## INTRODUCTION

### THE LEGAL COMPLEXITY OF IPR INVESTMENT CLAIMS

Kimani .F. Goddard

This monograph addresses the complexity of legal issues arising as a result of the deployment of international investment agreements (IIAs), as substantive regulatory and enforcement devices, for the protection of intellectual property rights. Its overriding analytical framework, proposes that *Philip Morris* and *Eli Lilly's* attempt at using investment based IPR clauses to avoid municipal legal measures, is ultimately a signal toward a fundamental transformation of the manner in which property is territorially conceived, legitimatised and regulated, in international and municipal law. This is evidenced by *Eli Lilly's* apparent desire to find customary or general principles of territorially independent, international patent law norms, seen in its second notice of arbitration, lodged against the Government of Canada in 2013. In this notice, the pharmaceutical company attempts to distil something akin to a specific international customary patent rule regarding '*usefulness*' and '*capable of industrial application*,'<sup>1</sup> by recourse to a restatement of the rules available in the municipal patent laws of the

---

<sup>1</sup> This refers to Canada's utility standard as analysed by Professor Norman Siebrasse in his expert report submitted into evidence in the *Eli Lilly v Canada* claim. In this analysis Prof. Siebrasse suggested that in the period between 2002 and 2008 Canada's utility test had shifted from the single standard '*mere scintilla test*' to a bifurcated test, with the addition of the '*Promise Utility Doctrine*'. This addition also modified the process for submitting evidence of utility, in that it now excluded post-filing evidence. If evidence of utility is not submitted at the filing date, patentees could only depend on information indicating 'sound prediction', disclosed in the patent itself. Siebrasse describes the '*Promise Doctrine*' as an extra-statutory requirement. However, in a common law legal system which is heavily shaped by judge-made law, extra-statutory legislation is a normal trajectory in the development of legislation over time, due to application in cases. The Tribunal itself highlighted that "*evolution of the law through court decisions is natural, and departures from precedent are to be expected*". Judge-made law is seen as having near equal standing to statutory law. The validity of the '*Promise Utility Doctrine*', cannot be challenged on the basis of which source of law it belongs to. See Expert Report of Professor Norman Siebrasse, (Case No. UNCT/14/2), UNCITRAL, NAFTA, For a discussion on the validity of judge-made law and critiques of same in common-law legal systems See Ben Depoorter and Paul H. Rubin, Judge-Made Law and the Common Law Process, in Francesco Parisi, The Oxford Handbook of Law and Economics: Volume 3: Public Law and Legal Institutions, Oxford University Press, 2017, For a discussion of the efficiency of judge-made law in commercial disputes See Nicola Gennaioli and Adrei Shliefer, The Evolution of Common Law, Journal of Political Economy, 2007, Vol 115 (1)

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

European Communities and the United States.<sup>2</sup> Unfortunately for *Lilly*, the disciplinary silos within which international law scholars and lawyers in intellectual property, international investment and international trade law work, produced a legal approach that failed to identify and provide a technical analysis of custom and general principles<sup>3</sup> as the most obvious and sound arguments for its challenge to Canada's '*promise doctrine*'. A more cogent approach to challenging the disputed measure would have been to present evidence identifying the ubiquity of the more widely practiced standard of utility known as the '*mere scintilla test*', in addition to evidence that the '*mere scintilla test*' is accepted as law among States Parties to TRIPS, the PCT and other relevant international agreements. This could then be buttressed by provision of evidence on general principles regarding utility, found in the patent laws of WTO and WIPO Member states. Such an analysis would of course need to be circumscribed by the said Member State's freedom to determine the appropriate method of implementing the provisions of TRIPS within their own legal system and practice under Article 1§1.<sup>4</sup> This would have assisted the Tribunal in avoiding the perception that its decision could be a direct challenge to Canada's sovereign right to regulate. It is clear from the Tribunal's analysis that there was a concern with not appearing to question the correctness of Canada's policies or the Courts' decisions.<sup>5</sup> A custom and general principles analytical approach would have also avoided

---

<sup>2</sup> §10-16 Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven (Strattera and Zyprexa); See paragraph 258 Final Award *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, June 2013, "Claimant argues that the dramatic change in Canadian law is also evident from the "recent divergence" between the utility requirement in Canada and in the other NAFTA Parties. According to Claimant, the utility requirement remains a low bar in both the United States and Mexico. This difference in law is reflected in "a stark divergence in outcomes"; while invalidations based on utility have become frequent in Canada, utility "is a non-issue in the rest of North America"."

<sup>3</sup> In international law Article 38 of the Statute of the International Court of Justice (ICJ) is the accepted legal standard for identifying sources of law in the entire international legal system. When parties involved in international disputes seek to challenge an applied measure that is perceived as deviating from accepted legal practice by states at the international and municipal levels, they will present their arguments on the basis of juridical analysis associated with Article 38 (b) Customary international law derived from the practice of States and Article 38(c) General principles of law recognized by civilised nations; and, as subsidiary means for the determination of rules of international law. There is a long and well developed jurisprudence on the development of international customary rules as well as the application of general principles to international disputes. Patent law lacks established international custom as can be found in International Humanitarian Law and the Law of State Responsibility. However, *Eli Lilly* could have cogently argued for the existence of custom with respect to the utility standard, using IP provisions in RTAs, TRIPS as well as general principles on utility found in the municipal laws of states. Such an analysis would need to be expanded to include all Member States of the WTO and WIPO. For a full discussion on the technicalities of the identification of customary international law see International Law Commission, Draft conclusions on identification of customary international law, with commentaries 2018, 70<sup>th</sup>, appears in Session Yearbook of the International Law Commission, 2018, vol. II, Part Two

<sup>4</sup> TRIPS Article 1§1

<sup>5</sup>§426 and §430 Award *Eli Lilly v Canada*, Case No. UNCT/14/2

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

what appears to be direct enforcement of WTO Law by a private actor, outside the WTO Dispute Settlement Body, contrary to Article 23 of the WTO Dispute Settlement Understanding.<sup>6</sup> Any dispute predicated on a violation, suspension of benefits or nullification in respect of any agreements within the Single Undertaking, must be resolved through recourse to dispute settlement in accordance with the rules and procedures of the WTO Dispute Settlement Understanding.<sup>7</sup> In the opinion of a number of legal scholars, the use of IIAs by investors directly enforcing the provisions of TRIPS against WTO members is not permissible. The set of agreements which make up the WTO Single Undertaking are mutual obligations of the States Parties and can only be enforced by them. Foreign investors established on the territory of a host state may not attempt to use the partial and sovereignty derived *locus standi* granted to them within international investment treaties to directly enforce TRIPS provisions; as these are rights and obligations that states owe to each other.

Instead of challenging on the basis of customary international law or general principles, paragraph 117 of the second 2013 notice of intent, which names both the *Strattera* and *Zyprexa* patents, unceremoniously challenges Canada's right to refine its utility standard in line with rights afforded to States Parties under Article 1§1 of the TRIPS Agreement.<sup>8</sup> It complained in relevant part that Canada's '*promise doctrine*' required it, "*to meet elevated and additional standards for utility and disclosure that are not required by the laws of the United States of America, the European Union, or the harmonized PCT rules.*" This is an attempt to suggest that a United States investor established in Canada, should expect to be subject to near identical legislation as is available in its home state and those of its trading partners. Both the PCT and the TRIPS Agreement provide Member States with a wide remit to determine the substantive content of their own patent laws. Even more egregiously, and absent the relevant legitimating legal basis of custom and general principles, *Lilly's* first 2012 notice of intent goes on to quote the custom and practice of

---

<sup>6</sup> Simon Klopschinski, The WTO's DSU Article 23 as Guiding Principle for the Systemic Interpretation of International Investment Agreements in the Light of TRIPS, *Journal of International Economic Law*, Volume 19, Issue 1, March 2016, Pages 211–239

<sup>7</sup> Article 23§2(a) WTO Dispute Settlement Understanding

<sup>8</sup> Article 27 of the TRIPS Agreement specifically exhorts member states to provide patents in all fields of technology to inventors that can demonstrate that these inventions are, 'new, involve an inventive step and are capable of industrial application.' The finer points of capacity for industrial application or utility are left to the specific practice in legal systems of member states.

the *European Patent Convention* in an attempt to suggest the existence of some supra-national harmonised utility and disclosure standard, explicitly accepted, both in the United States and Europe, in order to demonstrate the divergence of Canada's approach to utility. No such plurilateral, supra-national standard exists.

The Notice further enters into an analysis of substantive utility and disclosure requirements, which are specifically avoided by all existing international IPR Agreements. It emphasises that, “[U]nder *sic* the *European Patent Convention*, the condition precedent of susceptible of industrial application in Article 52(1) likewise is distinct from the disclosure requirements in Article 83. Article 83 does not require proof of utility to be included in the patent specification.” This attempt to argue for access to patent rules with respect to disclosure originating outside of Canada's legal system is unprecedented. Without an informed discussion attempting to establish the existence or non-existence of international custom or general principles of patent law surrounding utility and industrial application, *Eli Lilly's* position is hard to justify. It must be emphasised that there is no explicit legal provision in NAFTA Chapter 17, TRIPS Article 27 or the Patent Cooperation Treaty, which establishes the common law ‘*mere scintilla*’<sup>9</sup> standard as an accepted custom of international patent law, as opposed to ‘*the promise of the patent*’ standard. In fact, the uniqueness of Canada's ‘*promise doctrine*’ and the invalidation of patents for non-compliance with it, is not an aberration within international patent law, and international IP law in general. Substantive and specific legal rules of patent law on fundamental issues can vary widely among States Parties to TRIPS and the WIPO Treaties. A clear example of this is that, on the issue of patent eligibility, an investor whose home state is a European Union member could not legitimately expect to be awarded a United States patent for an isolated, naturally occurring DNA sequence, even where it had already received a similar patent within the European Union. The *European Patent Convention* allows for biological material to be patentable, even where the gene sequence has only been isolated in its naturally occurring form<sup>10</sup>. However, under United States Patent Law, following the *Association for Molecular Pathology v Myriad Genetics Inc.* decision, naturally occurring

---

<sup>9</sup> See *R v Smith Incubator Co*, [1936] “*The invention is undoubtedly small and simple, but smallness and simplicity are not necessarily an object and will not prevent a patent being good; a mere scintilla of invention is sufficient*”)

<sup>10</sup> §5.2(i) *European Patent Convention*

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

human genetic sequences which have only been isolated from the rest of the genome are not patent eligible.<sup>11</sup> Therefore, if an EU investor's naturally occurring gene sequence patent, forming part of its investment operation was rejected by the USPTO or invalidated after the *Myriad* ruling, the investor in question could not claim violations of fair and equitable treatment (FET) or expropriation.

*Lilly's* arguments envisioned a harmonised global substantive patent law, which is not yet effectively available under the TRIPs Agreement, The Patent Cooperation Treaty (PCT) or even NAFTA itself; despite efforts under the shelved 1997 Multilateral Agreement on Investment (MAI) and Anti-Counterfeiting Trade Agreement (ACTA)<sup>12</sup>. In fact, the failed ACTA Agreement mirrors the regulatory language associated with all other international IPR agreements by stating clearly that, "*A Party may implement in its law more extensive enforcement of intellectual property rights than is required by this Agreement, provided that such enforcement does not contravene the provisions of this Agreement. Each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement within its own legal system and practice.*" There is no broad consensus on substantive IPR property norms, beyond the minimum standards established by the TRIPS Agreement. In fact, efforts which began in 2000, to create a Substantive Patent Law Treaty (SPLT), as part of the work of the WIPO Standing Committee on the Law of Patents, were abandoned in 2006.<sup>13</sup> Article 16 of the Draft SPLT on utility/industrial applicability goes no further

---

<sup>11</sup> See analysis of patent eligibility of DNA and cDNA where the court determine that a naturally occurring DNA sequence could not be said to be an invention, and therefore did not meet the criteria for patent eligibility. Association for Molecular Pathology et al v Myriad Genetics, Inc., et al, United States Supreme Court, June 13<sup>th</sup> 2013

<sup>12</sup> Article 3 § 1-2 of the Draft Anti-Counterfeiting Trade Agreement lays bare the problem of sovereignty, territoriality and property even among like-minded economies, in relevant part the agreement provides that, '*1. This Agreement shall be without prejudice to provisions in a Party's law governing the availability, acquisition, scope, and maintenance of intellectual property rights.*

*2. This Agreement does not create any obligation on a Party to apply measures where a right in intellectual property is not protected under its laws and regulations.*' For a thorough discussion in international intellectual property norm-setting and ACTA see Pedro Roffe and Xavier Seuba, 'ACTA and the International Debate on Intellectual Property', in Pedro Roffe & Xavier Seuba, *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath*, Cambridge University Press: Cambridge, 2014, Michael Blakeney, *Intellectual Property Enforcement: A commentary on the Anti-Counterfeiting Trade Agreement*, Edward Elgar Publishing; Cheltenham,UK: Northampton: USA, 2012

<sup>13</sup> The SPLT has been on the discussion agenda of the WIPO Standing Committee on the Law of Patents since 2001, See World Intellectual Property Organisation, Draft Substantive Patent Law Treaty, SCP/5/2, ORIGINAL: English, DATE: April 4, 2001, [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_5/scp\\_5\\_2.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_5/scp_5_2.pdf), See also World Intellectual Property Organisation, Draft Regulations and Practice Guidelines Under the Draft Substantive Patent Law Treaty, SCP/5/3 ORIGINAL: English, DATE: April 4, 2001, [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_5/scp\\_5\\_3.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_5/scp_5_3.pdf)

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

than Article 27 of TRIPS, “ *An invention shall be considered industrially applicable (useful) if, according to its nature, it can [be made or used in any kind of industry][have a specific, substantial and credible utility], as prescribed in the Regulations.*” No substantive instructions on a legal test to determine utility or sufficiency of disclosure is indicated in the Draft SPLT, or the Draft Regulations and Practice Guidelines under the Draft Substantive Patent Law Treaty. Furthermore, were the Draft SPLT to contain a specified utility test, an investor could not legitimately expect to benefit from this, as the draft treaty is not in force and does not form part of international patent rules which are accepted as law by the international community. With the exception of the EU countries, which form a multi-territorial single economic space and harmonise IP law through Directives, international law has clearly and aggressively avoided the creation of substantive international patent law norms. Despite this, both notices of arbitration filed by Eli Lilly in 2012 and 2013 respectively, put forward a decidedly inelegant argument, lacking in technical rigour, which appears to challenge Canada’s ‘*promise doctrine*’ on the basis of general principles of patent law accepted in the municipal legal systems of NAFTA Member States (though not explicitly stated or analysed on these technical grounds).

A comparable line of legal reasoning adopted by *Philip Morris* (imagined customary and general principles on property norms), is apparent in relation to the scope of trademark rights assumed by claimant in the *Philip Morris v Uruguay* dispute. *PMP* and *Abal Hermanos*’ claims appear to suggest that Uruguay’s right to regulate in the interest of public health, should not curtail property rights in trademarks, pursuant to TRIPS and the Paris Convention on Industrial Property Rights.<sup>14</sup> Here, *PMP* assumes that Uruguay has an *erga omnes* obligation to provide the company with a specified ‘*right to use*’ its trademarks in addition to the right to exclude third parties. In its 2010 Request for Arbitration, *Philip Morris* asserts that Uruguay’s Decree 287/2009 requiring an 80% health warning package coverage, “*unfairly limits Abal’s right to use its legally protected trademarks and prevents Abal from displaying them in their proper form.*” As property rights, trademarks have a slightly different character from other IPRs, they essentially represent the ownership of exclusive rights in speech, communication or expression in relation to consumers. Communication, speech and expression (though commercial in

---

<sup>14</sup> §85-86 Request for Arbitration, FTR Holdings et al v Uruguay, February 2010

nature) are strictly within the control of the state and restricted by several other bodies of law, including defamation, public order and censorship laws. Uruguay's health legislation adopted in compliance with its obligations under the WHO Framework Convention on Tobacco Control (FCTC), fall within a similar category of laws, limiting the nature of communication that companies may engage in with their consumers. There exists no '*right to use*', or near absolute property right for trademarks, as can be found in the case of freehold land tenure or the standard term of protection granted to copyright [life of the author plus 70 years]. Here, Philip Morris conflates the scope of 'the right to exclude' use by third parties, with '*a right to use*'. In *Pinterest Inc v Premium Interest Ltd [2015] FSR 27*, the Courts asserts that, "... it is acte clair that registration of a Community Trademark: (a) confers no positive right to use that mark; ...". Trademarks and associated brand messaging are commercial speech, and as such are subject to the normal legal limitations placed on such speech, in the vast majority of jurisdictions<sup>15</sup>. In a series of cases directly related to the Philip Morris investment claims, the Tobacco Industry was roundly disabused of this notion of an untrammelled '*right to use*' trademarks. In this case involving the UK Secretary of State for Health, fielding several adjoined actions from British American Tobacco, Philip Morris, JT International and Imperial Tobacco Limited, the outcome turned on the nuances of a negative right to exclude and the positive right to use. The UK Secretary of State's analysis found the scope of rights granted under trademark law stem narrowly from the right to prevent third party use. Thus, any property rights in relation to use can only be construed within the context of use as it relates use by third parties. It is emphasised that the only trademark owner use addressed by the law, is in respect of non-use, where a trademark property right may be rescinded for non-use. The UK Secretary of State for Health emphasises that, "... there is no conceivable basis in TRIPS for saying that the "essence" of a trademark includes a right to use that property right to facilitate a lethal health epidemic." The exercise of trademark

---

<sup>15</sup> United States case law on the subject. *Central Hudson Gas & Electric Corp. v. Public Service Commission* asserts that "government may regulate truthful, non-misleading commercial speech about lawful activity if the regulation serves a substantial government interest, the regulation directly advances the government interest, and the regulation is no more extensive than necessary to serve that interest." See Rebecca Tushnet, "Trademark law as Commercial Speech", 58 S.C. L. Rev. 737-756 (2007), For a comprehensive discussion on trademark rights, property and freedom of expression in the EU context see Wolfgang Sakulin, *Trademark Protection and Freedom of Expression: An Inquiry into Trademark Rights and Freedom of Expression Under European Law*, Kluwer International: Netherlands, 2011, Rebecca Tushnet, *Truth and Advertising: The Lanham Act and Commercial Speech Doctrine*, in in Graeme B Dinwoodie et al, *Trademark Law and Theory: a Handbook of Contemporary Research*, Edward Elgar Publishing: Cheltenham, 2008

rights must thus, “yield to limitations imposed in the pursuit of superior public policy considerations”<sup>16</sup>, such as the prevention of the proliferation of tobacco related illnesses. Property rights cannot be upheld to the point of actively creating pervasive social, economic and cultural upheaval. Taking this into consideration, thesis eschews all natural rights philosophical foundations as it relates to property, intellectual property and the exercise of property rights. For this reason, this thesis avoids heavy use of the jurisprudence of the European Court of Human Rights, particularly as it relates to the notion of a human right to property. Property, particularly intellectual property is a social resource created by the state, subject to certain conditions, bestowing privileges of ownership on those possessing the requisite legal personality; and meeting the relevant conditions. It is above all, not a right. An in-depth review of the historical development of English Patent Law from the 1624 Statute of Monopolies onward, reveals the construction of such IPRs as monopolies and patents of privilege.<sup>17</sup> The grant of a privilege of monopoly remains the foundation of modern patent law, as exemplified by the core function of the patent bargain, the grant of a time and subject matter limited ‘property right’ in exchange for the invention’s full disclosure for the benefit of society. The over-use of rights terminology often obfuscates the reality of how IP law functions as a tool for economic and social regulation. The notion of patents, copyright, trademarks as rights, with some resemblance to human rights is of much more recent vintage; arguably rooted in the post WW II preoccupation with human rights, property and state expropriation of said property.

### **The Philip Morris and Eli Lilly Claims in Context**

How then, do we situate the *Philip Morris* and *Eli Lilly* IPR investment claims, within the larger development of global property norms and the more specific field of IIA regulation of intellectual property rights? The highly publicised *Philip Morris* and *Eli Lilly* claims, and the legal processes subsequently triggered<sup>18</sup> by same, can be interpreted as catalysts for

---

<sup>16</sup> § 186 *British American Tobacco and Others v Secretary of State for Health*, [2016] EWCA Civ 1182, See also *Philip Morris Brands SARL and others v The Secretary of State for Health* (Case C-547/14, 4 May 2016)

<sup>17</sup> For a comprehensive understanding of the foundations of patents as a social resource created by the state to reward ‘deserving’ applicant through a system of monopolies and privileges see generally William Hyde Price, *The English Patents of Monopoly*, The Lawbook Exchange Ltd., 2006 (reprint of 1906 edition)

<sup>18</sup> The *Philip Morris v Uruguay* and *Eli Lilly v Canada* claims triggered a series of municipal and regional cases where the scope, character and legitimacy of specific kinds of title to property were among the key



Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

a much closer convergence of specific municipal property law norms, in tandem with the evolution of two international property protection legal regimes;<sup>19</sup> around the central task of identifying and securing property rights in an international multi-territorial context. In the preceding 60 years, property rights rulemaking activity at the municipal, regional and global level, has been concentrated within the legal domains of intellectual property and investment asset protection. An example of the drive to diminish the territorial restrictions on property can be seen in the fair and equitable treatment standards outlined in Article I of the 1959 Draft Convention on Investments,

*“[T]reatment to the property of the nationals of the other Parties. Such property shall be accorded the most constant protection and security within the territories of the other Parties and the management, use and enjoyment thereof shall not in any way be impaired by unreasonable or discriminatory measures”.*<sup>20</sup>

This represents a negotiated approach to dealing with the potential deleterious effects of the territorial principle, on the legal exercise of property rights beyond the borders of the home state of an investor. The OECD Draft Convention on the Protection of Foreign Property further developed and replicated<sup>21</sup>the language of the Draft Convention on

---

points of law adjudicated. In the UK *British American Tobacco Inc. and others v The Secretary of State for Health*, the Court of Appeal clarified that intellectual property rights, in particular trademarks could not confer positive right to use, but instead an exclusive right to prevent use by third parties. *British American Tobacco Inc. and others v The Secretary of State for Health*, Case No: C1/2016/2607,2624,2612 and 2614, [2016] EWCA Civ 1182. The decision by the Tribunal in in the *Eli Lilly* claim and the matters discussed therein, influenced the outcome in *AstraZeneca Canada Inc v Apotex Inc.*, where it provided the impetus for the nullification of the ‘*promise doctrine*’, broadening the scope of utility and increasing the likelihood of meeting the standards for award of a patent. “*La doctrine de la promesse n’est pas la méthode appropriée pour établir si le brevet satisfait à la condition d’utilité prévue à l’art. 2 de la Loi sur les brevets.... En effet, la doctrine de la promesse risque, comme en l’espèce, de priver une invention autrement utile de la protection conférée par un brevet parce que toutes les utilisations promises n’ont pas été suffisamment démontrées ou valablement prédites à la date de dépôt.*” *AstraZeneca Canada Inc. v. Apotex Inc.* 2017 SCC 36: File No.: 36654., 2016: November 8; 2017: June 30.

<sup>19</sup> See also OECD Draft Convention on the Protection of Foreign Property 1963, Abs Shawcross Draft Convention on Investment

<sup>20</sup> Georg Schwarzenberger, ‘The Abs-Shawcross Draft Convention on Investments Abroad: A Critical Commentary’,

<sup>21</sup> Article 1 of the OECD Draft Convention makes an affirmative statement which suggest that there exists an *erga omnes* ICJ Article 38(b) and (c) obligation in international law that requires States to respect and protect the property of nationals of another state. It then mirrors the property language used in the FET standard of the Abs Shawcross Documents

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

Investment in its treatment of foreign property.<sup>22</sup> In the early 1990s, in parallel to negotiations for the TRIPs agreement and NAFTA, the OECD attempted for a second time to deal with harmonisation of the protection of foreign property under the Multilateral Agreement on Investment, it was unsuccessful. However, the Draft MAI Commentary offers an insightful analysis of Member States' perceptions of intellectual property rights as investments.<sup>23</sup> In particular, in cases of expropriation where the '*investment consisted in total or in part of intellectual property rights, was seen as critical. It was decided not to suggest specific language on this issue and that it would need to be further revisited in a global context.*'<sup>24</sup> Since the 1966 entry into force of the International Convention on the Settlement of Investment Disputes (ICSID), under the auspices of the World Bank very few investment-based multilateral treaties, addressing the cross-border recognition and enforcement of property rights, have been successful. Instead the international investment protection system has witnessed a spaghetti bowl<sup>25</sup> proliferation of IIAs similar to that witnessed with international trade agreements, following the creation of the WTO. The result for IIAs is an intensification of the age-old problem of the nebulous definition of both property and investment; "*we know property ... [investment]*<sup>26</sup> ... *when we see it*"<sup>27</sup>. One might expect that the category of intellectual property as investment, would add significant clarity to the investment definitional debate. International intellectual property norms are among the most highly developed international property regimes.<sup>28</sup> However, the wide-ranging variance of substantive customary rules and

---

<sup>22</sup> Christophe Schreuer et al see also See also an analysis of debt instruments as investments and property, For a discussion on property rights and investment see Ursula Kriebaum, 'The Nature of Investment Disciplines', in Zachary Douglas, Joost Pauwelyn, Jorge Vinuales, *The Foundations of International Investment Law: Bringing Theory into Practice*, Oxford University Press: Oxford: New York, 2014, For the conventional definition of investment see Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco, ICSID Case No. ARB/00/4, Decision on Jurisdiction, para 52. Fedax N.V. v. The Republic of Venezuela, ICSID Case No. ARB/96/3, Decision of the Tribunal on Objections to Jurisdiction

<sup>23</sup> OECD Negotiating Group on the Multilateral Agreement on Investment (MAI), The Multilateral Agreement on Investment Commentary to the Consolidated Text, DAF/MAI(98)8/REV1, 22, April, 1998

<sup>24</sup> Ibid at page 7-30

<sup>25</sup> See Richard Baldwin and Patrick Low, *Multilateralising Regionalism: Challenges for the Global Trading System*, Cambridge University Press, World Trade Organization, Cambridge; Geneva, 2008

<sup>26</sup> For a comprehensive discussion of investment narrowly construed under NAFTA see *Apotex v the United States* See generally UNCTAD, *The Scope and Definition: UNCTAD Series on Issues in International Investment*

Agreements II, UNCTAD/DIAE/IA/2010/2, [https://unctad.org/en/Docs/diaeia20102\\_en.pdf](https://unctad.org/en/Docs/diaeia20102_en.pdf)

<sup>27</sup> Justice Rosalyn Higgins, 'Introduction: The taking of property - legal tasks underlying the labels' in *The taking of property by the state: recent developments in international law, Collected Courses of the Hague Academy of International Law* (Volume 176), 1982

<sup>28</sup> TRIPS, The Bern Convention, The Patent Cooperation Treaty, WCCPT, Beijing Treaty

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

general principles and practice in municipal IP regulation (particularly as it relates to patents), clouds rather than illuminates the issue of property and investment.

Therefore, the recent IP investment claims represent an additional step in the process of the codification of systemic global property norms, which deconstruct the territoriality principle, in order to construct a seamless legal space for the exercise of an untrammelled right to property, and avoidance of the arbitrary deprivation of said right.<sup>29</sup> These investment claims offer a limited glimpse of the development of possible general principles of international property law, through the lens of intellectual property and investment protection. They are part of a broader series of related international shifts, all pointing toward the attainment of a global property right, where the most active rulemaking has focussed on international regulation of IPRs<sup>30</sup> and the international protection of property rights in relation to investment.<sup>31</sup> These investment claims are situated within the context of a global consolidation of custom and general principles on property rights.<sup>32</sup>

This can be further illuminated on a specific regulatory level, by a juxtaposition against parallel international commercial private ordering, of transborder rule-making by copyright collecting societies, in the form of a complex international network of reciprocal recognition agreements (RRAs)<sup>33</sup>, which attempt a contractual solution to lacunae created

---

<sup>29</sup> Universal Declaration of Human Rights 17 (1)-(2)

<sup>30</sup> An example of this intensification is the failed Anti-Counterfeiting Trade Agreement (ACTA), in which a powerful bloc of IP intensive economies sought to create a recognition of a regionalized property right focused on intellectual property, which would complement “the TRIPS Agreement, for the enforcement of intellectual property rights, taking into account differences in their respective legal systems and practices would”.

<sup>31</sup> The International Convention on the Settlement of Investment Disputes (ICSID) has been extremely successful in articulating international standards for the protection of the property of foreign investors through the Convention of the same name. However, the OECD’s attempt to create the MAI to forge more exacting international standards on investment protection were unsuccessful (ISDS Reform)

<sup>32</sup> John G. Sprankling, *The International Law of Property*, Chapter 9, ‘Toward the Global Right to Property’, Oxford University Press: Oxford: New York, 2014

<sup>33</sup> Collecting Societies who are members of CISAC (or other international private cross-border copyright organizations) may negotiate the right to license on behalf of a plurality of right holders. This bestows an international right to enter into RRAs with Collecting Societies in other territories. Through a process of international rulemaking by private actors RRAs facilitate CMOs’ reciprocal licensing of each other’s pool of property rights/repertoire, in the other party’s territory. See generally Daniel Gervais, ‘Collective Management of Copyright: Theory and Practice in the

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

by the territoriality of property rights. The objective of RRAs is to allow their members to retain control over their exclusive economic rights, while facilitating effective cross-border use and remuneration in connection with their property rights. This trans-border contractual approach to the creation of a seamless space for international management and enforcement of property rights was challenged in the well-known CISAC<sup>34</sup> case, pursuant to anti-competition complaints from *RTL Group SA* and *Music Choice Europe Ltd*, in 2000 and 2003 respectively. A deeper look at the Copyright Reform project within the EU, also reveals the Portability Regulation<sup>35</sup> as another among several transnational legal devices, designed to address practical international legal difficulties inherent to exercising the full bundle of constituent property rights, across borders. These international commercial private ordering processes<sup>36</sup> taking place in relation to copyright reform, are mentioned here in order to demonstrate that the IP investment cases are a highly specialised example of several parallel IPR and property rule-making dialogues taking place within international law epistemic communities, using IPRs and cross-border investment as a vehicle for the concretisation of a discrete global property right. Justice Rosalyn Higgins would describe this recent convergence of necessity, [exemplified by IPR investment claims] as the international law of the reallocation of property rights<sup>37</sup>. More recently, John G. Sprankling's analysis of accepted sources of international law surrounding property, '*potentially provides an independent basis [legitimised by something other than the unit of territorial state] for recognizing the global right to property*'.<sup>38</sup>

It is important to provide some context, in relation the global processes external to international law, which are potential drivers of the push to create predictable and clear

---

Digital Age', in Daniel Gervais, *Collective Management of Copyright and Related Rights*, eds 2, Kluwer Law International: Netherlands, 2010

<sup>34</sup> International Confederation of Societies of Authors and Composers

<sup>35</sup> Regulation (EU) 2017/1128 of the European Parliament and of the Council of 14 June 2017 on cross border portability of online content services in the internal market

<sup>36</sup> For a discussion on the legitimacy of commercial private ordering rule enforced by sovereign actors see generally Steven L Schwartz, 'Private Ordering', *Northwestern University Law Review*, Vol. (97) 1, 2002, For a discussion on the *erga omnes* nature of general property right and specific intellectual property rights, see Jürgen Basedow, *The Law of Open Societies: Private Ordering and Public Regulation in the Conflict of Laws*, The Hague Academy of International Law: The Hague, 2015, p.194-222

<sup>37</sup> Justice Rosalyn Higgins, 'Introduction: The taking of property - legal tasks underlying the labels' in The taking of property by the state: recent developments in international law, *Collected Courses of the Hague Academy of International Law* (Volume 176), 1982

<sup>38</sup> John G. Sprankling, *The International Law of Property*, Chapter 9, 'Toward the Global Right to Property', Oxford University Press: Oxford: New York, 2014,

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

property rights across borders. This publication shall briefly engage in an analysis of select IP intensive cross-border mergers and acquisitions, with the intent of demonstrating how this aggressive approach to IPR enforcement through IIAs, can be correlated with patterns of foreign direct investment (FDI) flows and regulatory peculiarities prevalent in certain IPR intensive industries [particularly pharmaceutical patents]. This analysis of IP intensive mergers and acquisitions will focus primarily, on pharmaceutical research and development. The basis for this approach stems from *Eli Lilly's* precedent setting investment claim against the Government of Canada, challenging the Supreme Court's adverse decision, in relation to Canadian Patent No. 2, 209, 113<sup>39</sup> and Canadian Patent Number 2, 041, 735<sup>40</sup>. Subsequently, the *Eli Lilly* claim triggered a series similar potential pharmaceutical patent investment claims, from *Novartis*, *Gilead* and *Pfizer*. It shall be shown how the legal analyses provided by the tribunals in the *Philip Morris v Uruguay* and *Eli Lilly v Canada* claims, suggest that tribunals are more likely to accept jurisdiction in pharmaceutical patent claims. Additionally, pharmaceutical patents have a higher likelihood of becoming the subject of investment disputes, due in part to the dual nature of the presumptive validity rule<sup>41</sup>, coupled with the complexity of the

---

<sup>39</sup> Canadian Patent No. '113 is associated with the chemical compound olanzapine, marketed as Zyprexa. The invalidated patent made claims that olanzapine showed promise in the treatment of schizophrenia. Zyprexa is a drug used to treat schizophrenia and related psychotic disorders. Novopharm (Teva Canada Ltd.) sought an action before the Canadian Federal Courts to have patent '113 invalidated, alleging that it was not a valid selection patent. Eli Lilly & Company and the Government of Canada, Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter 11 (Strattera and Zyprexa), <https://www.italaw.com/sites/default/files/case-documents/italaw1530.pdf>

<sup>40</sup> Canadian Patent No. '735 is related to the chemical compound atomoxetine, marketed for the treatment of ADHD, under the brand name Strattera. Generics manufacturer Novopharm (Teva Canada Ltd.) challenged the '735 patent based on the usefulness criteria. This resulted in the patent being invalidated by a decision of the Canadian Federal Court in 2010.

<sup>41</sup> The Statement of Defence provided by the Government of Canada in *Eli Lilly* case gives a comprehensive analysis of the status of initial patent grants, as presumptively valid property rights awarded by administrative decision of the Patent Office. Initial grants of such property rights remain open to challenge before the Federal Court pursuant to the Canadian Patent Act. The presumptive validity of patent rights is not peculiar to Canadian Patent law. It is a standard feature of the patent law of many countries, as it is one of the legal devices which protects patent rights while allowing governments to maintain the patent bargain and guard their right to regulate in the public interest. For example U.S.C. Title 35. Patents Part iii. Patents and Protection of Patent Rights Chapter 29. Remedies for Infringement of Patent, and other Actions: Section 282. Presumption of Validity; Defenses, provides that 'A patent shall be presumed valid. .... The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.' Although this is traditionally interpreted as according a high degree of deference to the initial decision to grant the patent by the USPTO, it also means that the legal status of a patent right is administrative and open to invalidity claims even after it is granted; rendering it presumptively valid. This can be seen in *Sciele Pharma Inc. v Lupin Ltd.* where the court found that references to prior-art which were not considered by the Patent Office during patent examination could constitute a threat to patent validity.; See Doug Lichtman and Mark A. Lemley, 'Rethinking Patent Law's Presumption of Validity', *Stanford Law Review*, Vol. 60, p. 45, 2007; See the discussion on the presumption of patent validity in Amalia Athanasiadou, Patent Settlements in the Pharmaceutical Industry and Under

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

patenting process and rules regarding generics marketing approval in the pharmaceutical industry. This, along with the signal sent by the *Eli Lilly v Canada* and *Philip Morris v Uruguay* tribunals, makes it likely that ISDS is more readily seen as a viable IPR dispute settlement strategy.

Therefore, what may appear outwardly, as a sudden move to make full use of investment treaty-based IP provisions (which create a systemic overlap between IIAs and international intellectual property law), must be analysed within the broader phenomenon of the expansion and intensification of transnational legal mechanisms for overcoming the territoriality principle, toward effective recognition of property rights across borders.<sup>42</sup> This paper suggests that a confluence of IP driven free trade agreements (FTAs) supported by the TRIPS Agreement and the expansion of international IP treaties under the auspices of WIPO, is triggering the concretisation of not only IP norms, but also international property norms, leading to emerging legal notions of true international property rights, or an international law of property.<sup>43</sup>

---

US Antitrust and EU Competition Law, Kluwer Law International B. V., Netherlands, 2018; Shanad Basheer et al 'Pharmaceutical Patent Enforcement: A Development Perspective', in Ruth L. Okedji and Margo A. Bagley, *Patent Law in Global Perspective*, Oxford University Press: Oxford: New York, 2014

<sup>42</sup> John G. Sprankling, The Emergence of International Property Law, 90 *N.C. L. Rev.* 461 (2012), Graeme Dinwoodie, 'Developing a Private International Intellectual Property Law: The Demise of Territoriality?', 51, *Wm. & Mary L. Rev.* 711 (2009) , In a World Bank Paper, Keith Maskus poses an insightful discussion how the incongruence between nature IP as an asset which is intrinsically international and the territorial basis of property protection systems. He pinpoints the rise in bilateral and multilateral agreements as a substitute for the lack of a property protection system which is not wholly dependent on state sovereignty. Keith E. Maskus, "The International Regulation of Intellectual Property", Prepared for the IESG Conference, "Regulation of International Trade and Investment," University of Nottingham, Nottingham, UK, September 12-14, 1997. M Sonarjah, 'Creating Jurisdiction Beyond Consent', M Sonarjah, in *Resistance and Change in the International Law on Foreign Investment*, Cambridge University Press, 2015; For a discussion on the tendency toward convergence of property norms across borders see Amnon Lehavi, *Property Law in a Globalizing World*, Cambridge University Press, Cambridge: New York 2019, 54 -62, Veijo Heiskanen, 'Borderlines: Is There a Difference Between Protection of Property and Protection of Investment?', *Transnational Dispute Management*,

<sup>43</sup>For a discussion on the concept of property and the institutional expression of property rights see Jesse Wall, "The Concept of Property Law", in Jesse Wall, *Being and Owning: The Body, Bodily Material, and the Law*, Oxford: Oxford University Press, 2015, See also Jesse Wall, "The Structure of Property Law", in Jesse Wall, *Being and Owning: The Body, Bodily Material, and the Law*, Oxford: Oxford University Press, 2015, For a discussion of concepts of property as they relate to evolving social and economic relationships over time see Jean Axelrad Cahan, "The Concept of Property in Marx's Theory of History: A Defense of the Autonomy of Socioeconomic Base, Science and Society, Vol. 58, No. 4, 1994, 392 - 414

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

In September 2013, pharmaceutical company *Eli Lilly* filed a NAFTA Chapter 11 notice of arbitration against the government of Canada, as a last recourse to challenging the invalidation of its previously issued patents for *Strattera*<sup>44</sup> and *Zyprexa*<sup>45</sup>. This was the first ever investment claim which turned wholly on court decisions regarding intellectual property measures<sup>46</sup>; two patent invalidations, pursuant to Canada's bifurcated patent utility standard<sup>47</sup>. *Eli Lilly's* dispute with the Government of Canada is the culmination of a legal approach to cross-border enforcement of intangible property right which originated with generic drug manufacturers and can be described as '*the perfected anatomy of an IPR investment claim*'. The Tribunal's analysis in the *Eli Lilly Award* provides IPR owners with a nuanced overview of likely legal challenges associated with bringing an investment claim, based on harm to IP intensive investments.

While the investment claims of IPR owning research & development intensive multinationals have received significant attention, the legal approach that they have adopted originates with generic pharmaceutical manufacturers. The legal approach in *Eli Lilly's* notice of intent, and subsequent legal arguments can be clearly correlated with the legal strategy for intangible property rights enforcement, first adopted by Canadian generics giant *Apotex Inc.*, against the United States, in defence of its ANDAs<sup>48</sup>. The *Philip Morris* trademark expropriation investment claims came swiftly on the heels of this

---

<sup>44</sup> In 2011 the Canadian Federal Court invalidated Eli Lilly's patent for Strattera. The decision was as a result of the case *Novopharm Limited v Eli Lilly*, in which Novopharm was seeking to have Eli Lilly's patent No. 2, 209, 735 declared invalid pursuant to s. 60(1) of the Canadian Patent Act. Eli Lilly asserted that atomoxetine, a specific compound which was covered by the '735 patent had a degree of utility for the treatment of attention deficit hyperactivity disorder (ADHD). However, the Canadian Federal Court found that the promise of patent '735 (atomoxetine) which had been to treat effectively ADHD in humans was not met at the patent filing date. Further, that the study conducted by Eli Lilly was too limited to make a sound prediction about the efficacy of atomoxetine for treating ADHD. In addition to this the '735 patent lacked the necessary disclosure with respect to the findings that atomoxetine was useful in the treatment of ADHD. As such the proprietary right initially awarded to Lilly was declared to be invalid.

<sup>45</sup> Eli Lilly's patent for Zyprexa (olanzapine) was invalidated by a decision of Justice James O'Reilly before the Canadian Federal Court in 2010. The Olanzapine patent (2,041,113/ '113) is a selection patent, olanzapine is also covered by Canadian patent '687.

<sup>46</sup> Eli Lilly asserted that Canada's the application of the 'promise utility doctrine' to patents '735, '638 and '131 constituted an unlawful (uncompensated) indirect expropriation of its investments under NAFTA Article 1110.

<sup>47</sup> For an authoritative discussion on 'utility' and 'operativeness' 'The Promise of the Patent in Canada and Around the World', Vol 30:1 *Canadian Intellectual Property Review* 35 (2014), Canada's patent utility standard provides a two-pronged test for determining whether a patent submission demonstrates utility at the date of filing.

<sup>48</sup> ANDAs is an acronym 'abbreviated new drug applications', for a facility established pursuant to the Hatch-Waxman Amendments to the United States Patent Act. Under this carve-out, generic manufacturers are allowed to begin using patents just prior to their expiration to start synthesising and stocking pharmaceutical biosimilars to facilitate quick market entry upon expiration of a patent.

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

dispute. However, *Eli Lilly's* dispute with Canada is unlike any of the cases which preceded it, including the two high profile trademark expropriation investment claims, involving cigarette manufacturer *Philip Morris* in 2010 and 2011, against Uruguay and Australia respectively. In these disputes the company cited public health legislation which it claimed restricted its “right”<sup>49</sup> to use its lawfully acquired trademarks, leading to *defacto* regulatory expropriation. The measure being challenged in the *Philip Morris* claims were neither intellectual property legislation, nor an appellate court judgment on IPRs. They were public health legislation and policy measures implemented to comply with international obligations under the World Health Organization’s (WHO) Framework Convention on Tobacco Control (FCTC). The measures hampered the investor’s ability to fully utilise its intellectual property, in the form of its trademark and brand portfolio. In these two cases the state’s interference with trademark property rights is completely tangential to an unrelated legislative process regarding the regulation of tobacco. Uruguay and Australia’s policy measures were not aimed at shaping trademark legislation, but instead toward stricter tobacco control legislation.

However, there are two IPR related (industrial/intangible property rights) investment claims which constitute precursors to the trademark and patent enforcement strategies adopted in the *Philip Morris* and *Eli Lilly* cases. Paradoxically the two seminal claims involved Canadian generics manufacturer *Apotex*, which filed notices of arbitration against the United States in 2008<sup>50</sup> as *Apotex Inc.*, and again in 2012<sup>51</sup> as *Apotex Holdings Inc.*, for perceived harm to its abbreviated new drug applications (ANDAs) for Sertraline<sup>52</sup> and Pravastatin<sup>53</sup> respectively. Under the Hatch-Waxman Amendments in

---

<sup>49</sup> Counsel for Philip Morris interpreted the right of exclusive use to mean an absolute right of use, similar to that accorded owners of freehold title to land.

<sup>50</sup> See generally, Notice of Arbitration: UNCITRAL/NAFTA Rules, *Apotex Inc. v The Government of the United States of America*, 2008 at <https://www.italaw.com/sites/default/files/case-documents/italaw1323.pdf>

<sup>51</sup> See Generally Award: UNCITRAL/NAFTA Rules, *Apotex Holdings Inc. & Apotex Inc v The Government of the United States of America*, 2012, at <https://www.italaw.com/sites/default/files/case-documents/italaw3324.pdf>

<sup>52</sup> Sertraline is a generic version of Pfizer’s anti-depressant drug, Zoloft or sertraline hydrochloride. The patents connected to Zoloft were No. 4,356,518 or the “518 patent” and No. 5,248,699 or the “699 patent”

<sup>53</sup> Bristol Myers Squibb is the owner of the patent for Statin Pravachol and *Apotex* developed pravastatin as the generic version for marketing and distribution in the United states. The drug, which is used for reducing cholesterol and as a preventative treatment for cardiovascular disease, was the subject of an FDA decision and three federal court decisions.



Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

United States patent law,<sup>54</sup> approved ANDAs, can be described as patent-related rights that provide a shorter route to market entry for generic pharmaceuticals.<sup>55</sup> While general ANDA applications are not IPRs in the strict legal sense, final USFDA approval of paragraph IV ANDAs gives the generic manufacturer concerned, a 180-day generic exclusivity for a specific dosage formulation.<sup>56</sup> The first generic manufacturer to apply for ANDA approval is rewarded with the exclusive right to synthesise, manufacture, market and distribute generic versions of branded drugs, within a commercially viable window of a patent's expiration; ensuring quick market entry and diminished competition from other generic companies, once the originator company's patent exclusivity no longer applies. *"If that first generic is entitled to its 180 days, no one else can enter until after the exclusivity period has expired or been forfeited"*.<sup>57</sup> This exclusivity is for marketing and distribution rights of a specific generic version of a branded drug. The Hatch-Waxman provisions results in a narrow modification of the scope of a patentee's right to exclude. General patent law allows the patentee to exclude others from making, using and selling the claimed invention. The right to exclude is a defining feature of property, followed by a conditional right to use.<sup>58</sup> This means that approved paragraph IV ANDAs take on some of the characteristics of intangible property rights; as they bestow a narrow right to exclude generic competitors and can be traded among companies, where they are often subject to similar processes of commercial valuation as those applied to patents.<sup>59</sup> They

---

<sup>54</sup> G. J. Mossinghoff, 'Overview of the Hatch-Waxman Act and its impact on the drug development process, *Food Drug Law J.* 1999;54(2):187-94;

<sup>55</sup> James J Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*

<sup>56</sup> Scott Hemphill and Mark A. Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman ACTC', 77 *Antitrust Law Journal* No. (2011),

<sup>57</sup> Ibid at 948, see also Timothy R. Holbook, 'Possession in Patent Law', 59 *SMU L. Rev.* 123 (2006) at 142

<sup>58</sup> Timothy R. Holbook, 'Possession in Patent Law', 59 *SMU L. Rev.* 123 (2006)

<sup>59</sup> See Cipla Press Release, "Cipla completes acquisition of generic businesses in US", India, Mumbai, February 18, 2016, [https://www.cipla.com/uploads/mediakit/1455769166](https://www.cipla.com/uploads/mediakit/1455769166_Press%20Release%20-%20InvaGen%20Final.pdf)

[\\_Press%20Release%20-%20InvaGen%20Final.pdf](https://www.cipla.com/uploads/mediakit/1455769166_Press%20Release%20-%20InvaGen%20Final.pdf), A prime example of ANDAs taking on the characteristics of industrial property can be seen in the 2016 completion of the acquisition of U.S. generics manufacturer InvaGen, by the UK arm of Indian pharma giant Cipla. This cross-border acquisition allowed Cipla to acquire 40 approved ANDAs; 32 marketed products; and 30 pipeline products which are expected to be approved over a 4-year period following the acquisition. See also Marc André Gagnon and Karena D. Volesky, *Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016*, *Globalization and Health* (2017) 13:62, See also § 220 to 224 *Apotex v The United States Government*, Award on Jurisdiction and Admissibility, 2012. Here the Tribunal validates Apotex's assertion about ANDAs being used and traded among companies within the pharmaceutical industry, in the same manner as other property rights, See also OECD Directorate for Financial and Enterprise Affairs Competition Committee, *Generic Pharmaceuticals: Note by the United States*, DAF/COMP/WD(2014)51 at [https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/generics\\_us\\_oecd.pdf](https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/generics_us_oecd.pdf)

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

fall into the category of a *sui generis* proprietary right (somewhere between an intangible property right and a license)<sup>60</sup>. The Tribunals in *Apotex Holdings Inc. v USA* (2012 claim) and *Apotex Inc v USA* (2008 claim) regard both tentative approved ANDAs and ANDAs with final approval as mere licenses to export, nothing more. *Apotex Holdings Inc.* filed the 2012 claim in order remedy the *rationae materiae*, *raionae temporis* and *rationae personae* deficiencies of its first claims; which resulted in a finding by the Tribunal in the first claim that *Apotex Inc.* (2008 claim) was not an investor. This also raises a technical issue concerning the legal boundaries between property rights and other kinds of exclusive rights which may be created and awarded by the state. The prevalent use of ANDA's in this manner, in the generic pharmaceutical industry, prompted *Apotex* to argue that its ANDAs were an investment, and a *sui generis* intangible property right. *Apotex* opined that its ANDAs were property rights and covered investments pursuant to NAFTA 1139 § (g), which speaks of intangible property "*acquired in expectation or used for the purpose of economic benefit or other business purposes*". *Apotex's* claimed failed for two main reasons;

- 1.) *Apotex* lacked United States incorporation and substantive industrial activity; neither did it provide evidence that it was a shareholder of its U.S. affiliate and distributor *Apotex Corp*, or that this distributor undertook any portion of the manufacturing value chain.
- 2.) *Apotex's* ANDA applications were not finalised at the time it launched its claim, so that even under the broadest definitions of property and investment they did not meet the standard of, "*property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.*"

In the later investment claim (*Apotex II*) the Tribunal used the principle of *res judicata* to avoid the practical problems associated with declaring a finalised and approved ANDA along with associated products, as property rights, that could constitute an investment where *rationae personae* requirements are met. At that time (prior to the *Eli Lilly* and *Philip Morris* arbitrations), the analysis offered by the Tribunal for the definition of

---

<sup>60</sup> "International Investment Law and Arbitration Review: 2013 in Review Laird", Sabahi, Sourgens, Birch, Duggal and Coyne in *Andrea Bjorklund, Yearbook on International Investment Law & Policy 2013-2014*, Oxford University Press: Oxford, 2015

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

investor, investment and intangible property rights, provided patent holding investors with a nuanced perspective of how IPRs/intangible property rights might be treated if enforcement were pursued through international investment arbitration. However, the prevailing *res judicata* avoidance strategy employed by the Tribunal in its analysis of the definition of property and investment in relation to ANDAs was rejected by Arbitrator Rowley in his dissenting opinion. On that subject he wrote that,

*“As to whether Apotex Inc.’s finally approved ANDAs are properly characterised as an “investment” for the purposes of NAFTA Article 1139(g), Mr. Rowley considers the uncontroverted evidence that: (i) Apotex’s finally approved ANDAs were being used for the purposes of economic benefit at the time of the Import Alert; (ii) such ANDAs are regularly bought and sold in the US (often for substantial amounts); (iii) FDA regulations explicitly recognise that ANDAs are “owned” by the applicant; and (iv) US tax law treats ANDAs as franchises or intangibles for the purposes of the US tax code, is sufficient proof that Apotex’s ANDAs here in issue constitute intangible property for the purposes of NAFTA Article 1139(g).”<sup>61</sup>*

*Apotex Inc. v United States (2008)*, as well as *Apotex Holdings Inc. & Apotex Inc. v United States(2012)* therefore, also fall within the category of IPR related investment claims, as examples of a broader move toward consolidation of a coherent international property norm, which may provide increased legal certainty for IPR investors.<sup>62</sup> More recent examples of the use of IIAs to influence the substantive implementation of intellectual property rights across borders, can be seen with disputes involving *Gilead*<sup>63</sup>, *Novartis*<sup>64</sup> and *Pfizer*<sup>65</sup> which have all made use of international investment dispute mechanisms to

---

<sup>61</sup> (1) *Apotex Holdings Inc.* (2) *Apotex Inc.* (ICSID Case No. ARB(AF)/12/1), Award

<sup>62</sup> For a nuanced discussion of ways in which international investment law creates and amplifies property rights see Valentina Sara Vadi, *Through the Looking-Glass: International Investment Law through the Lens of a Property Theory*, Vol. 8 *Manchester Journal of International Economic Law* No. 22, 2011

<sup>63</sup> *Gilead Sciences Inc. and Ukraine* settled a dispute concerning the manufacture and distribution of hepatitis c drug sofosbuvir (Sovaldi) for the Ukrainian market. Gilead withdrew a notice of investment arbitration after the parties were able to negotiate favourable pricing for provision of the drug in Ukraine.

<sup>64</sup> *Novartis* letter to the Director for Investment Services and Intellectual Property, Colombia. The letter requests consultations regarding their patents and the

<sup>65</sup> *Ireland Pharmaceuticals* a subsidiary of *Pfizer*, served Ecuador with a notice of dispute on April 27, 2016. To date, it does not appear that the company has yet turned to arbitration. The *Pfizer* notice of dispute against Ecuador concerns the drug sildenafil (brand name *Viagra*). *Pfizer* was in a long running dispute with Argentinian generics manufacturer *Acromax*, which began to produce sildenafil under the

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

protect their patent exclusivity from efforts by Ukraine, Colombia and Ecuador to use patent flexibilities as a tool for affordable medicines policies that encourage price competition in the pharmaceutical industry. In particular, the dispute between Ukraine and *Gilead Sciences Inc.* concerning the patent for the Hepatitis-C drug sofosbuvir (Sovaldi), lead the company to propose investment arbitration to resolve differences with Ukraine. *Gilead* challenged the government listing of Grateziano<sup>66</sup>, the generic version of sofosbuvir, produced by an Egyptian owned generics company, *Europharma International*.<sup>67</sup> *Gilead* and the Ukrainian government finally negotiated a settlement, under which the pharmaceutical company agreed to refrain from pursuing its investment claim against the government Under this settlement *Gilead* promised to provide Sovaldi and combination therapy Harvoni to Ukraine at reasonable prices.<sup>68</sup> In this case Ukraine's right to use TRIPS flexibilities to limit the content, scope, application and recognition of patent rights granted within its territory, in line with public health policy, Article XX of

---

name Max, while Pfizer still retained patent exclusivity. In the several legal actions taken against Acromax, Pfizer accused the courts of illegal conduct in favour of the generics firm. Acromax filed a suit for damages against Pfizer before the constitutional court; the damages were granted. The fact that a constitutional court awarded damages to Acromax may suggest that a compulsory license could have been issued for the production of sildenafil, which would explain why Acromax was openly producing the drug with only mild intervention from the judicial system. The IAREporter article does not provide details on this. Documents for this dispute are confidential but overall reports of the subject matter of the dispute can be gleaned from IAREporter.

<sup>66</sup>The confidentiality rules which often apply to many investment disputes means that it has been difficult to determine some facts. For example, whether *Europharma* was producing Sofosbuvir through a compulsory license issued by Ukraine. This is likely, in light of Ukraine's intervention during a WTO Trade Policy Review where Malaysia sought to explain its compulsory license for Hepatitis-C drugs. The following is the relevant question asked by Ukraine and answered by Malaysia; "10. In view of the entry into force of the Protocol Amending the TRIPS Agreement (on 23 January 2017), could Malaysia kindly inform on national implementing measures providing for special compulsory licences and its scope (for export or import of medicines)?"

*Answer: Malaysia has submitted the acceptance of the Protocol Amending the TRIPS Agreement in December 2015. Hence, Malaysia is amending the Patents Act 1983 to include the provision of the Article 31bis of TRIPS Agreement. 15. Considering Press Statement of Minister of Health of Malaysia of 20 September 2017 (available at: <https://goo.gl/SaznZu>), could Malaysia, please, clarify the state of play of the implementation of the decision to initiate the Rights of Government to exploit the patented invention of Sofosbuvir?"*

*Answer: MDTCC and MOH are working closely on the implementation of the decision to initiate the Rights of Government. Malaysia is currently finalizing the procurement of generic Sofosbuvir tablets.*

16. Has Malaysia examined the possibility of using the system, set out by the Protocol Amending the TRIPS Agreement, while making above mentioned decision?

*Answer: The decision on this issue is based on the current provision of the Patents Act 1983.*

<sup>67</sup> Luke Eric Peterson and Zoe Williams, Pharma corp withdraws investment arbitration after Ukraine government agrees to settlement of dispute over monopoly rights to market anti-viral drug, *IAREporter*, 2017 at <https://www.iareporter.com/articles/pharma-corp-withdraws-investment-arbitration-after-government-agrees-to-settlement-of-dispute-over-monopoly-rights-to-market-anti-viral-drug/>

<sup>68</sup> Id

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

the GATT Doha Declaration on TRIPS and Public Health, was effectively chilled. Similarly, the *Novartis* and *Pfizer* disputes concerned efforts by Colombia and Ecuador respectively, to use TRIPS flexibilities to determine the exercise of patent rights in their territory, to facilitate the creation of affordable versions of Glivec (Imatinib) and Viagra (Sildenafil). The series of disputes discussed here demonstrates the effectiveness of IIAs in affecting the manner in which States implement international patent regulations when there is a possibility of a direct commercial conflict with patent holding investors. Investment treaty IP clauses are thus able to multilateralise regulation and content of property norms, beyond the strict confines of the principle of territoriality in intellectual property law. This also shows how IPR clauses in IIAs can be used to shape the substantive content and regulatory structures around property rights in general and IPRs in particular. In doing so, IIAs provide a direct and effective challenge to the sovereign right to regulate and the state's power to determine the limits of property rights, expanding the territorial scope of property rights enforcement. Multinationals whose asset bases are highly dependent on the value of IPRs, are thus free to use the partial international *locus standi* granted to them under IIAs, to influence the creation of an international law of property based on practice, by asserting a legitimate expectation to benefit from harmonised or largely identical IP laws subject to provisions of RTAs and FTAs.<sup>69</sup>

This brings us to the second prong of the development of an international law of property through expansion of IIAs and international intellectual property rights. This thesis suggests that the current situation is much more than a challenge to the sovereign right to regulate. In fact, IIAs were developed precisely to expand protection for foreign property and influence host country legislation. IIAs, like IPRs are in fact property protection regimes. As a property protection regime, international investment agreements (IIAs) provided a solution which offered partial international *locus standi*, allowing companies to defend their own property rights without the need for the politically charged dispute settlement process under the WTO dispute settlement body.<sup>70</sup>

---

<sup>69</sup> In *Eli Lilly v Canada* the company's argumentation rested partially on the idea that it had the right to expect the same or similar patent laws as was available to it in the United States

<sup>70</sup> Statement by the South African Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), See 1999 USTR Special 301 Report (also stating that "South Africa's Medicines Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

IAs define intellectual property as a covered investment, within the meaning of protected assets under IAs and normative practice of the International Centre for the Settlement of Investment Disputes' under article 25§1 of the (ICSID) Convention on the Settlement of Investment Disputes, hereinafter the ICSID Convention. The *Philip Morris* claims are founded on intellectual property and related provisions in the 1988 Switzerland – Uruguay bilateral investment treaty (BIT) and the 1993 Australia - Hong Kong (BIT) – conventional BITs. In contrast the Eli Lilly claim was based on Chapter 11 of the North American Free Trade Agreement (NAFTA) dealing with the regulation of international investment and; chapter 17 of same which addresses intellectual property commitments of the States Parties. NAFTA represents the first of the modern hybrid treaties, covering trade, investment and intellectual property in the same agreement.

The *Eli Lilly* and *Philip Morris* claims have magnified a previously ignored source of systemic legal tension created by the parallel existence of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), alongside a robust but generally *ad hoc* international investment law regime, and its particular approach to IP protection. IAs represent a much older system of cross-border protection of 'alien property', stretching as far back as the first Friendship Commerce and Navigation Treaties (FCNs) of the 18<sup>th</sup> Century, including the 1778 Treaty of Amity and Commerce between the United States and France. Though this paper will provide a brief analysis of older forms of investment agreements, to demonstrate the development of the concept of international investment protection of IP assets, it is primarily concerned with more contemporary IAs which came into force after the creation of the World Trade Organization in 1994.

IP provisions in contemporary IAs consist of standard clauses designating intellectual property rights as protected assets, as well as newer provisions that incorporate regulatory language from the agreement on Trade Related Aspects of IP (TRIPS). Prior to the entry into force of the TRIPS Agreement, under the auspices of the WTO, IP had always benefitted from international investment protection, for as long as various incarnations

---

patent rights"), See United States Department of State Report on U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(C) of the South African Medicines and Related Substances Act of 1965 (February 5, 1999), See Statement by the U.S. Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), pp. 33-34, See U.S. Request for Consultations, WT/DS199/1 (June 8, 2000), See Brazilian Request for Consultations, WT/DS224/1 (February 7, 2001), See Joint Notification of Mutually Agreed Solution, WT/DS199/4 (July 19, 2001).

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

of IIAs have existed. However, prior to the creation of the WTO Dispute Settlement Mechanism, transnational IP disputes and enforcement cases were nearly always construed as disputes of private commercial actors and settled before national courts, in international commercial arbitration or less often, under WIPO arbitration and mediation.<sup>71</sup> This is confirmed by a report of the ICC Commission on Arbitration with respect to intellectual property disputes and arbitration. The report found that 11.7% of cases filed at the ICC Court between 1990 and 1996 contained a significant intellectual property component.<sup>72</sup> It also found that choice of law clauses in commercial contracts were the preferred mechanism for selecting the manner in which the disputes would be settled in 80% of cases. The overwhelming practice was for private commercial transactions, also containing an element of state involvement to be heard before national courts. This is evidenced by numerous reports submitted during the Uruguay round. Submissions within the Negotiating Group on Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods discuss the difficulties of national litigation because,

*“Access to judicial remedies often suffer[s][sic] from the lack of discovery or some other means for obtaining evidence. Because the burden of proof is on the intellectual property owner, this makes it impossible to prove that infringement has occurred.”<sup>73</sup>*

Documents submitted by Norway in these sessions noted that, *“Time-consuming and costly legal procedures to obtain court orders necessary to enforce intellectual property rights subject to infringement place small IPR holders at a disadvantage.”* Though in this case, it is apparent that investment arbitration would also not be favourable for small IP holders.

In 1994 the WTO DSB strengthened state-state dispute settlement for transnational IPR disputes.<sup>74</sup> However, in recent years the shift toward hybrid trade-investment treaties has

---

<sup>71</sup> Julian D. M. Lew Chairman ICC Commission on International Arbitration, ICC Final Report on Intellectual Property Disputes and Arbitration, adopted October 1997

<sup>72</sup> Ibid

<sup>73</sup> Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights, MTN.GNG/NG11/W/7 29 May 1987

<sup>74</sup> WIPO Note, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for The Protection of Intellectual Property, MTN.GNG/NG11/W/24, 5 May 1988 This note by WIPO describes state-state IPR dispute settlement policies open to States Parties to the Paris convention. It discussed the fact that the Paris Convention made provision for IPR disputes to be submitted to the International Court of Justice, subject to the said member states' recognition of the jurisdiction of the Court. A review of several documents from WIPO and other agencies during the

exposed pre-existing IP enforcement clauses in BITs, allowing IIAs to bring transnational IP disputes into the realm of investor-state arbitration. The willingness of claimants to deploy investment treaty-based provisions to enforce IPRs in transnational disputes is a new phenomenon. This phenomenon can be correlated with a confluence of legal and economic variables which have emerged since the entry into force of the TRIPS Agreement. IP driven investment claims coincide with stagnation on the intellectual property upward-harmonisation discussion within the WTO's Doha Round; the increasing development centred approach to rule-making within WIPO; the failure of the Anti-Counterfeiting Trade Agreement (ACTA) and other similar treaties<sup>75</sup>; and the transformation of R&D financing/investment in many IP intensive industries, where patents and copyrights are now more readily incorporated into financial investment products (structured investment vehicles). Within such an international regulatory environment, IPR owners were in search of legal mechanisms that would allow them to expand international enforcement of their property rights, by-passing the increasingly development centred rule-making approach in multilateral organizations.

- 1.) The dissatisfaction of both developing countries and IP owners with the Doha round's inability to address various regulatory difficulties, particularly IP issues such as production and trade in generic pharmaceutical products; patenting of life forms; extension of controls on the use of geographical indications and proprietary protection for traditional knowledge.
- 2.) The increasing numbers of plurilateral and bilateral, hybridised international trade/international investment agreements with detailed IP Chapters.
- 3.) A general trend toward increasing use of international investment arbitration to enforce the protection of investor assets in the host state, with successful results for investors.
- 4.) The lack of a clear path to *amicus curiae* participation for investors and their industry associations pursuant to WTO third party participation rules under the

---

Uruguay Round reveals that there was not discussion on the potential for BITs to be used as IPR enforcement mechanisms. This is an interesting omission, as parallel negotiations for the North American Free Trade Agreement (NAFTA) recognize explicitly the link between its investment and intellectual property chapters.

<sup>75</sup> Pedro Roffe and Xavier Seuba, *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath*, Cambridge University Press; Cambridge, 2014,



Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

WTO Dispute Settlement Mechanism. As well as, the possible political ramifications for investors' home state.

- 5.) The global rise of intellectual property intensive, cross-border mergers and acquisitions; this is coupled with an acceleration of IP rights expiration in specific sectors, such as pharmaceutical patents (patent cliffs), causing IP owners to pursue high risk legal strategies.

The establishment of a shift toward both governments and investors perceiving IIAs as a realistic dispute settlement and regulatory option for IPRs, is evidenced by treaties such as the United States-Rwanda Bilateral Investment Treaty (BIT) and the intellectual property chapter of the Japan-China-Korea Trilateral Investment Treaty. The proposal of investment arbitration by Gilead, Novartis and Pfizer following the Lilly investment award, suggests a strong likelihood that the number of international investment claims seeking legal remedies for perceived breaches of fair and equitable treatment (FET) standards related to IP rights, are likely to rise. The reasons for this are four-fold; a.) Knowledge has arguably become the most vital competitive advantage for trade, investment and sustainable development in the global economy; b.) Following the adoption of the TRIPS agreement, it has become more common for economically advantageous knowledge to be protected by intellectual property rights; c.) This ubiquity of property rights in knowledge, has increased the likelihood that IPRs will become the subject of infringement claims and the need to maintain IPRs as a competitive advantage may push companies to use non-traditional dispute settlement forums [*Phillip Morris and Eli Lilly*]; d.) In addition to increased 'propertization' and national level disputes, the proliferation of investor state dispute settlement mechanisms in IIAs, increase possibilities for IP infringement to become the subject of an international investment claim, as they increase the likelihood that a given international investment may benefit from the protection of an existing IIA. The incentives for investors to explicitly structure their investments, to have the option of IPR dispute settlement via international investment arbitration have also increased.

This set of circumstances also constitutes a paradigm shift in the international enforcement of IP rights and IP harmonization. The prime factors which combine to support these ideas include the importance of IP as a driver of trade, investment and

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

economic development; the ubiquity of both IIAs and proprietary rights in IP (IPRs); the imbalance of obligations between states and investors in contemporary IIAs; and the inconsistent treatment of public order questions in investment arbitration claims thus far. A potential rise in the number of IP related investor-state arbitrations means that IIA-based IP provisions could present potential difficulties for the scope and content of multilaterally agreed IP norms. More importantly, arbitration claims rooted in substantive provisions addressing issues such as compulsory licensing, could have unanticipated regulatory effects for states. Investment protection practices (largely rooted in commercial arbitration) that have developed around IIAs suggests that there is a potential to destabilize the intricate web of international political compromises that have produced accepted multilaterally agreed IP norms and IP policy approaches.

This novel way in which IIAs are being utilised is evidence that the push to reduce cross-border dissonance of intellectual property (IP) laws has intensified during the last ten years. The perception that ever more treaties, with increasingly detailed IP provisions, will produce harmonization and cross-border legal certainty for investors is the philosophy behind agreements such as CETA. The legal arguments in these investment claims and position papers coming out of EU-US discussions on intellectual property, suggests that governments are prepared to make the legislative concessions necessary to create a seamless and consolidated set of international intellectual property rights. This perception is pervasive among legislators, IP owning economies, multinational corporations, and international organizations.<sup>76</sup> Substantive IP provisions in IIAs and highly complex IP chapters in FTAs have now been added to the list of legal devices used to facilitate IP harmonization. They are the devices currently at the forefront of the creation of an international law of property.

---

<sup>76</sup> See the ACTA question and answer session between the European Parliament and the European Commission on the text of ACTA. Anti-Counterfeiting Trade Agreement (ACTA) List of answers by the European Commission to written questions by the European Parliament, filed between 1 January 2010 and 31 January 2012 at [http://trade.ec.europa.eu/doclib/docs/2012/february/tradoc\\_149102.pdf](http://trade.ec.europa.eu/doclib/docs/2012/february/tradoc_149102.pdf), See Report of the 15th Round of Negotiations for the Transatlantic Trade and Investment Partnership, 2016 at [http://trade.ec.europa.eu/doclib/docs/2016/october/tradoc\\_155027.pdf](http://trade.ec.europa.eu/doclib/docs/2016/october/tradoc_155027.pdf), See TTIP Draft Provisions on International Agreements Relating to Intellectual Property, 2015 at [http://trade.ec.europa.eu/doclib/docs/2015/july/tradoc\\_153673.pdf](http://trade.ec.europa.eu/doclib/docs/2015/july/tradoc_153673.pdf)

Excerpt working paper series on Investment Treaty Protection of IP (under review for publication)

Prior to this and in the wake of TRIPS, regional trade agreements (RTAs) were the primary vehicles which facilitated IP transplantation across borders.<sup>77</sup> However, international investment agreements (IIAs) have become the newest frontier in IP harmonization, and arguably the basis of the articulation of an international law of property. More than the elimination of legal dissonance, it is thought that the use of substantive IP provisions in IIAs will facilitate 'upward harmonization'<sup>78</sup>, so that investors may have access to substantively identical IP rights in all states party to specific treaties. The potential for investment treaty based intellectual property provisions to regulate, enforce and harmonize IPRs is being tested for the very first time, despite their long-standing existence. Furthermore, this cross-fertilisation which is taking place between international intellectual property law and international investment law represents the most advanced example of the development of a true international law of property.<sup>79</sup>

---

<sup>77</sup> The inclusion of substantive IP provisions in the United States Model BIT is a departure from its own treaty practice as well as that of the vast majority of contemporary BITs and FTA investment chapters. Other exceptions to normative contemporary practice include the Canada Model BIT 2012 and the recently signed Japan-China-Korea Trilateral Investment Agreement. The recently signed Switzerland – China FTA departs from normal practice which includes a full investment chapter. This means that no obligation to include IP as a covered investment exists under this treaty. Instead it contains a general paragraph promising to encourage investment promotion. Switzerland already has numerous BITs with various countries which contain a general reference to IP under the definition of investment, like most contemporary BITs.

<sup>78</sup> See also Kluwer Law, 'The Blessings and Curses of Harmonization', in *Harmonizing European Copyright Law: The Challenges of Better Law Making*, Kluwer Law International: Alphen aan den Rijn:Maryland: Bedfordshire, 2009, provides a detailed case study of 'upward-harmonization' in relation to the seven European copyright directives and their potential to create legal uncertainty and obstacles for the internal market. See also Amy Kapczynski, "Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review*, 97:6, 2009

<sup>79</sup> For a discussion of property as a legal category in international law see Justice Rosalyn Higgins, *The Taking of Property by the State – Legal Tasks Underlying the Labels*, *Collected Courses of the Hague Academy of International Law*, Vol. 176, Leiden: Brill -Nijhoff, 1982, 267-278, For a discussion on the international law foundations of the relationship between sovereignty, sovereign property and private property see also Justice Rosalyn Higgins Chapter II: Tolerated Takings, *Collected Courses of the Hague Academy of International Law*, Vol. 176, Leiden: Brill -Nijhoff, 1982, 279-297 See John G. Sprankling's discussion of intellectual property law as the most advanced example of the march forward to an international law of property. John G. Sprankling, *Rights in Intangibles*, in John G. Sprankling *The International Law of Property*, Oxford: Oxford University Press, 2014, See generally Ammon Lehavi and Amir N. Licht, *BITs and Pieces of Property*, *Yale Journal of International Law*, Vol. 36, No. 1, 2011