Access to Essential Medicines & International Investment Law

The Road Ahead[**]

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I. INTRODUCTION

The complex regulatory web protecting intellectual property at the international level has caused growing concerns with regard to access to essential medicines. Access to essential medicines is a component part of the right to health and as such is a human right, fundamentally related to human dignity and the right to life. Independently of its formal qualification—be it customary law or treaty law[1]—it is internationally acknowledged that states have the right and duty to enact legislation to protect public health.

This contribution will investigate the particular intersection between investment treaties, intellectual property (IP) and the right to health.

As investment agreements regulate IP, the questions that arise in this connection are two. First, are investment agreements compatible with state international obligations to protect public health? Second, if internal measures aimed to protect public health can be challenged by foreign investors, is mixed arbitration a suitable forum to protect public interests?

The argument will proceed in three parts. First, after a brief look at the regulatory framework that investment agreements provide for pharmaceutical patents, their impact on access to medicines will be assessed. Indeed, as investment agreements generally increase the scope of intellectual property beyond current standards and reduce the flexibilities available to developing countries under international treaties, they can limit their access to essential medicines. Importantly, they offer investors the possibility to bring claims before a neutral forum that is an arbitral tribunal. Mixed arbitration—arbitration between a foreign investor and the host state—is considered to be the best means to protect the investor interests. Crucially, this option opens the doors to challenging national legislations that allegedly infringe investors' rights.

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[1] See, for instance, Valentina Vadi 'Balancing the Human Right to Health and Intellectual Property Rights after Doha' XIV Italian Yearbook of International Law (2004)195-224.

Second, the issue whether national measures aimed at protecting public health can be considered as *indirect expropriation* according to investment treaties will be scrutinised. It will be argued that, at the economic level, measures such as compulsory licenses may be deemed to be indirect expropriation. However, at the legal level, other considerations need to be done. The problem is that usually arbitral proceedings do not take into account the public dimension or the lawfulness of the measure to establish the exact amount of compensation.

In the third and last part of this contribution, the relevant policy considerations will be addressed.

My conclusions will be that investment law is part of international law, and thus it has to be consistent with its norms and it has to be interpreted in accordance with customary rules of treaty interpretation.

II. KNOWLEDGE GOVERNANCE AND INTERNATIONAL LAW

As knowledge has become one of the economic resources in society, its governance has recently become one of the strongest sub-sets of public international law.

In primis, Article 15 of the International Covenant on Economic, Social and Cultural Rights identifies the need to protect both public and private interests in knowledge creation and knowledge diffusion.[2] Accordingly, states are bound to strike a balance between the public interest in accessing new knowledge and authors and inventors' rights.

Proprietary approaches to knowledge governance have become stronger than ever since the inception of the Trade Related Aspects of Intellectual Property Rights Agreement[3] under the aegis of the WTO System. Importantly, the TRIPS Agreement introduced pharmaceuticals as patentable subject matter.

This move was very controversial as it is not certain whether an adequate balance between public and private interests is reached in the context of pharmaceutical patents. Indeed, in its interaction with public health policies, the patent system has not proved to be effective in absolute terms. By providing the patent owner with twenty years monopoly rights, pharmaceutical patents usually increase the price of medicines and this may result in a direct loss of patients' welfare.[4]

[2] Article 15 of the International Covenant on Economic, Social and Cultural Rights proclaims the right of everyone "to enjoy the benefits of scientific progress and its applications" and "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) Annex 1C to the Marrakech Agreement Establishing the World Trade Organization, 33 ILM 1994, p. 1197 ff. in force since 1 January 1995. The TRIPS agreement sets minimum intellectual property standards and is binding upon all WTO members. For commentary, see for instance, D Gervais *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, II edition, London 2003.

[4] David Evans and A Jorge Padilla 'Excessive Pricing: Using Economics To Define Administrable Legal Rules' 1 Journal of Competition Law and Economics 1, 2005, 97–122.

While the debate over the best ways of promoting scientific research and development is still going on,[5] the TRIPS Agreement attempts to strike a balance between the long term social objective of providing incentives for future inventions, and the short term objective of allowing people to use existing inventions and creations.[6] Indeed, it provides for general exceptions and flexibilities. Moreover, it has been recently amended in 2005 to cope with health emergencies.

Nevertheless, in recent years, the flourishing of bilateral and regional investment treaties in the form of all-encompassing agreements, that include intellectual property, has determined a paradigm shift in the international regulation of intellectual property.

This contribution investigates the regulation of pharmaceutical patents in international investment agreements. In particular, it provides a detailed analysis of some key provisions in order to shed some light on this dark corner of IP regulation.

While the TRIPS Agreement and its impact on public health has been extensively analysed, the legal and economic consequences of IP regulation in investment agreements are still unknown. As this area is continuously evolving, much intellectual effort is needed to capture its characteristics and explore the emerging case law.

III. A PARADIGM SHIFT: DIVIDING AND CONQUERING?

Since the conclusion of the North-American Free Trade Agreement (NAFTA), the negotiation of the failed Multilateral Investment Agreement (MAI) and the re-emergence of bilateral and regional investment agreements, IP rights have become the focus of intensive negotiation.[7]

In their vest of intellectual capital exporters, industrialised countries are interested in raising IP protection. While intellectual property rights in the WTO are virtually paralyzed, these countries have increasingly used bilateral and regional investment agreements in a strategic fashion to incorporate *TRIPS-plus* commitments that they would have not been able to obtain in the WTO or would have had to make considerable concessions in strategic fields to obtain.[8]

In their vest of intellectual capital importers, developing countries would benefit from laxer levels of protection. However, these countries generally accept higher IP standards to obtain favourable concessions in other areas, notably agriculture.

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[5] This issue has been approached both by economists and social scientists; it is enough to mention here the current debate over the introduction of a framework convention on Medical Research and Development (hereinafter MR&D Draft Treaty) at WHO. According to this Draft Treaty, medical research and development should be furthered by states not only through traditional proprietary approaches, that is pharmaceutical patents, but also non-proprietary approaches such as prizes and public funding etc.

[6] TRIPS Agreement, Articles 7 and 8.

[7] Laurence R Helfer 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' 29 Yale J of Int'l L 1, 2004, p 1.

[8] See M. Ryan *Knowledge Diplomacy – Global Competition and the Politics of Intellectual Property*, Brookings Institution Press Washington D.C. 1998 p. 92.

Thus, some authors compared the rationale of investment agreements to a form of imperialism, similar to the Roman strategy '*divide et impera*'.[9] As an author puts it '*la táctica del divide y reinarás está en el corazón del bilateralismo*'.[10] Under this regime shift, the world would be experiencing a policy of progressive *feudalization* of knowledge and knowledge-based products.[11]

From a legal perspective, the TRIPS Agreement sets international minimum standards for intellectual property protection. While Members cannot derogate or provide lower ceilings of protection, they still have the right to institute more extensive protection than is required by the Agreement, as long as they apply the general principles of the most-favoured nation clause and national treatment under the Agreement.[12] Therefore, any intellectual property agreement negotiated subsequent to TRIPS and involving WTO members can only create similar or higher standards—commonly known as *TRIPS-plus*. The problem is that this allowance does not set maximum levels of protection.

From a political science perspective, bilateralism and regionalism are undermining the world multilateral framework.[13] Extensive IP-related concessions made under a given investment treaty, throws away IP as a bargaining tool in the WTO with respect to other countries, because the Most Favoured Nation clause applies.[14] In case most advantageous conditions were granted to the members of a regional agreement, such conditions should be extended, automatically and unconditionally to all WTO Members.

After examining the conceptualisation of pharmaceutical patents as investment, and the TRIPS-plus provisions in investment treaties regarding pharmaceuticals, this contribution will investigate the issue whether investment agreements may undermine the pursuit of public policy goals by reducing the flexibilities available to member States under international treaties, to take necessary measures to protect public health.

IV. SUBSTANTIVE PROVISIONS

A. *PHARMACEUTICAL PATENTS AS INVESTMENT*

Although international investment agreements (hereinafter IIAs) do not include detailed regulation on intellectual property rights, they incorporate a broad definition of

[9] See Peter Drahos *Expanding Intellectual Property's Empire: the Role of FTAs*, 2003, available at http://www.grain.org/rights/tripsplus.cfm?id=28# last visited on 8 May 2007.

[10] Silvia Rodriguez Cervantez *TLCs: El conocimiento tradicional en venta*, 2006, p 16, http://www.grain.org/briefings/?id=198 last visited on 9 May 2007.

[11] See Peter Drahos and John Braithwaite *Information Feudalism – Who Owns the Knowledge Economy?* The New Press, New York 2003.

[12] TRIPS Agreement, Article 1.1.

[13] See Mohammed El Said 'The Road From TRIPS-Minus to TRIPS, to TRIPS-Plus: Implications of IPRs for the Arab World' 8 Journal of World Intellectual Property 1, 2005 pp 53–65, at 61.

[14] TRIPS Agreement, Article 4.

investment that generally covers both tangible and intangible property thus including intellectual property.

From an economic perspective, the main policy justification for protecting pharmaceutical patents through investment treaties is that they induce foreign direct investment (FDI) in research and development of new medicines, stimulating local inventive activities and encouraging transfer of technologies into the country.

Specifically, investment agreements provide for higher levels of intellectual property protection than the TRIPS Agreement. As Musungu and Dutfield point out, the concept of TRIPS-plus '*covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions under the TRIPS Agreement*'.[15] Some authors even argue that these *TRIPS-plus* standards reflect those of industrialised countries thus amounting to extraterritorial application of domestic IP regulation.[16]

It is important to draw attention to the *incremental nature* of each subsequent investment treaty. Usually negotiators take a cumulative country-specific approach, adding more features on top of current investment agreements. The upshot is that each agreement is being used as a standard model of negotiations with new countries, leading to a more enhanced *TRIPS-plus* recipe.

Consequently, there can be no fixed definition for the term *TRIPS-plus*. In fact, such a concept has evolved and has proven to be case and country-specific. Thus, the following list is clearly not exhaustive but has a pure illustrative nature.

In particular, the provisions included in investment agreements usually extend patent protection beyond the 20-year period required under TRIPS.[17] In some cases, these extensions may be at odds with privileges related to the transition periods under the WTO. For example, under the EU-Jordan Association Agreement,[18] Jordan was pressured to implement shorter periods of transition than those provided under TRIPS regarding patent protection.[19]

More generally, extending this monopoly period may prejudice the public interest in accessing generic medicines as soon as the patent expires. Off-patent drugs sold under

[15] Sisule F Musungu and Graham Dutfield 'Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organization', Quacker United Nations Office, Geneva 2003, p. 2.

[16] See Kelemen and Sibbit 'The Globalization of American Law' 58 International Organization 2004, pp. l03–156.

[17] See, for instance, AUSFTA Article 17.9.8.

[18] The Euro-Mediterranean Agreement Establishing an Association between the European Communities and their Member States, on the one part, and the Hashemite Kingdom of Jordan, on the other part, was signed on 24 November 1997 and entered into force in May 2002. Official Journal of the European Communities L129/3, 15 May 2002.

[19] EU-Jordan Association Agreement, Annex v 3 provides: '*Jordan undertakes to provide for adequate and effective protection of patents for chemicals and pharmaceuticals in line with Article 27 to 34 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, by the end of the third year from the entry into force of this agreement or from its accession to the WTO, whichever the earliest.*'

generic brand names are cheaper than drugs under patent. The availability of generic drugs, determining competition and lower prices, has favourable impact on access to medicines.

Investment agreements generally broaden the scope for patentability, including plants. Although protection of traditional medical knowledge is not even mentioned in investment agreements, clearly patentability of plants might give rise to issues of misappropriation or *bio-piracy*.[20] This may have implications for public health as most developing countries use traditional medicine based on local plants, to cope with their primary health needs.

Some agreements further extend the scope of patentability to *secondary-use* patents. *Secondary-use* patents provide protection for products which offer incremental innovation and improvements over a previously patented product. Incremental innovations consist of new and improved methods of administering a drug or new uses for chemical substances already known. One example is the development of a combination pill where patients previously needed to take multiple pills to achieve a particular medical result.

The risk, from a public welfare point of view, is that such a provision creates an incentive for companies to register *me-too drugs* and that the patent life-span is excessively prolonged, allowing *ever-greening* practises by pharmaceutical companies. Such patents may, of course, be challenged. But the cost of eventual challenges would fall on the generic company wishing to market the generic version of the medicine.

FTAs also introduce provisions which protect data submitted by companies in the drug registration process for at least five years from the date of approval of the pharmaceutical patent. The submitted data relates to the chemical characteristics of the drug as well as its safety and efficacy.

Drug developers demand secrecy for the data they submit to regulatory authorities. Allegedly, the purpose of data exclusivity would be to ensure that the initial registrant of a new medicine can recover the expenses of testing the compound for efficacy and safety. This goal would be achieved by requiring potential competitors to replicate the initial registrant's clinical studies.[21] Indeed, Article 1711 of NAFTA provides a temporary data exclusivity for five years, and treats data as a protected trade secret. Further, bilateral and regional FTAs negotiated by the United States and the EC similarly incorporate a data exclusivity obligation.

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[20] See Valentina Vadi 'Intangible Heritage, Traditional Medicine and Knowledge Governance' Journal of Intellectual Property Law and Policy, forthcoming, 2007. Some examples of investment agreements in which countries give up the exception of patent for plants and animals are the US-FTA with Jordan, Singapore and Australia.

[21] Article 39.3 of the TRIPS Agreement merely requires members to protect such data against unfair commercial use and does not specify the period of protection. Surely, the unfair commercial use language does not encompass a data exclusivity obligation *per se* as a matter of positive law. Nonetheless, the terms of the article indicate that some forms of protection might be envisaged.

However, the new compilation of comparable test data by competing manufacturers may take several years and may be very expensive. As a result, data exclusivity may constitute a regulatory barrier to generic manufacturers' entry into market, delaying registration and marketing approval of generics medicines.

BITs also tend to reduce the scope of exceptions; for instance, the US-Jordan FTA only allows the Bolar exception[22] but not other kinds of exception such as *research exception*.[23]

However, the proliferation of patents in medical research creates the so-called 'tragedy of the anti-commons'.[24] The existence of obstacles to scientific knowledge creation has a tremendous impact on development of science and thus, on access to medicines.

Some FTAs further prevent national drug registration authorities from granting marketing approval for generic versions of drugs until after the patent expires without consent or acquiescence by the patent owner.[25] Thus, the original patent owner has to be notified of the identity of the company seeking market approval to enter the market during the term of the patent. This disclosure allows patent holders to use spurious lawsuits to unnecessarily delay marketing approval for generics.

Finally, investment agreements set a *numerus clausus* of grounds for revocation of a patent.[26] Therefore, lack of use, for instance, could not constitute a ground to revoke a patent, even in the presence of important *ordre publique* reasons such as public health.[27] If a patent were revoked on different grounds than those listed by investment agreements, revocation or forfeiture would amount to a taking or expropriation and foreign investors might invoke investment provisions to seek compensation.

B. *LIMITATIONS TO COMPULSORY LICENSING*

Compulsory licensing is an important regulatory tool that allows governments to temporarily authorise the production of a patented invention without the patent owner's consent for public policy reasons.

[22] By effect of the *Bolar exception*, introduction of generic medicines into the market can be made as soon as the pharmaceutical patent expires. The TRIPS permits generic producers to manufacture a given pharmaceutical during the life of the patent; only stockpiling is deemed incompatible with Article 30. See *Canada – Patent Protection of Pharmaceutical Products*, Panel Report of 20 March 2000, WT/DS114/R available at: http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf last visited on 4 May 2007.

[23] This unfortunate trend reflects national jurisprudential trends. In *Madey v Duke University* the US Court of Appeals for the Federal Circuit denied an experimental use defence in a patent infringement lawsuit against Duke University, signalling that academic researchers may be liable for use of patented products or processes notwithstanding the non commercial character of their research. *Madey v. Duke University*, US Court of Appeal for the Federal Circuit, 3 October 2002, 307 F 3d 1351.

[24] See Michael A Heller and Rebecca S Eisenberg 'Can Patents Deter Innovation? The Anti-commons in Biomedical Research' 280 Science 5364 pp. 698–701.

[25] See, for instance, US-Chile FTA Article 17.10.2 (c), US-Bahrain FTA, Article 14.9.4 and AUSFTA Article 17.10.4.

[26] The TRIPS Agreement does not regulate the grounds for revocation of a patent only requiring member states to provide a judicial review for every decision to revoke a patent. Traditionally a patent can be revoked for lack of use, lack of payment of annual fees or abuse of dominant position.

[27] The US-Singapore FTA limits grounds for revocation to causes of fraud, misrepresentation, insufficiency or unauthorized amendments to patent specification. CAFTA limits it to cases when inequitable conduct occurs.

According to the Doha Declaration on the TRIPS Agreement and Public Health,[28] each WTO member has the right to grant compulsory licenses, the freedom to determine the grounds on which such licenses are granted,[29] and the right to determine what constitutes national emergency or other circumstances of extreme urgency.

International investment agreements generally limit the grounds for developing countries to use compulsory licensing.[30] Moreover, in some BITs, such as AUSFTA and US-Singapore, reference is made to *reasonable and entire compensation*. In others, the standard is *prompt, adequate and effective compensation*, thus involving a high standard *vis-à-vis* that provided by the TRIPS Agreement which requires '*adequate remuneration*.'[31]

The rationale for these limitations to compulsory licensing is to give broad protection to the investor's interests from possible strategic behaviour of host countries once an investment has been made.

An argument that has been made against aggressive use of compulsory licenses is that this mechanism may obscure other more participative courses of action. These would include cooperative measures that might persuade foreign producers to invest in local production facilities with greater long-term prospects.

A complementary argument is that any short-term benefits ensuing from the use of compulsory licenses as an instrument of technology transfer must be weighted against the possible loss of direct investments that might ensure better access to pharmaceuticals over time. Indeed, broad compulsory licensing may make foreign corporations invest in other more attractive economic environments. The genius of compulsory licensing lies in addressing short-term inefficiencies of the market of a given product, where the product offer is inadequate to meet the product demand.

However, restricting provisions on compulsory licensing in investment agreements causes grave concern, as compulsory licenses are an essential insurance policy to prevent abuses of the IP system or to cope with health emergencies. Importantly, the ability to grant compulsory licenses does not necessarily mean such licenses will actually be granted, as the long-term costs may outweigh the short-term benefits of this action.

It is worth mentioning that the Doha Declaration also recognized that a solution should be found to the problem of extraterritorial compulsory licensing. As, according to TRIPS, compulsory licensing had to be predominantly for the domestic market,[32] the practical effect of this provision was to render the compulsory licensing provisions practically worthless for the poorest countries with limited domestic manufacturing capacity.

[28] Declaration on the TRIPS Agreement and Public Health (November 14, 2001), DOC WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration] available at the WTO web site, http://www.wto.org.

[29] Doha Declaration, paragraph 5 b.

[30] For instance, AUSFTA allows only two grounds for issuing compulsory licensing: the first ground is to remedy a practice deemed, after judicial or administrative process, to be anti-competitive under the competition policy of the party. The other is the case of public non commercial use or of national emergency or other circumstances of extreme urgency.

[31] TRIPS Agreement, Article 31 h.

[32] TRIPS Article 31(f) originally required that compulsory licences should be granted mainly to supply the domestic market.

On 30 August 2003, the General Council waived the provision, allowing generic copies made under compulsory licenses to be exported to countries that lack production capacity, provided certain conditions and procedures are followed.[33] The waiver remained effective until December 2005, when an amendment has been put into effect to replace it and provide a permanent solution to this issue.[34]

However, among WTO members, only Rwanda has notified the WTO that it intends to use the procedure as an importer.[35] Indeed, the procedures for compulsory licensing requires an administrative and legal infrastructure that is absent in many developing countries. Moreover, developing countries fear that sanctions might be threatened, bilaterally or regionally. Given the current situation, the quasi-general lack of notifications is evidence that the current system is not working.

C. *PARALLEL TRADE*

While the TRIPS Agreement does not set a standard for parallel trade,[36] investment agreements generally set specific parameters to this mechanism.[37]

Parallel trade occurs when a product covered by intellectual property rights has been placed in a first market by or with the permission of the patent holder and then imported into a second market without the permission of the patent holder.

At the legal level, parallel imports are based on the principle of *exhaustion*. Under *national exhaustion*, patents rights in a particular product are exhausted within the country of sale when products are first sold in that market. This means that once the product has been sold, the patent owner has no more rights on the further commercialization of the product within the given country.

Regional exhaustion indicates the same phenomenon applied on a regional basis. For instance, in the European Community products sold in one country of the European Union will exhaust rights in all countries making up the single market.

International exhaustion means that countries which espouse it accept that placing a product on a market anywhere in the world exhausts the patent rights in their market, even where the patent owner has prohibited such uses or actions by contract.

At the economic level, parallel trade tends to force price convergence across markets, normally increasing economic welfare by permitting consumers in importing

[33] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, decision of the General Council of 30 August 2003, doc. WT/L/540, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.html last visited on 4 May 2007.

[34] Amendment to the TRIPS Agreement, Decision of the General Council of 6 December 2005, WT/L/641, available at http://www,wto.org/english/tratop_e/trips_e/wtl641_e.htm last visited on 4 May 2007.

[35] See the Dedicated Webpage for Notifications, at http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm last visited on 28 July 2007.

[36] TRIPS Agreement, Article 6.

[37] In particular, the FTAA draft contains a provision for the application of regional exhaustion. In the US-Singapore FTA, patent holders can block parallel imports by mandating cross-border enforcement of contracts.

countries to benefit from lower prices realized by more efficient producers in exporting countries. Thus, parallel trade can be an important tool for developing countries to save money by importing patented drugs from other countries where they are being sold at lower prices.

However, some authors argue in favour of limiting parallel trade in the pharmaceutical sector, as pharmaceutical arbitrage would represent '*the theoretical nemesis of differential pricing*'[38] or '*an issue of IP policy and not an issue of free trade or restricted trade*'.[39]

While parallel imports may facilitate access to drugs in the short term, in the long term, this policy option impedes *differential pricing*, according to which patent owners set a higher price in high-income countries and a lower one in low-income countries. Such a differential pricing would allow scale efficiencies and revenues to invest in research and development of new drugs.

Regulating the iridescent and enigmatic phenomenon of parallel trade is a challenge. Indeed, as it often happens when economic data must be interpreted, univocal solutions do not exist. Importantly, '*the laws of the market are not the only ones that apply to this kind of activity*'.[40] On the contrary, a balance needs to be struck between the short term positive impact that low prices can determine in national market, and the long term objective of optimizing allocation of resources and public welfare through differential pricing.[41]

Crucially, parallel trade may become a necessity if a state is facing a health emergency. In this context, access to medicines is very much alike the famous *prisoner's dilemma*[42] where short term effects of a given policy must be balanced with its long term effects. This decision pertains to national governments, and policy options should not be circumscribed by bilateral or even regional investment treaties.

V. Dispute Settlement

In case of a dispute concerning the issuance of regulatory measures on pharmaceutical products, several *fora* may be competent. Among other mechanisms, the investor-state dispute settlement mechanism in investment treaties enables foreign investors to bring suits before international arbitral tribunals for the settlement of

[38] Kevin Outterson 'Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets', Yale Journal of Health Policy, Law & Ethics, 2004 p.10.

[39] Carsten Fink *Does National Exhaustion of Intellectual Property Contradict the Principle of Free Trade?*, Draft Paper for Conference on Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Switzerland, November 6–7, 1998, pp. 3–4.

[40] Christopher Heath 'Parallel Imports and International Trade', Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, draft paper on file with the author, p. 1.

[41] Patricia Danzon 'The Economics of Parallel Trade' 13 Pharmaco-Economics 3 (1998), p. 293–304, at 297.

[42] The prisoner's dilemma is a theory concept showing the disadvantages of not being able to reach binding agreement. The name originates from a situation of two prisoners who must each decide whether to confess without knowing what the other will say, where a lighter penalty follows if you confess when the other does not. The given assumption is that if they both say nothing they will be free. See *prisoner's dilemma* in John Black *Oxford Dictionary of Economics* II ed. OUP, Oxford 2003.

disputes that could arise between him and the host state. Arbitral tribunals constitute an alternative forum that allows pharmaceutical companies to go shopping for another decision if they do not like the national court's decision. In addition, as claimants are not required to exhaust domestic judicial remedies, they can directly surmount national jurisdictions and bring investment claims to arbitrators.

Arbitration is primarily a private dispute resolution mechanism. Arbitration tribunals are neither open to the public nor accountable to democratic processes. They are not bound by precedents and are not obliged to publish final decisions. They lack the transparency generally afforded by normal judicial proceedings, even in disputes concerning public goods. Further, the decisions have only limited avenues for appeal and cannot be amended by the domestic legal system or a supreme court.

Two important preliminary remarks arise in this context. The first is the question how can the public interest be protected within a framework aimed primarily at protecting private interests. *Prima facie*, it seems that the current framework lacks adequate procedural protections for the public interest. The second remark concerns the claims available to the parties. Indeed, investors are given the possibility to bring not only violation complaints, but also non-violation claims.

A . *Non-Violation Nullification or Impairment of Benefits Complaints*

The inclusion of *non-violation complaints* in the dispute settlement chapter of investment agreements and their applicability to intellectual property rights is another matter of concern. Any measure that does not appear to directly violate treaty provisions, but is nevertheless disadvantageous to the investor's intellectual property, can fall within the category of non-violation complaints.

While the aim of the provision is to maintain the balance of benefits struck during negotiations, the vagueness of the clause may transfer decision authority from the treaty negotiating parties to arbitral panels.

Thus, extension of this clause to the IP regulation was extremely controversial, during the TRIPS negotiations.[43] While Article 64.2 of the TRIPS Agreement provides for such a remedy, for the time being, WTO members have agreed not to use these complaints under the TRIPS Agreement, adopting a *moratorium*.[44]

Looking at the GATT/WTO jurisprudence, panels held that such a complaint '*should*

[43] Under Article XXIII:1(b) of GATT 1994, a Member state can file a suit even when the Agreement has not been violated, if it shows that it has been deprived of an expected benefit because of a government's action or any other circumstance. For a critical assessment, see for instance, Sungjoon Cho 'GATT Non-Violation Issues in the WTO Framework: Are They the Achilles' Heel of the Dispute Settlement Process?' (2001) 39 Harvard Int'l L J 2, 311.

[44] Under Article 64.2 this moratorium (i.e. the agreement not to use TRIPS non-violation complaints) was to last for the first five years of the WTO, but it has been extended since then through the Doha Decision on Implementation-Related Issues and Concerns (Paragraph 11.1), the Decision adopted by the General Council on 1 August 2004 (Paragraph 1 h) and the Hong Kong Ministerial Decision (Paragraph 45).

be approached with caution and should remain an exceptional remedy'[45] and that '*the reason for this caution is straightforward. Members negotiate the rules that they agree to follow and only exceptionally would expect to be challenged for actions not in contravention of these rules*'.[46]

The uncertain consequences of non-violation complaints are evident in the WTO dispute *EC-Asbestos* which involved a French ban on Canadian asbestos on health grounds. In this *cause célèbre*, Canada claimed that the French ban on the sale and imports of products containing asbestos nullified or impaired benefits accruing to it under GATT Article XXIII:l(b).

In response, the European Communities argued *inter alia* that, while it may be possible to have legitimate expectations in connection with a purely commercial measure, this is not possible with respect to a measure taken to protect human life or health, which can be justified under Article XX of the GATT 1994. An important aspect of this argument was that a Member cannot have reasonable expectations of continued market access for products which pose a serious risk to human life or health.

The Panel rejected this objection, although it further concluded that, in the substance, Canada had not established the existence of a nullification or impairment of a benefit.[47] The Appellate Body confirmed the panel's report, stating that '*the text [of Article XXIII:l(b)] does not distinguish between, or exclude, certain types of measures. Clearly, therefore, the text of Article XXIII:l(b) contradicts the European Communities argument that certain types of measure, namely, those with health objectives, are excluded from the scope of application of Article XXIII:l(b).*'[48]

The AB stressed that '*In any event, an attempt to draw the distinction suggested […] between so called health and commercial measures would be very difficult in practice'.*[49] As *'the health objectives of many measures may be attainable only by means of commercial regulation […] thus in practice, clear distinctions between health and commercial measures may be very difficult to establish*'.[50]

The AB further highlighted that the European Communities' argument that Canada could not have legitimate or reasonable expectations of continued market access for products which are shown to pose a serious risk to human health and life, '*does not relate to the threshold issues [of the scope of application of Article XXIII:l(b)]. Rather [it] relates to*

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[45] *Japan – Measures Affecting Consumer Photographic Film and Paper*, adopted on 22 April 1998, WT/DS44/R §10.37, available at http://www.wto.org/English/tratop_e/dispu_e/disp_settlement_cbt_e/alslpl_e.htm, last visited 6 May 2007.

[46] *Japan – Measures Affecting Consumer Photographic Film and Paper*, §10.36.

[47] *European Communities-Measures Affecting Asbestos and Asbestos-Containing Products*, Panel Report, released on 18 September 2000, WT/DS135/R, § 8.257, report available at http://www.wto.org/English/tratop_e/dispu_e/cases_e/dsl35_e.htm last visited on 6 May 2007.

[48] *European Communities-Measures Affecting Asbestos and Asbestos-Containing Products*, Appellate Body Report, 12 March 2001, WT/DS135/AB/R, § 188, http://docsonline.wto.org/DDFDocuments/t/WT/DS/135ABR.doc last visited on 5 May 2007.

[49] *EC-Asbestos*, Appellate Body Report, § 189.

[50] *EC-Asbestos*, Appellate Body Report, § 189.

the substance of [the] claim […] whether a benefit has been nullified or impaired by a measure restricting market access for products posing a health risk.'[51]

This case shows that the application of the non-violation complaints may have unforeseen results, and that no deference is given to measures protecting public health. The introduction of non-violation complaints in the intellectual property sphere through investment agreements is a way to circumvent multilateral agreement on the issue. Further, from a public policy perspective, it raises important concerns with regard to public health.

The inherent ambiguity and the concomitant risk of misuse of non-violation complaints call for excluding this remedy in sensitive domains such as intellectual property regulation. From an historical perspective, non violation complaints were introduced into the GATT 1947 because of the vagueness of its obligations. There is not such need with regard to intellectual property, whose rules are clearly detailed into the TRIPS Agreement and other international conventions.

In conclusion, the provision of non violation complaints with regard to pharmaceutical patents might open a Pandora box. Unfortunately, aggressive negotiations have already determined the inclusion of these complaints in some recent investment agreements with regard to such a delicate field.[52] It has to be seen how concretely all the interests concerned will be adequately balanced in an eventual dispute settlement proceeding. Deciding this kind of issues may have a grave impact on the human right to health and life of the population concerned. Professor Burton observed that patents are too important to be left even to patent lawyers.[53] Would arbitrators be aware of the human rights' implications of their decisions on the matter?

B. *VIOLATION COMPLAINTS: DO REGULATORY MEASURES AMOUNT TO INDIRECT EXPROPRIATION?*

As IP is protected in foreign investment treaties, any state interference with foreign IP becomes a breach of treaty and thus has to be compensated.[54] Therefore, it may be questioned whether national measures regarding public health and access to essential medicine—by negatively affecting pharmaceutical patents—amount to takings and involve the state liability for breach of treaty obligations.

An important question is the extent to which countries can take TRIPS-consistent

[51] *EC-Asbestos*, Appellate Body Report, § 190.

[52] See for instance, AUSFTA Article 21.2.

[53] John H Burton 'Issues Posed by a World Patent System' in K Maskus and J Reichman (eds), *International Public Goods, The Public Domain, and The Transfer of Technology after TRIPS*, CUP, Cambridge 2004.

[54] One of the first cases in which the violation of an intangible property right was deemed to be an expropriation was the *Norwegian Ship-Owners*' case. *Nor. v US*, 1 R.I.A.A. 307, 332 (Perm Ct Arb 1922). In the 1926 case of *German Interests in Polish Upper Silesia-the Chorzow Factory Case*, the Permanent Court of International Justice found that the seizure by the Polish government of a factory plant and machinery was also an expropriation of the closely interrelated patents of the company, although the Polish government at no time claimed to expropriate these. F.R.G. v Pol, 1926 PCIJ (serA) No7 (May 1925).

regulatory measures to protect public health. The right of the state to regulate and even to expropriate in the public interest is not questioned under international law. The issue is whether compensation should be paid. The rule is explicit about the payment of compensation in the case of expropriation and transfer of property. It is not quite clear in the case of regulation that does not involve such a transfer.

It seems difficult to classify regulatory measures such as compulsory licensing as a case of *direct expropriation*. Indeed, the patent owner still maintains the title of the property and the possibility to commercialize the pharmaceutical product although non-exclusively. However, it may be asked whether measures such as compulsory licenses and parallel imports can effectively neutralize the enjoyment of property of the foreign investor.[55] The modern concept of expropriation is generally broadly construed, and investment agreements do not only include direct and full taking of property but also *de facto* or *indirect expropriation,*[56] that is measures that do not directly take investment property, but which interfere with the use of property, depriving the owner of its economic benefits.

A preliminary observation is that, the determination of whether a compulsory license amounts to a *de facto* or *indirect expropriation* must be made case by case. The mere fact that it may have an adverse economic effect on an investment, standing alone, does not establish that a *de facto* or *indirect expropriation* has occurred. As the arbitral tribunal held in *Feldman Karpa v United Mexican States*,[57] '*not every business problem experienced by a foreign investor is an indirect or creeping expropriation nor does the protection under the treaty cover commercial risks*.'[58]

At the legal level, a compulsory license would not be questionable if it has been taken in the public interest and it has a legitimate purpose and it is applied in a non-discriminatory way, provided that an adequate remuneration is available. International standards for the issuance of compulsory licenses already exist. If the conditions listed by Article 31 of the TRIPS Agreement, as interpreted by the Doha Declaration and modified by the recent amendment, are fully respected, a compulsory license has to be considered lawfully issued.

An interesting argument that has been made is that compulsory licenses are inherent limits to IP and therefore constitute not an *exception* to the rule but a *natural boundary* of the right. As Sornarajah underlines, *the notion of creeping expropriation is based on the unbundling of property rights*.[59] In order to understand what constitutes an expropriation, the notion of property must be clearly defined and delimited.

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[55] In *Middle Eastern Shipping and Handling Co. v. Egypt*, indirect expropriation was described as '*measure taken by a state the effect of which is to deprive the investor of the use and benefit of his investment even though he may retain nominal ownership of the respective rights*'. See *Middle Eastern Shipping and Handling Co. v. Egypt* (2002) ICSID ARB 99/6, § 107.

[56] See for instance, Article 1110 of NAFTA.

[57] *Marvin Roy Feldman Karpa v United Mexican States*, Award of 16 December 2002, ICSID Case No ARB(AF)/99/1, http://www.worldbank.org/icsid/cases/feldman_mexico-award-en.PDF accessed 9 July 2007.

[58] *Feldman Karpa v United Mexican States*, § 102.

[59] See M Sornarajah *The International Law of Foreign Investments*, II edition, CUP, Cambridge 2004, p. 352.

According to Roman law, *dominium est ius utendi et abutendi, quatenus iuris ratio patitur*: the concept of property includes the use, enjoyment or disposition of the property right within the limits established by the law. This definition of property rights has been transposed into modern terms by the Napoleon Code[60] and appears in most modern constitutions,[61] giving a useful conceptual framework. Property rights are not absolute, but their owners can enjoy them within the limits established by the law.[62]

Intellectual property, which is a special form of property, is never absolute. To the contrary, the notion that intellectual property serves a social function has wide acceptance in international law, as expressly indicated by Articles 7 and 8 of the TRIPS Agreement and by Article 15 of the International Covenant on Economic, Social and Cultural Rights. Thus, private remuneration should not be given more weight than the social welfare.

A following argument relates to the amount of compensation that should be paid or not paid in case compulsory licenses were granted. The theory of inherent limitation of property rights would constitute the ground for non-compensation.[63]

Notwithstanding the appeal of this position, generally international arbitral tribunals do not embrace it. For instance, in *Pope & Talbot v Canada*,[64] it was underscored that regulations can indeed be characterized in a way that would constitute *creeping expropriation* even if fashioned in a non-discriminatory manner. The arbitral tribunal further held that an exception for regulatory measures would create a gap in international protection against expropriation.

VI. A LOOK AT THE THEORY OF EFFICIENT BREACH

According to economic literature, *efficient breach* is a situation where the benefit of the breach for the rule-breaker exceeds the harm to the other party resulting from the breach.[65] Thus, the breaching party considers it desirable having considered the legal and economic consequences of such a breach.[66] Legal scholars have growingly questioned its eventual transplantation from contract law to treaty law.

From a legal perspective, a party to a legal instrument (be it a treaty or a contract)

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[60] Napoleon Code, Article 544.

[61] See, for instance, Italian Constitution, Article 42.

[62] See Joseph William Singer 'The Ownership Society and Takings of Property: Castles, Investments and Just Obligations' 30 Harvard Environmental Law Review 309 (2006) 309 ss.

[63] Interestingly, this inherent limitation analysis was adopted by the American Supreme Court in the case *Lucas v. South Carolina Coastal Council*. In *Lucas*, Justice Scalia held that '*where the State seeks to sustain regulation that deprives land of all economic beneficial use, we think it may resist compensation only if the logically antecedent inquiry into the nature of the owner's estate shows that the proscribed use interests were not part of his title to begin with*'. 112 S Ct 2886 (1992) at 2899–2900. See Andrew Newcombe The Boundaries of Regulatory Expropriation in International Law' 20 ICSID Review Foreign Investment Law Journal 1, 2005 pp. 1-57, at 28.

[64] *Pope & Talbot v Canada* Interim *Award*, June 26, 2000, 40 ILM 258 (2001), at § 99.

[65] Efficient breach theory is associated with Richard Posner and the Law and Economics school of thought.

[66] See Robert Birmingham 'Breach of Contract, Damage Measures, and Economic Efficiency' 24 Rudgers Law Review (1970) 273, 284.

is under a legal obligation to perform a bargain promise. The basic principle of treaty law is the proposition that '*treaties are binding upon the parties to them and must be performed in good faith. This rule is known in legal terms as pacta sunt servanda and is arguably the oldest principle of international law*'.[67]

However, the theory of efficient breach takes the position that, from an economic perspective, breach is acceptable, and indeed should be encouraged by law if such an action results in an outcome that benefits the breaching party and society as a whole. In any case, efficient breach would not represent a legal defence to a suit for breach of treaty law, but a *mitigating consideration* that arbitral tribunal would take into account when balancing opposing interests.

From a law and economics perspective, it may be questioned whether the adoption of pro-health measures may lead to an efficient breach of investment treaty law.

In the parallel WTO context, some authors argue that the WTO already permits such efficient breaches. A paradigmatic example of this methodology would be given by the *EC-Hormones* case, where non-compliance has continued for years in combination with a suspension of equivalent concessions by the members that won the dispute.[68] When the EC banned hormone-treated beef for public health reasons, the measure was deemed to be illegal under WTO rules. However, given the democratic support of its constituencies, the EC decided to maintain such measures. Thus, Pauwelyn correctly describes this kind of efficient breach as a '*safety valve that may, in the long run, serve to legitimize WTO obligations, rather than to undermine them*'.[69]

Coming back to investment law, in a preliminary way, the adoption of a regulation aimed at protecting public health cannot be deemed to be necessarily violating investment agreement provisions. The burden of proof lies on the investor: it is the investor who has to demonstrate that a given national measure is violating his rights as provided by treaty law. If the national measure has a legitimate purpose, is applied in a non-discriminatory manner and has no discriminatory effects, it may be extremely difficult for the investor to show his case.

In case the state were found liable of investment treaty violation and it were condemned to pay damages, then the question would be whether it is convenient for the state to maintain its national legislation, notwithstanding the risk of facing other challenges by foreign investors or by contracting parties in other *fora*, such as the WTO. The theory of efficient breach calls for this type of balancing analysis.

As Reichman puts it, '*compulsory licensing converts exclusive property rights into de facto*

[67] M Shaw *International Law* IV edition, CUP Cambridge 1997 p. 633.

[68] Decision by the Arbitrators, *European Communities – Measures Concerning Meat and Meat Products (Hormones)* – Original Complaints by the United States – Recourse to Arbitration by the European Communities under Article 22.6 of the DSU, WT/DS26/ARB (12 July 1999), DSR 1999: III, 1105.

[69] Joost Pauwelyn 'WTO Dispute Settlement: Of Sovereign Interests, Private Rights and Public Goods' in *International Public Goods and Transfer of Technology Under a Globalised Intellectual Property Regime*, Keith E. Maskus and Jerome H. Reichman (eds), CUP, Cambridge 2005, pp. 817–830, at 823.

liability rules'.[70] The problem is that economists know little about how liability rules operate in the intellectual property law context.[71] However, the author concludes '*So long as liability rules provide innovators with truly adequate compensation […] they need not undermine the innovator's incentive to invest*.'[72]

Standards of compensation for the patent owner may vary from jurisdiction to jurisdiction, but in assessing its adequacy, arbitrators should bear in mind the economic rationale of compulsory licensing and the public policy goal furthered by the national measure. It would be illogic to impose huge compensation on a developing country which is issuing compulsory licenses to get affordable medicines. If overcompensation is likely to occur, going beyond an optimal point, then promoting socially valuable goals may become unsustainable. Developing countries will need to develop rules and procedures adapted to their own circumstances for setting royalty rates, but the implication of other countries' experience is that royalty rates need not be very high.

From a legal perspective, authors have rejected an application of the theory of efficient breach to international law, considering efficient breach as merely speculative in international relations.[73] In the words of Pauwelyn, '*international law is protected by a property rule, not a liability rule*'.[74]

However, it may be argued that the legal approach is a bit too formalistic.[75] A state will take into account several factors before deciding to comply with a given treaty provision where fundamental public policy interests are at stake.

The fact that the jurisprudence concerning borderline cases where efficient breach might fit is scarce is not a casualty. These empirical data merely reflect the fact that compliance may be the easier option for a state to avoid economic and political pressures.

Thus, from a legal perspective, the preferable view would be considering compulsory licensing as a special norm provided by international intellectual property regime. According to this line of argument, issuing compulsory licenses would not amount to breach of treaty law, but to inherent limitations of pharmaceutical patents.

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[70] J Reichman and C Hasenzhal, *Non-Voluntary Licensing of Patented Inventions*, ICTSD and UNCTAD Issue Paper No. 5 Geneva 2003, p 24.

[71] See F M Scherer 'The Economic Effect of Compulsory Patent Licensing' in P.M. Scherer *Competition Policy, Domestic and International*, 327–342, Edward Elgar Pub 2001.

[72] J Reichman and C Hasenzhal, *Non-Voluntary Licensing of Patented Inventions*, *cit.*, p 24.

[73] The literature is broad with regard to WTO law. See for instance the debate between Judith Hippler Bello and John J Jackson. See J Hippler Bello 'The WTO Dispute Settlement Understanding: Less is More, 90 AJIL 416 (1996); John H Jackson 'The WTO Dispute Settlement Understanding – Misunderstandings on the Nature of Legal Obligations' 91 AJIL 60 (1997) and, of the same author, 'International Law Status of WTO Dispute Settlement Reports: Obligation to Comply or Option to 'Buy Out'? 98 AJIL 1 2004, 109–125.

[74] Joost Pauwelyn *Optimal Protection of International Law: Navigating Between European Absolutism and American Voluntarism* p 43. Paper presented at the Conference on Public International Law and Economics, Max Planck Institute, 14–16 December 2006, Bonn, Germany, available at http://www.law.duke.edu/fac/pauwelyn/pdf/optional_protection.pdf last visited on 9 May 2007.

[75] See J H Reichmann 'Of Green Tulips and Legal Kudzu: Repackaging Rights in Sub-Patentable Innovation' 53 Vanderbilt Law Review 1743 2000.

Analogous to the jurisprudence elaborated by the European Court of Human Rights, this argument would be based on the intrinsic limits of the right to property and its social function.[76] From this point of view, a lawfully issued compulsory license could not be considered breach of patent.

VII. A Taxonomy of Claims in the Intellectual Property Area

Notwithstanding the traditional lack of transparency surrounding investment disputes, certain emerging patterns may be glimpsed at and, accordingly, two kinds of dispute may arise in the IP area.

First, although the proof may so difficult to constitute a *probatio diabolica*, an affected patent owner may attempt to prove that an illegal expropriation has taken place. Second, claims could be made when a patent owner is dissatisfied with the determination of the level or mode of remuneration.

With regard to the first claim, the trial will be concerned with the issue as to what acts of the state may be characterised as amounting to taking and with the circumstances in which such taking would be considered unlawful.

If a compulsory license or similar measures are considered to be a taking, the legitimacy of the measure has to be assessed. Importantly, in order to be lawful, a measure tantamount to expropriation has to be taken in the public interest, has to be not discriminatory, carried out under due process of law as required under the fair and equitable treatment standard and accompanied by the payment of compensation.

Secondly, claims could be made when a patent owner is dissatisfied with the determination of the level or mode of remuneration. Expropriation rules, if found applicable, may in some cases, be more beneficial to the patent owner than the compulsory licenses rules, particularly because the obligation to pay will rest with the government. Further, customary compensation rules, uniformly enshrined in investment protection treaties, do not differentiate between various public purposes of expropriations, posing instead a single standard. The full compensation is often described as having the characteristics of promptness, adequacy and effectiveness.

For instance, in *Campañìa del Desarollo de Santa Elena v. Republic of Costa Rica*[77] the arbitral tribunal concurred with the claimant that the particular public policy objective pursued by the expropriation could not *per se* affect the level of compensation. In other words, the question of compensation was not linked to the legality of taking.[78]

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[76] See, *inter alia*, Riza Coban *Protection of Property Rights Within the ECHR* Ashgate Publishing Ltd, UK 2004, chapter 7.

[77] *Compañìa del Desarollo de Santa Elena v. Republic of Costa Rica* Final Award February 17, 2000 (ICSID Case No. ARB/96/1), 15 ICSID Review-FILJ 1 pp. 169-204.

[78] As Sornarajah puts it '*It is generally accepted that a lawful taking creates an obligation to pay compensation, whereas an unlawful nationalization creates an obligation to pay restitutionary damages*'. See M. Sornarajah *The International Law of Foreign Investments*, II edition, CUP, Cambridge 2004, p. 345.

As the Santa Elena Tribunal held, '*Expropriatory environmental measures—no matter how laudable and beneficial to society as a whole—are, in this respect, similar to any other expropriation measures that a state may take in order to implement its policies: where property is expropriated, even for environmental purposes, whether domestic or international, the state's obligation to pay compensation remains*'.[79]

An argument that could be made is that, being compulsory licenses on pharmaceuticals justified by an overwhelming public interest, compensation should be limited. The problem is that usually arbitral proceedings do not take into account the public dimension or the lawfulness of the measure to establish the exact amount of compensation.

VIII. Case Studies

Five cases will be examined to show the kind of disputes which can arise on the issuance of compulsory licenses on pharmaceutical patents.

The first case to be dealt with is the notorious South African case which involved South Africa and major pharmaceutical companies. In 1997, in response to the HIV/AIDS epidemic, the South African government enacted legislation to guarantee access to essential medicines through parallel imports and compulsory licenses.

However, an association of pharmaceutical companies challenged the legality of the Medicines Act in light of the TRIPS Agreement before the High Court of Pretoria. In addition, the US Trade Representative put South Africa on the Section 301 Watch List as a country which might be subject to trade sanctions.[80]

Because of pressures from NGOs and international public opinion, the court action was withdrawn, and South Africa was taken off the trade sanctions list.

The South African case, amongst others, has increased the public awareness on the problem of access to essential medicines during health emergencies.

Similarly, the Philippine case *Smith Kline and French Laboratories LTD v. Court of Appeals, Bureau of Patents*[81] is paradigmatic of the issues that can arise when a state grants compulsory licenses on pharmaceutical products.

In 1994 the Philippine competent authorities granted a compulsory license to a company to manufacture GlaxoSmithKline's medicine, *Cimetidine*. The petitioner

[79] *Supra* note 77, § 72.

[80] The Special 301 provision of the US Trade Act of 1974 requires the United States Trade representative to conduct an annual review of the IP practices of US trading partners, identifying countries which fail to provide adequate and effective levels of intellectual property protection for US companies. Trade associations may petition the United States Trade Representative (USTR) to list a country in the Watch List. Section 301 is the principal statutory authority under which the United States may impose trade sanctions against foreign countries that are deemed to act inconsistently with their trade obligations.

[81] *Smith Kline and French Laboratories LTD v. Court of Appeals, Bureau of Patents, Trademarks and Technology Transfer and Doctors Pharmaceuticals Inc*, Supreme Court of Manila, G.R. No. 121867, July 24, 1997.

opposed the decision, arguing that the state measure amounted to expropriation and that the compensation was not just. The Supreme Court affirmed *in toto* the challenged decision of the Court of Appeal, stating that the award of compulsory license is a valid exercise of police power, and that the royalty at 2.5% of the net wholesale price is a just compensation.

One sees in the ruling, the potential conflict between national legislations protecting social objectives—namely health—and international investments treaties protecting foreign investment. In particular, the broad definition of investment and the coverage of *indirect expropriation* may be used to raise expropriation complaints in case compulsory licenses were granted.

The third case that is worth mentioning for its policy implications is contemporary. On January 29th 2007, Thailand's military government has issued compulsory licenses on *Plavix*, an anti-blood-clotting medicine, whose patent owner is a French company—Sanofi-Aventis—and on *Kaletra*, an HIV treatment supplied by US firm Abbott Laboratories. According to the Thai Health Ministry, as the government does not have enough monetary resources to buy the necessary medicines, it is applying measures allegedly consistent with the TRIPS Agreement and the Doha Declaration.[82]

According to the national regulation, the Government Pharmaceutical organisation is authorised to import generics from India until domestic production comes on line. The license will concern supply to poor patients within the public health system—those who cannot afford to buy Abbott's version of the medicine. Further, Abbott will receive royalties when the medicines are produced under compulsory licenses.

However, on May 1, 2007, the US Trade Representative has put Thailand on the Priority Watch List, as the country would not provide an adequate level of IP protection. This move could open the country up to retaliatory trade measures such as loss of generalised system of preferences (GSP). For its part, Abbott Laboratories has announced that it will not register any new medicines in Thailand, unless Thailand reverses its decision. This is a clear attempt to pressurize Thailand and to inhibit other developing countries from using compulsory licensing procedures.

This controversy gives rise to some considerations. While strategies of dialogue and negotiation may be appropriate in the long term, in the short term, if health emergencies arise, the state may feel compelled to intervene in a prompt manner.

Second, the case is interesting also because a compulsory license was given also on a heart medicine, which treats a non-communicable disease. Solution of the political impasse would imply clarification on the delicate point whether there is a scope of disease limitation on the medicines for which compulsory licenses could be issued. Professor Abbott emphasises that international law instruments such as the Doha

[82] See Jean François Tremblay 'Drug Patent Struggles in Asia' in 85 Chemical & Engineering News 6, February 5, 2007 p. 11.

Declaration include a mere exemplificative list of diseases, and that any such limitation would be spurious.[83]

Third, the impact of the different types of pressures will be felt far beyond Thailand. If Thailand, a middle-income country, struggles to assert its rights to use the TRIPS flexibilities, then low-income countries, that face even greater financial and technical barriers, will be discouraged from even attempting to use the same process. It may be questioned what would have happened if Thailand had signed a bilateral investment agreement with the United States. Indeed, the Thai-US talks fell apart at the end of 2006, partly due over a failure to agree on IP issues.[84]

Looking now at proper investment disputes, there have not been many challenges to regulations designed to protect public health or discipline pharmaceutical patents. To interpret and clarifying this circumstance two cases can be mentioned.

In the NAFTA case *Signa S.A. v. Canada*,[85] a Mexican generic pharmaceutical company challenged a national Canadian measure concerning the duration of pharmaceutical patents. Signa claimed that the extensive protection would have frustrated its legitimate expectations under Article 1105 of the NAFTA which provides fair and equitable treatment to foreign investors. There is not publicly available information on this case as it was soon settled by the parties. Probably, this withdrawal was due to the inception of the TRIPS Agreement.

Whether the filing of the Notice of Intent to Arbitrate had any strategic or other impact is not known. However, it is worth highlighting that this case showed the possibility for corporations to file a suit against state regulatory measures diminishing corporate profits. It is argued that the scarcity of cases in this matter is not due to absence of conflicts, but to the will not to transform these conflicts in legal ones. In other words, it may be convenient for the corporate actors not to make the conflict legal. Legal scrutiny implies public scrutiny on the balance between corporate profits and public interest. Further, even when the disputes are legal, it is difficult to be fully informed, given the characteristics of arbitration.[86]

For instance, with regard to the specific topic of this contribution, the author has become aware of an investment dispute concerning the issuance of a compulsory license on pharmaceuticals looking through a major law-firm's website. The case involves an East European Country and it is discussed at the ICC. Nothing else is known, and when the author wrote to the involved law firm, she did not get any answer.

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[83] See 'Thailand Authorizes Generic production of Two More Patented Drugs' in 11 Bridges 3, 31 January 2007.

[84] See 'US Postpones FTA Talks with Thailand' November 6, 2006, available at http://www.bilateral.org/article-print.php3?id_article=6404 accessed on 16 May 2007.

[85] *Signa v Canada* Notice of Intent to Submit a Claim to Arbitration under Section B of Charter 11 of the North American Free Trade Agreement, New York March 4, 1996.

[86] See, among others, Karl-Heinz Böckstiegel 'Enterprise v. State: the New David and Goliath? 23 Arbitration International 1 (2007) 93-104.

Clearly, due to the confidentiality requirements, lawyers may prefer not to disclose any kind of information to academics. Still, it may be questioned whether providing some *sunshine* to the process would be preferable, especially when human rights are at stake.

IX. Policy Options

A. *Dispute Avoidance Mechanisms*

Some investment agreements anticipate possible disputes by providing exceptions with regard to compulsory licensing. For instance, NAFTA provisions on expropriation and compensation provides an exception with regard to compulsory licenses.[87]

Also, the FTA between Chile and USA[88] stipulates that the provision on expropriation and compensation does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement.

A similar discipline of eventual conflicts between different treaty regimes is provided by the *side letter* to the US-Morocco FTA that states that nothing in the intellectual property chapter of the agreement shall '*affect the ability of either party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency*.'[89]

The side letter also clarifies that the IP chapter of the FTA will not prevent the effective utilization of the waiver allowing developing countries that lack pharmaceutical manufacturing capacity to import drugs under compulsory license.

Similarly, when the DR-CAFTA was signed on August 5, 2004, a side letter or understanding on intellectual property and public health was included in response to criticism that the intellectual property restrictions in the agreement could undermine public health. In particular, this understanding states that CAFTA provisions '*do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all'* or from '*effective utilization*'[90] of the WTO waiver.

However, the legal value of these side letters or understandings may be questioned. From a legal point of view, these clauses may be virtually meaningless if interpreted as declaratory statements and not as legally binding exceptions. The hierarchy of these statements *vis-à-vis* other investment treaty provisions are extremely ambiguous.

Moreover, express reference to these issues only in some recent investment treaties

[87] NAFTA, Article 1110.7.
[88] Chile-US FTA, Article 10.9.5.
[89] US-Morocco FTA Agreement, Side Letter.
[90] US-Central America FTA, Side Letter.

and not in others reflect that the ones in which such reference is absent are in fact introducing public health limitations.[91]

If the clause is interpreted as merely having interpretative value, many problems may arise with regard to its implementation and concerns remain with the regard to the concrete issuance of compulsory licenses. Why the available case law is so limited? The risk is that the philanthropic declarations and conflict clauses come to a standstill because of economic pressures exercised by pharmaceutical corporations and their home countries. These pressures may prevent States—in particular developing countries—from taking effective measures to give effect to their international obligations to protect the right to health of their citizen.

B. *Strategic Bargaining and Policy Considerations*

This overview leaves some space for policy considerations. At a macro-level, it is necessary to strike a balance between the competing interests of the host state and the foreign investor.

On the one hand, as foreign investors can challenge national laws or regulations, even if these are enacted for protecting public health, the threat of litigation by investors could create a chilling effect on policy-makers. Thus, countries need the capacity to resist political pressures when adopting public health safeguards.

For instance, in Thailand, NGOs campaigned invoking the use of compulsory licenses to reduce the prices of DDI, an anti-retroviral drug against AIDS. The US Trade representative placed Thailand in the Special 301 Watch List, a precursor to trade sanctions, and prevented Thailand from pursuing the idea. Simply appearing on the List discourages investment.[92]

On the other hand, countries in state of necessity may menace the threat of compulsory licenses to obtain price reductions. It is interesting to underline that both developing and developed countries have used the threat of compulsory licenses to bring down medicine prices.

For instance, the Government of Brazil was able to obtain, in 2001, a price reduction of up to 70% for AIDS drugs from Roche and Merck. It is notable that, in that circumstance, Brazil successfully used the threat of compulsory licensing in price negotiations, without issuing a compulsory license. The development of public sector manufacturing capacity was substantial enough to determine successful negotiations with pharmaceutical companies.

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[91] R Castro Bernieri 'Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America' 9 Journal of World Intellectual Property 5, 2006, 548–572, at 553.

[92] See E Ghanotakis 'How the US Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries' 7 Journal of World Intellectual Property 4 (2004) 563–591.

Still, there are relatively few developing countries which are in the same position as Brazil, so the threat will lack credibility in most developing countries unless they are able to rely on imports from countries with the requisite capacity.

Importantly, developing countries are not the only to menace and adopt compulsory licenses. The United States obtained a drastic reduction in the price of stockpiled *Cipro* during the anthrax scare in 2001 by threatening to impose a compulsory license for government use.

X. INVESTMENTS, IP AND HUMAN RIGHTS

The provisions of investment agreements give extensive protection to the economic interests of the investors. Therefore concern arises that new investment regimes may override the human right to health by impairing the power of States to legislate in the field of access to essential medicines. Is this criticism right?

Indeed, in the absence of a conflict clause, some provisions of the FTAs in the pharmaceutical area can be seen as being at odds with the spirit of the Doha Declaration that clearly reaffirmed the right of WTO members to use the flexibilities of the TRIPS '*to promote access to medicines for all*'.[93] Thus, international investment agreements generate grey areas which may be used to challenge national measures even if they are TRIPS-consistent.

In a preliminary way, if it is true that FDI has the potential to generate growth and well-being, these results should not be given for granted: indeed, especially in the IP area, empirical studies have shown that benefits of a strict IP regulation are proportioned to the particular level of development of a given country. In other words, more stringent rules to protect IP are more beneficial to those countries which have already a given level of infrastructures.

As levels of development are not equal, IP regulation should reflect this reality.[94] Thus IP regulation should be at *variable geometry*, depending on different levels of development.[95] The TRIPS Agreement accounted for different levels of economic development in establishing transition arrangements. Accordingly, investment agreements which include IP obligations should provide for calibrated rules and gradual implementation, accordingly to the countries' developmental needs.

What is needed is a human rights impact assessment before ratifying any investment agreement, in order to shape their provisions in a manner compatible with human

[93] Doha Declaration on TRIPS and Public Health, paragraph 4.

[94] During the earlier stages of the industrial development cycle, for structural and cost reasons, the national interest lies in borrowing and imitating foreign technology. At a certain cross-over point, there are enough local innovators that the country's interest in protection begins to outweigh its interests in appropriation. See Keith E. Maskus *Intellectual Property Rights in the Global Economy*, Institute for International Economics, 2000, Ch 4.

[95] See Frederick M Abbott 'Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism' 8 JIEL 1, 77–100, at 77.

rights. This is not an entirely new idea, as something akin is well known in environmental law. Translating the concept of Environmental Impact Assessment (EIA) to the human rights sphere is a difficult but necessary task.

For instance, the Thai National Human Rights Commission prepared a human rights impact assessment of the FTA that Thailand was negotiating with the United States, concluding that it would have violated the human rights of Thai people.[96]

With regard to the IP regulation set out by IIAs, due consideration has to be paid to the specificities of the IP matter and, in particular, of pharmaceutical patents. While investment agreements generally tend to liberalize a given economy sector, their regulations in the IP area tend to create broader monopolies. In doing so, they may clash with public policy goals such as public health. Thus a more sensible balance needs to be introduced, according to parallel developments in the WTO context.

Intellectual property is a form of property, and thus, it has not an absolute character, but a social function. Adherence to principles of justice should prevent excessive uses of the IP system for commercial purposes. IP must remain tied to its socio-economic objectives.[97]

Thus, linkage bargaining diplomacy, taking into account only macroeconomics and not the specificities of a given sector—is not very suitable to IP regulation. With regard to macroeconomics, professor Straus has recently argued that: '*A country cannot demand access to the US market for agricultural products […], while at the same time demanding access to medicines developed within the United States at a lower price than the US population pays*.'[98]

This conception reflects the current state of the art. However, it may be questioned whether other solutions may be envisaged.

First, medicines are not mere investments. They also serve a social function being related to health and life. Thus, it is important to conceptualise pharmaceutical patents in a contextual perspective, taking into account not only their proprietary dimension, but also their impact on public health. Indeed, while it is generally recognized that at the macroeconomic level, linkage bargaining has positive effects, because it broadens the scope of negotiations and thus the total sum of different comparative advantages tends to be conspicuous, it may not be the best option at a legal level, at least for a very specific sector such as pharmaceuticals. Thus, this strategic sector would need an *ad hoc* consideration, and not to be balanced with other issues.

Second, pretending to adopt similar prices in different contexts, reflects a liberal

[96] See Sanya Smith 'Thai Human Rights Commission Attacks FTA with US' 6176 South-North Development Monitor January 25, 2007, available at http://www.bilaterals.org/article-print.php3?id_article=7012 accessed on 16 May 2007.

[97] See P Drahos *A Philosophy of Intellectual Property*, Dortmund 1996, p. 199 *et seq*.

[98] Joseph Straus 'The Impact of the New World Order on Economic Development: The Role of The Intellectual Property Rights System 6 The John Marshall Rev of Intellectual Property Law 1 (2006) 12.

conception of the principle of equality. It would be suitable to an ideal world where countries have the same contractual abilities and economic and political position. As a Roman poet once said, if there is a chicken and two persons, and one eats the chicken, the word *average* suggests that half a chicken was eaten by both although this does not necessarily correspond to reality.

Third, as proprietary knowledge governance in the pharmaceutical field has been severely criticized by both civil society and academics,[99] interesting proposals have been done to introduce a treaty on Medical Research and Development (hereinafter MRDT).[100] This draft treaty, currently under discussion at the WHO, would include both proprietary and non proprietary approaches to medical knowledge governance.

Crucially, besides providing state obligations for minimum levels of investment in medical research and development and incentives to support medical research and development,[101] the draft includes provisions that member countries reduce intellectual property protection in certain areas as to permit exceptions to patentability relating to certain open source medical databases, and increase flexibility in issuing compulsory licensing and in broadly interpreting research exception. In the light of these recent initiatives, the balance between protection of investors' intellectual property and equitable access to essential medicines needs to be rethought.

About the delicate issue whether compulsory licenses can be deemed to be a kind of indirect expropriation, no doubt that in economic terms, the compensation paid to the patent owner amounts to almost nothing *vis-à-vis* the normal retail price.

However, in legal terms, I would suggest a more balanced and holistic approach, interpreting regulatory measures as intrinsic limits to property. Compensation should be reduced in case of health emergencies. Importantly, the issuance of compulsory licenses should not be considered breach of patent, and consequently, breach of treaty, but as the concrete application of an abstract *special norm* provided by national and international IP laws.

XI. CONCLUSIONS

Investment agreements may strengthen investors' rights and affect the policy choices of Governments.

At the substantive level, investment agreements should not be considered as isolated from public international law. As investment law increasingly intersects with

[99] For instance, Joseph Stiglitz has commented that the structure of intellectual property rights has become so extreme that it is harmful to society and especially harmful to developing countries. See J Stiglitz *Globalization and Its Discontents* WW Norton and Company New York 2002.

[100] Medical Research and Development Treaty (MRDT) Discussion Draft 4, February 7, 2005, http://www.cptech.org/workingdrafts/rndtreaty4.pdf. On the 27th May 2006, the WHA adopted a milestone resolution (WHA59.24), establishing an intergovernmental working group open to all interested member states to develop a global plan on medical research and development.

[101] MRDT, Article 2.2.

other values, such as public health and human dignity, it is necessary to carefully rethink this relationship. In particular, a holistic approach is needed. International law should be interpreted as a whole, and synergy between different treaty regimes should be found,[102] according to customary rules of interpretation as restated by the Vienna Convention.[103]

Pursuant to those rules, treaty terms must be interpreted not only according to their strict textual meaning, but also in good faith, in context and in the light of their object and purpose.[104] Moreover, terms must be interpreted taking account of any relevant rules of international law applicable in the relations between the parties.[105]

In this regard, the UN Commission on Human Rights has called upon States, at the international level, to take steps '*to ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of […] health and that the application of international agreements is supportive of public health policies which promote broad access to […] pharmaceutical products*'.[106]

This new approach requires not only careful drafting by policy makers but also systemic interpretation by arbitral tribunals. Arbitrators should be expected '*to map the interactions between multiple sources of law*'.[107] Arbitral awards violating human rights and principles which represent an international consensus as to universal standards might be challenged on public policy grounds.[108]

Coherence is possible and desirable; *de iure condito*, several interpretative instruments are already available: *de iure condendo*, negotiations should not be linked to other trade-related issues, but should be furthered in an independent manner taking into account the right to health and human dignity. It is important that States maintain the flexibility to promote the right to health and to implement special measures to protect vulnerable or poor people. As a mere trade approach has proven to be ineffective, it is time to rethink access to medicine in a comprehensive manner. As Albert Einstein once wrote, '*We shall require a substantially new manner of thinking if mankind is to survive*'.[109]

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[102] For the debate about similar concerns in the WTO area, see for instance, Joost Pauwelyn, 'The Role of Public International Law in the WTO: How Far Can We Go?' (2001) 95 AJIL 535.
[103] Vienna Convention on the Law of Treaties adopted 22 May 1969, 1155 UNTS 331.
[104] Vienna Convention, Article 31.1.
[105] Vienna Convention, Article 31.3 (c).
[106] Commission on Human Rights Resolution 2003/29, Access to *Essential Medicines in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, (E/CN.4/2003/L.11/Add. 3), adopted on 22 April 2003.
[107] C Arup 'The 2004 United States-Australia Free Trade Agreement' (2004) Nordic J Int'l L 2.
[108] See New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, Article V.2.
[109] Albert Einstein *Ideas and Opinions*, Crown Publications, New York 1954.