ASIL Panel Proceedings

Session: Investment Chapters in Trade Agreements: IP rights as protected investments

(Consolidation of drafts transmitted to American Society of International Law on May 21, 2014 for incorporation in 2014 Proceedings) (F. Abbott, S. Sell & J. Reichman)

April 11, 2014

Frederick M. Abbott (Moderator's Introduction)

There is a long historical arc surrounding the question of host country protection of alien property. Traditionally there has been a distinction between trade agreements, on one side, and investor protection agreements on the other. The former were multilateral, regional or bilateral, while the latter were more typically bilateral. More recently, starting in the 1980s, there has been a trend toward incorporating investor and investment protection in bilateral, regional and plurilateral trade agreements. (There was a failed effort to conclude a Multilateral Agreement on Investment in the mid-1990s.) One of the earlier exemplars is the NAFTA, signed in December 1992, and entered into force on January 1, 1994. Within the United States, the approval process for the NAFTA involved the most politically contentious discourse surrounding a trade agreement during the past 50 years, at least.

Investment and investor protection is a key element of the NAFTA, situated in its Chapter Eleven. Chapter Eleven establishes standards of protection and provides for investor-to-state dispute settlement, based on diversity of nationality, under ICSID or UNCITRAL Rules, employing panels of arbitrators appointed by the parties through a prescribed process.[1] The NAFTA does not expressly refer to "intellectual property" in its definition of a protected "investment", but Article 1139(g) includes among defined investments "(g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes". Article 1110(7), in setting standards regarding expropriation and compensation states: "This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property)." Regarding the standard of protection to be provided by the host country, Article 1105(1) provides: "Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."

What is the standard of treatment prescribed by customary international law? To my mind, the best articulation of that standard is by the NAFTA Chapter Eleven arbitral panel in *Glamis Gold v. USA*, decided June 8, 2009, stating:

[1] See generally, Frederick M. Abbott, *The North American Free Trade Agreement (NAFTA): Structure, Dispute Settlement and Case Law*, VII MAX PLANCK ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW 776 (Rüdiger Wolfrum ed.) (Oxford 2012), < http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2080209>.

> "to violate the customary international law minimum standard of treatment codified in Article 1105 of the NAFTA, an act must be sufficiently egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons—so as to fall below accepted international standards and constitute a breach of Article 1105(1). The Tribunal notes that one aspect of evolution from *Neer* [*Neer v. Mexico*, 4 R. Int'l Arb. Awards, 60-62 (Oct. 15, 1926)] that is generally agreed upon is that bad faith is not required to find a violation of the fair and equitable treatment standard, but its presence is conclusive evidence of such. Thus, an act that is egregious or shocking may also evidence bad faith, but such bad faith is not necessary for the finding of a violation." (*Glamis Gold v. USA*, para. 616).

Eli Lilly, a US-based pharmaceutical company, has initiated a claim against Canada under UNCITRAL Rules alleging, principally, that the legal methodology developed by the Supreme Court of Canada in 2002 for assessing the criterion of utility, the "promise doctrine", and more specifically the "doctrine of sound prediction", violates customary international law and treaty law, and constitutes an unlawful expropriation. The claim specifically refers to decisions by Canadian federal courts invalidating Eli Lilly patents on the drugs Straterra and Zyprexa and demands $500 million in damages.

The doctrine of sound prediction, as articulated by Justice Binnie of the Canadian Supreme Court in *Apotex v. Wellcome*, [2002] 4 S.C.R. 153, provides that if a patent applicant has not "demonstrated" utility at the time of initial application (i.e., priority date), the application must disclose a sound prediction of utility that embodies three elements: (1) a factual basis for the prediction; (2) an articulable and sound line of reasoning at the time of the patent application from which the desired result can be inferred from the factual basis, and (3) proper disclosure, normally, a full, clear and exact description of the nature of the invention and the manner in which it can be practiced.

The question to be put to a NAFTA panel is whether that judicial doctrine is a violation of customary international law or the NAFTA text. Applying the standards of *Glamis Gold*, the question is whether its application is so egregious and shocking as to constitute a denial of fundamental justice.

This claim is the tip of a looming iceberg. Recent trade and investment agreements include intellectual property as protected subject matter, and the United States is proposing extensive intellectual property-related investor protection in the Trans Pacific Partnership (TPP) agreement and the Transatlantic Trade and Investment Partnership (TTIP). These proposals are now facing pushback from some TPP negotiating countries, from within the European Union with respect to the TTIP, and from civil society.

Questioning the subject matter scope of dispute settlement under NAFTA Chapter Eleven is not new. There have been a number of Chapter Eleven cases in which participating governments and civil society raised serious question whether the intent of the NAFTA parties was to allow such intrusion into areas of regulation characteristic of the exercise of national regulatory sovereignty. But, the claim brought by Eli Lilly appears to intrude into sovereign discretion at a newly deepened level -- questioning the considered opinion of the Canadian Supreme Court in interpreting patentability standards for which international rules allow considerable flexibility. A

NAFTA arbitral panel would essentially be acting as an ordinary court of appeal from the highest judicial authority established by the Canadian Constitution regarding a traditional matter of government regulation. It is extraordinarily difficult to make a case that there is an international legal standard regarding the criterion of utility that precludes the Canadian Supreme Court's doctrine of sound prediction. One might go so far as to say that the Canadian Supreme Court doctrine is an excellent model on which other countries should base assessments of utility.

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Susan K. Sell (Panelist Presentation)

The United States is pressing for Investor-State-Dispute-Settlement provisions in both the Trans-Pacific Partnership negotiations and the Transatlantic Trade and Investment Partnership. These provisions would permit investors directly to challenge states' policies and practices. As economic integration has proceeded apace trade negotiations have become less about tariffs and more about domestic regulation. This integration increasingly is reaching much deeper into the domestic regulatory arena and threatens to disrupt carefully and democratically developed domestic regulations.

With the expansion of intellectual property protection such provisions stand to disrupt regulations governing everything from public health, energy, finance, education, privacy, and free expression. Under these provisions investors can attack domestic social bargains and, if successful, override legitimate sovereign regulatory discretion. Recently the US-based firm Eli Lilly accused the Canadian government of indirect expropriation of Eli Lilly's patented drug because the Canadian government invalidated the patent. Tobacco firm Phillip Morris is suing the Australian government for trademark infringement for its policies mandating cigarette package labeling that seek to discourage smoking. There is a great deal at stake in these developments as they could give firms carte blanche to sue governments over laws that firms happen not to like. It could lead to an overlay of policy requirements above domestic law that sharply could constrain national policy discretion. It is a means to push for regulatory harmonization without going through a democratic process of debate and deliberation.

I will present three points and offer a brief conclusion. First of all, despite all the rhetoric of economic competitiveness, states are not firms. Second, the lack of transparency in so-called "trade

negotiations" (which in fact are really more about regulation than trade) creates opportunities for mischief and a profound lack of accountability regarding the substance of these agreements. Finally, states and firms have increasingly engaged in vertical forum shifting to achieve results that they know would be unacceptable if debated and considered openly and multilaterally. They increasingly are short-circuiting what many of us consider to be legitimate processes. Bad processes lead to bad outcomes. I will discuss each of these in turn.

States are not firms. Firms have it easy, especially in the US system of shareholder capitalism. They only have to worry about one thing – shareholder value. The bottom line is always to earn a profit and they have one clear goal – to increase shareholder value. Policymakers face a much more complicated array of issues and priorities. They are stewards of their constituencies and need to worry about health, safety, food, privacy, labor, and the environment (just to name a few). They engage in regulation in which they must balance conflicting priorities to satisfy diverse constituencies. States need to square the circle of global economic engagement with the domestic price that they have to pay. This is particularly the case in democracies.

Similarly, firms can treat intellectual property as a commodity – a thing to be bought, sold, licensed, withheld, or traded. Yet intellectual property is not real property; it is not like a hammer that can only be used by one person at a time. Intellectual property is a temporary monopoly privilege that the state grants to encourage both creation and dissemination of new knowledge. It is not a "right"; it is a privilege that the state may grant at its own discretion within the binding commitments that the state has made through the World Trade Organization and other agreements. Intellectual property is not a commodity in the traditional sense; it is a means to an end and not an end in itself. Historically all states have balanced these temporary privileges against public policy goals. For example, the United States refused to recognize foreign copyrights for many years to encourage the development of a literate public and an indigenous American literature. United States land-grant universities were founded to give away seeds to encourage the development of arable land to feed a rapidly growing population. Under the Agreement on Trade-Related Intellectual Property Rights, (TRIPS) states still have notable degrees of freedom to tailor their intellectual property regulations to fit their level of economic development, their pressing needs, and their comparative advantages in either imitation or innovation.

Several examples from public health help to illustrate this quest for balance and how firms relentlessly have challenged that balance. Eli Lilly's tactic is nothing new. When Nelson Mandela became President of South Africa, the government sought to address the medical apartheid of the previous regime. It passed a new medicines law that would permit South Africa to engage in parallel importation (perfectly legal under TRIPS) to acquire patented medicines at a lower cost. 39 US-based pharmaceutical firms, with the full backing of President Clinton, sued the South African government. South Africa was in the grips of the HIV/AIDS pandemic at the time and the backlash against the pharmaceutical firms was sharp. However, it was not until AIDS activists disrupted Vice-President Albert Gore's presidential campaign that the Clinton administration finally backed away from the firms' claims. In the Philippines a pharmaceutical firm sued two civil servants in their personal capacity, because they had approved regulations that the firm did not like (again, despite them being compliant with the government's obligations). Pharmaceutical firms have sued India multiple times in an effort to quash generic competition and expand their opportunities for "ever greening" (getting continual patent term extensions despite no new efficacy or active ingredients). The Indian Supreme Court has repeatedly upheld the validity of India's regulations for public health. In Thailand a well-respected American World

Health Organization employee, William Aldis, published an op-ed in the *Bangkok Times* in the midst of US-Thailand bilateral trade negotiations. Aldis warned the government that if Thailand agreed to the US terms on pharmaceutical, it would bankrupt Thailand's public health system. A subsequent World Bank analysis proved him to be correct. The US-based pharmaceutical firms went directly to the head of the World Health Organization to complain about Dr. Aldis, who was swiftly demoted and sent to a remote corner of India. Recently US pharmaceutical firms have continued to pressure India, and in late 2013 leaked documents revealed a PhRMA campaign to create an astro-turf (faux grass roots) campaign to get South Africa to stall the passage of a new medicines law designed to increase affordable access to medicines. This is, as Frederick Abbott indicates, just the tip of the iceberg that ISDS for intellectual property issues represents.

The non-transparency that characterizes contemporary so-called "trade negotiations" can be traced to the United States Trade Representative (USTR). As Margot Kaminski has pointed out, the USTR is unlike any other federal agency.[2] It is the least accountable of them all. The advisory committee structure assures that only one side in intellectual property debates has access to policymakers in USTR. Global firms have a privileged position in USTR and they relentlessly press for more rights. They dismiss any attendant obligations to the public at large and efforts to strike a balance between protection and dissemination. The USTR is an agency that cloaks itself in secrecy and is notorious for the revolving door to and from lucrative intellectual property lobbying jobs. This leads to unbalanced policy at the expense of the public interest. Consumers, Internet users, public health experts, privacy advocates and librarians (to name a few) are denied opportunities for meaningful input and influence. Asymmetrical access leads to lopsided policy; a flawed process is bound to result in flawed outcomes that cost the public a great deal. There is a profound democratic deficit in trade policymaking. Citizens and Congress have been shut out.

Finally, states and firms increasingly engage in vertical forum shifting. With increased public awareness of the stakes involved in intellectual property policies the United States has encountered more resistance to its demands in this regulatory arena. The HIV/AIDS pandemic was the first big public jolt in which millions of people understood the link between patents and high drug prices. More recently Internet users banded together to defeat two US domestic bills, the Stop Online Piracy Act (SOPA) and the Protect Intellectual Property Act (PIPA) that would have placed new limits on how users can access the Internet. Ironically the defeat of the US bills inspired the European Parliament to kill the US's plural-lateral Anti-Counterfeiting Trade Agreement (ACTA). The US-based firms, and the USTR that faithfully carries their water abroad, understand that they would not be able to achieve their ambitious goals in open, multilateral forums. The focus on public health and patents chased them out of the World Trade Organization, and the so-called Development Agenda chased them out of the World Intellectual Property Organization. WTO and WIPO no longer are hospitable forums for US firms to achieve their TRIPS-plus agenda. Thus they shift to plural-lateral, regional and bilateral forums either with "like-minded" parties or with weak states who are unable to resist economic coercion and promises of US investment. Most importantly the US knows that the world is becoming more multipolar with the rise of China, India, Brazil and other emerging middle-income countries. The US seeks to lock in its preferred intellectual property visions before it is too late for the US to call the shots. It is no surprise that these

[2] M. Kaminski, "The U.S. Trade Representative's (USTR's) Democracy Problem", (2012), 9 Suffolk Transnational Law Review, 519-551.

countries, that the US is most concerned about, are conspicuously absent from the Trans-Pacific Partnership negotiations. These countries are the very targets of all of the activity, including TTIP in which the US and EU can band together against these rising powers. The US hopes that if it can get enough countries to enroll in these stringent agreements that later countries like China and India will have no alternative but to jump on board.

In conclusion the current system is flawed in terms of process and substance. Rights holders continually complain about states' unwillingness to enforce stringent intellectual property provisions. But one should not reasonably expect enforcement of agreements under which the distribution of costs and benefits is so highly skewed. Nor should one expect enforcement of regulations that targeted publics had no say in, and that threaten to jeopardize domestic social and regulatory bargains that undermine objectives as fundamental as public health.

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Jerome H. Reichman (Panelist Presentation)

Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection

Patents on chemicals, pharmaceuticals, gene sequences, and computer programs all raise similar issues about what functional effects are actually being claimed, described and substantiated at the time of filing for patents. Because ground-breaking inventions are rare in these subject matter areas, would-be patentees are tempted to over promise on utility in order to avoid challenges sounding in obviousness. (Gold and Short (2014), at 4-5). The common policy at issue in all such cases is that patentees should not be allowed to "claim subject matter that goes beyond known or soundly predicted results on… [the] date of filing."[3]

Lately, this problem has arisen in connection with certain pharmaceutical patents in Canada, largely because the pharmaceutical companies try to evergreen prior patents by claiming that a small selection of a number of previously patented compounds provide a "substantial advantage" that merits new patent protection. The "promise of the patent" doctrine in Canada seeks to ensure that firms do not obtain a legal monopoly on the basis of speculative claims about increased utility–especially claims about therapeutic efficacy–that were unsubstantiated at the time of filing. Under this test, some of Eli Lilly's patented pharmaceutical products have been invalidated retroactively, notably, Strattera (a

[3] E. Richard Gold & Michael Short, *The Promise of the Patent in Canada and Around the World,*30 CANADIAN INTELLECTUAL PROPERTY REVIEW (forthcoming 2014).

medicine to treat attention-deficit hyperactivity (AHP)) and Zyprexa (a treatment for schizophrenia and related psychotic disorders). (Notice of Arbitration (2013), at 1.

After losing an appeal against these decisions before Canada's supreme Court, Eli Lilly filed a Notice of Arbitration against Canada under the North American Free Trade Agreement (NAFTA). Plaintiffs claim that, because Canada's "promise of the patent" doctrine of utility violates international minimum standards of patent protection set out in both NAFTA and the WTO TRIPS Agreement of 1994, judicial invalidation of their patents on these grounds constituted a de facto expropriation inconsistent with the investment protection provisions of NAFTA.

Plaintiff's Notice of Arbitration in the Eli Lilly Case against the Union of Canada raises so many specious claims that to answer them all would take an entire afternoon. I will do the best I can in 15 minutes. Let me add, by way of disclaimer, that I was a consultant for Canada in the case that the Canadian Supreme Court dismissed last year.

For example, the plaintiff's claim that Canada's "promise" doctrine of utility is some new, *ad hoc* creation of its courts and that no other country applies such an approach. Richard Gold and Michael Short (2014) demonstrate instead that the promise of the patent has a long history in Canadian and British (pre-1977) patent law, and that similar tests are used in other Commonwealth countries, notably Australia and New Zealand.

Gold and Short also show that the U.S. applies a parallel approach by combining the doctrine of utility with the test of enablement, even though the U.S. authorities are more tolerant of "me-too" drugs on the whole. Yet, in certain other respects, the U.S. utility doctrine of "specific and substantial utility"–adopted in 2005–can invalidate more biotech patents than Canada, which does not impose a "substantial utility" test. Looking ahead, if Canada's old "promise of the patent test" allegedly violates international law as adopted in the 1990s, why did the tightened utility doctrine adopted by the U.S. in 2005 not similarly violate international minimum standards of patent protection?

Gold and Short also show that the EPO follows a parallel approach by combining its peculiar definition of invention as "the solving of a technical problem" with the EPO's own test of industrial applicability. In the end, the EPO applicant must show that it has achieved a technical effect or solution that amounts to an industrial application, which means that the product must demonstrate actual therapeutic efficacy beyond that of existing drugs to merit a legal monopoly. (Gold and Short, at 44). And, of course, as many of you know, India adopts a similar test in Article 3(d) of its patent law, in order to exclude pharmaceutical derivatives lacking enhanced therapeutic efficacy as not constituting "inventions."

If, as Gold and Short demonstrate, Canada's 'promise of the patent' doctrine is neither new or idiosyncratic, we must ask how it could possibly violate international laws applicable to patented inventions, particularly the TRIPS Agreement of 1994, which is said to mirror the relevant provisions in NAFTA. The Plaintiffs most central claim is that Canada's approach violates the standard of utility set out in Article 27.1 of the TRIPS Agreement.

However, Art. 27.1 of TRIPS does not even use the term utility. It adopts the term "capable of industrial application" and, in a footnote, states that the term "capable of industrial application may be deemed by a Member to be synonymous with the term useful." But the text does not claim they are the same, and research shows they are, in fact different. States must use one or the other approach, but they are not the same. (See Gold and Short (2014))

More importantly, neither TRIPS nor any other international agreement attempts to establish the substantive content of industrial applicability (utility), or for that matter, of novelty and nonobviousness. The reason is that there is no consensus on how to apply these doctrines: state practices differ. What we find here are open-ended standards, not rules, whose content continues to evolve over time.

For example, we saw that, in 2005 the United States changed its utility criterion to "specific and substantial utility" to address overly broad claims in biotech patents. Similarly, the U.S. Supreme Court has repeatedly elevated the nonobvious standard since 1995, and it recently disqualified patents on some forms of isolated or purified DNA as patentable subject matter. The U.S. Supreme Court may invalidate more business method patents that rely on computerized applications for their novelty.

All these and other approaches are valid precisely because there is no consensus on how to apply the novelty, nonobviousness and utility standards of Article 27.1. To limit state flexibility under Art. 27.1, we would need to negotiate and adopt uniform standards under the proposed Substantive Patent Law Treaty (SPLT) at WIPO, which Rochelle Dreyfus and I criticized in 2007.[4] But there is no consensus, and these negotiations broke down years ago.

In the absence of a consensus on the SPLT, there is no uniform or implicit standard of utility under TRIPS, other than the duty to implement treaty obligations in good faith. There are a lot of different state practices, which as we have seen, continue to evolve. These practices are covered by the language of Article 1.1 of TRIPS, which expressly preserves states' sovereignty in this regard:

> "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

This space reserved for state sovereignty is further strengthened by the WTO's Understanding on the Settlement of Disputes (DSU), Art. 19.2, which declares that WTO panels and the Appellate Body in their findings and recommendations "cannot add to or diminish the rights and obligations provided for in the covered agreements." The WTO Appellate Body has chastised a panel for deviating from these norms in the *India Mailbox Case* of 1997.[5]

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[4] Jerome H. Reichman & Rochelle Cooper Dreyfus, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty,* 57 Duke L. J. 85 (2007)

[5] WTO Appellate Body, India—Patent Protection for Pharmaceutical and Agricultural Chemical Products (1997) WT/DS/50/AB/R at ¶¶ 47-48; *see* Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After U.S. v. India*, 4 J. INT'L ECON. L. 588 (1998)

The reasoning is clear: in the trade context, there can be no unbargained-for trade concessions. Hence, the WTO Appellate Body says there can only be explicit obligations set out within the text of the TRIPS Agreement. The space for internal sovereignty concerning the implementation of eligibility standards is further strengthened under TRIPS Arts. 7-8, viz:

TRIPS (Part I) Article 7—Objectives

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

TRIPS (Part I) Article 8—Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

More recently, the force of these safeguard provisions was further strengthened by the Doha Declaration on TRIPS and Public Health, especially ¶4:

> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we affirm the right of WTO members to use, to the full, the provisions of the TRIPS Agreement which provide flexibility for this purpose.[6]

These provisions show that TRIPS does not impose uniform law in any manner or shape. It established barely harmonized international minimum standards of protection that, in the absence of any Agreed Statement or official Acts, WTO members continue to apply differently in their respective efforts to adapt nineteenth century patent law to twenty-first century innovations.

Nor does the application of Canada's utility doctrine discriminate against pharmaceuticals under Art. 27.1. As Gold and Short show, that doctrine has always been applied to different subject matters in Canada and other countries for a long period of time. Besides, the nondiscrimination doctrine does not prevent reasonable differentiation when applying patent eligibility standards to different subject matters. On this issue, see the Max Planck Declaration on Principles of International Patent Protection

[6] *See generally* Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy Under the Amended TRIPS Provisions,*10 J. INT'L ECON. L. 921 (2007)

(2014), signed by some fifty or more distinguished law professors from all major countries and continents.

Against this background, we are asked to believe that the investment protection provisions of NAFTA, drafted in the mid-1990s, somehow overruled or froze the intellectual property provisions otherwise embodied in TRIPS and NAFTA. This claim is preposterous on its face.

It would mean, among other things, that every decision by the U.S. Supreme Court or the Canadian Courts that changes the application of domestic eligibility standards is potentially *ultra vires* because those whose patents were adversely affected somehow have claims under the investment provisions of NAFTA. On what possible authority could the negotiators have agreed to freeze U.S. or Canadian intellectual property laws when the intellectual property provisions of the same treaties proclaim a totally different message, a message of reserved power of sovereignty over these same issues on which U.S. state practice has consistently relied?

Historically, investment protection laws bear on the conditions surrounding potential loss of specific investments by specific foreign investors in a host country. These laws may modify the general principles of customary public international law as applied to the expropriation of aliens' property as a *quid pro quo* for inducing particular aliens to invest in particular projects within the foreign host country.

Eli Lilly has made no specific investments in Canada pertaining to the drugs in question nor has it negotiated any specific investment deals bearing on the facts of these cases. The only test of the patent standards applied by Canada or the U.S. under international law is whether or not they conform to TRIPS and the related international minimum standards embodied in the parallel intellectual property provisions of NAFTA, which they do. Implementing these standards cannot be treated as an illegal expropriation under any existing investment treaties, although certain pending investment treaties, if adopted as proposed, could unwisely move in this direction.

To claim that the investment provisions in NAFTA froze the international patent standards of TRIPS is to say that all the patent laws in U.S., Canada, and elsewhere since the 1990s that have tightened patent eligibility standards to obtain better quality patents were illegal. That is tantamount to saying that the investment treaties were devised primarily to benefit patent trolls. Any attempt to freeze the intellectual property standards retroactively via a doctrine of estoppel under the investment treaties would constitute an abuse of the investment provisions themselves, one that would not withstand judicial scrutiny.

The hard truth that Big Pharma cannot swallow is that U.S. patent law did not become global law under TRIPS, and that the U.S. cannot prescribe universal patent standards for the rest of the world any more than France could prescribe uniform patent law in 1883, when the Paris Convention was first negotiated. Since TRIPS in 1994, there is, for the first time, a barely harmonized set of international minimum standards of eligibility. However, there is no duty to harmonize (despite scandalous "expert testimony" before the Canadian Supreme Court to the contrary).

Under both TRIPS and NAFTA, instead, there is built in flexibility to implement patent eligibility standards in each WTO Members' domestic laws so as to advance the states' own technological and economic development needs.[7] No huffing and puffing about investment treaties will change these facts of life under international law as currently adopted.

[7] *See, e.g.*, Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries lead or Follow?* 46 HOUSTON L. REV. 1115 (2009) (Symposium Issue).