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Heiko Baumgärtner

## **Patents, Power, and Rhetoric: Intellectual Property Rights and the Politics of Regime Complexity**



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With its working paper series “Glocal governance and democracy” the Institute of Political Science at the University of Lucerne provides the opportunity to present conceptual ideas, normative debates and empirical findings regarding current political transformations of the modern state system. The term “glocalization” addresses key transformations in respect to levels of governance and democracy – multiplication and hybridization. These features can also be observed in the processes of horizontal interpenetration and structural overlaps among territorial units (transnationalization), in new forms of steering with actors from the private, the public and the non-profit sector (governance), in the interferences among functional regimes and discourses and in emerging new communities and networks between metropolitan centres and peripheries on various scales. One of our core themes is migration and its consequences for development, transnational integration and democracy. A second field of research and discussion is governance and democracy in functionally differentiated and multi-level systems.

Heiko Baumgärtner was an academic assistant and PhD student at the Department of Political Science of the University of Lucerne and a visiting scholar at George Washington University in 2009/2010. He passed away unexpectedly on 24.12.2010.

**Contact:**

University of Lucerne  
Faculty of Humanities and Social Sciences  
Department of Political Science  
Frohburgstrasse 3  
Postfach 4466  
6002 Lucerne

T +41 41 229 55 91

F +41 41 229 55 85

E-Mail: [polsem@unilu.ch](mailto:polsem@unilu.ch)

**Abstract**

The contemporary governance of intellectual property rights (IPRs) is an important illustration of how dense regime complexity shapes international politics. In particular, it enables a strategy of “forum shifting,” whereby states, NGOs, and multinational companies move issues and agendas to those venues that are most closely aligned with their interests and priorities. This article looks into the multifaceted nature of these dynamics by analyzing the “North-South” politics of two of the most critical areas of IP intersection – patents on medicines, and IPRs in biogenetic resources and associated traditional knowledge.

I shall argue that developing countries have “prevailed” in each of these conflicts not by securing rules that they desire, but by preserving more policy space for implementing IPRs than the U.S. and the European Communities were willing to concede. This finding poses a puzzle for realism – the most pertinent and developed approach on regime complexity. I therefore advance an argument that combines a focus on the institutional set-up of regime complexes with ideational variables derived from a frame-analytic perspective. Such an approach reveals how developing countries and supportive NGOs raised the legitimacy costs of acting on a maximalist IP agenda by deploying rules and rhetoric developed in more hospitable institutional settings, such as the CBD (Convention on Biological Diversity), the WHO (World Health Organization) and various U.N. human rights bodies.

## Introduction

The regime governing intellectual property rights (IPRs) is a prominent example reflecting the mounting pressures of legalization on processes of institutional change. Due to the rapid pace of enabling technologies and the concomitant expansion of international intellectual property (IP) protection frameworks the regime has gradually evolved into a “regime complex,” with a plethora of actors, institutions, and issues involved in the IP law-making process (Raustiala 2006-07; Yu 2007). The gravitational centerpiece of this complex governance system is the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an outcome of the Uruguay Round establishing the World Trade Organization (WTO).<sup>1</sup>

The conclusion of the TRIPS Agreement marked a watershed in the evolution of international IP law. When this controversial Agreement entered into force in 1995 it ushered in a set of detailed and comprehensive IP minimum standards that dramatically strengthened protection for IP rights holders. Yet TRIPS did not set an end to the drive towards global upward harmonization. Soon after its inception, multinational companies and their supportive home governments began to push for a *TRIPS-plus agenda* aimed at raising standards beyond the requirements set out in the Agreement (Deere 2009). To do so, they pursued their agenda at all levels and in all venues. This holds true for their shift back to the World Intellectual Property Organization (WIPO) as well as the proposed Anti-Counterfeiting Trade Agreement (ACTA); yet, it most clearly shows up in the ongoing proliferation of bilateral and regional trade agreements (RBFTAs).

Less developed countries and supportive NGOs countered these moves by pursuing a development-oriented IP agenda (Helfer 2004; Yu 2009). They increasingly relied on environmental and human rights regimes in order to defend TRIPS “flexibilities” or even roll back what they perceived as the most egregious treaty terms.<sup>2</sup> Their activities boosted IP work programs in venues other than the WTO and WIPO, including the Convention on Biological Diversity (CBD), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the Food and Agricultural Organization (FAO), the World Health Organization (WHO), or various U.N. human rights bodies (Gurry 2004).

In this article, I examine the “North-South” dynamics of regime complexity in two of the most critical areas of IP governance – patents on pharmaceuticals, and IPRs in biogenetic resources and associated traditional knowledge (TK). To do so, I develop my own ideationist approach against realism. Realism focuses on the effects of power, while ideationism focuses on the interplay of rules and rhetoric. According to realism, regime complexity enhances the capacity of rich countries to set unequal norms in the property of knowledge. However, such a perspective cannot entirely explain how public health- and biodiversity-related IPRs have come to be institutionalized the way they have. Indeed, careful analysis of the interdependent implementation of regimes reveals that materially weak actors were surprisingly effective in slowing down and even halt the progressive institutionalization of TRIPS-plus policies – albeit with a greater degree of success in public health than in biodiversity. The *central research questions* of this article, then, are: How

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<sup>1</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights*. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round, Vol. 31, ILM 81 (1994) [hereinafter TRIPS].

<sup>2</sup> The term “TRIPS flexibility” denotes domains of IP law that may be adjusted, consistently with TRIPS, to respond to local context and priorities. See World Trade Organization, *Ministerial Declaration of 14 November 2001*, paras. 4-5(a)-(d), WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) (explicitly using this term and listing some public health-related flexibilities, such as compulsory licensing or parallel import).

and why did weak actor coalitions succeed in shifting public health and biodiversity-related IPRs towards more balanced outcomes? And why have weak actors been more successful in favorably shaping the balance between incentives and access in the realm of public health than in biodiversity?

Addressing this research puzzle defies any one parsimonious explanation. In this article, I argue that “rhetorical norm manipulation” – the strategic deployment of competing rules and rhetoric – explains variation within and across the two cases. What we see is that within a broad set of structural constraints that is determined by the distribution of resources, weak actors were able to shape the global patent agenda by deploying competing rules and rhetoric. In the following, I will expound the structure of my argument. The first part highlights the background of the study and summarizes the conflicts surrounding public health- and biodiversity-related IPRs. The second part sets out to outline a power-based perspective and substantiates the claim that realism alone cannot sufficiently explain the institutionalization of public health- and biodiversity-related IPRs. In the final part, I present my own ideationist argument on rhetorical norm manipulation and conclude with a critical reflection on the strengths and limits of such an approach.

Before proceeding, a short caveat is in order. Throughout this article, I tend to treat poor and rich countries as a homogenous block. Doing so is problematic, to say the least, and may invite reasonable objections. To be sure, not all rich nations spread the gospel of TRIPS-plus policies, nor are all poor countries unified in their quest to roll back IP protection. For example, due to internal variations in industrial development across sectors many transitional economies do not have a coherent national IP approach at all. However, notwithstanding these observations, there exist basic underlying cleavages in the area of patents based on the asymmetrical distribution of wealth. It is in a “North-South” context that differing perspectives over the legitimacy of public health- and biodiversity-related IPRs arise; and these tensions provide the fuel for endemic and persistent conflicts fought out within an increasingly complex system of overlapping institutions.

### **Background of the Study: Density and Conflict in the Intellectual Property Rights Regime**

Early formulations of regime theory have acknowledged that regimes are typically upheld by a network of legal instruments and customary rules: indeed, the classical definition developed by Stephen Krasner defines regimes as “principles, norms, rules, and procedures, around which actors expectations converge *within a given issue area*” (Krasner 1983, 3, emphasis added). The association of regimes with specific issue areas turned out to be important for the analysis, since it permits a reasonably clear delimitation (Stokke 2001, 2). Yet, due to the pressures mounting from the proliferation of hard- and soft-law rules an increasing number of issues do no longer fall within the purview of one single regime (Leebron 2002, 7). Instead, they arise at the intersection of two or more *overlapping regimes*. For instance, the issue of access to medicines is subject to competing concerns in three major regimes, including those governing liberalized trade, patent rights protection, public health, and human rights (Shaffer 2004). The presence of such dense areas of regime complexity gives rise to patterns of interplay between the elementary regimes involved – that is, they affect each other’s formation, operation, development and effectiveness.

Today, research on regime interplay has emerged as a major agenda item for international relations theory.<sup>3</sup> Yet for all that has been written on the topic, *theoretical knowledge*

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<sup>3</sup> Oran Young and his colleagues pioneered efforts in this regard. See (King 1997; Young 1996, 1999 [2005]). This initial conceptual work was extended by the Norwegian scholars

remains sharply limited. Some scholars have therefore called for giving greater consideration to the causal mechanisms driving regime interplay (Gehring and Oberthür 2009; Shaffer and Pollack 2009). In this analysis, I expand on the conceptual lens of “regime complexity” to analyze regime density and the resultant interplay (Alter and Meunier 2009; Raustiala and Victor 2004). According to Kal Raustiala and David Victor, a regime complex can be defined as “a collective of partially overlapping and even inconsistent regimes that are not hierarchically ordered, and which lack a centralized decisionmaker or adjudicator” (Raustiala and Victor 2004, 279). In contrast to single regimes which are marked by high levels of normative coherence, regime complexes are laden with conflicts among the non-hierarchically ordered elemental regimes.

### ***The Origins of IP regime complexity***

The domain of IPRs has not been immune to density and conflicts (Raustiala 2006-07, 1025). Once limited to a set of relatively weak treaties, in the past two decades the regime has been transformed by a dense array of new institutions and agreements that dramatically expanded IP law.<sup>4</sup> In 1995, TRIPS introduced IP “minimum standards” far beyond the then-existing level in most developing countries. Perhaps most important for present purposes, TRIPS requires all WTO member states to make available product patents of twenty years “in all fields of technology,” thereby reducing countries’ discretion in excluding, as a matter of public policy concern, different classes of goods from patent protection. Further, TRIPS sharply circumscribes the conditions under which countries may issue compulsory licenses. Unlike most other international law, TRIPS is binding *and* enforceable. Noncompliance with TRIPS can trigger meaningful sanctions through the “hard-edged” dispute-settlement mechanism of the WTO. However, the expansion of international IP law did not stop with TRIPS.

Indeed, the U.S., EU, and their IP-based companies have always regarded “TRIPS as a floor, not a ceiling” (Esper 2010) – a dynamic platform from which to “ratchet up TRIPS standards, to eliminate TRIPS flexibilities and close TRIPS loopholes” (Sell 2007, 59). With the WTO stalled, they have embarked on the bilateral and regional route pressing their less developed counterparts into trade, investment, and IP agreements that all contain “TRIPS-plus” provisions.<sup>5</sup> Developed countries have also advanced new law-making initiatives in WIPO thereby pushing the organization back to the forefront of global IP policy-making (May 2006; Musungu and Dufield 2003).<sup>6</sup> The latest and potentially most important example of such an initiative is a proposed criminal enforcement treaty – the Anti-Counterfeiting Trade Agreement (ACTA) – which will further expand the substantive scope

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associated with the Fridtjof Nansen Institute (Andersen 2002; Rosendal 2001; Stokke 2001) – and the German scholars Thomas Gehring and Sebastian Oberthür (Oberthür 2001; Oberthür and Gehring 2006).<sup>3</sup> The political science analysis is complemented by a growing legal scholarship. See (Alvarez 2001; Brown Weiss 1993; Chambers 2001; ILC 2002; Pauwelyn 2004; Wolfrum and Matz 2003).

<sup>4</sup> See, generally, (Gurry 2004; Helfer 2004, 2009; Raustiala 2006-07; Sell 2009). On forum proliferation in the IP regime complex, see (Latif 2005; May 2006).

<sup>5</sup> The notion of “TRIPS-plus” refers to provisions that (i) extend IPRs to new kinds of subject matter; (ii) eliminate or narrow permitted exceptions; (iii) extend protection terms; (iv) introduce TRIPS mandated rules earlier than the transition periods; and (v) ratify new WIPO treaties.

<sup>6</sup> See, for example, World Intellectual Property Organization Copyright Treaty, Dec. 20, 1996, 36 I.L.M. 65 (1997); World Intellectual Property Organization Performances and Phonograms Treaty, Dec. 20, 1996, 36 I.L.M. 76 (1997).

of IP, even though enforcement norms are usually considered procedural (McManis 2009).

Taken together, these developments have strengthened the international IP system to a hitherto unprecedented extent. However, the expansion has also made the regime relevant to a wide array of value-laden issues governed by other public policy regimes (Helfer 2004; Maskus and Reichman 2004). Indeed, whether one looks into the domains of biodiversity, biotechnology, food and agriculture, public health, cultural self-determination, education, or the Internet and media sector, we are bound to encounter dense spaces of “TRIPS and ...” overlap where the commercial agenda of IP creates tensions with the norms contained in other regimes. Two of the politically most contested areas of IP intersection are public health- and biodiversity-related IPRs.

### ***Regime conflicts over public health and biodiversity-related IPRs***

Substantive tensions between TRIPS and the public health regime revolve around the issue of access to medicines and the right to issue compulsory licenses. Stemming from the implementation of TRIPS are incentives for business activity that threaten the progressive realization of the right to health and the corresponding duty of states to facilitate access to medicines (Hestermeyer 2007; Wohan 2001/02).<sup>7</sup> Perhaps most importantly, the availability of product patents on drugs leads to an upward pressure on prices (CIPR 2002, 37). The product patent standards, demanded by TRIPS, are designed to ensure that drug companies can obtain effective monopolies over products thereby excluding generic competition for a limited period of time. The granting of such exclusive ownership rights is believed to spur medical innovation.<sup>8</sup> Yet, the flip side of this monopoly-based model is that in order to recoup their controversially estimated R&D investments and to make profits on top, companies rely on charging excessively high drug prices (UNDP 1999).<sup>9</sup> In so doing, however, they threaten access to life-saving medicines, including HIV/AIDS treatment, for millions of people living in resource-poor settings.

This holds true even if we accept the controversial claim that anti-retroviral drugs (ARVs) are still not extensively patented throughout the countries hit hardest by the AIDS crisis (Attaran and Gellespie-White 2001). Indeed, most developing countries lack sufficient manufacturing capacity for high-quality drugs and therefore depend on expensive drug imports from jurisdictions affected by the TRIPS. For many years, this problem could be attenuated by the availability of cheap donor-funded generic ARVs from India (Waning et al. 2010). However, the implementation of TRIPS in India since January 2005, which required the re-introduction of product patents, now effectively precludes this possibility for newer generations of ARVs (Shadlen 2007). Yet as most new ARVs are patented worldwide, the only way to manufacture generic versions of them and, hence, bring prices down

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<sup>7</sup> The right to “the enjoyment of the highest attainable standards of health” (right to health) is recognized in the Preamble of the Constitution of the WHO, signed July 22, 1946. It is further expressed in a number of human rights treaties, among them art. 25 of the Universal Declaration of Human Rights, G.A. Res. 217A (III), at 71, U.N. Doc. A/810 (December 10, 1948) (UDHR) as well as art. 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), G.A. Res. 2200 (XXI) (December 16, 1966).

<sup>8</sup> Nevertheless, there are voices questioning this mechanism as a whole (Love 2001; Love and Hubbard 2007).

<sup>9</sup> Drug discovery is a costly process. According to pharmaceutical companies, R&D of a successful drug costs between 800 million to one billion USD (PhRMA 2007, at 10). Yet, these figures include the cost of success and failure, and for capital, and have been criticized as inflated (Young and Surrusco 2001).

is either through voluntary or compulsory licensing.<sup>10</sup> And indeed, TRIPS provides for a framework allowing states to enact this instrument in order to protect public health needs (Oxfam 2006). However, enormous external pressure from the U.S. and EU discouraged many developing countries from taking advantage of this option (t'Hoen 2009, 69ff).

A second fundamental patent barrier to access is the lack of R&D into diseases disproportionately affecting poor countries (so-called 'Type III-diseases') (WHA 2003). In fact, the "push and pull" mechanisms of global health markets skew research priorities of the pharmaceutical industry away from poor countries towards those with the greatest purchasing power, not medical need (Dhanarajan 2010; Rai and Eisenberg 2003). Specifically, problems typically inherent to middle- and high-income countries are prioritized over diseases that disproportionately affect the poor, such as tuberculosis or malaria (MSF 2001; WHO 1996). As a consequence, the situation in global health is characterized by a "10/90 gap" whereas 90 percent of the burden of global diseases is shouldered by a population to whom only 10 percent of R&D is directed (GFHR 2002).

Substantive tensions between access and patents are not confined to the area public health, however. They also arise at the intersection of TRIPS and the Convention on Biological Diversity (CBD) (Andersen 2002; Rosendal 2001).<sup>11</sup> The potential for disruptive effects in the TRIPS/CBD overlap is primarily the result of the fact that each regime pursues divergent policy objectives. One of the core objectives of the CBD is to implement "access and benefit sharing" (ABS) (Ten Kate and Laird 1999; Tvedt and Young 2007) – a mechanism to address research-based companies that use genetic resources as well as countries and indigenous communities from which these resources origin.<sup>12</sup> Article 15 reflects this quid pro quo arrangement. Provider countries commit themselves to enable access to genetic resources (art. 15.2). Yet the Convention also endows countries with *sovereignty* over genetic resources (art. 15.1) and recognizes the idea of communal knowledge (art. 8j).<sup>13</sup> This sets governments into a position to demand the sharing of benefits arising from biotechnology R&D (arts. 1, 15) and/or to transfer proprietary technology (art. 16).

Conversely, TRIPS is predominantly geared towards user-related concerns, i.e. the granting of *private* property rights as a means to control biotechnologies (Safrin 2004). To be sure, article 27.3 (b) of the Agreement contains important exceptions to patentable subject matter in biodiversity thereby providing countries discretion to enact laws according to their cultural or socio-economic interests. Nonetheless, TRIPS clearly extends patent protection to micro-organisms and requires countries to introduce some form of protection for plant varieties. This extension sets TRIPS in direct conflict to the sovereign rights countries enjoy under the CBD (Chambers 2008, 114). It further runs counter to the idea of communal ownership rights. First, corporate monopolies and control over seeds and seed choices potentially threaten the agricultural practices and livelihoods of small-scale farmers thereby undermining the realization of "farmers' rights" (Barton and Berger 2001).

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<sup>10</sup> See TRIPS, arts. 13, 17, 26.2, 30 & 31, arts. 41-61. Compulsory licensing enables a competent authority to license the use of a patented invention to a third-party without the consent of the patent-holder when such production is warranted by public interest.

<sup>11</sup> Convention on Biological Diversity, June 5, 1992, U.N. Doc. UNEP/Bio.Div./N7-INC5/4, 31 I.L.M. 818 [<http://www.cbd.int/doc/legal/cbd-un-en.pdf>] Rev. 09-04-2008.

<sup>12</sup> Genetic resources are the elements of biological diversity containing hereditary qualities and are of actual or potential economic value.

<sup>13</sup> In the context of the FAO, communal rights find their expression in the loosely defined concept of "farmers' rights." See Farmers' Rights, Res. 5/89, FAO Conference, 25<sup>th</sup> session (1989). Available at [<ftp://ftp.fao.org/ag/cgrfa/Res/C5-89E.pdf>] Rev. 12-12-2009.



Second, since patents grant exclusive rights to only some of those who have contributed to the benefit, TRIPS can hardly serve the objective of *equitable* sharing (Chasek 1999; Correa 2008; Görg and Brand 2006). Natural products R&D is a long and costly business and local communities have neither the technological nor financial capacity to engage in this process. Thus, the valuable utilization of genetic resources, which may result in the development of patentable drug discoveries, is usually carried out by large transnational companies. The majority of developing countries have however not enacted a legal framework that would ensure that genetic resources have been acquired in compliance with the CBD or national access legislation (UNU-IAS 2003). Perhaps more controversially, many of the patented products which are then placed on sale for high prices in the genetic marketplace strongly build on the collectively owned traditional knowledge and practices of farmers or indigenous people. As a result, companies have been accused of expropriating their knowledge without authorization and compensation – an act which has been condemned by activists as *biopiracy* (Shiva 1997).

Such substantive tensions over public health- and biodiversity-related IPRs are further enhanced by the procedural asymmetries resulting from the WTO's more stringent enforcement system. Indeed, as for the governance of "trade-related" IPRs, the WTO provides a unique and rigorous framework whereby treaty bargains can be enforced through mandatory dispute settlement which may lead to retaliatory trade sanctions. The anticipation of such sanctions may set incentives for countries to give priority to IPRs in cases where the norms contained in regimes with lesser degrees of legalization run counter to TRIPS. In principle, overlapping treaty rules may be equal on a normative level (Pauwelyn 2004, 535-8).<sup>14</sup> In reality, however, the WTO's strong dispute settlement mechanism sets TRIPS into a position of *factual hierarchy* vis-à-vis U.N.-based regimes (Kelly 2006; Okejidi 2008).<sup>15</sup>

### The "North-South" Dynamics of IP Regime Complexity

It is in the context of these 'regime encounters' (Chon 2006) that the "North-South" *politics* of public health- and biodiversity-related IPRs arise. In fact, due to their structural positioning in each policy field, developed and developing countries have fundamental different perspectives over how to prioritize the colliding regime objectives. The cross-regime conflicts outlined above have therefore not appeared accidentally (Andersen 2008, 37). Rather, they are reflective of and, at the same time, fuelled by some sort of "forum shifting" behavior – a strategic move whereby actors use different regimes "to create inconsistency with another in the hope of shifting the understanding or actual adoption of rules into a particular direction" (see generally Braithwaite and Drahos 2000; Helfer 2004; Shaffer and Pollack 2009, 738-9). For instance, the TRIPS/CBD overlap can be interpreted as an attempt by some well-organized developed countries to circumvent the unfavorable norms stemming from the CBD by securing their interests in the arguably "harder" law of the TRIPS Agreement (Rosendal 2001).<sup>16</sup> Thus, negotiation parties were well aware that

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<sup>14</sup> See Vienna Convention on the Law of Treaties, 11 U.N.T.S. 331 (May 23, 1968).

<sup>15</sup> The consequences of this procedural imbalance can be quite profound. In the field of pharmaceuticals, for example, WTO Panels have tended to interpret the TRIPS consistency of IP laws and practices very rigidly. See, for example, (WTO 2000). This approach may have further discouraged developing countries from interpreting their options under TRIPS in a more flexible manner (Dinwoodie and Dreyfuss 2004).

<sup>16</sup> On the distinction between "hard" and "soft law," see (Abbott and Snidal 2000) (measuring the "hardness" of law along the dimensions of obligation, precision, and delegation).

there is potential for conflict but deliberately forged obstructive issue linkages to bolster their bargaining position in the implementation game (Sebenius 1983).<sup>17</sup>

Overall, regime complexity raises a host of intriguing questions none of which have been fully explored yet. For example, does institutional fragmentation raise barriers to developing country participation, i.e. favor the rules supported by materially strong actors? Or, can the presence of a complex institutional environment enhance the quality of developing country participation, i.e. favor weak parties' objectives? And, which set of rules – or groups of actors – lends ultimate authority and legitimacy on the use and distribution of medicinal products and/or transactions in genetic resources and associated TK? Current scholarship on IP regime complexity, as on this phenomenon more generally, does not point into a single direction (Alter and Meunier 2009, 14). In fact, the very concept of “winning” and “losing” in regime complexes becomes murky as actors can proclaim victory in one regime while being on the losing side in another (Sell 2009). What we therefore need is a better understanding of *the conditions under which regime complexity reinforces or undermines the institutional logic*. The next section looks at two theoretical perspectives that bring different tools and emphases to bear to answer this question.

### ***Realism: The power politics of IP regime complexity***

Realists have come forward with the most developed and pertinent approach to analyzing regime complexity (see, in particular, Drezner 2007). They posit that the prospects for international cooperation in dense regime environments cannot be understood without theorizing both *distributive conflicts* and *the role of state power to decide these conflicts* (Krasner 1991).

In applying these insights to the “North-South” politics of public health- and biodiversity-related IPRs, the first thing realists therefore emphasize is that the metaphor of a prisoner’s dilemma – and the underlying assumption of common interest – may not be adequate to analyzing the subject matter at hand (Shadlen 2009, 4). As many scholars point out, “behind the border issues” such as IPRs have very different political implications for economic development and, thus, inter-state politics than standard issues of trade (Gruber 2000; Mattli and Büthe 2003). For example, the sort of health-related IPRs promoted by developed countries are highly unlikely to be embraced by less developed countries (Gerhart 2004). In the subsequent sections, I shall explain these underlying cleavages in more detail. For now, it is sufficient to say that strategic interactions in the IP issue area are far better understood if regarded through the lens of a “Battle of the Sexes” game. The key point here is that states, while sharing a *common* interest in cooperation, have actually *different* interests over the distribution of costs and benefits arising from cooperation (Stein 1983). Each country group gains differently from various regime arrangements and the distributive conflict comes center stage.

Given such conditions, the expectations of realism are rather simple and straightforward: states that have more capabilities in an issue area, and thus power, will determine where

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<sup>17</sup> This study highlights aspects where actors purposefully advocate rules that conflict with those of other regimes. However, I note that both cases may also be interpreted in a different manner. For example, both the TRIPS and the CBD agreement have been negotiated by delegations including specialized ministries. Thus, colliding objectives may also reflect inter-departmental rifts within states (Chambers 2008, 51; Pauwelyn 2003, 15-6; Saez 2010). Further, business actors can enroll states on their behalf or set up their own private regimes with similarly situated groups in foreign countries in order to impose externalities on their governments and rival domestic groups (Benvenisti 1999, 169; Shaffer 2010, 151).

ultimate regime authority rests. Structural leadership is the mechanism that translates capabilities into bargaining power and effective control over outcomes (Young 1989). In dense policy spaces, forum shifting strategies are the predominant form through which structural leadership is carried out (Drezner 2007, 63-4). In the context of the overall bargaining game, forum shifting functions as a “coordination suppression strategy” by which strong actors strip developing countries off their ability “to engage in the logrolling that is necessary for them to bargain more effectively with powerful states” (Benvenisti and Downs 2007, 597). In this vein, they can isolate single states or country groups until they eventually succumb (Steinberg 2002). The proposition here is, of course, that the objectives primarily associated with less developed countries will lose out.

Seen through the realist lens, public health and biodiversity should be *most likely cases* (cf. Eckstein 1975). This is because both the facilitating structures as well as the preconditions on which this approach rests are largely given. Indeed, both issue areas are characterized by vast structural asymmetries. Economic concentration in pharmaceutical and agrichemical markets is enormously high and has only increased over the past decade (3D 2010; Rosenberg 2004; UNCTAD 2006). These sectors have also witnessed the ascendance of the “life science corporation” – a completely new type of business enterprise that integrates research expertise, product development, and marketing strength across a wide range of areas, including agrochemicals, seeds, processed foods or biopharmaceuticals (Dutfield 2008, 170-9). Virtually all patents in these areas are claimed and owned by these companies mainly situated in the economies of the U.S., EU, Japan, and Switzerland.<sup>18</sup> With annual turnovers greater than some industrialized countries, these industries are among the most profitable and powerful in the world, especially in the U.S. trade-policy-making context; and because their profitability wholly depends on the rents accruing from large patent portfolios, they share a vested interest in strengthening IPRs at home and abroad.

These actors have achieved many of their goals with the TRIPS Agreement. Indeed, TRIPS was largely written at the behest of IP owners, most notably the brand name pharmaceutical industry (Drahos and Braithwaite 2002, 125-6; Ryan 1998; Sell 2003); TRIPS promotes an expansive rights-approach for producers, but says little about access by consumers to information, i.e. the rights of users (Grosse Russe-Khan 2009). Nevertheless, developed countries were not fully content with the Agreement. On the one hand, most developing countries did not show much enthusiasm to implement and enforce legislation which raised the costs of knowledge products of the North while not acknowledging their informational wealth, such as indigenous knowledge (Dreyfuss 2009). On the other hand, emerging economies such as Brazil, China or India, are increasingly challenging great powers’ technological and economic lead rendering extended protection as the only viable means to sustain their competitive advantage (Kimes 2010; New 2009). In the post-TRIPS era, developed countries therefore adopted a highly protectionist agenda, including a swift and narrow implementation of TRIPS, expanded IP protection and the Agreement’s stringent enforcement (Deere 2009). What they actually wanted was TRIPS-plus – global patent harmonization pitched at a level that TRIPS is the *protection floor* – the absolute minimum baseline that is acceptable.

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<sup>18</sup> The World Patent Report presents data on the total share in patents in the period from 2000 to 2006. Measured by country of origin the top ten developed countries accounted for 87.4%, with Japan (29.9%) and the USA (21.3%) alone accounting for approximately 50% (WIPO 2008). Patenting is also becoming a central tool in the R&D, commercialization, and marketing strategies of the cosmetics and perfume sector – particularly in the context of innovations based on natural ingredients (UEBT 2010).

In order to give effect to such an agenda, the U.S. and (to a lesser extent) the EU embarked on a variety of institutional pathways: (1) *unilateral pressure*, i.e. the continued use of threats of economic sanctions under Section 301 of the U.S. trade act of 1974, (2) enhanced efforts to provide *technical assistance* to patent offices<sup>19</sup> and “missionary work” in key target countries,<sup>20</sup> (3) *vertical forum shifting*, i.e. the incorporation of TRIPS-plus standards into bilateral and regional free trade and investment agreements (RBFTAs) as well as the push for the IP enforcement agenda, including the proposed plurilateral Anti-Counterfeiting Trade Agreement (ACTA)<sup>21</sup>, and (4) *horizontal forum shifting*, i.e. the push for a uniform global patent system via the proposed Substantive Patent Law Treaty (SPLT).

One of the central levers for implementing a TRIPS-plus agenda is unilateral retaliation via the Special 301 process in the U.S. Enacted by Congress in 1988, the Special 301 provisions of the Trade Act of 1974 has functioned as the primary tool in the USTR’s approach towards unilateral adjudication of third countries’ compliance with IP standards and enforcements efforts (Flynn 2010). The report threatens and rewards countries via inclusion on or delisting from its annual ‘Watch List’ and ‘Priority Watch List’ and has the power to implement unilateral trade sanctions when U.S. demands are not met.<sup>22</sup> A careful reading of the USTR’s annual Special 301 Reports between 1995 and 2008 illustrates that IPRs were almost invariably privileged at the expense of public health needs. Throughout this period, the USTR routinely placed countries on the ‘Watch List’ or ‘Priority Watch List’ that were compliant with TRIPS but that had enacted IP laws and practices that the U.S. deemed objectionable. For example, between November 2006 and January 2007 Thailand’s Ministry of Health granted compulsory licenses for two AIDS drugs and one antihypertension drug which are owned and sold by American companies Abbott Labora-

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<sup>19</sup> Patent Controllers in developing countries heavily rely on USPTO and in particular EPO doctrines and precedents (Kapzcynski 2009, 1626-7). The Patent Office manual applied by Indian controllers, for example, instructs them to ignore the strict novelty standards required by the new Indian Patent Act (2005). As a result, the manual bypasses the provisions of the patent act (Gopakumar 2010, 359).

<sup>20</sup> For example, since 2003, the George Washington University (GWU) Law School coordinated an IP lobby programme known as the India Projects. Under this project, GWU coordinates an annual lobby visit by a US delegation consisting of pro-IP academics, corporate executives and judges of the US Federal Circuit Courts. This delegation meets the judges of High Courts and the Supreme Court to advocate the need for strong IP protection. For a brief description, see (KEI 2009).

<sup>21</sup> See (Sell 2008) (providing numerous examples of various IP enforcement initiatives supported by the U.S., including the SECURE initiative at the World Customs Organization (WCO) or the IMPACT initiative at the WHO). See also (Porteuz Viana 2007). The latest version of the text as well as useful background information can be accessed at [<http://www.keionline.org/acta>] Rev. 09-12-2010.

<sup>22</sup> The annual USTR reports and related press releases can be accessed at [<http://www.ustr.gov/>] Rev. 05-15-2010. Construction of the report is heavily influenced by the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annually submits a detailed report containing allegations about the IP policies of countries around the globe and delineates those that it wishes to be targeted for threats of sanctions. For the most part, PhRMA findings and recommendations simply pass through into USTR’s Special 301 Report. Or, as one interviewee put it, “Special 301 reports are by and large a copy and paste exercise.” Interview with NGO representative, Washington, D.C., November 2009.

atories and Bristol Myers Squibb, respectively (KEI 2007; PIJIP 2008). Pressured by PhRMA, the USTR countered this move by placing Thailand on the 'Priority Watch List' in 2007, expressing "serious concerns" over "the lack of transparency and due process exhibited in Thailand" (USTR 2007b).

Yet, although Special 301 served as a valuable instrument to communicate U.S. trade preferences, the evidence suggests that it proved not to be highly effective in raising the actual level of protection (Sell 1998). In this regard, a far more effective pathway appeared to be the RBFTA approach.<sup>23</sup> Let us first look into the area of biodiversity. In fact, many of the RBFTAs incorporate provisions that frequently eliminate the flexibility of art. 27.3(b) thereby further undermining the sovereign rights countries enjoy under the CBD (GRAIN 2008; Medaglia 2008). The most restrictive FTAs such as those with Morocco (art. 15.9.2) even require patent protection for plants and animals. Less restrictive agreements such as those with Chile (article 17.9.2) or US-CAFTA-DR (article 15.9.2) require parties to make "reasonable efforts" to make patent protection available for plants (Fink and Reichenmüller 2005, 2). In the absence of plant patents, all FTAs require signatories to introduce UPOV 1991 which is not mentioned in TRIPS (Shadlen 2005, 13).

Similar developments can also be observed in the area of public health (Drezner 2007, 195-7). For example, the USTR routinely uses RBFTAs to pressure countries into accepting obligations that 1) limit the grounds or reasons for issuing compulsory licenses, 2) restrict or eliminate parallel imports, 3) require parties to grant extensions to patent term, and 4) require parties to link regulatory approval of new drugs to patent status. Perhaps most controversially, all U.S. FTAs invariably contain a new form of IP requiring countries to grant exclusive protection to agrichemical and pharmaceutical test data submitted to regulatory authorities (Clift 2007; MSF 2004). Along with the border measures mandated by the proposed ACTA treaty, such provisions aim at blocking, or at least, retarding generic competition thereby further undermining states' ability to access affordable medicines.

Finally, it is noteworthy that most-favored nation treatment (TRIPS, art. 4) picks up any higher standard of protection that WTO members may agree to in a FTA (Drahoš 2007, 14). Thus, once an economic more vulnerable country grants TRIPS-plus standards in order to enhance its trade balance, it means that all the advantages, favors, or privileges could be automatically demanded for all nationals of another WTO member. *In sum, complexity enabled powerful countries to advance the economic interests of their IP-based industries by sidestepping rules – emanating from external regimes – that are giving effect to human rights and/or environmental objectives.*

### ***The fallacies of a power-based perspective***

The governance processes outlined above speak to the enduring realities of structural power in the issue area of IP and underline the relevance of a realist perspective on regime complexity. Indeed, by combining forum shifting with vast material resources great powers have been relatively successful to strengthen IPR at the expense of regimes embodying social and/or environmental agendas. The problem with this perspective is, however, that it only tells us half of the story. Indeed, for all their efforts to rewrite public health- and biodiversity-related rules, powerful actors have not won 'all the way down.' In contrast, the U.S. has been unable to achieve formal, legally binding FTAs with key emerging economies such as China, Russia or India (Morin 2009). Moreover, if one considers the effects of existing FTAs on third countries, there has been only limited success

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<sup>23</sup> The literature on "TRIPS-plus"-related developments in RBFTAs is voluminous. For a survey, see (Abbott 2004; Correa 2004; Drahoš 2001; Krikorian and Szymkowiak 2007; Morin 2009).

in achieving increased protection *beyond* the contracting party (GAO 2007, 7-9). Multilateral coalition dynamics, for instance, have not substantially shifted in recent years. At closer look, therefore, a wide range of “process observations” does not match with realism’s expectations.

As for the biodiversity area, developing countries and supportive NGOs were successful in pushing back strong actors’ campaigns at eliminating flexibility in article 27.3(b) within the WTO. Indeed, since 2001 the U.S. refrained from any attempts to address this controversial issue in TRIPS Council deliberations. Further, they succeeded in incorporating many of their concerns into the Doha Development Agenda. For example, Paragraph 19 of the Doha Ministerial Declaration included “the relationship between [TRIPS] and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members” to be pursued under the review of Article 27.3 (b) of the TRIPS Agreement (WTO 2001b). The inclusion of this issue is of great significance, in so far as it constitutes an outright recognition of compatibility problems between the CBD and the TRIPS. Moreover, weak actors have recently gained the EU’s support to take up text-based negotiations on a disclosure requirement in patent applications which is believed to ensure that inventions based on genetic resources have been acquired in compliance with the CBD’s ABS requirements (WTO 2008). Such defensive measures can also be found in the recently adopted ABS protocol within the framework of the CBD which specifically aims at preventing the misappropriation of genetic resources and TK (IISD 2010; MacFarquhar 2010). Finally, weak actors have advanced both positive and defensive protection of TK in the arguably weaker WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGCGRTKF) with some degree of success (WIPO 2009).

In the realm of public health, the push towards a development-oriented IP agenda has been even more accentuated. Beginning in 1999, developing countries and public health advocates launched an access-to-medicines campaign that successfully enrolled the WHO and U.N. human rights bodies on their behalf (Nunn et al. 2009; t’Hoen 2002). These bodies defined medicines as a human rights issue (see, for instance, UN 2000; UNCHR 2001) emphasizing the responsibilities for both governments *and* corporations to facilitate access (UNSRHR 2007). The human right frame culminated in the adoption of the Doha Declaration on TRIPS and Public Health in 2001, in which all WTO members “affirm that the [TRIPS] 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” (WTO 2001a). The passage of the Declaration is widely regarded as an important victory for developing countries (Abbott 2005, 332). The Declaration clarifies WTO members’ rights to use TRIPS flexibilities, creates new rights by stretching the transition periods for least-developed countries, and affirms the primacy of public health over IPRs. The U.S. and other WTO members also agreed to grant conditional waivers in 2003 to paragraphs (f) and (h) of Article 31 of the TRIPS Agreement (WTO 2003). However, on a practical level, the perhaps most significant measure of the success of the campaign has been the drastic fall in the price of antiretroviral medicines.<sup>24</sup> It might become important in this context that the Indian generic sector together with civil society actors have successfully lobbied the Indian parliament to adopt wide range of flex-

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<sup>24</sup> Competition among generic manufacturers in India helped bring prices down from US\$10,000 per patient per year in 2000 to less than US\$90 today. Producing “one-fifth of the world’s generic drugs,” India has thus been called the pharmacy of the developing world (MSF 2008).

ibilities in its new Patent Law in 2005 (thereby potentially affecting the prices of medicines on a global scale).

Developing countries and NGOs have also successfully pressed the WHO to consider aligning innovation and access in 2003 (WHA 2003). This process culminated the adoption of the landmark WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008) which for the first time broadens the meaning of innovation to include “delivery” (WHA 2008). UNITAID’s (still uncertain, though keen) campaign towards the adoption of patent pool is but one example how this new normative linkage is implemented (Bermudez and ‘t Hoen 2010). Yet the human rights framework is also slowly beginning to talk hold in U.S. trade policy as strong IP protection at home and abroad becomes more controversial in Congress. For example, Washington-based NGOs successfully lobbied for the Kennedy-Feinstein-Feingold Amendment to the 2002 Bipartisan Trade Promotion Authority requiring USTR to respect the Doha Declaration when negotiating FTAs (CIEL 2007, 7-8). More fundamentally, a recent bipartisan agreement on trade policy has ratcheted back USTR’s mandate to increase IP protection through FTAs, particularly with regard to developing countries (USTR 2007a). This decision could potentially herald an important policy shift towards greater sensitivity of public health concerns.<sup>25</sup> Crucially, the bipartisan agreement creates an exception to test data exclusivity rules for measures to protect public health.

Thus, a comparative review of institutional development reveals that – from 2001 onwards – weak actor coalitions have knocked a few significant bricks from the TRIPS-plus wall. Working through the complex legal terrain of the IP system, they were able to set agendas, advance new arguments, and promote rules that more accurately reflected their concerns. While the TRIPS minimum patent requirements were not relaxed in any fundamental ways, their strategies proved instrumental in preserving more policy space to implement flexibilities in each domain than the U.S. and the EU would have otherwise allowed. Nevertheless, the cross-case perspective also reveals some marked differences between the cases. In the realm of biodiversity, the U.S. has so far successfully shielded off TRIPS from being “softened” by the equity norms stemming from the biodiversity regime. Health advocates, by contrast, have “hardened” their agenda by injecting health-related development concerns into TRIPS law and even some notable FTAs. *That said, neither the within nor cross-case observations matches with realist expectations. In fact, what seemed to be most-likely cases turned out to have puzzling implications for the dominant approach.*

### **Ideationism: Patents, rules, and rhetoric**

In the following, I will therefore expound the heuristic of an ideationist approach providing a fuller picture of the cases. In a nutshell, my argument combines a focus on the institutional set-up of regime complexes with a frame-analytic perspective based on *rhetorical norm manipulation* as the main behavioral pathway.<sup>26</sup>

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<sup>25</sup> Interviews with NGO and industry representatives as well as academics, Washington, D.C., September - November 2009.

<sup>26</sup> The mechanism of “rhetorical norm manipulation” builds upon Schimmelfennig’s analysis of “rhetorical action” (Schimmelfennig 2000, 2003). On the strategic conception of rules, see (Goffman 1974). Rhetorical action is the main conceptual alternative to Habermas’ “consensus-oriented action” (*verständigungsorientiertes Handeln*). “Consensus-oriented action” conceives of communication as a “rational” discourse leading up to a “true” consensus among the participants (Deitelhof 2009; Risse 2000).

Embedded in the very idea of rhetorical norm manipulation is a more nuanced understanding of regime complexity – one in which the presence of overlapping rules and institutions serves not only as a resource for great powers' bargaining strategies, but also as a constraint on their actions. Viewed through the ideationist prism, the most defining feature of regime complexes is the *fluidity* of the legal and institutional environment. In fluid environments, both strong *and* weak actors can and will strategically exploit the abundant hard- and soft law regimes by engaging in forum shifting behavior. However, the capacity to favorably exploit regime complexity is not determined by control over large domestic markets alone. It equally depends on how issues are positioned, filtered and organized in the highly complex institutional terrain. Thus, while ideationism is also conceived of actors as primarily driven by their material preferences over public health- and biodiversity-related IPRs, it highlights institutional and normative features of the fragmented governance process that enhance weak actors' bargaining strategies.

There are two main reasons for this. First, fluidity creates environments that favor *network-based forms of organization*. Indeed, the unitary state actor model is of limited when it comes to analyzing IP regime complexity (Drahos 2004; Sell and Prakash 2004). In the nascent transnational culture of the post-TRIPS period, battles over IP-related issues were barely fought out between states alone, but rather raged between two archetypical IP 'teams' (Deere 2009, 17-8). One team – the 'patent community' – is composed of OECD-country governments, multinational firms, industry lobbyists and members of IP offices. The other team – the pro-development team – is a loosely coupled coalition of developing countries, NGOs, and development-oriented IOs. Basically, network-based structures enhance the ability of both corporate actors and NGOs to gain access to the decision-making apparatus. Yet they disproportionately favor resource-poor, but highly flexible NGO activists. In fact, dense network-based relationships allowed these actors to provide developing countries with the expertise necessary to navigate through the highly technical field of IP law.

Second, fluidity gives rise to multiple institutional entry points thereby creating additional *voice opportunities* (Hirschman 1970). Again, this disproportionately favors resource-poor actors. One of the most important strategies for poor countries in the political economy is the promotion of competing norms that question the legitimacy underlying dominant legal orders. Yet within single institutions, such as the WTO, they are likely to enjoy limited opportunity to do so. Rather, developing countries often find themselves in a relatively marginalized position (Steinberg 2002). In fluid governance structures, however, the prospects for institutional reform are greatly expanded. In such environments, weak actors can shift their activities to venues (such as UN-bodies) that afford them better access, greater participation and whose philosophies more closely resonate with their own goals.

The key point here is that the legal norms that lay dormant in such venues can be *rhetorically manipulated* to an extent that they come to serve as "counterregime norms" (Helfer 2004, 14, 58-9; Morin 2008). To be sure, such soft law norms generated in UN-based bodies generally lack legal efficacy. Politically, however, they can have hard-edged consequences. The reason for this is that such law can, over time, facilitate the development of *competing discourses* that reframe the social and moral context in which IP issues are prioritized, interpreted, and decided (Kapczynski 2008). Counterregime norms entangle great powers into "webs of dialogue" (Braithwaite and Drahos 2000, 553) through which advocates deploy new "schemes of interpretation" that allow them to "locate, perceive, identify, and label" (Goffman 1974, 21) IP negotiations, laws, and practices in novel ways.

Such successful attempts at rhetorical norm manipulation profoundly alter the institutional dynamics underlying specific IP issues. Indeed, new framings impose *legitimacy costs* on actors whose behaviors and practices are not in line with new interpretative schemes,



even though they may possess superior institutional and material power. However, the effectiveness of such strategies – and, hence, *variation in the legitimacy costs* involved – depends on the presence of several conditions. First, normative linkages embodied in competing discourses must *resonate* with the prior held beliefs about cause-effect linkages prevalent in an issue area. Second, advocates of this strategy must put forward consistent and *coherent* models that have analytical and distributive appeal. Third, alternative frames must be *salient* – that is, they must match with the domestic norms and values or fundamental beliefs of state representatives.

In applying these insights to public health- and biodiversity-related IPRs, we can see how weak actors' rhetorical norm manipulation played out. In both areas, developing countries closely worked together with NGO activists to counter the “hard law” of TRIPS and TRIPS-plus agreements with the rules and rhetoric developed in more hospitable regimes. In the realm of biodiversity, developing countries used the principle of sovereign ownership (CBD, arts. 3 and 15.1), as well as the concepts of “common heritage of mankind” and “farmers' rights” enshrined in the FAO's treaty on plant genetic resources for food and agriculture (ITPGRFA) to build up a “biopiracy” narrative that questioned the legitimacy of IPRs in biogenetic resources. The “biopiracy” rhetoric reframed biodiversity-related IPRs as a *development issue* portraying corporate users of biodiversity as “biopirates” on the genetic resources and TK assets of developing countries (Dutfield 2006). Similar strategies were adopted with regard to pharmaceutical patents and their relation to the pursuit of public health policies, particularly in the area of HIV/AIDS. Here, the strategies molded into a “public health discourse” anchored in the right to public health (and the corresponding duty to offer, or at least, facilitate access to medication). Working through the WHO and various U.N. human rights bodies, weak actors reframed IP as a *human rights issue* reformulating the previous paradigm that “patents = free trade = economic growth” with the paradigm “generics = lower prices = life” (Nunn et al. 2009; Odell and Sell 2006). In recent years, this discourse has slightly changed in focus so as to more strongly address public health-related IPRs in the context of incentivizing both access *and* innovation.

The successful reframing attempts in these parallel regimes fundamentally altered the bargaining context over public health- and biodiversity-related IPRs in the WTO. To understand why, it is necessary to grasp that the epistemological horizon of TRIPS had long been defined by strong actors which “sold” high levels of IPRs as a necessary predicate to boost economic development. As long as this “efficiency” narrative remained uncontested, strong actors could socialize poor countries into accepting their preferred TRIPS-plus policies at relatively low cost. Material and legitimacy-related resources worked in tandem reinforcing each other in the process. Once the development-oriented framings took over, however, material and ideational power drifted apart. Although the U.S. and E.U. steadfastly clung to their TRIPS-plus preferences, *the legitimacy costs of acting on those opportunistic preferences became prohibitive*. As a consequence, strong actors had to back down from their TRIPS-plus positions in the WTO, even though they were not convinced by the arguments of their opponents and possessed superior material power. The most visible illustration of this development is the Doha Declaration (2001) in which strong actors finally agreed to a human rights reading of TRIPS, despite strong opposition from their drug firms (Klug 2008). For weak actors, however, rhetorical norm manipulation did not come free of charge, either. Indeed, legitimacy is a double-edged sword serving both as a resource of support as well as a constraint on action. Once weak actors had *rhetorically* committed to TRIPS, they had identified and became identified themselves with their commitments. As a consequence, their more ambitious goal of pursuing a TRIPS-minus agenda in biodiversity, i.e. pushing back IPRs over (varieties of) living organisms, lost credibility.

That being said, weak actors' reframing strategies did not equally play out across the two domains. As noted above, advocates' campaigns proved far more successful in the area of public health than biodiversity. In particular, the aspect of resonance varied significantly across the cases studied. True, the "patent community" and public health advocates regarded each other with a high level of mistrust (Morin and Gold 2010). As one interviewee put it, "Don't trust in any single word they [the pharmaceutical industry] say."<sup>27</sup> Ironically, analysis of their rhetorical interactions also demonstrates that these groups were nonetheless able to "communicate," precisely because health advocates were willing to operate within the dominant language set by the inherited TRIPS discourse. This willingness most clearly shows up in the latest shift of the public health discourse towards an understanding which much more strongly focuses on innovation. Overall, this discourse clearly embraces patents as one instrument (among others) to facilitate R&D in neglected diseases (see e.g. Bessen and Meurer 2006). The proprietary "biopiracy" discourse, by contrast, rejected the legitimacy of the very idea of IP in biogenetic resources as a form of "Western" neocolonialism rendering "communication" impossible.

## Conclusion

In reviewing public health- and biodiversity-related IPRs, this article finds that regime complexity – in particular the fluidity of its environment – endowed weak actors with more influence and power than we might have expected from a simple reading of the distribution of material power alone. After all, life science companies and their supportive home governments have enormous resources at their disposal and we should expect them to impose their preferences onto weaker parties. Yet, for all of their efforts at reforming multilateral IP rules, they have not succeeded. Instead, poor countries have advanced, with some degree of success, their development-oriented objectives within multiple regimes, including the WTO. Given the glaring disparities in power, this was no easy achievement and represents a clear tick in the ideationist column. Indeed, the fluidity of the regime environment enabled weak actors successfully manipulated the discursive context in which bargaining over public health- and biodiversity-related IPRs is embedded. As a result, "the implementation of the flexibilities set out in the TRIPS Agreement ... became as much a matter of legitimate multilateral concern as compliance with proprietors' exclusive rights" (Reichman 2009, 1172).

Nonetheless, it would be premature to declare "victory" for the weak in the battle that rages over public health- and biodiversity-related IPRs. As we have seen, both cases also demonstrate that economic coercion always remains a viable weapon of the strong which sets clear limits to the causal efficacy of weak actors' framing strategies. After all, the power that weak actors' have exercised has been essentially "blocking power." Indeed, as the U.S. and EU faced the constraints of their eroding legitimacy resources on the multilateral stage, they moved their initiatives back to the bilateral level (Benvenisti and Downs 2007, 611; Drahos 2001). Such relatively enclosed decision-making settings could be easily insulated from the political "noise" created by competing discourses thereby allowing powerful actors to strive for more robust IP norms in areas where they believe to have vital interests at stake.

Consider the proposed ACTA treaty, for example. For more than two years, the treaty has been negotiated in secret and the text has been disclosed only after it had already been leaked several months before by NGOs. With the secrecy steadily eroding, the prospective agreement has increasingly drawn fire. Public health advocates, for instance, have criticized that the treaty's provisions go far well beyond addressing willful commercial

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<sup>27</sup> Interview with representative from UNITAID, Geneva, December 2009.

trademark counterfeiting to include border measures that potentially threaten the free transit of legitimate generics (Maybarduk 2010). Likewise, India has recently sharply criticized the envisaged instrument as a “TRIPS-plus” measure (Mohanty 2010). Amidst the wave of criticism, parties have agreed to narrow some of the provisions. Nevertheless the process is fast moving and parties have signaled their intention to conclude negotiations as soon as possible (Mara 2010). As envisaged by the current Obama administration, the final text would then not become subject to normal constitutional procedures, however. Instead, ACTA might open an entirely new chapter in the ongoing story of shifts and counter-shifts in the IP area. In fact, the administration has suggested it will adopt ACTA as a “sole executive agreement” thereby circumventing Congressional approval (Goldsmith and Lessig 2010).

In concluding this article, I therefore take up Susan Sell’s insight that the notion of “winning” and “losing” may be far less obvious and stable in regime complexes than one might expect (Sell 2009, 8). The dynamism that inheres in the linkages of a regime complex shape strategies, interests, and choices dynamically in a way that cannot be anticipated or controlled by anyone power alone. As for the domains of public health- and biodiversity-related IPRs, where actor preferences sharply diverge and a comparatively high level of regime density exists, this means that interactions are never fully stabilized. Instead, the “losers” from today may have strong incentives to reach out and seek more hospitable institutional fora where they could become tomorrow’s “winners” (Pierson 2004, 163).

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