

# To enforce or not to enforce? Judicialization, venue shopping, and global regulatory harmonization

Dirk De Bièvre, Arlo Poletti, and Lars Thomann

*Universiteit Antwerpen, Antwerpen, Belgium*

## Abstract

The regulation of intellectual property rights takes place in a range of international venues. This proliferation of international venues greatly enhances the potential for venue shopping. We argue that different levels of domestic regulation and differing degrees of judicialization account for actors' preferences over institutional venues. We take into consideration two scenarios. Conceiving of judicialization as the delegation of adjudication to an independent third party and the enforcement through multilaterally authorized sanctions, we show that: (i) upward regulatory harmonization leads actors preferring weak regulatory intellectual property rights standards to strive for venues with low degrees of judicialization, whereas those favoring stringent intellectual property rights protection prefer highly judicialized venues; and (ii) downward harmonization leads to the opposite constellation of institutional preferences. We show how these expectations hold by way of in-depth case studies of two instances of global intellectual property rights regulation: the regulation of plant genetic resources and intellectual property rights for medicines.

**Keywords:** intellectual property rights, judicialization, regulatory harmonization, venue shopping, WTO.

## 1. Introduction

The creation of the World Trade Organization (WTO) in 1995 increased both the scope and the bindingness of international trade rules. The 1995 Uruguay Agreements expanded the international trade agenda from “at the border” issues (tariffs and quotas) to “behind the border” issues (national laws and regulations), touching upon questions traditionally falling within the universe of domestic economic regulation (Young & Peterson 2006). Members of the international trading system also strengthened the enforcement mechanism of rules by replacing the General Agreement on Tariffs and Trade's (GATT's) political–diplomatic settlement of disputes with the WTO's quasi-judicial system of dispute resolution. The dispute settlement mechanism of the WTO delegated adjudication to an independent third party (panels and Appellate Body) and strengthened enforcement by introducing a credible threat of multilaterally authorized sanctions in case of non-compliance, greatly enhancing WTO members' ability to challenge WTO-incompatible policies pursued by other trading partners (Hudec 2000; Zangl 2008). We define this institutional evolution as the judicialization of the present international trade regime.<sup>1</sup>

Correspondence: Arlo Poletti, Antwerp Centre for Institutions and Multilevel Politics (ACIM), Department of Political Science, Universiteit Antwerpen, St-Jacobstraat 2, 2000 Antwerpen, Belgium. Email: arlo.poletti@ua.ac.be

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The most visible effect of the twin pressure of the increased regulatory scope of the WTO and the enhanced bindingness of its rules has been an increase in the number and the salience of international trade disputes. As the strengthened enforcement mechanism of WTO rules enables them to reach deeply into the traditions and practices of domestic regulatory governance, trade disputes have increasingly been a source of broad constituency mobilization, widespread media coverage, and heated political debate, also raising concerns about the legitimacy of the current institutional structures that govern the trade regime.

These developments, however, have also affected international trade relations in a less visible, but perhaps a more fundamental, way. A variety of analyses have shown that the presence of a judicialized venue to negotiate and adopt international trade agreements greatly affects the strategic calculus domestic actors, key economic interest groups, and policymakers alike make when deciding whether to commit to new multilateral trade rules (Goldstein & Martin 2000; Rosendorff 2005). This strand of literature, however, mostly focuses on how judicialization in the WTO affects actors' preferences over cooperation on at-the-border issues, that is, on the elimination and/or reduction of tariff barriers to trade. Surprisingly little research has so far investigated whether and how WTO judicialization influences domestic actors' preferences over behind-the-border issues, namely international efforts aimed at harmonizing domestic regulatory practices. With this article we aim to contribute toward filling this void. Our main goal is to investigate how WTO judicialization affects WTO members' preferences over international regulatory strategies. More specifically, we formulate hypotheses on the conditions under which WTO member states choose a judicialized venue, such as the WTO, to pursue their regulatory strategies.

In order to achieve this goal, we rely on the concept of venue shopping – a concept that has proven a useful tool for policy analysis both on the national and the international level. The concept of venue shopping helps capture the ideas that different institutional venues offer different incentive structures and that actors tend to choose the venue in which they can achieve the greatest expected utility (Baumgartner & Jones 1993). Where several institutions have the potential to deal with a given policy issue, negotiating over where to locate the negotiations in the first place becomes part and parcel of state interaction itself. This international regime complexity, namely the existence of multiple regimes with a similar issue scope, increasingly permits actors to apply venue shopping to achieve specific policy objectives (Alter & Meunier 2009).

We locate the motive for venue shopping in the fact that the relevant actors – that is, mainly states and interest groups on whose behalf they negotiate – consider the enforceability of potential rules as an important element of international negotiations. In a nutshell, we argue that the key to understand and account for states' venue choices for international regulatory harmonization lies in the conceptual distinction between two different types of regulatory harmonization: upward harmonization and downward harmonization.

If a dyad of countries seeks to harmonize regulatory standards at a higher level – either by creating new rules or by upgrading existing rules – we expect that a country will prefer a venue with a high degree of judicialization when its domestic regulatory standards are set at a high level, whereas we hold that the country with a relatively low level of regulation will rather prefer a venue with a low degree of judicialization.

This is not the end of the story, however. In a second scenario, in which states strive for downward harmonization, the question is whether to allow for exceptions and/or carve-outs to commitments already agreed upon in a highly judicialized venue. Our argument is that in this scenario the constellation of preferences over institutional choice is reversed. We show why, under these circumstances, countries with a low level of regulation come to prefer a judicialized

setting, whereas highly regulated countries opposing this strategy either seek to preserve the status quo, or prefer to locate such negotiations in a venue with a low degree of judicialization.

While we formulate our hypotheses in general terms, empirically our story is essentially about the WTO and the regimes with which it is nested. Because our argument concerns preferences over global regulatory harmonization and applies to situations in which there are at least two venues with an overlapping functional issue scope, one of which is highly judicialized and one (or more) of which is not, our empirical universe of cases boils down to situations in which states have to choose between the WTO and other international regulatory venues.

We illustrate the explanatory force of the argument by way of in-depth case studies of two instances of global intellectual property rights regulation: regulation in the area of genetic resources and regulation in the area of public health and access to medicines. Intellectual property rights (IPR) protection has become an important feature of contemporary international political economy. Whereas formerly nation states were the relevant loci of regulation that steered the allocation of rights and obligations and affected the socio-economic conditions of many, nowadays intellectual property rights regulation is decided upon at the international level. The regulatory framework governing the global intellectual property rights regime is spread across a host of international venues. The World Intellectual Property Organization (WIPO) holds sway over this area of global regulation, and also the WTO, the United Nations Food and Agricultural Organization (FAO), the World Health Organization (WHO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Convention on Biodiversity (CBD), and the International Union for the Protection of New Varieties of Plants (UPOV), are occupied with this particular issue area. While WIPO and UN specialized committees and agencies are characterized by a low degree of judicialization, the WTO has judicialized dispute resolution that makes its rules binding and enforceable. The wide array of institutional venues dealing with global IPR regulation and their different degrees of judicialization make this field particularly fit to test the explanatory force of an argument about how different institutional features of regulatory regimes affect venue shopping behavior of states.

While we have chosen to concentrate on the issue area of IPR protection, our argument may also shed light on venue shopping behavior in other issue areas. Given its broad functional scope, the WTO is nested with a wide array of international regimes across issue areas. This means that there are multiple issue areas in which states face a choice between the WTO and other international regulatory venues, namely those issue areas known as the “trade and” issues, that is, trade and environment, trade and development, trade and labor standards, trade and competition, and trade and consumers and health safety. We, thus, offer a theoretical template that may well generate interesting insights into the broader topic of international regulatory governance in issue areas that overlap with the broad functional scope of the WTO.

The article is structured as follows. In the second section, we trace the contours of the debate on how judicialization may affect preferences over regulatory strategies of WTO member states, and highlight shortcomings in the existing literature. In the third section, we develop our argument. In the fourth, we show how our expectations hold in the fields of plant genetic resources and intellectual property rights for medicines. In the conclusion we summarize the key findings of the article.

## 2. Existing explanations

The literature on the effects of WTO judicialization on regulatory strategies of states can be categorized in two groups. According to one view, judicialization may turn the WTO into an

attractive institutional location for governments of industrialized countries willing to negotiate regulatory issues demanded by their constituencies (De Bièvre 2006). While regulatory agreements entail high implementation costs, especially with respect to enforcement, the WTO offers the possibility to cross-retaliate against non-compliant countries, thereby giving higher certainty, stability, and predictability to commitments and issue linkages made under the WTO. This argument suggests that countries willing to engage in international regulatory harmonization are likely to value the increased credibility brought about by stronger enforcement of rules, hence that they will be prone to locate such rules in a highly judicialized venue.

However, drawing on the existing literature, one could also argue in the opposite direction, namely that strong enforcement might reduce propensity to commit to new agreements in the WTO. Fearon (1998) highlighted how stronger enforcement might raise the stakes during negotiations, causing states to bargain harder and hold out in hope of getting a better deal, or even defect from cooperation. By increasing enforceability, judicialization does not only make agreements more credible. Judicialization also makes international trade rules more tightly binding, decreasing flexibility of agreements and limiting the ability of governments to opt out of commitments. This, in turn, can lead governments to deem that the costs of signing such agreements outweigh the benefits. Governments value institutional flexibility as a tool to deal with the uncertainty of future economic interactions, for example, economic shocks, allowing them to deviate from agreed upon commitments without paying a cost (Goldstein & Martin 2000). This argument builds on the findings of Downs and Rocke (1995) concerning the relationship between, and uncertainty and design of, international rules and finds further corroboration in the so-called rational design literature (Koremenos *et al.* 2001). When states face uncertainty about the distributional implications of a particular agreement they are more likely to support negotiations in a setting with a high degree of flexibility. Because gains and losses of regulatory harmonization tend to be difficult to ascertain (Wilson 1973), it is fair to expect actors to greatly value institutional flexibility.

The state of the art of this debate, however, falls short of accounting for the empirically observable variation of states' preferences over institutional venues for regulatory harmonization. Developed countries with similar levels of domestic regulation do not have stable preferences for judicialized settings across the board. For instance, the preferences of the EU and the US over the inclusion of the so-called trade-and issues (i.e. trade-and-labor, trade-and-the-environment, the "Singapore issues") in the Doha Round of multilateral trade negotiations greatly diverged, with the former strongly supporting the inclusion of these issues in the WTO framework, and the latter resisting such a move. In addition, developing countries with a relatively low level of domestic regulation sometimes also have a strong preference for international regulatory harmonization in the WTO. As we will discuss in the empirical analysis, developing countries have consistently sought to include new IPR rules concerning access to essential medicines in the WTO framework, whereas industrialized countries have opposed this strategy.

How can this variation be accounted for? What are the underlying sets of incentives and constraints that determine this varying constellation of preferences both *within* and *across* countries? We contend that the key to understand and account for states' venue choices over international regulatory harmonization lies in the conceptual distinction between two different types of regulatory harmonization.

### 3. Venue shopping and regulatory strategies: Two scenarios

Actors engage in venue shopping when the possibility for moving around different access points exists (Baumgartner & Jones 1993). Venue shopping can occur either between the same levels of

government (horizontal venue shopping), across different levels of government (vertical venue shopping), or both (Princen & Kerremans 2008, p. 1137). Logically, prior to any form of venue shopping is the existence of multiple institutions with a similar issue scope.

Diverging actors' preferences are linked to actual or perceived distributional costs or benefits of a particular regulatory initiative. Venue shopping takes place because actors hold diverging preferences over specific policies. Actors consequentially choose the venue where they expect to achieve their greatest expected utility. A particular venue will be preferred by those that support a given policy outcome if such venue is expected to make such policy outcome more likely. Similarly, a venue that makes a certain policy outcome unlikely will be preferred by those that oppose such policy outcome.

In this section, we consider how the degree of judicialization of a regime affects venue shopping behavior of states concerning international regulatory harmonization. The literature identifies a number of dimensions for the concept of judicialization or legalization. These include the degree to which state and non-state actors have access to the enforcement procedure, the scope of jurisdiction of the adjudicating body, the independence of the adjudicators from the litigating parties, the embeddedness of the adjudicators' rulings in domestic legal systems, and, finally, the remedies or sanctions that are available (Goldstein *et al.* 2000). We define judicialization as compulsory and binding third party adjudication, enforceable through the imposition of multilaterally authorized sanctions (De Bièvre 2006; Zangl 2008).

### 3.1. Upward regulatory harmonization

In a scenario of upward regulatory harmonization, states either deal with the creation of new international rules to harmonize existing divergent domestic rules and then decrease the negative externalities that these engender, or seek to further tighten already existing international rules.

The literature dealing with the dynamics that underlie international regulatory competition offers useful insights in order to derive hypotheses as to which actors will be likely to support such type of regulatory harmonization in judicialized regimes. This literature stresses the political economic dynamics that underlie governments' choices over international regulatory policies, and argues that such choices are driven by a desire to satisfy the demands of organized societal groups. In essence, this view posits that states with stringent domestic regulatory standards have an incentive to export costly regulation abroad: the more costly domestic regulatory standards, the higher the incentives for both domestic producers and policymakers to support similar international standards to create a level playing field through a race-to-the-top strategy (Falkner 2007; Kelemen 2010; Kelemen & Vogel 2010). Producers in states with stringent domestic regulatory standards have an incentive to support the export of costly regulation abroad because this would reduce the competitive advantage of producers in countries with lower regulatory standards, as well as open up market access opportunities in foreign markets. The incentives to spread domestic norms internationally are even stronger when producer and civic groups join forces in Baptist–bootlegger coalitions (Vogel 1995; DeSombre 2000).

While this perspective tells us why certain constituencies' and policymakers' defending their interests may wish to have stringent domestic regulatory standards spread onto the international level, this leaves the question of what type of regime states are then likely to prefer unanswered. It seems fair to deem these groups' preferences over different institutional venues to depend on whether they expect their interests in regulatory export to remain stable over time. Such expectations may depend on a number of factors, for example, political salience of an issue, or domestic institutional rules favoring policy stability. For instance, when issues are highly

politically salient, touching upon widely held and strongly rooted values and opinions within society, constituencies and policymakers preferences over international upward regulatory harmonization are not likely to fluctuate over time. Similarly, it seems fair to expect preferences for international upward regulatory harmonization to be more stable in political systems where a high number of institutional actors who have a say in the decisionmaking process minimizes the chances for movements away from the status quo (Scharpf 1988; Tsebelis 2002). Under these conditions, we can expect actors to value flexibility less, hence creating incentives for them to care more about enforceability of commitments. Indeed, when actors anticipate that their preferences will not change in the future, they are likely to want to make sure opting out of agreed upon rules becomes more difficult.

In contrast, producers in countries with lower domestic regulatory standards have strong incentives to oppose the setting up of new international regulatory standards for exactly the same reasons. New rules requiring a costly upward movement of domestic regulatory standards promise to create adjustment costs for domestic producers, decreasing their competitiveness in the international as well as domestic market. It is true that the so-called California effect may lead countries with lower domestic regulatory standards to be brought to surrender competitive advantages they have derived from lower domestic standards because of the large and attractive internal market, as well as the political influence of states pursuing higher regulatory standards (Vogel 1995; Young 2003). In normal circumstances, however, one can expect producers and policymakers defending their interests in countries with relatively less stringent regulatory standards to oppose upward regulatory harmonization, because this would likely entail substantial adjustment costs and loss of competitiveness.

By extension, if the absence of any regulatory harmonization is the preferred outcome for these actors, one can derive the expectation that, if there is to be upward harmonization, they will prefer this in non-judicialized venues rather than in judicialized ones. If for some reason these countries are unable to veto these international regulatory initiatives, they prefer an institutional venue with weak enforcement, so as to allow for cost-free deviations to agreed-upon rules. In other words, when actors cannot prevent regulatory action on a specific issue, they may grudgingly accept new substantive rules in a setting with a low degree of judicialization in order to ensure that particular undesired policy outcomes never become binding standards.

Although in this article we are not primarily concerned with whether actors actually attain their preferences, bargaining power to shape negotiation outcomes is likely to crucially depend on the costs of non-agreement (Moravcsik 1993). Whether developing countries with lower domestic regulatory standards give in to, or are able to resist, developed countries' requests to place new substantive rules in a judicialized venue, is, thus, likely to depend on the availability of better outside options for developing countries. If developing countries deem it more costly to resist developed countries' demands than to accept the terms of the agreement, the latter are likely to prevail. By contrast, if developing countries dispose of a better alternative, that is, costs of non-agreement for them are low, they are likely to be able to resist and block developed countries' initiatives. In the universe of cases we consider, the availability of outside options for developing countries mainly depends on whether advanced industrialized countries can make a deal attractive through issue linkage, or whether they can force reluctant developing countries to accept upward harmonization through the threat of exclusion.

### 3.2. Downward harmonization

Upward regulatory harmonization, however, is not the only possible type of regulatory harmonization states engage in. Countries not only face a choice between committing or not commit-



ting to binding agreements that create new rules or upgrade existing rules in a given policy area. The WTO includes binding regulatory agreements in a host of different areas, such as services, intellectual property rights, investments, technical standards and food safety, and animal health issues, that were traditionally regulated at the national level (Hoekman & Kostecki 2009). In this context, countries sometimes wish to decrease, rather than increase, the level of international regulatory commitments they are bound to. This may be so for different reasons. States that had previously committed to existing regulatory agreements may find out they are incapable of converging on stringent rules or changed economic circumstances may lead them to a change of preferences. Whatever the reasons driving these preference changes, we empirically observe that states increasingly seek to bring back some of the flexibility they had given up by committing to regulatory agreements in the WTO. This preference translates in initiatives aimed at allowing for greater latitude and flexibility in their implementation. These can be achieved in two ways. On the one hand, flexibility from already agreed upon rules can be obtained by directly amending and/or replacing existing rules with more flexible ones. On the other hand, such flexibility can also be brought about indirectly by introducing new affirmative rights within the same judicialized venue that deviate from previously agreed upon rules, hence having the concrete effect of amending such rules. We use the concept of downward harmonization to describe both types of situations because, irrespective of whether the new rules take the form of limitations to existing rules or of new affirmative rights, the aim is to decrease the degree of stringency of already agreed upon rules, thus enabling states to contravene such rules without paying a cost.

In this scenario, the constellation of actors' preferences tips over with respect to the previous one. Countries with less stringent regulatory standards face compelling incentives to address the most judicialized regime, whereas highly regulated countries are likely to strongly oppose negotiations in that venue. When states have already committed to binding agreements in the WTO, or to commitments with long implementation periods, the state with the lower level of domestic regulation may have a stake in increasing flexibility of such commitments to accommodate domestic rules that are likely to be found WTO incompatible and the change of which would entail high adjustment costs (Poletti & Sicurelli 2012). Domestic constituencies and policymakers are likely to anticipate that this can only be achieved by changing and/or replacing such rules already agreed upon in the WTO.

In principle, downward regulatory harmonization could also be pursued in other venues. Yet the relationship between WTO rules and rules agreed upon in other non-judicialized regimes is inherently, although often implicitly, hierarchical. Indeed, when a clash between such rules emerges, WTO rules prevail because WTO rules can be invoked to activate WTO dispute settlement against non-compliant members and to impose costs on them, whereas rules agreed upon in non-judicialized venues have no biting force (Eckersley 2004). In other words, countries with a low level of domestic regulation, usually developing countries, can only immunize themselves from already agreed upon binding rules in the WTO by changing and/or replacing rules in the WTO itself. It is important to stress that this is so precisely because of judicialization. In the absence of a venue with strong enforcement, countries preferring downward regulatory harmonization have no particular preference for where to locate rules introducing flexibility. In the presence of a highly judicialized venue, however, the option of shifting to another venue or even of creating a new venue is simply not an option that can lead to the attainment of actors' preferences. When states have already committed to enforceable rules, they can only achieve downward harmonization within the venue where such rules were agreed. In sum, while in the absence of a judicialized venue actors could try and achieve downward harmonization also by addressing different venues, judicialization restricts actors' room for maneuver, forcing them to

**Table 1** Regulatory harmonization and venue shopping behavior of countries

	Upward harmonization	Downward harmonization
Highly regulated country	Judicialized setting	Status quo or non-judicialized setting
Non-highly regulated country	Status quo or non-judicialized setting	Judicialized setting (WTO)

WTO, World Trade Organization.

pursue such strategy of downward harmonization in the highly judicialized venue, because only then will the more flexible rule overrule the more stringent one.

Precisely for the opposite reasons, highly regulated developed countries that prefer the status quo are likely to prefer no downward harmonization at all, and, in case they were unable to block such an initiative, are likely to acquiesce to the adoption of new rules only in a non-judicialized setting. The obvious reason for this is that they wish to retain the right to force their partners to comply with agreed upon rules. As they greatly value enforceability of commitments, they are likely to oppose any attempt to bring flexibility back in through the back door.

Again, whether developing countries with lower domestic regulatory standards manage to achieve their desired downward regulatory harmonization in the judicialized venue crucially depends on whether a better alternative to such negotiated agreement is available to developed countries. If developed countries with higher domestic regulatory standards deem the costs of non-agreement to be higher than those resulting from the proposed agreement, they are likely to give in. The opposite holds when the costs of non-agreement are low for developed countries. In other words, whenever developing countries can link their approval of other issues to the introduction of flexibility for already existing stringent international regulation, they are likely to prevail.

Whether developed countries manage to keep the status quo or agree to developing countries' demands to adopt new rules in a non-judicialized setting is of secondary importance to them, as their primary concern is to avoid any change of existing binding rules in the judicialized setting, and, hence, to keep their ability to enforce these rules. Table 1 provides an overview of the argument.

#### 4. Venue shopping in the field of intellectual property rights protection

Having set out strategic reasons for why states may engage in venue shopping in a systematic way, we now turn to the empirical testing of our argument. More specifically, we develop an in-depth case study analysis of two specific instances of global intellectual property rights regulation to trace the causal links of our argument: regulation in the area of genetic resources and in the area of public health and access to medicines. Consistently, with our factor-centric research design, the case studies have been selected so as to provide for the needed variance on the side of the explanatory conditions (Gschwend & Schimmelfennig 2007).<sup>2</sup> In both case studies, we consider situations in which states can choose among different institutional venues and draw on process related evidence to show the plausibility of the contention that states' venue preferences are affected by both the level of domestic regulation and the type of regulatory harmonization. In addition, in the case studies we adopt an inter-temporal approach that allows us to multiply the observation points of the empirical analysis, hence strengthening the internal validity of the case studies. Indeed, in both instances of global intellectual property rights regulation we are able to



trace how preferences of states evolve over time in response to changes in the value on one of the key explanatory conditions, namely the type of regulatory harmonization.

#### **4.1. Genetic resources and biological diversity: Between WTO TRIPs, UPOV, FAO, WIPO, and CBD**

The Trade-Related Intellectual Property Rights (TRIPs) agreement considerably expanded the range of economic sectors and technologies subject to intellectual property rights protection. Bestowing and expanding property rights has shifted the boundary between the public domain and the realm of property (Boyle 2004). However, one regulatory area where safeguard devices, such as patents, have not been fully adopted on the international level is the field of biotechnology. Advancements in biotechnology have given rise to the question whether living organisms and their genetic resources, which include genetic codes, seed varieties, or plant extracts, can be subjected to intellectual property rights protection.<sup>3</sup>

For most of the 20th century, the view had been that private ownership over plants and animals and their genetic resources *per se* should not exist and should belong to the common heritage of mankind, meaning that open access to these resources is guaranteed (Raustiala & Victor 2004, p. 281). Advocates of patentability, in contrast, argue that biotechnology is a means to secure the sustainable development of agriculture, to yield higher results with less use of pesticides and other environmentally harmful products, and to meet the challenge of soaring international commodity and food prices. In order to achieve this, investments in technologies that make use of genetic resources and other biological material have to be protected and secured through the allocation of private property rights.

The evolution of states' preferences over venue choice in the field of IPR protection of plant genetic resources is consistent with our theoretical expectations. In a first phase, we observe a typical case of upward harmonization in which states harmonize domestic practices through new international rules. On the one hand, developed countries with a high level of IPR protection sought to secure the interests of commercial plant breeders through the adoption of international rules, which could then be placed under the framework of the WTO with its strong enforcement mechanism. On the other hand, biodiversity-rich developing countries with low levels of IPR protection first sought to oppose the adoption of strongly enforceable rules that would harm their interests. Once these rules were agreed upon, however, this became a case of downward harmonization. The constellation of interests then changed, with developing countries seeking to incorporate new rules in the WTO to increase the flexibility at their disposal and allow for the public availability of plant genetic resources, and industrialized countries resisting this strategy and trying to locate this agenda in other non-judicialized venues.

Industrialized countries' preference for upgrading global intellectual property regulation on plant genetic resources developed gradually throughout the last half century. Many of the agricultural innovations of the 1970s had been brought about through improvements of wild plant genetic resources or those stored in seed banks (Raustiala & Victor 2004, p. 281). These countries regulated plant genetic resources through so-called plant breeders' rights, meaning that simply copying innovations in plant varieties is not permitted, but breeders have the right to use another breeder's innovations for their own new variety.

In 1961, industrialized countries brought their concept of plant breeders' rights with limited intellectual property protection onto the international level through the International Convention for the Protection of New Varieties of Plants (UPOV Convention<sup>4</sup>). Because plant breeders were almost exclusively located in industrialized countries, this so-called *sui generis* system of

intellectual property protection set up within the venue of UPOV mainly mirrored the interests of commercial plant breeders of the developed world (Helfer 2004a). Indeed, the UPOV Convention of 1961, as well as its 1978 amendment, conferred property rights only over modified plant genetic resources, leaving the natural and unmodified ones in the domain of the common heritage system. Basically, this implied that commercial and non-commercial plant breeders had access to this resource. While biodiversity-rich developing countries mostly provided raw plant genetic resources, plant breeders in industrialized countries subsequently commercialized these. In the 1991 revised version of the UPOV convention, plant breeders' rights were strengthened, whereas so-called farmers' privileges – the saving of seeds for reuse – were restricted (UNCTAD-ICTSD 2005), strengthening the intellectual property rights of agro-technical industries in industrialized countries.

Meanwhile, a group of developing countries tabled the topic in the FAO in 1983 by adopting the non-legally binding FAO International Undertaking on Plant Genetic Resources (Raustiala & Victor 2004, p. 286), which stated that all plant genetic resources – whether modified, found in nature, or stored in seed banks – belonged to the common heritage of mankind (Correa 2001). With this provision, the downward regulatory harmonization of the FAO Undertaking stood in clear contradiction with the UPOV conventions.

In addition, state representatives within the UN Environmental Program also developed a redistributive system of benefit sharing for commercial research and development on plant genetic resources within the framework of the Convention on Biological Diversity (CBD) entering into force in 1993. The CBD upheld the principle of national sovereignty over genetic resources, and developing countries set up the benefit sharing principle with the objective to offset the effects of increased intellectual property protection.

Thus, two competing international sets of rules were juxtaposed next to one another without any hierarchy when it came to their degree of enforceability. This changed, however, when representatives of industrialized countries tabled intellectual property rules on genetic resources in the GATT Uruguay Round negotiations. While already disposing of a relatively effective dispute settlement mechanism by 1989, GATT contracting parties had decisively increased the degree of judicialization of that venue by introducing compulsory jurisdiction and increasing the independence of its so-called panels (GATT 1990; Hudec 2000). By the end of the Round in 1994, they added the multilateral authorization of sanctions in order to pressure non-compliant states into implementation, and created the WTO Appellate Body, turning the WTO into the most highly judicialized international venue.

With the explicit motivation of bringing more stringent intellectual property rights under WTO dispute settlement jurisdiction, industrialized countries drafted the WTO Agreement on TRIPs (Sell 2003). More specifically, they inserted Article 27.3 (b) into this particular WTO treaty, requiring members to grant patents for microorganisms and establish a *sui generis* system for worked plant genetic resources, meaning that all microorganisms, non-biological and microbiological processes can be patented, even though the treaty does not provide a clear definition of terms (Wissen 2003). Industrialized countries with high levels of IPR protection, hence, considered the UPOV Conventions as an adequate *sui generis* system for worked plant genetic resources. Most developing countries were opposed to this attempt to locate such stringent intellectual property rules in the highly judicialized venue of the WTO, yet had to grudgingly accept its adoption, as it constituted one of the building blocks of the single undertaking of the Uruguay Round (Steinberg 2002). In other words, the cost of non-agreement was high for them, as developed countries with higher domestic regulatory standards could resort to the threat of exclusion from pre-existing market access commitments embodied in the GATT.

At the same time, this was not a complete victory for industrialized countries. Because the TRIPs section on the patentability of animals and plants was left vague, without explicitly incorporating any pre-existing intellectual property agreements, such as UPOV, and because not all countries signed up to the UPOV Convention, this particular section was made subject to a later review process (Raustiala & Victor 2004).

When engaging review of the contentious Article 27.3 (b) during the Doha Round, initially industrialized countries sought agreement on the interpretation that UPOV should be considered as the only *sui generis* system. Soon after, however, preferences for venues tipped over. On the one hand, developing countries no longer only pursued their policy objectives in the FAO and the CBD, but tried to pursue these also in the WTO, as their efforts in the other venues would remain without tangible effects, while industrialized countries argued strategically that the complexity of the matter demanded discussions to take place, not in the framework of the WTO, but in more specialized and, more importantly, less judicialized venues.

Developing countries' strategy of bringing flexibility back into TRIPs consisted of developing new rules in FAO, the CBD, and WIPO, with a view to establishing a definition of what qualifies as a *sui generis* system of patentability in line with their preferences, and then have such a definition incorporated into the WTO TRIPs agreement during its review process. In 2000, developing countries concluded the Cartagena Protocol on possible dangers arising out of the use of biotechnology and genetically modified organisms (Raustiala 1997). In November 2010 in Nagoya, the CBD parties also agreed on a protocol on access and benefit sharing regarding genetic resources used in inventions, but postponed negotiations on enforcement to a later stage – perpetuating the low degree of judicialization of this international venue. Developing countries with a preference for a relatively low level of regulatory harmonization on the topic also engaged in negotiations on a specification of the CBD provisions on plant genetic resources in the FAO Commission on Plant Genetic Resources for Food and Agriculture, leading to the International Treaty on Plant Genetic Resources for Food and Agriculture (IT/PGRFA) in 2001, revising the earlier FAO undertaking. This treaty stipulated farmers' rights and established a fund to which private parties contribute a part of profits realized through commercial products made from a communal seed treasury (Helfer 2004b, p. 39), yet also left implementation and enforcement to the discretion of member states (Zerbe 2007, p. 104). The regulation of genetic resources was also dealt with in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTRK).

After having developed such rules in these non-judicialized regulatory venues, developing countries then sought to put a number of elements on the negotiation table of the WTO review process, knowing that the desired flexibility with respect to TRIPs could only be achieved if these CBD and FAO rules could be made part and parcel of WTO law. They asked for a clarification of the term microorganism, a determination of what should be considered an effective *sui generis* system of plant variety protection, an incorporation of the CBD into WTO law, especially with regard to benefit-sharing, potential disclosure requirements for the use of genetic resources in order to prevent what they called bio-piracy, and protection of traditional knowledge (Wissen 2003).

In the face of this attempt to bring flexibility back into WTO TRIPs rules, industrialized countries argued strategically that the complexity of the matter demanded that discussions on the new legal concepts – such as benefit sharing, traditional knowledge, farmers' rights, or prior informed consent – should be conducted in a venue with more specialized expertise on the subject, while knowing lucidly well that WIPO had abandoned any attempt to introduce judicialized enforcement in 1997 already (Gurry 1999). While developing countries prefer the

maintenance and extension of public availability of plant genetic resources to be discussed in the TRIPs review process, industrialized countries – most notably the US and Japan – wanted to keep the issues in WIPO – a venue where any decision would not become subject to a highly judicialized form of enforcement. In other words, as the costs of non-agreement were low for developed countries, they could resist the other side's demands.

#### **4.2. Public health: Between WIPO, WTO, WHO, UNAIDS, and World Bank**

The debate concerning how to allow deviations from WTO TRIPs rules to protect public health in poor countries also appropriately illustrates our theoretical reasoning. In a first phase, advanced industrialized countries introduced and defended the high level of intellectual property rights protection for their patent-based pharmaceutical companies under the TRIPS Treaty in the highly judicialized venue of the WTO, while developing countries had to grudgingly accept this location of IPR rules, instead of in the less judicialized WIPO or the WHO. Yet in a second phase, developing countries with public health crises sought exceptions to existing rules *within* the WTO in the WTO TRIPs Council, and later as a precondition for the start of the Doha Development Agenda negotiations. Simultaneously, industrialized countries strove to shift the topic to non-judicialized international venues, such as the World Bank, UNAIDS, and the Global Fund to Fight Aids, Tuberculosis and Malaria.

Patent-based manufacturers of medicines and their allies in national public administrations in industrialized countries had pushed their governments to engage in venue shopping in international intellectual property protection. Companies with bases in the US, the EU, and Japan were among the most active in the international coalition that advocated a shift from the granting of national *privileges* to the provision of global property *rights*, arguing in favor of institutional change to achieve this substantive shift in international regulation (Correa 2000; Maskus 2002; Sell 2003). These actors had been especially disappointed with the lack of substantive and obligatory intellectual property rules under WIPO, as these resemble guiding standards whose implementation is left to the discretion of signatory states. And even if an upgrading of substantive intellectual property rules would be achieved within that organization, WIPO did, and still does not, possess a high degree of judicialization, which would allow the enforcement of those rules. While WIPO negotiations on a Draft Substantive Patent Law Treaty failed in 1992, those on Dispute Settlement in intellectual property failed in 1997. For developing countries, the cost of non-agreement in these venues was nil, while industrialized countries could not entice them into an agreement by offering issue linkages, or credibly threaten exclusion from any benefits in WIPO. Instead, industrialized countries advocated a shift to a venue with a greater promise of judicial enforcement, the GATT/WTO, where the threat of trade sanctions would allow states to link the issue of market access to the implementation of stricter intellectual property legislation (Sell 2003). Intellectual property became part of an overall package deal, linking intellectual property protection worldwide to enhanced market access in goods and services for developing countries.

The WTO TRIPs Agreement effectively introduced the positive obligation to adopt national patent legislation, grant 20 years of exclusive rights, and empower domestic courts to enforce those rights. Moreover, the establishment of the WTO dispute settlement system created compulsory jurisdiction whenever a member state would file a dispute on non-compliance with these rules, created the WTO Appellate Body, and provided for the (threat of) imposition of trade sanctions in cases of continuing non-compliance after an adverse WTO ruling. Although developing countries expressed concerns about the creation of an institutional setting that developed countries could use in order to impose costs on them, that is, by enforcing the implementation

of TRIPS treaty rules, they were forced to accept the terms of the agreement, because developed countries could resort to the threat of exclusion embodied in the single undertaking of the Uruguay Round (Steinberg 2002).

Soon after the adoption of the TRIPS agreement, non-governmental public health organizations and developing countries raised objections to the high degree of intellectual property protection and the shadow of hard enforcement through the judicialized WTO dispute settlement, especially those organizations concerned with access to essential medicines in developing countries. Developing countries raised the topic in the WTO TRIPS Council, as well as in the World Health Organization (Helfer 2004b; Dür & De Bièvre 2007), expressing concern that the TRIPS agreement did not provide for a sufficient degree of flexibility necessary to ensure easy and affordable access to medicines in countries with public health problems.

The TRIPS agreement already included provisions allowing states to partially overrule the payment of patent royalties through the granting of so-called compulsory licenses.<sup>5</sup> The agreement also states, however, that production under compulsory licensing must be predominantly for the domestic market, hampering the ability of countries that are unable to produce pharmaceutical products from importing cheaper generics from other countries. Developing countries with insufficient or no manufacturing capacities in the pharmaceutical sector, thus, protested that the flexibility foreseen in the TRIPS agreement was of no use to them. As the TRIPS implementation period of 10 years for developing countries and 15 years for least developed countries approached, they argued that in cases of a health emergency – outbreaks of diseases, such as HIV/AIDS, malaria, and tuberculosis – they would not be able to deal with such crises. India and Brazil, countries with manufacturers of drugs produced and distributed without patent protection, so-called generic pharmaceuticals, thus, joined the ranks of least developed countries and started to advocate the principle that the exportation of their products to countries with a health emergency should be explicitly allowed.

Those actors who had a stake in increasing the flexibility of already agreed upon rules attempted to modify rules in the highly judicialized venue of the WTO, rather than in other non-judicialized venues more specialized in the issue areas of intellectual property and health. In contrast, those who opposed such a move tried to shift negotiations to international venues outside the WTO, lacking judicialized enforcement.

Developing countries, thus, tabled the issue of compulsory licensing in the WTO TRIPS Council and in the negotiations leading to the launch of the Doha Round. In 2001, the Doha Declaration on the TRIPS Agreement and Public Health mandated members to find an “expeditious solution” to the problem. In 2003, WTO members agreed to a waiver from TRIPS obligations making sure that production under compulsory licensing would not only be allowed for the domestic market, but also for foreign markets. In 2005, this decision was made permanent in the form of an amendment of the TRIPS agreement, as soon as two-thirds of the membership had ratified the amendment (Dür & De Bièvre 2007). Developing countries, thus, achieved their preference for rules relaxing the strictures of the TRIPS agreement to be located in the judicialized WTO. Developed countries attached a high value to a successful launch of the Doha Round, making them prepared to concede as much in order to ensure that the developing countries would be on board. The 9/11 attacks made the US particularly keen on reiterating their commitment to multilateral cooperation (Blustein 2009), while the pending expiration of the peace clause on agricultural subsidies created incentives for the EU to broaden the scope of negotiation in the Doha round as much as possible (Poletti 2010). Because the costs of non-agreement were high for developed countries, they were willing to concede to developing countries on a *prima facie* relaxation of TRIPS provisions concerning access to medicines.

In the course of these negotiations, the US, the EU and other industrialized states tried, yet failed, in their attempt to include an exhaustive and, hence, limiting list of diseases for which developing countries could declare a health emergency. The agreement reached thus specified the conditions under which compulsory licenses would be possible and the procedure to be followed.<sup>6</sup>

In the following phase, countries that had wanted the maintenance of the status quo of existing IPR rules, such as the US and EU, tried to shift the issue of access to medicines to international venues without judicialized enforcement, foremost the WHO, the World Bank, and UNAIDS. They strategically argued that the main problem of access to medicines was a question of public infrastructure and resources, rather than of intellectual property. WHO documents started to adopt a compromising tone with regard to public health and intellectual property, while cooperation between government agencies, pharmaceutical companies, and public health NGOs was formalized in the Global Fund – first established under an administrative services agreement with the WHO, since 2009 an autonomous international financing institution.

In sum, countries that sought to bring flexibility back to allow for derogation to rules agreed upon in judicialized settings anticipated that their goals can be achieved only by changing and/or replacing those very same rules. In contrast, those who wish to maintain the status quo try to resist this move and, when this turns out to be impossible, prefer to shift the issue onto a non-judicialized venue in order to retain, as much as possible, their right to exert pressure on their partners to comply with their obligations.

## 5. Conclusion

In this article, we have sought to develop an explanation for how an institutional characteristic of different international venues, namely their degree of judicialization, affects venue shopping behavior of states interested in international regulatory harmonization. While the argument that states anticipate whether the prospective agreement will be highly enforceable is a key factor affecting their propensity to commit to such agreements is not new, we seek to specify how and under what conditions enforceability of prospective rules increases, or rather decreases, the attractiveness of a specific venue for countries wishing to engage in regulatory harmonization. We have suggested that distinguishing between different types of regulatory harmonization is key to make sense of the empirically observable variation of venue shopping behavior of states.

The first situation we take into consideration is one in which states consider either to establish new rules to harmonize domestic regulatory standards or to tighten already existing rules. We conceptualize this as a case of upward harmonization, arguing that in this scenario highly regulated states that stand to benefit from spreading domestic norms onto the international level will value the enforceability of commitments, whereas countries with a relatively low level of domestic regulation that stand to lose from the prospective agreement will prefer a non-judicialized venue if the status quo cannot be maintained. The second situation we consider is one in which states confront the question of whether to allow for a loosening of already agreed upon rules backed by strong enforcement mechanisms. We conceptualize this as a case of downward harmonization and contend that in this scenario states' preferences tip over, with highly regulated states clearly preferring venues with a low degree of rule enforceability, and countries with a relatively low level of domestic regulation seeking to replace and/or change judicialized venues.

Our in-depth case studies of two instances of global intellectual property rights regulation lend support to our argument, showing that negotiating actors took into account the degree to which a prospective agreement would subsequently be enforceable.



While we have illustrated the cogency of the argument proposed by relying on empirical evidence concerning different instances of global intellectual property rights regulation, there is no reason to limit the applicability of our hypotheses to the analysis of this particular field of international regulation. The WTO is not only highly judicialized, but beginning in the mid-1990s has become a key venue in international regulatory governance, and an attractive institutional location for states striving to locate new rules under its jurisdiction. Since then, debates on global regulatory harmonization in a number of different issue areas have often confronted state actors with the choice of whether to locate these rules in the WTO, in other more specialized and non-judicialized venues, or even to explicitly keep them out of the scope of WTO jurisdiction. Because our argument reveals systematic preferences in cases where actors face a choice between a judicialized and a non-judicialized institutional venue for global regulatory harmonization, we suggest our line of reasoning could shed light on such choices in other issue areas.

For instance, some industrialized countries with a preference for upward regulatory harmonization of labor standards have attempted to make core labor standards codified in the International Labour Organization (ILO) enforceable by bringing them under the jurisdiction of the WTO. This venue shopping move has been fiercely and successfully resisted by developing countries, which have all subscribed to those ILO conventions, and have continued to value the flexibility in their application because of their low degree of enforceability. Similarly, advanced industrialized countries have often tabled the idea of a multilateral treaty on investment, only to find out that its conclusion could not be achieved in the absence of an attractive issue linkage package, apart from other reasons confounding the demand and support for such an initiative (Walter 2001).

The question of whether or not to introduce environmental standards in the WTO has followed a similar logic. Seeking to preserve its ban on imports of hormone-treated beef and genetically modified crops, the EU sought to increase the scope of legitimate exceptions to WTO rules and to the threats these could pose to the domestic regulatory status quo in the EU. More specifically, during the Doha Round, the European Union sought to obtain flexibility in the application of the already agreed upon rules of the WTO Sanitary and Phytosanitary Standards agreement. At first, the EU set about introducing new international rules on the precautionary principle in a non-judicialized venue, such as the UN-led Cartagena Protocol on Biosafety. Soon after, however, the EU realized that this venue strategy would not lend it full legal cover. This forced the EU to shift venue and seek to incorporate new environmental rules in the highly judicialized WTO in order to introduce carve-outs to the Sanitary and Phytosanitary (SPS) Agreement that would de facto grant immunity to its domestic regulations. Those states opposing this strategy refused to follow suit and blocked negotiations on a definition of the precautionary principle in the WTO, as well as on making multilateral environmental agreements concluded in other venues as part and parcel of WTO law (Poletti & Sicurelli 2012).

Finally, this article also sheds light on several important aspects of the international political economy of international regulatory cooperation. The expansion of the international trade regime's regulatory reach with the conclusion of the Uruguay Round was possible because developing countries that could reasonably expect to lose from such agreements were confronted with the threat of exclusion from previously agreed upon traditional market access commitments (Steinberg 2002). Our argument suggests that in the absence of this threat of exclusion, the prospects for further regulatory cooperation in a highly judicialized setting such as the WTO are bleak, because states with relatively low regulatory standards are likely to oppose such a prospect. The inability of key developed countries to bring developing countries to agree to negotiate on the Singapore issue or on trade-and-labor, as well as the lack of significant

advancements in negotiations concerning IPRs or trade-and-environment in the current Doha round, bear witness to the obstacles that stand in the path toward upward regulatory harmonization in the WTO.

Furthermore, our analysis suggests that these same states are likely to exert pressure on the WTO to bring flexibility in through the back door to avoid the adjustment costs that regulatory harmonization at a high level would bring about. This has important policy implications. Increasing flexibility may be an attractive way to deal with increased diversity of preferences that the ever-larger membership of the WTO has brought about – witness the attempt by a limited set of WTO member states for an Anti-Counterfeiting Trade Agreement (ACTA), or developing countries' demand to extend the TRIPS implementation deadline yet again. A high degree of judicialization and strong enforcement of rules may well, therefore, be feasible and stable over time only in small clubs composed of countries with similar levels of domestic economic regulation. It should come as no surprise, therefore, that states increasingly prefer the venue of preferential trade agreements, bilateral and regional, to locate regulatory harmonization.

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## Notes

- 1 While legalization is the most commonly used concept within this literature, in this article we opt for the term judicialization as we focus on the effects of strengthened mechanisms of rule enforcement, and not on the broader topic of the increased scope of international lawmaking.
- 2 A factor-centric research design is primarily interested in the explanatory power of causal factors, whereas an outcome-centric research design is primarily interested in explaining policy outcomes.
- 3 According to the Convention on Biological Diversity (CBD), biotechnology is “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses.”
- 4 UPOV is the French abbreviation for Union for the Protection of New Varieties of Plants. Even though formally independent, UPOV is closely associated with WIPO.
- 5 States still must compensate owners at a lower fixed percentage.
- 6 In fact, the tricky detail of its implementation revealed that this 2005 amendment of the TRIPs treaty was a pyrrhic victory for developing countries, as the procedure for compulsory licensing turned out to be so excruciatingly difficult as to de facto severely limit its feasibility (Third World Network 2010).

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