How to Reshape Treaties without Negotiations: Intellectual Property Enforcement as a Case Study of Global Governance by Stealth

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Adam Smith’s theory argued that individuals in pursuit of their self-interest (firms in pursuit of maximizing profits) were led as if by an invisible hand to the general well-being of society. One of the important results of my work, developed in a number of my papers, was that the invisible hand often seemed invisible because it was not there."

Joseph Stiglitz

1. Introduction

In recent years, some of the most developed nations and their Intellectual Property Rights (hereinafter IP or IPR) knowledge industries have started a worldwide campaign for the repression of counterfeit and pirated products. The campaign is grounded on claims of rising levels of counterfeiting and piracy mostly originated in China and its harmful effects to the potential exporting revenues mainly in the music, movie and pharmaceutical industries. It has been argued that those infringements bear a close link with the organized crime and terrorism, and pose health and safety risks for consumers.

The paper accounts for those claims to analyze the economic grounds, legal parameters and strategic mechanisms through which IP knowledge exporting countries have recently advanced new standards of IPR enforcement in intergovernmental organizations.

The study adopts the normative assumption that counterfeiting and piracy are not to be justified and IP holders are entitled to seek enforcement of their rights. There is already in the IP system set in place under multilateral rules, the 1994 Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) of the World Trade Organization (WTO). From the beginning, technology-abundant countries were not satisfied with the levels of rules on IPR infringement and have called for more stringent standards of repression. On the other side, developing countries had to promote a sharp increase in the levels of domestic regulation to achieve those agreed in the TRIPS, as they more closely reflected standards already applied by states with advanced technology. But the assessment of, among others issues, whether the current rules should be modified and, if so, what should be the common grounds for deterrence on IPR enforcement, what tools should be used for this purpose, who should bear the costs, how third parties’ rights should be taken into account, and to what extent variations of economic development, priorities and

2 Carolyn Deere, The Implementation Game (Oxford University Press 2009), p. 304
policies of different countries are balanced in the new international agenda, has necessarily to be promoted to accommodate the rights of all interested parties. Such a debate is not taking place anywhere.

Instead, principles and rules on substance and procedure devised by specific interest groups have been advanced at the unilateral, bilateral, regional and multilateral levels, under the argument that concerted efforts have to be made by governments to stop counterfeiting and piracy to their highest extent, according to parameters devised by those groups. The IPR enforcement agenda adopts the assumption that the problem is of disproportionate measures, existing enforcement rules are not enough to provide deterrence, the issue is grounded on a minimum set of rules already subject to state consensus in the international legal system and the agenda is only expanding the level of implementation.

Intergovernmental organizations focused on standard setting rules and procedure, as well as on enforcement activities, have been closely involved in the promotion of rigorous standards of IPR enforcement, departing from the existing multilateral rules. The World Customs Organization (WCO), International Criminal Police Organization (INTERPOL), World Health Organization (WHO), Universal Postal Union (UPU) and, more recently, the United Nations Office on Drugs and Crime (UNDOC) are multilateral regimes where initiatives have been advanced, in addition to the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO). Failed attempts to create soft law to advance new standards in some of these organizations, notably the WCO and WHO, have not prevented the direct implementation of new levels of IPR enforcement in member countries. Liaison among foreign and domestic enforcers through networks fostered by international organizations has provided the required legitimacy for the i) establishment of joint operations to seize products allegedly infringing IPR, ii) promotion of international events for the exchange of ‘best practices’ and iii) provision of technical assistance to directly advance the preferred standards at the domestic level.

These multilateral dynamics have been complemented by an unsuccessful project at the Organization of Economic Co-Operation and Development (OECD) to produce data to validate the claimed urge for new benchmarks of IPR enforcement. Behind the strategies lies the Group of Eight (G8)\(^3\).

The present study is grounded on the claim that a new mechanism has been developed by the G8 to create legal normativity and thereby exercise global governance in multilateral IPR enforcement. It consists, at the one hand, in subverting the traditional stages of norm production and implementation, and seeks to avoid negotiations and overcome the resistance of other states to the agenda. The new mechanism introduces new strategies to advance the agenda, which delays its

\(^3\) Comprised by countries that together, until recently, enjoyed the highest GDP in the world: the U.S., UK, Japan, Italy, Germany, France, Canada and Russia.
detection and reduces the ability of opposition by central foreign policy organs of affected states. It also diverts attention away from what is actually happening and the dimension of the intended outcomes. The elements of this mechanism comprise a new way to make global governance in a world of economic power shift, by using the power of networks to quietly advance the implementation of new normative standards. In addition, the invisibility, redesign of the core issues, subversion of the existing system and diversion extensively applied characterizes the exercise of global governance by stealth.

Section one of the paper illustrates the stalemate of trade negotiations at the WTO and WIPO, as well as the impossibility to advance their preferred agenda through the use of the dispute settlement system, leading IP-exporting countries and their industries to seek other regimes to advance their preferred agenda on IPR enforcement.

Section two focuses on the new dynamics of global governance - global governance by stealth - in place to establish new IPR enforcement normativity at the international level. It introduces its core elements and explains how the traditional dynamics of international norm creation and implementation are subverted. The central claim is that, although taking place elsewhere, the ultimate goal of strategies to increase legal normativity on IPR enforcement is to have the latter multilateralized by the WTO dispute settlement system.

In section three, case studies will dismember the strategies across various intergovernmental organizations, selected by the promoters of the agenda in view of their structural characteristics and issue areas. The analysis will support the conclusion of the impossibility to completely block the agenda in multilateral organizations, as well as the basis for such limitations, accounting for the need of new international mechanisms to bring agents into compliance with rules on procedure and accountability.

Section four refutes the major arguments used to justify the new IPR enforcement agenda and the legal grounds upon which it is allegedly established. It begins by acknowledging the role of technology in facilitating IPR infringement, on the one hand, and need to establish economic grounds and data to determine the extent of the issue, as well as to assess alternative and negotiated solutions leading to reasonable and balanced standards, on the other hand. It further provides evidence that the current practices allegedly based on existing multilateral legal normativity under the TRIPS are not, as argued by its proponents, build from the minimum grounds and principles set forth therein (TRIPS-plus). Rather, it promotes a de facto departure from TRIPS grounds, principles, rules and safeguards, both in terms of substance and procedure, leading to the redesign of existing substantive and procedural standards. What is common with TRIPS is only the use of elements already present in the Agreement. It is therefore a TRIPS-else, not a TRIPS-plus agenda.
Section five accounts for the costs of the implementation of the new legal standards presented in the previous section from the perspectives of trade, competition, access to medicines and private rights. The goal is to provide a dimension of the implications of the implementation of the legal normativity sought.

Finally, section six explains the choice for more stringent normativity and related strategies from an international political economy perspective. It contextualizes the findings of the previous sections by arguing that the current IPR enforcement agenda has increasingly less to do with counterfeiting and piracy, as it targets a much broader spectrum of IPR enforcement. The international economic and political scenarios where the agenda is inserted (to be explained in this section), the lack of evidence on the actual extent of the problem (section four), the scope of the legal normativity intended in terms of delimitation, procedures, distribution of rights, duties and sanctions (section four), the serious implications to third parties arising from the model (section five), and the strategies by which it has been promoted (sections two and three), are indicators of the use of the agenda to create barriers, decrease incentives for foreign competition and secure regulatory and economic advantages for IP technology exporting countries and their industries. In the last instance, the agenda tries to contribute to the reversion of the ongoing shift of economic wealth from established to emerging powers, and to secure and increase the economic power of industrialized countries.

The conclusion will be drawn from the previous sections. It will be argued that the same countries that established the existing system are now subverting it to be able to control the process and achieve their preferred outcome. It will further acknowledge that it leads to an increased democratic deficit in multilateral organizations. Lastly, it will account for the need of further studies to assess the alternatives i) under Global Administrative Law, to refrain the use of the strategies; ii) on IPR enforcement standards and other regulations that could lead to the elaboration of reasonable and balanced rules for all implicated parties; iii) of strategies to be adopted domestic and internationally to reduce the incentives and success in advancing this mechanism in other areas.

As the new mechanism to advance new multilateral IPR enforcement standards is at the core of the paper, the next section will be dedicated to its delineation and analysis.

3. Dynamics of Global Governance by Stealth

3.1. Strategies to Advance New Normativity at the Multilateral Level

Attempts by IP knowledge exporting countries to advance more stringent IPR enforcement at the WTO were largely unsuccessful. Emerging economies were able to block the inclusion of this agenda for debate in the TRIPS Council. In
addition, the WTO panel decision on the case *China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (section 2.3. above) ruled against the extensive interpretation ambitioned by the U.S. on the matter.

Similarly, at WIPO developing countries were able to limit the scope of IPR enforcement policy debates. The Advisory Committee on Enforcement, created in 2004, had norm setting expressly excluded from its competence, which has been limited to technical assistance and coordination among member states.

The outcomes at the WTO and WIPO evidence the loss of power to set the agenda in these Organizations, either to constrain the preferences and strategies of other members⁴, or to shape initial preferences and perceptions⁵.

The alternative for established powers to advance the new IPR protection and enforcement agenda was to apparently promote – as it will be explained later - a *de facto* exit from the WTO and shift to regimes and venues in other issue areas, resorting to bilateral, regional, plurilateral and multilateral initiatives. The first three are outside of the scope of the current paper, although it can be mentioned as an example that ACTA provisions sought to overrule, in practice, the decision of the WTO panel in the *China - IPR enforcement* dispute previously mentioned. This is still the goal of the current multilateral strategies, with a touch of irony. It aims at reframing the issue elsewhere and bringing it back the WTO, to have the dispute settlement body overrule its own decision on *China- IPR enforcement*.

At the multilateral level, the first choice has been to adopt strategies that avoid debates on standards of normativity and their implications. This has been achieved, firstly, by shifting to technical organizations - meaning those holding primarily standard-setting and enforcement roles. Secondly, by reframing the issue as one of standard procedures, which has led to the treatment of new legal standards as a matter of enhancing enforcement measures to secure compliance with “existing” levels of IPR protection and enforcement. Additionally, it has been left for each country to determine the parameters of such levels, increasing the uncertainty on the substance while at the same time decreasing the visibility of the standards encouraged.

As a result, new standards of IPR protection and enforcement have been shaped and promoted as more efficient measures of enforcement through networks of governmental officials within technical organizations. Technical assistance, global events to debate the best measures and technology to fight piracy and


⁵ Referred to as the third face of power, as established by Steven Lukes, *Power: A Radical View* (2nd edn, Palgrave Macmillan 1974). See also Joseph S. Nye, pp. 12-13
counterfeiting, joint operations among domestic enforcers, an integrated structure for communication, and exchange of data and information have been the main instruments used for that purpose.

Along with enforcement operations, these instruments have focused on the establishment of domestic regulations, justified by public policy concerns arising from IPR counterfeit and pirated goods - such as health and safety of the population, as well as links with terrorism and the organized crime, neither evidenced with data so far. This reframes the enforcement of IPR, from a private right to a matter of public policy and interest.

The above paragraphs summarize the strategies that will be considered in the following sections, consisting of 1) regime shifting and coordination across regimes; 2) reframing norms, standards and values as a result of 3) the use of networks to redesign and disseminate than at the domestic (and regional) levels; and 3) promoting their reintegration in the original regime where they have initially faced opposition (in the present case, the WTO).

Strategies of such nature, which comprise global governance by stealth, will tend to be increasingly observed in issue areas with similar characteristics, namely, where 1) state interests are on opposite sides; 2) there is no willingness to compromise on the results or pay compensation for losses of the other part; 3) multilateral cooperation is not required to advance interests; it is possible to advance the strategies away from the control of foreign affairs departments and influence governmental representatives working in other issue areas; 4) it is possible to use tactics such as diversion and the surprise element to enable the strategies from advancing without or delaying the realization by other parties of their ultimate results and by constraining their ability to react.

A comparison between previous and new strategies recently developed in interdisciplinary analyses of social networks will be advanced below. That framework will be used to untangle the elements of the strategies in subsequent sections.

### 3.2. Dynamics of Norm Creation in Social Networks

The traditional mechanism of interaction between institutions, norms and implementation follows the rationale that norms are negotiated and created in institutions – from our perspective, both at the multilateral level - and function as constraints imposed to define and limit the behavior of agents at the stage of domestic enforcement. In other words, implementation derives from the

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framework of international norms established by the international institution, which dictates the behavior of agents. The institution oversees the execution of the norms, and their implementation might feed back to the Organization\textsuperscript{7}. Norms are mechanisms endogenous to the system and there is no communication among agents, which face themselves in a Prisoner’s Dilemma\textsuperscript{8}.

In a different scenario, which represents the current set of strategies forming the new global governance mechanisms, norms are seen as equilibria, which leads them not as defining the game (as in the previous setting), but rather as defined by it\textsuperscript{9}. Norm innovation will be introduced and spread by someone in the system and involves a dual process: 1) bottom-up, as a result of the interaction between autonomous agents, able to interact, evolve and take autonomous decisions; and 2) top-bottom, resulting from the modification of the mind of agents, introduced in the system to affect their preferences and thereby allow the introduction of a new pattern of norms\textsuperscript{10}.

This is the representation of norm innovation in a complex social system of networks:

\begin{verbatim}
\textsuperscript{7} This is the cycle that took place during the implementation of TRIPS by member countries; see Deere, p. 305
\textsuperscript{8} Where they either choose to cooperate or defect, with four different outcomes, without knowing the choice of the other agent. As the gains for one agent are bigger if he chooses to defect while the other agent collaborates, the game ends with both eventually defecting and thus achieving the lowest gains.
\textsuperscript{9} D. Grossi, L. Tummolini and P. Turrini
\textsuperscript{10} Giulia Andrighetto, Rosaria Conte and Paolo Turrini, ‘Emergence In the Loop: Simulating the Two Way Dynamics of Norm Innovation’ (Dagstuhl Seminar Proceedings 07122: Normative Multi-Agent Systems)
\end{verbatim}
Global governance by stealth results from the subversion of four elements - institutions, actors, norms and their dynamics of interaction - under which the new mechanism for its exercise has been developed. It allows for the invisible modification of the behavior of agents and results in the innovation of norms, favoring the preferences introduced in the network by or through the institution. The resultant norm is exogenous to the system and continues to evolve along time, reflecting both new preferences introduced and interactions among agents.

In the sections below we unravel each of the four elements as they have been explored in the current ongoing process to create new multilateral standards of IPR enforcement, and how the cycle leads to a checkmate at the WTO.

3.2.1. Institutions

a. Shift to Technical Intergovernmental Organizations

The first characteristic of the current strategy is the shift of power away from multilateral institutions with direct surveillance and participation of foreign affairs officials and higher levels of formal governance\(^\text{11}\) – that is, with higher levels of formal control, which leads states to adhere to its rulings and makes it harder to exercise influence to affect its outcome in the case of resistance by other states.

\(^{11}\) What changes in the configuration between more formal and informal models of governance is the extent of exercise of power considered as a combination of structural power, formal control and informal influence of state actors in each organization. See Randall W. Stone, *Controlling Institutions: International Organizations and the Global Economy* (Cambridge University Press 2011), p. 47
Organizations such as the WTO and WIPO have higher level of formal governance, although it varies across sectors and programs. Delegation of powers to an international organization by states is lower in relevant issue areas, where there is a sharp conflict of interests among the relevant actors. This is the case, for example, of the WTO. States exercise strict control over the procedures of the Organization, detailed rules have been created, and the Secretariat does not have a high level of autonomy. The executive function, the one that is the most easily captured by informal governance, is closely controlled by member states. Legalism prevails in the interpretation and application of the rules, and oversight by the dispute settlement body rulings secures compliance by states to the terms negotiated. Consensus ensures that each state has a formal power to oppose agendas that do not observe its interests. The WTO is the organization with the highest level of formal governance amongst those object of the present study. Its dispute settlement mechanism provides a powerful mechanism to secure compliance with its rules, by both developed and developing states. Enforcement is secured through possible retaliation and emerging economies have extensively used the system against their trading partners, which has not been predicted by the established powers that created the rules.

On the other hand, organizations such as the World Customs Organization (WCO), Universal Postal Union (UPU) and INTERPOL have high levels of delegation, in view of converging interests in the promotion of harmonized standards of procedures and enforcement cooperation in technical areas that have not traditionally been considered as politically sensitive or as leading to legal implications for the observation of agreements in other regimes. For this reason, the voting system is usually based on majority rather than consensus, there is a gap of procedural rules that increases opportunities for exercise of informal governance through low levels of transparency and member state participation, high levels of control of the conception and implementation of the initiatives by a small group and of autonomy of the secretariat to promote initiatives and/or execute them. These characteristics favor the second face of power and make it harder for states to detect and oppose the IPR enforcement agenda.

The current strategy promotes a shift from organizations - or sectors of it - subject to higher levels of formal governance and scrutiny by member states towards organizations - or specific sectors within the same organization - where higher levels of informal governance can be exercised.

*De facto* exclusion of the topic from the WTO has been an illusion. Unsuccessful attempts to bring the discussion of the IPR enforcement agenda to the TRIPS Council and have new legal parameters recognized by the dispute settlement body (DSB) will be reverted at a later stage, as already explained. The issue is only dormant at the Organization.

\[12\] Ibid, p. 32.
WIPO is an example of shift of the *locus* of the debate with the consequent promotion the IPR enforcement agenda within the Organization. The creation of the WIPO Advisory Committee on Enforcement (ACE) in 2002 led to a structure subject to a high level of control by member states. ACE activities have been limited to technical assistance and cooperation, and its mandate expressly excludes norm setting.

However, the IPR enforcement agenda is being promoted within the Organization by its department on Building Respect for Intellectual Property, an initiative approved by the 2008 WIPO General Assemblies, of which implementation the majority of member states do not closely participate. The office has coordinated initiatives to disseminate the new IPR enforcement standards, such as the Global Congress on Combating Counterfeiting and Piracy, together with INTERPOL and the WCO. Further, technical assistance under the new IPR enforcement agenda has been provided. It is doubtful that awareness on its implications and consideration to the needs of different countries has been promoted. An external report commissioned by WIPO to review the technical assistance programs of the Organization revealed, among other findings, that there is i) lack of transparency and availability for member states of information on the characteristics and details of technical assistance provided throughout WIPO; ii) failure to provide assistance tailored to the actual needs of demanding countries; iii) lack of methodology and uneven results at the implementation level; iv) lack of adequate coordination across different sectors of WIPO on the substance and procedure of implementation of projects; v) lack of transparency of information available to the public; vi) lack of participation of recipient member states in the design of technical assistance programs or their goals.

Similar features allowed the advance of IMPACT, an initiative aimed at establishing the new standards of IPR enforcement by creating a soft law instrument in the WHO. It was kept away from the view of foreign affairs representatives of states as it was developed in the technically oriented Expert Committee on Specifications for Pharmaceutical Preparations, which invited only health authorities for its meetings.

The shift to organizations dealing with standard-setting procedures and enforcement activities was an attempt to reshape the issue as a-political and efficiently advance the agenda. The argument on the technicality of the treatment of the issue in such organizations is absolute flaw; different studies have demonstrated that standard-setting institutions and soft law parameters of compliance represent economic interests leading to choices that impact the regulatory space of countries and ability of competing internationally.

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14 Robert Howse, 'A New Device for Creating International Legal Normativity: The WTO Technical Barriers to Trade Agreement and 'International Standards” in
In all technical and enforcement organizations analyzed the structural and procedural mechanisms also favor the exercise of informal governance. Simple majority approves recommendations on broad and vague basis, and decisions are delegated to a steering group for conceptualization and implementation. The secretariat enjoys a high level of autonomy for the development and implementation of initiatives, and in some cases – as in the WCO – also for elaborating and carrying out its own initiatives. Lack of transparency is the rule in these organizations. Information is restricted for the public and even for member states. One way of limiting information is to invite only technical officials to participate in the initiatives and meetings, leaving diplomats outside. Another is to organize meetings outside of Geneva, as these organizations are headquartered in other European countries. Restricted allowance for the participation of civil society representatives, in contrast with the direct participation of private holders in the design and implementation of the agenda, is also common across these organizations. Additionally, voluntary budget contributions directed towards enforcement initiatives favors dictating priorities at these organizations. A high number and variety of informal mechanisms and procedures provide innumerous opportunities for the exercise of power at the organizations subject of the present study, as it will be confirmed by case studies at section 4.

**b. Coordination Across Regimes**

Regime shifting is a very well known strategy employed by both developed and developing countries to advance their interests in organizations where they are able to influence the agenda\(^{15}\). It has been responsible for the outcome of both the WTO and the TRIPS. When the Uruguay Round of negotiations for the establishment of the WTO was facing resistance, the U.S. and the then EC exited from the GATT, which compelled countries to negotiate with them under the terms they sought to advance with the creation of a new trading system. At the same time, IPR shifted from the IP (WIPO) to the trade regime (WTO). This strategy that allowed established powers to reach a multilateral IPR agreement with much higher levels of protection than its predecessors, as a result of the exchange of IPR protection for market access with developing countries.

In contrast, under the current strategy coordination across various intergovernmental organizations, as well as with state and non-state actors, has

\(^{15}\) For examples of regime shifting practices see Laurence R. Helfer, ‘Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking’ 29 The Yale Journal of International Law 1
been a dominating feature. The IPR enforcement agenda has shifted from the WTO to WIPO, WCO, INTERPOL, UPU and now the UNOCD concomitantly, under the supervision of the G8 and assistance of the OECD. In other words, the agenda has moved away (momentarily) from international trade to global health, customs, postal and criminal police regimes. And all these regimes have enhanced the scope of dissemination and success of the strategy through joint coordination and complementarity on implementation. Joint operations, exchange of information, technical assistance and organization of events that increase exchange of information and strengthen ties among different enforcers have been extensively promoted.

By contrast, the WTO has remained highly silent about the new IPR enforcement agenda. Both in keeping participation in the activities developed across other organizations at a minimum level, as well as technical assistance in this field. It has failed to clarify the implications of the new standards for trade and to bring the complexity of terms and procedures closer to the parameters established in the TRIPS. The joint publication between WTO, WIPO and WHO on the promotion of increased access to innovation acknowledges the intersections and divergences but fails to defend the integrity of definitions of counterfeiting and piracy found in the TRIPS and to account for the actual consequences of the seizures of generic drugs by customs authorities in Holland after their release\(^\text{16}\). WTO has been watching the dynamics of the IPR enforcement agenda as if it were an outside actor. Some of its members have been against the discussion of the agenda in the Organization, but it has chosen to remain quiet and fails to clarify extensively the actual multilateral parameters of IPR enforcement and to call other organizations for greater coherence. This need is clearly envisaged from the case studies that will follow in the next section of this paper, and its theory has been established in the IP literature\(^\text{17}\).

3.2.2. Actors

\textit{a. Public-Private Partnerships}

In a world of economic wealth towards emerging countries, an increasing practice in different areas, mostly adopted by established powers, is the direct integration and participation of private actors in governmental strategies. In the IPR


\(^\text{17}\) Graeme B. Dinwoodie and Rochelle C. Dreyfuss, \textit{A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime} (Oxford University Press 2012). The authors defend the recognition of core principles of IPR under TRIPS (acquis) that would underlie and inform the development of related norms in other regimes and provide for greater coherence.
enforcement agenda, the so-called public-private partnerships (PPP) allow
governments to use the economic wealth and power of non-state actors in a
symbiotic method, according to which private parties assist their home states to
regain power and control over international economic agendas that the former have
created and from which they will benefit. By its turn, states expect to regain their
economic power to secure and expand political/military power as a result.

Delegation of powers to non-state actors provides an additional advantage,
deriving from their lack of accountability to domestic constituencies\textsuperscript{18}. Private actors have a higher degree of independence and autonomy to conduct their
preferences without transparency, as they are subject to lower public scrutiny\textsuperscript{19}.

Private holders have been called to participate directly in the
implementation of the agenda in intergovernmental organizations, and are even
responsible for its elaboration. At the WHO, a representative of the European
Federation of Pharmaceutical Industries and Associations (EFPIA) elaborated the
first draft of the IMPACT standards on IPR enforcement that was directly circulated
among all members of IMPACT’s Regulatory Implementation Working Group\textsuperscript{20}. A
representative of the International Pharmaceuticals Association, PhRMA, is the chair
of the IMPACT Technology Working Group. The WCO is a safe heaven for the private
sector, which for long has benefited from high levels of participation in meetings
and initiatives at the Organization. By its turn, in March 2013 INTERPOL launched a
global initiative, together with the pharmaceutical industry, to fight ‘counterfeiting’
medicine under the claim that it endangers the lives of millions – needless to say
that no data is presented in support. Ironically, no representatives of the very civil
society that is at the core of the risks, that is non-governmental organizations with
expertise in the field of health, have been called to participate in the elaboration of
the strategy that is ready for implementation. Whatever the claims, of private or
public interests concerns, only private holders have been integrated in the debates,
decision-making process and enforcement initiatives. As a result, there has been a
\textit{de facto} privatization of the IPR enforcement agenda in intergovernmental
organizations. In other words, private holders have been directly advancing the
agenda in multilateral organizations by various means, including funding,
elaboration of soft law, participation in technical assistance programs, organization
of joint events and others.

\begin{itemize}
\item Daniel W. Drezner, \textit{All Politics is Global: Explaining International Regulatory
Regimes} (Princeton University Press 2007), p. 73
\item Ibid
\item World Health Organization, ‘Proposal for Revision of WHO Good Distribution
Practices for Pharmaceutical Products’ (Sep. 2009)
\end{itemize}
\url{http://www.who.int/medicines/services/expertcommittees/pharmprep/170909
Clean_GDP-counterfeits-QAS08252Rev1.pdf}
b. Networks of Domestic Enforcers

Power to disseminate the agenda derives from the power to control the networks of domestic enforcers in charge of initiatives by changing their perceptions and establishing preferences. Developed countries are on top of it and have been promoting increasing network integration in the field of IPR enforcement, horizontally i) inside and across intergovernmental organizations, also including non-state actors represented at the international level; ii) inside the same sector and across sectors of the national government, with the inclusion of private holders from different economic sectors; and iii) vertically between international and national actors. There is possibly also a diagonal integration between different domestic and international sectors but it has to be subject to further analysis.

The promotion of innumerous international conferences, joint operations, capacity building initiatives and social pressure among different enforcers, both by rewards and shame, reinforces the idea that in order to be part of the group there is a need to share its values. Such initiatives also extend the boundaries for cooperation across sectors. This is an ongoing process, which has been fast-tracked by various enforcement initiatives carried out in various intergovernmental organizations. In organizations dedicated to setting standards and to enforcement, where higher levels of informal governance prevail, networks enjoy enhanced autonomy to articulate and cooperate out of the sight and control of their home states.

Anne-Marie Slaughter acknowledges this new reality, explaining that after the signature of a treaty in the international order, the official representatives of states step out and technocrats take their place to promote the implementation of the new rules, cooperation with counterparts in other states, exchange of information and development of best practices, among others. This has increasingly represented the experience of technical organizations, which demand expertise from different departments of the state. The compartmentalization of the treatment of a topic allows for its fragmentation and redesign simultaneously in the international and domestic levels, followed by a re-integration that brings the reframed legal normativity back to the regime that had initially rejected it. Diplomats encounter increased difficulties to get inserted in these specialized forums, as any actions from their part are viewed as undue interference in the field of responsibility of another governmental agency. Developing countries face problems of internal coordination, limited expertise and human resources to allow them to adapt and keep control of their agents in a networked environment.

In organizations with higher levels of informal governance, close control over processes is traded for increased efficiency, and informal networked exchanges among participants prevail. Lack of expert knowledge on international IPR rules and

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politics favors control over the agents of the network and further contribute to the exercise of power in its realm.

States that have a higher level of internal coordination are in clear advantage to ensure coherence of policies and control agendas in networks. Developed countries have realized this and have sponsored studies focused on social networks integrating interdisciplinary perspectives such as economics, physics, social sciences and mathematics, which use sophisticated economic analysis to understand how social networks operate, how innovation of norms is promoted in networks and many other related questions that will lead to enhanced knowledge and control over them.

Network integration is already taking place in different governments. In the European Commission there is a promotion of horizontal dialogue across its Directory-Generals and vertically with domestic authorities to ensure coherent elaboration and implementation of different policies and minimize conflicts. The U.S. also has this tradition in trade policy – Section 242 of the Trade Expansion Act of 1962 provides for interagency organization on trade policy. More recently, in view of the priority given to the IPR enforcement agenda, the Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC) was created in the White House, to coordinate policies across federal agencies in this area. At same time, coordination of enforcement activities on the ground is advanced by the U.S. National Intellectual Property Rights Coordination Center. The latter has been coordinating not only with domestic authorities, but also the WCO and INTERPOL, among others, which in practices provides an advantage to direct the work of peers in networks.

An additional and more traditional instrument to control the agenda of technical organizations, which allows the promotion of the agenda and facilitates its dissemination through networks, relates to the staff of organizations. Mostly in organizations with high levels of informal governance (but also in other organizations, such as WIPO and the WHO), the secretariat enjoys considerable autonomy from member states to propose and implement agendas. Holding key positions allows a country to exercise power and direct the priorities of the organization in a given area. It is extremely important for states setting the agenda to have a staff that shares their incentives and values. For this reason, with one exception, fieldwork conducted for this paper evidenced that, in all organizations, all the key staff in charge of the IPR enforcement agenda are nationals of a G7 country.

Some of the findings described in the above sections are summarized below for an integrated description of the current scenario.

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### 3.2.3. Legal Norms vs. Technical Standards and Direct Implementation

The public-private partnerships previously described led to the increasing privatization of regulation in the field of IPR enforcement inside intergovernmental organizations. Private actors are in charge of drafting soft law through ‘best practices’, participate in the decision-making process and in the implementation of strategies from which they will benefit. Failure to advance soft law standards at the multilateral level (IMPACT and SECURE), as well as hard law at the plurilateral level (ACTA), has only resulted in a shift of venues. Focus has been given to Asia, as the U.S. expressed the intention to develop best practices within APEC, as well as to ‘revive’ counterfeiting of pharmaceuticals through the WHO IMPACT initiative. Along with these soft law strategies, hard law production has been promoted through plurilateral (the Trans-Pacific Partnership Agreement) and bilateral agreements.

But what are the consequences of the establishment of soft law if its adoption is voluntary? Not only would they become the major reference, thereby causing even greater diversion from the TRIPS. Bilateral trade agreements negotiated have included a clause whereby IPR has to be protected by its parties “in conformity with the highest international standards”. This clause is found, among others, in the EU agreements with South Africa (1999), Tunisia (1998), the Palestinian Authority (1997), Israel (2000), Morocco (2000), Chile (2002), Jordan (2002), Algeria (2005) and Lebanon (2006). Although the meaning of the term “international standards” might be debatable, in practice said clause provides a mandatory mechanism for the enforcement of voluntary standards.

Technical assistance adds to the efforts to modify legal normativity and practices and exert direct influence at the domestic level. Technical assistance and

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23 Executive Office of the President of the United States, *Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress* (March 2011), pp. 13-15
consultancy for the elaboration of new domestic legislation has been provided by established powers. The influence and assistance of the EU resulted in the enactment of the Kenyan Anti-Counterfeit Act in 2008.\(^{24}\)

One of the key features of the strategies is the shift from norm production to its direct implementation. National regulators interpret the IPR enforcement agenda as procedural standards rather than new rules and incorporate them directly into their practices. Enforcers are implementing new standards of IPR normativity that have not been debated or agreed anywhere. Customs, postal and police officials are already participating in operations to detect, detain and seize IPR infringement. INTERPOL has promoted innumerable regional operations with the participation of police officials of its network to seize products under the labels of ‘counterfeiting’, ‘fake’ or similar terms, without clarifying the origin of the operations, under what criteria and parameters they have been conducted, who participates and benefits. The WCO and the Universal Postal Union have promoted increased cooperation and coordination in their activities, with the cooperation of INTERPOL, to secure borders and postal packages against movements of products that might account as IPR infringement.

The missing stages of norm negotiations and creation that should precede enforcement operations might come to the domestic setting at a later stage and still without debate, in the form of regulations of the Legislative or Executive branches. The latter have the additional advantage of usually not being subject to the scrutiny of other areas of the government and might be conceived and approved by the issuance of an executive order, which contributes for its invisibility. In any case, the goal is for the new legal standards treated as enforcement procedures to lead to norm creation in the domestic and international settings, subverting the traditional cycle.

3.2.4. Closing the Cycle of the Dynamics

a. Reframing the Issue as a Public Policy

Another core feature of the strategies is, following the shift of regimes and together with the reconfiguration of norms, the redesign of the goals of the latter. In the case of IPR enforcement, it means changing its perception as a private right by ultimately reframing it as a public interest issue. This consists in focusing on possible consequences of counterfeiting and pirated products (after deviating from the original and narrower meaning of these terms under the TRIPS, as it will be seen in the next chapter) for the health and safety of the population and for any potential links between the infringements with terrorism and the organized crime, even if no statistics have been produced to this date. According to the promoters of this perspective, IPR enforcement is THE instrument to target these public policy issues.

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\(^{24}\) See section 4.2. above
This has raised many concerns by representatives of the civil society, notably in relation to the inconsistent proposition of having issues of quality, safety and efficiency of drugs addressed by IPR enforcement measures and the inherent conflict of interests. The result has already emerged in practice: the Kenyan Anti-Counterfeiting Bill that came into force in 2008, after technical consultancy provided by the EU, alleged to focus on consumer protection against counterfeit drugs, but resulted in an instrument that in fact protected IPR holders to the expense of access to essential medicines to consumers at affordable prices. Deviation from the actual causes and solutions to address the issue from a public health perspective are at the core of the problem.

The immediate visible consequence of this strategy is the shift of responsibility and costs of IPR enforcement from private holders to national governments. The latter become the major enforcers of private rights, and need to provide further regulation, human resources, financial resources, technology and build capacity to address IPR infringements. On the other hand, private holders see their responsibilities and costs decrease while enjoying a more efficient and enhanced protection of their interests.

**b. Checkmate: Incorporating New IPR Enforcement Standards at the WTO Through the Backdoor**

Where does the above process lead to? The most immediate consequence is the establishment of new IPR enforcement legal standards in various countries. But the main target of the intended measures is China, considered to be a major source

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27 Solutions that would directly and efficiently target issues of quality, safety and efficacy of medicines would include i) improving access to affordable medicines, including by reducing prices (high prices, rather than IPR infringements, are considered as one of the main causes for the commercialization of non-authorized medicines that might affect consumers’ health); and ii) enhancing the capacity of national regulators in developing countries to improve and control the quality, safety and efficacy of medicines in the country (Shashikant)
of IPR infringement. Neither China nor the other BICS countries (Russia, as a member of the G8, is not included) seem inclined to adopt stringent IPR enforcement standards domestically. They have been resisting in multilateral regimes, but have they succeeded in promoting policy coherence at home? Or do they risk having regulations on customs, postal, criminal police passed with elements of more stringent IPR enforcement?

Even if emerging countries successfully deal with internal issues and secure policy coherence over different governmental agencies, they will still feel the consequences of the modification of national regulation and policies on IPR enforcement by other countries and may be affected by them. A less visible and more far reaching consequence of the strategies is the the modification of TRIPS and GATT rules in the WTO through the backdoor, by reintegrating IPR standards redesigned and incorporated elsewhere, either as soft (or hard) law in other international regimes or as national regulations per se. Both alternatives would reintroduce the IPR enforcement reframed elsewhere in the WTO through its dispute settlement system.

One is the establishment of soft law instruments in another international organizations, following similar initiatives as the failed IMPACT and SECURE, at WHO and WCO respectively. Although not binding, such legal normativity could be brought to cases under the WTO dispute settlement and lead to its interpretation as a binding obligation, using an equivalent interpretation as that promoted under the TBT Agreement. Accordingly, in EC-Trade Description of Sardines the ruling of the panel led to the mandatory application of voluntary international standards established elsewhere, which did not take into account governance issues involved in the negotiating process nor political implications of the substantive outcome. However, this option would require convincing arguments that soft law produced in other regimes does not represent substantive standards of IPR enforcement, which is unlikely to be successful in a WTO dispute, in view of the high expertise of the Organization and its members on TRIPS rules and policies.

A much more efficient alternative is to have the new IPR enforcement standards reintroduced in a case where they treated as a matter of public policy.

So far the possibility of taking into account other policies without characterising them as violations to WTO obligations has been promoted under the general exception provisions of Art. XX of GATT. There is a considerable body of

28 Brian T. Yeh (Coordinator), CRS Issue Statement on Intellectual Property Rights (Congressional Research Service, Jan. 15, 2010), p. 3
29 See Graeme B. Dinwoodie and Rochelle C. Dreyfuss, pp. 156ss.
30 See Howse
32 “Art. XX: General Exceptions
WTO decisions clarifying the meaning of the test that shall be met by member states to be entitled to benefit from Art. XX exceptions, and the thresholds of compliance are high in order to prevent abuses. In the case of measures (such as domestic regulations) creating barriers to trade under the claim of protection of public health interests, for example, there would be the need for the member state of its origin to provide evidence that 1) the subject of the domestic regulation can be considered within the scope and concept of “protection of human health” found in Art. XX (g); 2) the need to protect health under the regulation is assessed against the availability of less-restrictive alternatives, which also leads to the 3) weight and balance of costs upon foreign states and companies resulting from the measures; followed by the assessment that they do not constitute 4) an “arbitrary discrimination between countries where the same conditions prevail”; nor 5) nor an “unjustifiable discrimination” (under the same conditions of item 6) nor a “desguised restriction of international trade”. For each of these steps there have been established parameters to determine their compliance, and it has been so far effective in detecting and differentiating between public policies in issue areas outside of trade that are not justifiable from those that can be justified and thus exempted under Art. XX although restricting trade as a result.

However, the 2012 WTO Trade Report suggests a dangerous shift from that understanding and opens the door for the creation of an alternative approach. It signals to a potential and significant modification of interpretation in the treatment of public policies under WTO rules, which moves away from the parameters of Art. XX to focuses instead on the national treatment principle for the assessment of discriminatory measures of non-trade regulations. National treatment provisions, according to GATT Art. III:4, establish that it should be granted to a foreign product at least the same treatment provided to domestic products.

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(b) necessary to protect human, animal or plant life or health;

...(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices”


35 See ibid
Under the allegation of flexibilizing the scope of application of national treatment under GATT Art. III and other WTO Agreements (namely, art. 3 of TRIPS, art. 2.1 of the TBT or art. XVII of GATS) to achieve a more efficient outcome in the integration of other domestic policies in the WTO, the Report suggests a change in the perception of domestic measures that affect trade and supports the treatment of discriminatory measures under Art. III36, which implies the diversion of their treatment under Art. XX.

This proposal departs from the assumption that there is no assymetry of information among governments; and that, in the absence of perfect information, transparency mechanisms will suffice to address such failure. The previous sections evidence that this simplistic approach does not provide a solution for the complexity of the dynamics surrounding this issue.

The practical result is that this interpretation would open the door for non-tariff barriers into the Organization, by significantly lowering the parameters for their acceptance. As developed countries have constrained themselves to low bond tariff rates at the WTO, they have made extensive use of non-tariff barriers, which due to their non-quantitative nature are harder to identify and measure. The use of non-trade barriers has increased significantly under the current international economic scenario, as a result of economic and financial losses and the reduction of trade gains vis-à-vis emerging economies.

The new interpretation would allow domestic measures that would fail to meet the thresholds of Art. XX to be considered as compliant with WTO rules under the extremely lower threshold provided by Art. III GATT. Without even bringing to other thresholds established by Art. XX, the sole standard of discrimination established under Art. III:4 of GATT is already significantly lower than those of Art. XX (listed in items 4, 5 and 6 two paragraphs above)37. The Appelate Body in US-Gasoline 38 has expressly recognized the significant difference between the

37 Among other decisions that clarified and established the parameters to be considered when evaluating the standards of discrimination of Art. XX, see United States - Import Prohibition of Certain Shrimp and Shrimp Products Appelate Body Report, DS58, Oct 12, 1998, United States - Standards for Reformulated and Conventional Gasoline and European Communities - Conditions for the Granting of Tariff Preferences to Developing Countries Panel Report, DS246, Dec 1, 2003
38 United States - Standards for Reformulated and Conventional Gasoline
application of the test of Art. XX in contrast with Art. III:4 by affirming that “[t]he enterprise of applying Article XX would clearly be an unprofitable one if it involved no more than applying the standard used in finding that the baseline establishment rules were inconsistent with art Article III:4” (...) and that the two omissions of the U.S. in the case (namely, to consider the governments of other members states and costs of its measures for foreign competitors) went “well beyond what is necessary for the Panel to determine that a violation of Article III:4 had occurred”.

As the WTO has moved from norm production through treaty negotiations (with features that resembled a civil law system) towards norm creation through its dispute settlement (more similar to a common law system), although the decision of each dispute is binding only to its parties, it is increasingly considered as establishing a precedent to other cases in order to provide coherence to the system. By this rationale, a ruling over a policy in an issue area other than IPR enforcement, which integrates a domestic policy in the WTO under Art. III rather than Art. XX, would possibly impact in the interpretation provided to domestic IPR enforcement measures, extending to it the same benefit of integration. Additionally, a shift favoring the application of Art. III would make it very difficult to argue against regulations on IPR enforcement that clearly represent a barrier to trade but are justified under public interests such as the protection of a population’s health or security, repression of terrorism or organized crime, which are disseminated as the grounds of the present agenda. Under Art. XX, even if considered as legitimate on such grounds, public policies still have to be assessed in contrast with less restrictive alternatives and have to overcome a higher threshold on the scope of the discriminatory measures.

While developing countries might be focusing on the potential benefits of enjoying increased flexibility to apply domestic regulations, they may be missing the harmful consequences that would overcome any potential gains in enhancing their regulatory space, which in any case would not be as much as a useful resource as for developed countries.

The strategies to establish international soft law and domestic regulations mentioned above are rather complementary than alternative. The establishment of soft law in international regimes outside of the WTO would facilitate and speed the process of its acceptance and domestic incorporation by countries. This is still a possibility and there is evidence that it is already under implementation. Despite the rejection of the IMPACT handbook containing soft law provisions at the WHO in 2010, this document is still available online at the official WHO website and nothing indicates that it has been rejected by the members of the Organization. In an official report of May 2011, issued a year after the rejection of the IMPACT initiative by the WHO, the U.S. Government Inter-Agency Working Group on Counterfeit declared that “IMPACT brings together private and public sector experts to address public health aspects of drug counterfeiting and is developing technical tools for countries to use and adopt to fight drug counterfeiting. These tools can be used to strengthen legislative, regulatory, technological, enforcement and communication
infrastructure and build capacity for surveillance, identification and prevention of counterfeit drugs from reaching patients. The USG [U.S. Government] will continue to support complementary partnerships, including continued development and implementation of IMPACT”39. Foreign domestic enforcers from different issue areas (criminal police, customs, postal officials and others) would not be aware of the outcome in the health regime and would be easily submitted to the principles of IMPACT through technical assistance and other communication mechanisms in their networks.

39 Executive Office of the President of the United States, p. 14
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