INSTITUTE FOR INTERNATIONAL LAW AND JUSTICE
NEW YORK UNIVERSITY SCHOOL OF LAW

IILJ Working Paper 2018/2
MegaReg Series

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Treaty Requirements for Regulatory Procedures

Paul Mertenskötter & Richard B. Stewart

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IILJ / NYU LAW

Institute for International Law and Justice
Wilf Hall, 139 MacDougal Street, 3rd Floor
New York, NY
www.iilj.org | @nyuiilj

ISSN: 1552-6275

New York University School of Law
New York, NY 10012
U.S.A.

Version of 21 March 2018

Cite as:
IILJ Working Paper 2018/2
(MegaReg Series)

REMOTE CONTROL: TREATY REQUIREMENTS FOR REGULATORY PROCEDURES

Paul Mertenskötter* & Richard B. Stewart†

[forthcoming in 104 CORNELL L. REV. __ (November 2018)]

Abstract: Modern trade agreements have come to include many and varied obligations for domestic regulation and administration. These treaty-based commitments aim primarily to improve the freedom of firms to operate in the global economy by aligning the ways in which governments regulate markets and private actors engage governments through administrative law. They strike at the core of how economies are ordered and entail important distributional questions. An increasingly prevalent and diverse—but hitherto largely neglected—type of treaty obligation prescribes specific procedures for domestic administrative decision-making. This Article frames such treaty requirements for regulatory procedures as instruments of remote control. They are negotiated for by government officials in strong states that seek to advance the interests of the commercial interests they take to represent. These commitments empower private actors—predominantly well-organized business interests—to directly use these procedures to pursue and defend their interests in other states. To make this case, the Article for the first time synthesizes McNollgast's conception of regulatory procedures in the purely domestic context as instruments of political control and Putnam's theorization of international treaty negotiations as a two-level game. By applying this new synthesis to trade agreements, the Article shows how procedural obligations can be designed to stack the deck to favor certain private interests and why treaty negotiators may find it easier to agree on procedures than substantive commitments. The Article uses its synthetic conception to explain the accelerating rise of procedural requirements in post-war international economic law and demonstrates its explanatory potential by analyzing the variation between strong regulatory procedures for intellectual property rights and weak procedural protections for the environment in the newly-revived Trans-Pacific Partnership.

* Fellow, Institute for International Law and Justice, NYU Law School. e: paul.mertenskoetter@law.nyu.edu. We are grateful to Anne van Aaken, Julian Arato, Michelle Ratton Sanchez Badin, Eyal Benvenisti, Benedict Kingsbury, Michael Livermore, Charles Sabel, Thomas Streinz, and Joseph Weiler for thoughtful comments and discussions on earlier drafts. Thanks also to participants at the MegaReg/IILJ workshops in New York and Tokyo. All errors are our own. This Article grew out of the MegaReg project at the Institute for International Law and Justice at NYU Law School. iilj.org/megareg.

† University Professor; John Edward Sexton Professor of Law, NYU Law School; Director, Frank J. Guarini Center on Environmental, Energy, and Land Use Law.

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Introduction

Trade and regulatory agreements have been the vehicles for the proliferation of a hitherto neglected type of inter-state obligation: requirements to adopt specific domestic regulatory procedures.[1] Not only have these commitments grown in prevalence—to thousands today, including far over a hundred in the newly-revived Trans-Pacific Partnership—but they vary starkly in design and intensity both within the same and across different agreements. We argue that obligations for domestic administrative law procedures are instruments negotiated by powerful states with the aim of controlling regulatory decision-making by government officials in other states—they are tools for remote control.[2] We show how commitments for procedures in treaties empower private actors—predominantly well-organized transnational firms—to pursue and defend their interests. For executive branch officials negotiating treaties, they are not only a means to satisfy their constituent's specific demands, they are also often easier to negotiate than substantive provisions.[3] Our account helps to explain the rise of this type of obligation as the regulatory state—and not tariffs—has become the main concern for globally active business. It further allows us to make sense of variation among procedural obligations in the same treaty as deliberate choices by negotiators to stack the deck in favor of some constituents while largely paying only lip service to more diffuse social interests such as those for environmental protection and labor rights.

This article is foremost a critical exposition and reappraisal of the existing procedural infrastructure for private actors underpinning international economic ordering. Making visible the power dimension in what at first sight seem to be arcane procedural details is the initial step in developing a robust understanding of these underappreciated instruments of global regulatory governance. How these inter-state commitments for domestic procedures function is not only theoretically significant but carries practical and political importance.

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[1] For exceptions, see Henrik Horn, Petros C. Mavroidis & Erik N. Wijkstrom, *In the Shadow of the DSU: Addressing Specific Trade Concerns in the WTO SPS and TBT Committees*, COLUM. L. & ECON. WORKING PAPER 494, at 732, 735 (March 2013) (discussing the Specific Trade Concerns mechanism as well as the enquiry points as sites of economic governance); Padideh Ala'i & Mathew D'Orsi, *Transparency in International Economic Relations and the Role of the WTO,* in RESEARCH HANDBOOK ON TRANSPARENCY 368, 371-373 (Ala'i & Vaughn, eds., 2014) (examining the use of treaty-based transparency requirements for domestic regulators).

[2] We understand control as going beyond compliance and capturing more complex interactions of legal obligations and politics, such as socialization, agenda-setting, and general changes to the relative influence of different actors in regulatory decision-making in other countries. See Robert Howse & Ruti Teitel, *Beyond Compliance: Rethinking Why International Law Really Matters*, 1 GLOB. POL'Y 127 (2010), for a wide conception of international law's influence on state and individual action. *See also* Gregory Shaffer, *How the World Trade Organization Shapes Regulatory Governance,* 9 REG. & GOV. 1 (2015) (discussing multiple pathways for the World Trade Organization's rules and practices to influence state behavior); Nikolas Rose & Peter Miller, *Political Power Beyond the State: Problematics of Government,* 43 BRIT. J. SOC. 173, 180-81 (1992) (discussing the idea of governance at a distance more generally).

[3] *See infra* section I.H.

To make our argument we combine two hitherto separate strands of political economy scholarship and apply them to the study of international law and regulation.[4] The first strand, pioneered by McNollgast in the context of United States (US) administrative law, understands rules of administrative procedure as instruments adopted by political principals with the aim of influencing decisions of their administrative agents in favor of particular political constituencies in return for the constituencies' support in reelection.[5] The second strand, following Putnam, conceives of the negotiation of international commitments as a two-level game in which negotiators need to arrive at a deal that is acceptable in both the domestic and the international diplomatic arenas.[6] Combining these two strands to analyze procedural requirements in global economic and regulatory treaties provides a framework for understanding the abundance and variety of such requirements and their role in global governance.

Commitments between states to adopt procedures that empower private actors to participate in domestic regulatory decision-making first prominently appeared in the 1947 General Agreement on Tariffs and Trade (GATT). They have since steadily expanded as they have been adopted in the World Trade Organization's (WTO) agreements and subsequent bilateral and regional trade agreements, especially those initiated by the US and the European Union (EU).[7] The Trans-Pacific Partnership (TPP)—now going ahead with 11 countries but without the United States as the rebranded Comprehensive and Progressive Trans-Pacific Partnership (CPTPP)—is the latest manifestation of this trend, with states' commitments to specific regulatory procedures permeating the vast majority of its 30 chapters and annexes.[8]

The large majority of procedural commitments in treaties are responses to demands from private economic actors for influence over government regulation in other states, although labor and environmental groups have increasingly sought them as well. Having started as generic Global Administrative Law (GAL) requirements for transparency, participation, reason-giving, and review, procedural requirements have evolved into increasingly sophisticated and specific treaty commitments.

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[4] The burgeoning literature in this field includes Eyal Benvenisti & George W. Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60 STAN. L. REV 595 (2007); EYAL BENVENISTI & GEORGE W. DOWNS, BETWEEN FRAGMENTATION AND DEMOCRACY: THE ROLE OF NATIONAL AND INTERNATIONAL COURTS (2018); Katerina Linos & Jerome Hsiang, *Modeling Domestic Politics in International Law Scholarship*, 15 CHI. J. INT'L L. 1 (2014); David Kennedy, *Law and the Political Economy of the World*, 26 LEIDEN J. INT'L L. 7 (2013); DAVID KENNEDY, WORLD OF STRUGGLE (2017); THE POLITICAL ECONOMY OF INTERNATIONAL LAW: A EUROPEAN PERSPECTIVE (Alberta Fabbricotti, ed., 2016).

[5] McNollgast, *Administrative Procedures as Instruments of Political Control,* 3 J. L., ECON., & ORG. 243 (1987) [hereinafter McNollgast, *Administrative Procedures*].

[6] Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INT'L ORG. 427 (1988) [hereinafter Putnam, *Two-Level Games*].

[7] *See infra* Part II.

[8] Trans-Pacific Partnership (signed 4 February 2016), https://www.tpp.mfat.govt.nz/text [hereinafter TPP12]. [A table of all these commitments will be made accessible online upon publication.] The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (signed 8 March 2018), https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-concluded-but-not-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text/ [hereinafter CPTPP]

These requirements are often targeted toward particular interest groups and the substantive outcomes that they favor.[9] They create winners and losers as different parts of domestic regulatory decision-making are opened to different forms of proceduralized influence by private actors pursuing their interests.

Business demand for such procedures has intensified as tariffs have fallen and regulatory barriers to trade and investment assume relatively greater importance: the falling tide of tariffs has exposed all the "snags and stumps" of justified or unjustified, but in many instances unaligned, regulations which inhibit firms from freely operating across the global economy.[10] The new dynamics of business organization, in which production and distribution activities are unbundled and distributed across many jurisdictions but linked through global and regional value chains, have further increased corporate demand for cross-jurisdictional compatibility of regulatory rules and more open and better domestic regulatory governance.[11]

The innovation in information and communication technologies that enabled firms to deconstruct their activities while building regional and global value chains has also dramatically lowered the costs for organized interests to engage systematically the regulatory administrations in multiple states.[12] Without having to employ large numbers of people or needing a physical presence, and by using e-mail and the world wide web, organized interests act in strategic concert to collect, comment on, and initiate the review of regulatory decision-making in capitals and local administrations all around the world. Many multinational businesses are already familiar with this type of regulatory process from their experiences

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[9] On Global Administrative Law, see Benedict Kingsbury, Nico Krisch & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 LAW & CONTEMP. PROB. 15 (2005). The Global Administrative Project at NYU Law starts from the premise that "[m]uch of global governance can be understood as regulatory administration. Such regulatory administration is often organized and shaped by principles of an administrative law character. Building on these twin ideas, [its proponents] argue that a body of global administrative law is emerging. This is the law of transparency, participation, review, and above all accountability in global governance. [They] posit an increasingly discernible "global administrative space" in which the strict dichotomy between domestic and international has broken down, administrative functions are performed in complex relations between officials and institutions not organized in a single hierarchy, and regulation using non-binding forms often proves highly effective in practice."
See the dedicated project page of the Institute for International Law and Justice at NYU Law, at www.iilj.org/GAL/.

[10] *See* UNCTAD, *Key Statistics and Trends in Trade Policy* (2013), http://unctad.org/en/PublicationsLibrary/ditctab20132_en.pdf ("The last decade has seen the process of global tariff liberalization continue largely unabated. Developed countries further reduced tariffs or maintained these at the very low levels of 2002, while the vast majority of developing countries reduced their tariffs, in some cases quite substantially."); ROBERT BALDWIN, NONTARIFF DISTORTIONS OF INTERNATIONAL TRADE 2 (1970) ("The lowering of tariffs has, in effect, been like draining a swamp. The lower water level has revealed all the snags and stumps of non-tariff trade barriers that still have to be cleared away.")

[11] *See generally,* Gary Gereffi, John Humphrey & Timothy Sturgeon, *The Governance of Global Value Chains*, 12 REV. OF INT'L POL. ECON. 78 (2005); Richard Baldwin, *Multilateralising 21st Century Regionalism*, OECD CONFERENCE PAPER (Feb 2014), https://www.oecd.org/tad/events/OECD-gft-2014-multilateralising-21st-century-regionalism-baldwin-paper.pdf [hereinafter Baldwin, *Multilateralising Regionalism*].

[12] RICHARD BALDWIN, THE GREAT CONVERGENCE: INFORMATION TECHNOLOGY AND THE NEW GLOBALIZATION 79-110 (2016) (arguing for the fundamental importance of information and communication technologies in the new dynamics of globalization).

with such systems in the United States and Europe.[13] Pharmaceutical trade organizations, for example, are often organized on a national basis but in practice are global, sharing a largely identical membership of transnational companies. They participate regularly and simultaneously in a myriad of regulatory processes in different states as well as in global regulatory bodies.[14] Transnational environmental and labor groups attempt to follow the same strategy, albeit with far fewer resources.[15] Due to these technological changes, the opening of regulatory procedures to private actors through treaties is being extensively used to advance the interests of those that can participate.

Taken as a whole, the various procedural requirements in treaties are rooted in a globally diffusing model of regulatory capitalism which emphasizes administrative law mechanisms to secure facially neutral access to regulatory decision-making and open government.[16] In its interactions with the market, the state's role is to promote beneficial economic activity by establishing an institutional framework to facilitate markets, prevent market failures, and avert unlawful and arbitrary administrative decisions. To realize its goals for an efficient market, regulatory capitalism—in its Weberian ideal type—creates an "ecology of patterned niches" by delegating significant authority from politicians to experts and making use of new regulatory technologies such as the regulatory-checks-regulator dynamics of regulatory impact assessments.[17] As a result the state has to grow with the market—rather than having one flourish at the cost of the other.[18] In the evolving interface between the state's administrative institutions and private economic actors that regulatory capitalism requires, administrative law enables procedural regulation *of*—as opposed to by—the state by private actors.[19]

The article proceeds in three parts, with the first part building the theory that the second and third parts use to explain the rise of procedural requirements in treaties and the variation among them in the TPP. Part I of the article introduces McNollgast's framework for understanding administrative

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[13] *See, e.g.,* Jason Webb Yackee & Susan Webb Yackee, *A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy*, 68 J. POL. 128 (2006) (for the United States); Adam William Chalmers, *Trading Information for Access: Informational Lobbying Strategies and Interest Group Access to the European Union*, 20 J. Eur. Pub. Pol'y 39 (2013) (for the European Union).

[14] Deborah Gleeson, et al., *How the Transnational Pharmaceutical Industry Pursues Its Interests Through International Trade and Investment Agreements: A Case Study of the Trans Pacific Partnership*, in HANDBOOK OF RESEARCH ON TRANSNATIONAL CORPORATIONS (Alice De Jonge & Roman Tomasic eds., 2017).

[15] See Margaret E. Keck & Kathryn Sikkink, *Transnational Advocacy Networks in International and Regional Politics*, 51 INT'L SOC. SCI. J 89, 92 (1999) (noting the cost of international lobbying activity).

[16] Jacint Jordana, David Levi-Faur & Xavier Fernández i Marín, *The Global Diffusion of Regulatory Agencies: Channels of Transfer and Stages of Diffusion*, 44 COMP. POL. STUD. 1343 (2011) (showing the diffusion of the regulatory agency model for the period 1966-2007); Jacint Jordana & David Levi-Faur, *The diffusion of Regulatory Capitalism in Latin America: Sectoral and National Channels in the Making of a New Order*, 598 ANNALS AM. ACAD. POL. & SOC. SCI. 102 (2005) (early work developing the concept of regulatory capitalism); JOHN BRAITHWAITE, REGULATORY CAPITALISM: HOW IT WORKS, IDEAS FOR MAKING IT WORK BETTER (2008) (presenting a theoretical account of regulatory capitalism and its critiques); David Levi-Faur, *Regulatory Capitalism* in REGULATORY THEORY 289 (Peter Drahos ed., 2017) (giving an overview of the scholarship on regulatory capitalism).

[17] BRAITHWAITE, *supra* note 16, at xii.

[18] *Id.* at 25.

[19] *Id.* at 21.

procedures and extends it to the transnational context by linking it to Putnam's work on the two-level game (sections A & B). We analyze different patterns of interest group alignment, their role in the creation and operation of treaty obligations for administrative decision-making, and discuss their implications for democratic decision-making (sections C, D, & E). We go on to show how domestic and international review mechanisms can exacerbate or correct existing imbalances in access to procedures and their resulting distributional effects (section F). While the strong attractions of procedural commitments for officials negotiating treaties may explain their proliferation, they also have limitations as instruments of transnational control (sections G & H). Part II explains the rise of procedural requirements in international economic agreements from the 1947 GATT to the Uruguay Round Agreements and EU and US trade agreements of the 1990s and 2000s (sections A & B). We highlight the connections of exercising transnational control by way of procedures in the EU and US treaties with the workings of regulatory capitalism (section C) and compare and contrast procedural commitments for economic actors with those for environment and labor interests (section D). Part III uses the TPP's diverse procedural commitments as a case study and shows the analytical traction of our hypotheses by rationalizing the variation between provisions for intellectual property rights—where procedural commitments are strong, and for environmental protection—where they are weak.

I. Regulatory Procedures as Instruments of Transnational Control

Proceduralized regulatory governance provisions in international agreements can be understood and theorized by joining two classic works of political economy scholarship: McNollgast's conceptualization of regulatory procedures as instruments of political control in domestic government, and Putnam's framing of international negotiations as a two-level game.[20] This synthesis explains and illuminates the growing use in international agreements of administrative law mechanisms for governance at a distance to control regulatory decision-making in other countries, a major phenomenon which has nonetheless received scant scholarly attention.

A. Extending McNollgast to the Transnational Setting

McNollgast, applying positive political theory, views legislation in a democracy as a 'deal' by legislators to target benefits to constituencies in return for their support.[21] Ideally, the deal should be stable and remain faithfully implemented over a long time in order to deliver commensurately greater benefits. In the language of principal-agent frameworks, the administrative officials tasked with

[20] McNollgast, *Administrative Procedures*, *supra* note 5; Putnam, *Two-Level Games*, *supra* note 6.
[21] McNollgast, *Administrative Procedures*, *supra* note 5, at 247; Mathew McCubbins, Roger Noll, and Barry Weingast, *The Political Economy of Law: Decision-Making by Judicial, Legislative, Executive, and Administrative Agencies*, SIEPR DISCUSSION PAPER No. 04-35, 21-22 (2005) [hereinafter McNollgast, *Positive Political Theory of Law*].

implementations are the agents, and the political actors are the principal(s).[22] As in any other principal-agent relationship, the principals will incur agency costs from the delegation due to the agents' differing agendas and interests and the principals' attempts to curb agency "slack" and ensure the agents' conformity to the terms of the delegation.[23] The principals will seek to minimize total agency costs through the mechanisms of control and the incentives at their disposal.

To channel administrative officials' discretion, the political principals can themselves directly monitor agency performance and take corrective measures, including through hearings, budgetary adjustments, or statutory changes.[24] Direct oversight, however, is costly for legislators who have limited time and political resources. They can also seek to narrow the terms of the delegation, but this runs up against the need for legislative compromise and inability to predict future circumstances. *Figure 1* shows these direct instruments of political control of the bureaucratic actors.

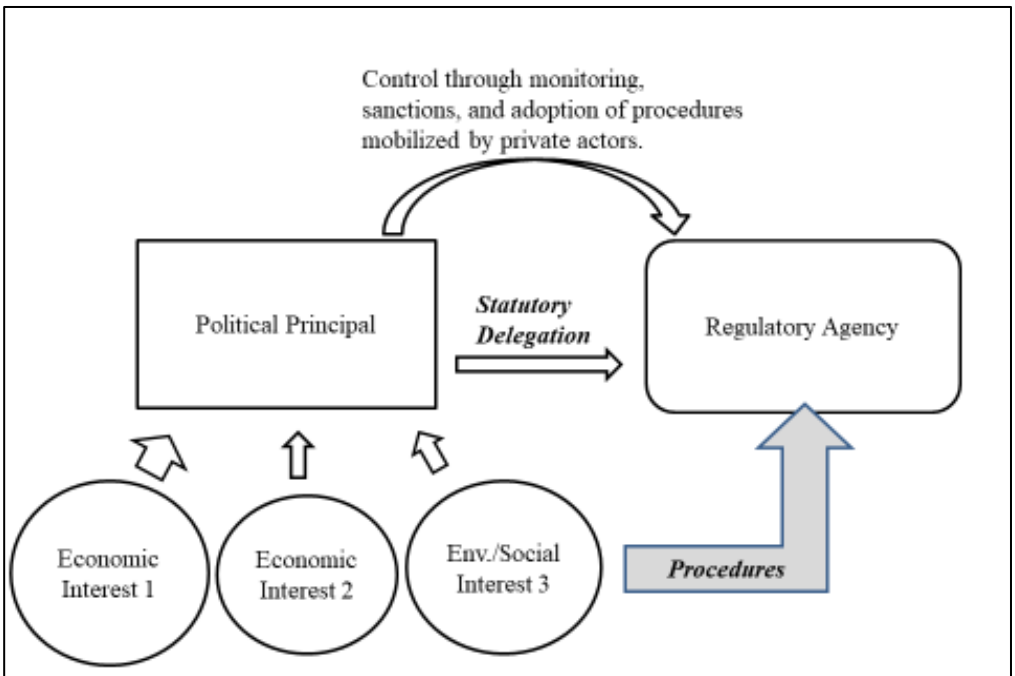

Figure 1: *McNollGast's Framework for Domestic Procedures*

McNollgast's major contribution is to identify an alternative control strategy: political principals can establish administrative procedures that can be mobilized by private actors to pursue their own interests in ways that are aligned with those of the principals by ensuring officials' adherence to the terms

[22] For a good overview of the positive political theory account of administrative procedures, see Lisa Bressman, *Procedures as Politics in Administrative Law*, 107 COLUM. L. REV. 1749, 1767 (2007).
[23] McNollgast, *Positive Political Theory of Law*, *supra* note 21, at 108.
[24] McNollgast, *Administrative Procedures*, *supra* note 5, at 248-253.

of delegation.[25] *Figure 1* also includes this procedural control mechanism. Private actors are given procedural rights to require agencies to act transparently, to submit evidence and argument to the agency as it formulates policy, and to receive reasons for the agency's decisions. These rights can be used not only to generate information that will activate political principals but also to empower private actors to directly assert their interests before the agency. Private actors also have access to judicial review to correct unlawful or simply unresponsive decisions by the administrative officials. This arrangement demonstrates how, as Croley noted, "rules that affect how all other regulatory decisions will be made constitute one crucial set of regulatory outcomes."[26]

Crucially, the political principals can manipulate the administrative process to 'stack the deck' toward favored interest groups by specifying a particular agency to implement a program or a particular design for agencies' decision-making.[27] Political principals can design regulatory procedures either as effective or deliberately ineffective instruments for implementing the underlying substantive deal, thereby choosing to enforce effectively or underenforce the substantive obligations in question. Varying the procedural set-up, resources, information required, and burdens of proof can operate as more fine-grained and targeted deck-stacking by changing the relative influence of different constituents on decisional outcomes.

For political principals, controlling agents through procedures mobilized by private actors has further benefits. Whereas political officials may not know what specific policy outcome their constituents will want under uncertain future conditions, they are likely to know which constituencies they want to empower procedurally.[28] The constituents will know best what is in their interest under changing circumstances and can use their procedurally privileged position to that end. Under this arrangement, the political principals do not incur further monitoring and control costs and alleviate the political risk of ending up on the "wrong side" of a controversial substantive issue.

We extend McNollgast's conception of administrative procedures as instruments of political control to international regulatory and economic governance. In the face of intensifying global interdependencies, economic and civil society actors are increasingly interested in regulatory decision-making in countries around the world.[29] Private actors who wish to influence decisions in other countries

[25] McNollgast developed this theory in line with their long-standing line of argument that the legislature, overall, has effective control over the regulatory state. *See also*, Daniel B. Rodriguez & Barry R. Weingast, *The "Reformation of Administrative Law" Revisited*, 31 J. L., ECON & ORG. 782 (2015) (arguing for the critical role of Congress and the President in the reformation of US administrative law).
[26] Stephen P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 88 (1998).
[27] McNollgast*, Administrative Procedures*, *supra* note 5, at 255.
[28] *Id.* at 263-264.
[29] *See* Baldwin, *Multilateralising Regionalism*, *supra* note 11, at 6-20 (presenting the fundamental changes in the global organization of production and decreases in tariff levels which make domestic regulations key determinants of competitiveness and the incidence of costs and benefits of economic activity).

can lobby and try to mobilize their own domestic political officials to influence governments and regulatory officials in other countries. But there are serious limitations to this approach. Because the political officials in one's own country (State A) are not in a principal-agent relationship with the regulatory officials in another country (State B), many of the instruments of control available to them in the domestic context are unavailable cross-nationally. Recourse to continuing oversight or *ex post* pressure is likely to be viewed as interference. Political actors in State A have no appointment, disciplinary, or budgetary powers regarding officials in State B; these are the prerogative of political principals in State B.[30] A strategy whereby political officials in State A seek directly to influence regulatory decision-making in State B therefore runs up not only against generic problems of informational asymmetries and low detection rates, exacerbated by the international legal order's foundational norms of sovereignty and non-interference.[31]

These limitations may be partially overcome if the parties to an agreement establish an international institution that oversees implementation of an international agreement. Examples include the WTO's Trade Policy Review Mechanism and the Specific Trade Concerns mechanism administered in the WTO's SPS and TBT Committees.[32] Also, an *ex post* control strategy might be to set up traditional state-to-state dispute settlement mechanisms.[33] The extent of State B's consent to these types of control is however likely to be limited and enforcement concerns are prone to persist.[34]

Following McNollgast, another way for political actors in one country (State A) to establish influence over bureaucratic action in State B is to negotiate in international agreements for regulatory procedures which directly empower private actors in State A in the processes of regulatory decision-

[30] Established political relationships, overseas development assistance, large export markets, etc. do, of course, also function as important levers of influence. See Ngaire Woods, *Whose aid? Whose influence? China, Emerging Donors and the Silent Revolution in Development Assistance*, 84 INT'L AFF. 1205 (2008); Anu Bradford, *The Brussels Effect*, 107 NW. U. L. REV. 1, 2-64 (2012) (for the global influence of European Union regulation).

[31] The tension inherent between the governance structures operating in the real world, and the legal concepts international law has used to explain them, has long been recognized. *See generally*, Benedict Kingsbury, *Sovereignty and Inequality,* 9 EUR. J. INT'L L. 599 (1998) (tracing the neglect of inequality as a global issue to the status of concept of sovereignty in international legal scholarship); ANNE-MARIE SLAUGHTER, NEW WORLD ORDER (1995) (showing the disconnect between traditional conceptions of foreign office diplomacy and the manifold international links between different parts of each state); JOHN H. JACKSON, SOVEREIGNTY, THE WTO, AND CHANGING FUNDAMENTALS OF INTERNATIONAL LAW (HERSCH LAUTERPACHT MEMORIAL LECTURES) (2006), at 57-78 (drawing attention to the growing concern for individual traders in international economic law).

[32] See Richard B. Stewart & Michelle Sanchez Badin, *The World Trade Organization: Multiple Dimensions of Global Administrative Law*, 9 INT'L J. CON. LAW. 556, 566, 594 (2011) (discussing the Trade Policy Review Body as a site of economic governance); Horn et al., *supra* note 1 (examining STCs).

[33] Benedict Kingsbury, *International Courts: Uneven Judicialization in Global Order*, in CAMBRIDGE COMPANION TO INTERNATIONAL LAW (James Crawford & Martti Koskenniemi, eds, 2012), 203-228 (taking stock of international courts and tribunals and highlighting the large variation in issues and states subject to their jurisdiction).

[34] Bernard M. Hoekman & Petros C. Mavroidis, *WTO Dispute Settlement, Transparency and Surveillance*, 23 WORLD ECON. 527, 529-533 (2002) (highlighting systemic issues which hamper even enforcement of the highly legalized WTO dispute settlement process).

making of State B. *Figure 2* shows this extension of the McNollgast framework to the transnational context.

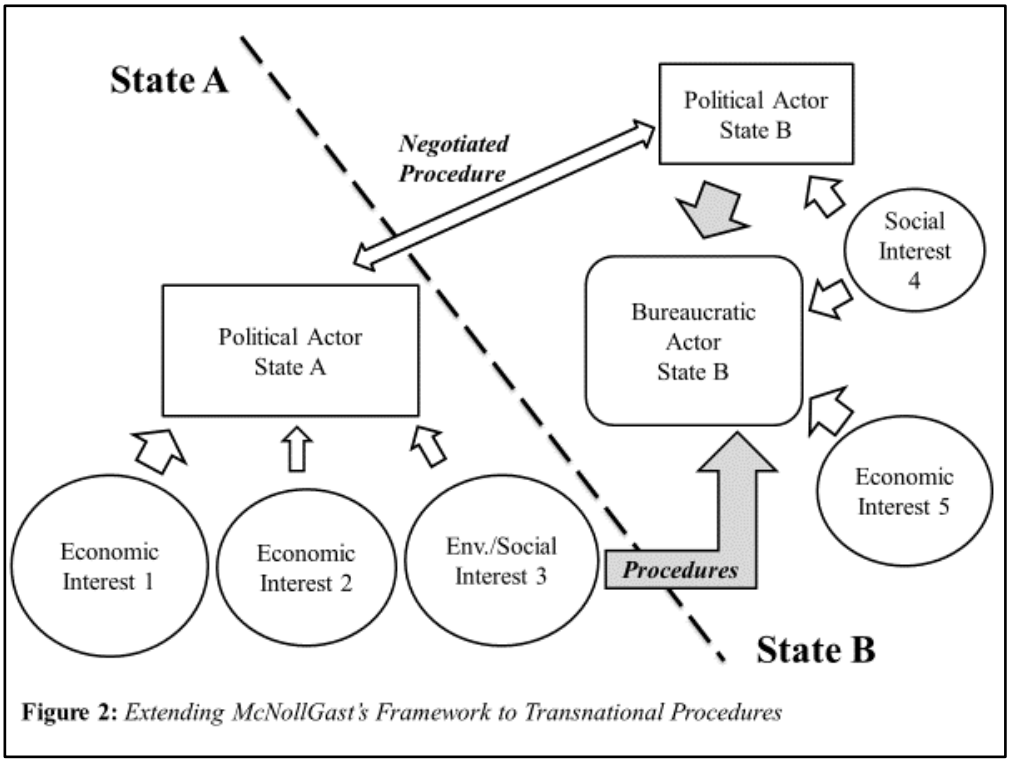

Figure 2: *Extending McNollGast's Framework to Transnational Procedures*

To ensure, even at a distance, that their and their constituencies' preferences are satisfied, the political actors of State A negotiating international commitments (ordinarily, but not necessarily, in the treaty form) can require State B's regulators to follow procedures of transparency, participation, reason-giving, and review. These Global Administrative Law technologies can operate as instruments of transnational control by enabling private parties to secure compliance with State A laws or with the substantive deal in the treaty, by channeling administrative discretion, by creating a more open system of regulatory governance based on reasons, and by incubating communities of practice.[35] Review mechanisms can augment this strategy of transnational control. These can include existing or newly created domestic courts or international courts and tribunals which either allow private actors direct access or make use of traditional state to state dispute settlement via diplomatic espousals.[36]

[35] See *infra* section I.E (discussing these four functions in detail); see Kingsbury, et al., *supra* note 9, at 27-42 (detailing the features of Global Administrative Law).
[36] See *infra* section I.G.

B. Negotiating for Procedures in the Context of Putnam's Two-Level Game

In our extension of the McNollgast model, the central venue for establishing transnational procedural obligations are inter-state negotiations for economic regulatory agreements.[37] The negotiations will involve higher officials from two (A and B) or more states who may have different domestic constituencies with differing interests regarding the appropriate role of such procedures.

Putnam powerfully analyzed the political economy of such negotiations.[38] International agreements are negotiated principally by states' central executives, which in his model are taken to act rationally and strategically. The negotiators' decision environment can be understood as a two-level game—at one level international diplomacy, at the other domestic politics.[39] In this game,

> each national political leader appears at both game boards. Across the international table sit his foreign counterparts, and at his elbows sit diplomats and other international advisors. Around the domestic table behind him sit party and parliamentary figures, spokespersons for domestic agencies, representatives of key interest groups, and the leader's own political advisors.[40]

The task for the negotiating political actors is to compose an agreement that can be accepted at all tables according to each table's decisional rules. The international decision rule is most commonly that of consensus, whereas domestically the rules and practices vary among political systems. Constitutional and statutory requirements, the structure of the political system, regard for the public's preferences, as well as dynamics of coalition-building among powerful constituencies close to the executive branch all factor into the calculus, along with the need for legislative ratification in cases where it is required. The key insight for our purposes from Putnam's two-level game is to think about commitments at the international level which will also satisfy the demands of the domestic tables. For reasons discussed below, we argue that the two-level game character of the negotiation process often makes agreement on domestic regulatory procedures more attractive than substantive commitments.[41]

Domestically, the decision environment of international negotiations often deviates significantly from ordinary legislation and regulation. The realm of diplomacy has long been considered to have its own logics and has often been protected from domestic administrative law requirements through

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[37] Our theory can also be applied, *mutatis mutandis*, to other treaties and even softer instruments of global governance such as MOUs.
[38] Putnam, *Two-Level Games*, *supra* note 6, 434.
[39] Recourse to the two-level game analysis is finding wider application in international legal scholarship. See, e.g., Eyal Benvenisti, *The Political Economy of International Law Making by National Courts,* in THE POLITICAL ECONOMY OF INTERNATIONAL LAW: A EUROPEAN PERSPECTIVE (Alberta Fabbricotti, ed., 2016), 260-261; Anne van Aaken and Joel P. Trachtman, *Political Economy of International Law: Towards a Holistic Model of State Behaviour,* in THE POLITICAL ECONOMY OF INTERNATIONAL LAW: A EUROPEAN PERSPECTIVE (Alberta Fabbricotti, ed., 2016), at 21-26.
[40] Putnam, *Two-Level Games*, *supra* note 6, 434.
[41] *See* section II.G below.

avoidance doctrines and exemptions.[42] Treaty negotiations have traditionally been confidential with limited or no roles for the legislature or courts before their conclusion. In the view of Benvenisti & Downs, this protection of the international domain from standard domestic controls on government has made the decisions at the domestic table particularly vulnerable to capture by organized interest groups.[43]

Kaminski's work on the United States Trade Representative's Office, for example, shows how the exemption of the realm of diplomacy from standard regulatory strictures such as the Administrative Procedure Act (APA), the Federal Advisory Committee Act (FACA) and the Freedom of Information Act (FOIA) due to an asserted need of secrecy in negotiations may, compared to standard domestic policy decisions, significantly favor participation and influence of organized economic interests.[44] By contrast, the publication of proposed negotiating texts or descriptions of the state of play as used by the European Union in the negotiations for the Transatlantic Trade and Investment Partnership (TTIP) altered the strategic interactions at the domestic and international tables by allowing otherwise uninformed and excluded interest groups to review the progress of creations and mobilize for changes in the draft texts.[45]

While in most cases it is inevitable for the executive to takes the leading role in foreign affairs—including in treaty negotiations—the precise institutional arrangements under which it operates affect the extent to which different interests have a say and ultimately diplomacy's substantive outcomes.

C. Interest Alignment at Putnam's Tables

Crucial elements in our translation of McNollgast to the transnational context are the configuration of private actors with an interest in the negotiations and their degree of influence with executives in different states. Along one dimension, private actors in States A and B that have an interest in the regulatory action in State B can be roughly divided into *economic interests* and *environmental or social interests*. (As shown in *Figure 2*) Social and environmental interest groups take a strong interest in regulatory administration both at home and abroad, aware that their concerns are often disregarded at the decisional or implementation stages of state action. They often advocate for and seek to use Global Administrative

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[42] *See* Ganesh Sitaraman & Ingrid Wuerth, *The Normalization of Foreign Relations Law*, 128 HARV. L. REV. 1897 (2015) (tracing the development of US foreign relations law doctrine to shield diplomacy from the standard strictures of domestic law).

[43] BENVENISTI & DOWNS, BETWEEN FRAGMENTATION AND DEMOCRACY, *supra* note 4, at 55.

[44] Margot E. Kaminski, *The Capture of International Intellectual Property Law Through the US Trade Regime,* 87 S. CAL. L. REV. 977, 994-998 (2014); *see also*, Robert Gulotty, *Structuring Participation: Public Comments and the Dynamics of US Trade Negotiations*, in MEGAREGULATION CONTESTED: GLOBAL ECONOMIC ORDERING AFTER TPP (Kingsbury, et al., eds., forthcoming) (detailing the asymmetric participation dynamics in the US negotiation process for trade agreements).

[45] *See* Evelyn Coremans, *From Access to Documents to Consumption of Information: The European Commission Transparency Policy for the TTIP Negotiations*, 5 POL. & GOVERNANCE 29 (2017) (showing how the provision of transparency can generate procedural changes and impact inter-institutional relationship); see also, European Commission, *EU Negotiating Texts in TTIP* (14 July 2016), http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230 (last accessed January 29, 2018) (giving access to the EU's "transparency initiative"—it is interesting to note that this approach was not followed in the later and now concluded negotiations between the EU and Japan).

Law procedures in order to help address these problems. Drawing on Olson's foundational insight and the work of Benvenisti & Downs, one would however expect that organized economic interests are not only better equipped to demand but also to make use of transnational procedural rights.[46] Collective action problems may be further exacerbated in the transnational administrative space, where greater coordination and more resources are needed to effectively influence regulatory action in other states.[47] Environmental and social actors may often lack the resources, internal organization, and incentives to use these procedures as effectively as businesses.[48] For this reason, even facially neutral treaty commitments regarding domestic regulatory procedures may, on balance, favor organized economic interests.[49]

A second distinction is whether the private actors with an interest in regulatory decisions in State B are *insiders* (i.e. from State B) or *outsiders* (i.e. from State A or a third state). Inter-state commitments for domestic regulatory procedures are likely to be more helpful to outsiders than to insiders who already have contacts and access to information from local officials. Procedures may realign the playing field by eroding the benefits that insiders can gather from their local connections. Examples of how Global Administrative Law may benefit outsiders are the WTO TBT Agreement's requirement for member states to notify draft technical regulations and to establish local enquiry points through which outside actors can

[46] MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION (1965) (developing a general theory explaining the structural advantage in the policy process of concentrated (economic) interests compared to diffuse (social) interests); BENVENISTI & DOWNS, BETWEEN FRAGMENTATION AND DEMOCRACY, *supra* note 4, at 52-86 (discussing the impacts of interest group activity in domestic politics on international law).

[47] *See* Alexander Cooley & James Ron, *The NGO Scramble: Organizational Insecurity and the Political Economy of Transnational Action*, 27 INT'L SECURITY 5 (2002) (arguing that the growth of internationally active NGOs has intensified competition, non-cooperation, and opportunistic behavior).

[48] See, John Ruggie, *Multinational as Global Institution: Power, Authority, and Relative Autonomy*, [X] REG. & GOV. 1, 5-7 (2017) (discussing the uneven dynamics of global business lobbying); *see also*, Melissa J. Durkee, *Astroturf Activism*, 69 STAN. L. REV. 201 (2016) (demonstrating how businesses use "front groups" to appear as varying forms of civil society organizations in the international legal process to strategically advance their interests).

[49] There is a growing empirical literature on the distributional impacts of the United States' notice-and-comment rule making process. *See* Brian Libgober & Daniel Carpenter, *Lobbying with Lawyers: Financial Market Evidence for Banks' Influence on Rulemaking*, WASHINGTON CENTER FOR EQUITABLE GROWTH (January 2018), http://equitablegrowth.org/working-papers/lobbying-with-lawyers-financial-market-evidence-for-banksinfluence-on-rulemaking (studying commenting activity on Dodd-Franck related rule-making and linking it to $ 7 billion in excess returns of publicly-traded banks in the post-Dodd-Frank era); Simon F. Haeder & Susan Webb Yackee, *Influence and the Administrative Process: Lobbying the US President's Office of Management and Budget*, 109 AM. POL. SCI. REV. 507-522 (2015) (finding that lobbying of the Office of Management and Budget at the time of its review of regulations is associated with changes to these rules—and finding more influence of business groups compared to public interest groups); Yackee & Yackee, *supra* note 13 (finding that business commenters, but not nonbusiness commenters, hold important influence over the content of final rules through submission of comments in the US notice-and-comment rule-making process). For a recent study of effects of lobbying the White House directly, see Jeffrey R. Brown & Jiekun Huang, *All the President's Friends: Political Access and Firm Value,* NBER WORKING PAPER 23356 (April 2017), http://www.nber.org/papers/w23356 (finding that corporate executives' meetings with key policymakers at the White House are associated with positive abnormal stock returns and regulatory relief for their companies).

comment on them, and the WTO's Government Procurement Agreement (and even more so its 2012 revised version) mandating detailed publication of tenders and standardized application processes.[50]

In other contexts, insiders and outsiders may share common interests, for example when they are members of the same industry or have the same environmental concern. As Putnam notes, an important feature of treaty negotiations is the alignment or even identity of certain economic or social interests across different state parties.[51] These may join forces and create transnational coalitions that succeed in binding their respective states through international treaty obligations when the ordinary domestic legislation or rule-making processes would be unavailing.[52] Embedding measures in international agreements is particularly attractive because states' international legal obligations are difficult to change due to the need of all other state parties to agree to modifications or terminations.[53] This lock-in effect, and the corresponding political benefits for principals—and the interest groups which they are aligned—are even greater than in the domestic setting, where future legislature can undo past deals. Where treaty obligations already exist, like-minded insiders and outsiders may use the available procedures to influence domestic regulatory policies in a strategically orchestrated fashion.

The insider / outsider distinction can mask significant alignment, or even active coalitions, between groups in different countries, creating alignments of *transnational coalitions of private corporate interests* against *general publics*.[54] An example is the group of large multinational proprietary pharmaceutical companies each with a large network of local subsidiaries. Subsidiaries of such firms in State A and B may appropriately be thought of as the same interests using their influence with executives in both states to push for treaty commitments that empower them in the regulatory processes of both States A and B.

Another twist is that private actors with no affiliation with either State A or State B will likely be able to make use of the procedural commitments arising under an agreement between the two states. TPP is an example: even though the United States is not a party to the agreement, firms and civil society groups from around the world, including from the US, may be given new procedural rights in the administrative

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[50] Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120, Art. 10 [hereinafter TBT Agreement]; Agreement on Government Procurement, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 4, 1868 U.N.T.S. 194, Arts. IX-XI [hereinafter WTO GPA]; Revised Agreement on Government Procurement, Annex to the Protocol Amending the Agreement on Government Procurement (Mar. 30, 2012), Arts. VI, VII, X, & XVI, https://www.wto.org/english/docs_e/legal_e/rev-gpr-94_01_e.htm [hereinafter WTO Revised GPA]. For discussions, see Horn, et al., *supra* note 32, 5, note 9; Christopher McCrudden & Stuart G. Gross, *WTO Government Procurement Rules and the Local Dynamics of Procurement Policies: A Malaysian Case Study*, 17 EUR. J. INT'L L. 158 (2006) (discussing the effects of transparency norms on Malaysian procurement practices which have a redistributional dimension).

[51] Putnam, *Two-Level Games*, *supra* note 6, at 444 ("transnational alignments may emerge, tacit or explicit, in which domestic interests pressure their respective governments to adopt mutually supportive policies").

[52] *Id.*

[53] BENVENISTI & DOWNS, BETWEEN FRAGMENTATION AND DEMOCRACY, *supra* note 4, at 72.

[54] We are grateful to Eyal Benvenisti for these suggestions.

processes of the eleven treaty parties as a direct result of TPP. The extent to which private actors with no affiliation to the treaty parties stand to gain from the procedural commitments will depend on the treaty language and exact content of the implementing legislation or regulation in each case. But the TPP treaty provisions we survey in Part IV do in the majority of cases grant rights to "interested persons", rather than, e.g., "interested persons of the Parties".[55] In the cases where they are explicitly more restrictive, the rights involved commonly concern environmental and labor governance, suggesting that states are aware of the possible usage of these obligations by private interests from third parties.[56] Most favored nation treatment arising under the WTO Agreements may also require states to open these regulatory processes to private actors from WTO countries equally.[57] If only for reasons of simple administration, it is likely that the procedural commitments will often be implemented on a non-discriminatory basis.[58] Furthermore, some benefits of procedures such as publication are unlikely to be excludable. The circumstances may give actors from nonparty countries an incentive to try to influence the negotiation of an agreement through coalitions with actors from the party countries or otherwise.

Ultimately, whether the framing of *economic* vs. *environmental/social interests*, *insiders* vs. *outsiders*, or *transnational actors* vs. *general publics* has more analytical purchase is likely to depend on the exact regulatory struggle at issue, the existing coalitions of interests and their fault lines across and within states, as well as the extent of influence by organized economic actors over the different state executives in the different negotiating countries.

D. Implications for Democratic Decision-Making

In light of this analysis, the dominance of the executive in international affairs and the proliferation of international agreements carries negative implications for the democratic legitimacy of procedures as instruments of transnational control by fencing out legislatures and courts. This situation stands in contrast to the conclusions of McNollgast's original analysis, which was concerned with the influence of elected officials (and, indirectly coalitions of voters and organized interests reflected in election outcomes) on the administrative state and bureaucratic politics. In the McNollgast model, regulatory procedures mandated by legislation are a mechanism by which elected officials can exercise control over the rule-making procedures, and therefore bolster the democratic legitimacy of bureaucratic

[55] *See, e.g.,* TPP12, *supra* note 8, Arts. 8.7.1 & 27.2.2.
[56] Jan Klabbers, *Megaregionals: Protecting Third Parties,* MEGAREG FORUM PAPER 2016/1 (28 April 2016) (discussing the general principle of *patan terriis nec nocent nec prosunt* in international law which generally does not allow treaty commitments to create rights and obligations for states not parties to the treaty).
[57] *See* Robert Howse, *Regulatory Cooperation, Regional Trade Agreements, and World Trade Law: Conflict or Complementarity?*, 78 LAW & CONTEMP. PROB 137, 142-43, 151 (2015) (arguing that the GATT's MFN guarantee is not covered by the Art. XXIV exception with respect to non-tariff measures.)
[58] Examples here include single-window customs administration, rights of review in national courts, or publication.

action.[59] Our extension of their framework to the transnational context cuts in the opposite direction. Where regulatory procedures and other provisions are negotiated among executive officials in the process of treaty-making, the measures may not be democratically legitimated and reflect the preferences of transnationally active organized interests with good connections to the respective executive branches of government rather than those of general publics. While legislatures may often better represent general publics, as political principals they have a harder time controlling the executive as their agent in the transnational setting.[60]

This concern is exacerbated in instances where international agreements do not require legislative approval either for the ratification of the treaty or for implementing legislation. But even where there is a further legislative step, the nature of the "package deal" and limited influence over the specifics where legislatures are veto-players rather than agenda-setters may result in outcomes that tilt against the interests of general publics and are driven by coalitions of transnationally active economic actors in powerful states.[61] Even where the legislature is involved in treaty making before ratification, as in the United States' fast-track procedure for economic treaties, its guidance often remains general.[62] Forced to leave space for the give-and-take of the inter-state negotiations, the legislature's delegation of authority to the executive gives the latter wide discretion.[63] In the case of TPP's fast-track legislation, for example, the high variation in the strength of procedural requirements between different issue areas and interests which we discuss further below was not reflected in the legislative guidance.[64] It was only in the ultimate treaty text resulting from inter-executive negotiations that procedural deck stackings became evident.[65]

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[59] McNollgast, *Positive Political Theory of Law*, *supra* note 21, 17. That is not to say that McNollgast do not themselves acknowledge the limits of this justification in the light of collective action problems. McNollgast*, Administrative Procedures*, *supra* note 5, 274 ("Of course, not every group will be included in an agency's environment. Influence will be accorded to those represented in the coalition that gave rise to the agency's organic statute. Well-organized special interests and the parochial interests of congressional districts will be well represented. Interests of a national constituency that is not well organized will not achieve representation unless it is built into the agency's process. And this will occur only if these broader interests are influential with elected politicians, usually because they are electorally significant. Thus, in the end, the politics of bureaucracy will mirror the politics surrounding the president").

[60] We are grateful to Eyal Benvenisti for this suggestion.

[61] See Iain Osgood, *Globalizing the Supply Chain: Firm and Industrial Support for US Trade Agreements*, INT'L ORG. (forthcoming), https://sites.google.com/a/umich.edu/iainosgood/research; Iain Osgood & Yilang Feng, *Intellectual Property Provisions and Support for US Trade Agreements*, REV. INT'L ORG. (forthcoming), https://sites.google.com/a/umich.edu/iainosgood/research.

[62] Ian F. Ferguson, Cong. Research Serv., RL33743, *Trade Promotion Authority (TPA) and the Role of Congress in Trade Policy* 11 (2015) (outlining the types negotiation objectives included in Congressional Trade Promotion Authority legislation).

[63] Harold Koh, *The Fast Track and United States Trade Policy*, 18 BROOKLYN J. INT'L L. 143, 170 (1992) ("Agreements enacted under the Fast Track thus tend to reflect the President's trade priorities and agenda more closely than Congress'").

[64] *See infra*, Part IV.

[65] Bipartisan Congressional Trade Priorities and Accountability Act of 2015, H.R. 2146, 114th Congress (2015) ("Trade Promotion Authority (TPA) for the Trans-Pacific Partnership (TPP) ((7) Regulatory practices: The principal negotiating objectives of the United States regarding the use of government regulation or other practices to reduce market access for United States goods, services, and investments are—(A) to achieve increased transparency and

These democracy concerns have added force in light of the popular backlash in the US and parts of Europe against international economic arrangements, negotiated and overseen by elites, which are perceived to (and may very likely in fact) provide disproportionate benefits to large business and financial institutions and wealthy individuals, while imposing disruptive costs on the less advantaged.

E. Four Functions of Inter-State Commitments to Domestic Regulatory Procedures

Irrespective of which type of interests they seek to empower, Global Administrative Law procedures can serve to influence administrative decision-making and secure the interests of private actors in four different ways. These functions are the means through which control can be exerted at a distance.

First, procedures can help to ensure compliance by state officials with the substantive commands and requirements of domestic law and of the international legal obligations applicable to their actions. Procedures generate information for the political branches as well as interested private parties to learn about the details of regulatory action, the reasons for it, and the underlying evidence. In the TPP agreement, for example, parties commit to require their telecommunications regulators to publish "an explanation of the purpose and of the reasons" for any proposed regulatory action.[66] The generation of information has a self-regulating function by incentivizing regulators to adhere to the law applicable to them and be mindful of public concerns. Information can moreover serve to mobilize direct control by political principals. The information may provide a basis for judicial review, initiated by private parties, of administrative decisions if the agency nonetheless deviates.[67] It may also help private actors to mobilize political support from other governments which can approach the decision-making states' political principals on their behalf.[68]

A second function of procedures stems from the inevitable ambiguities in laws, regulations, and treaties resulting from the need to reach a compromise and the uncertainty of future circumstances. Such ambiguity necessarily affords interpretive discretion to the public officials to whom the implementation has been delegated.[69] Obliging these officials to make decisions according to specific procedures which guarantee access to information and responsiveness to comments from the public can influence these

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opportunity for the participation of affected parties in the development of regulations; (B) to require that proposed regulations be based on sound science, cost benefit analysis, risk assessment, or other objective evidence; (C) to establish consultative mechanisms and seek other commitments, as appropriate, to improve regulatory practices and promote increased regulatory coherence […] (F) to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products; (G) to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for United States products …")

[66] TPP12, *supra* note 8, Art. 13.22.1(b).

[67] *Id.*

[68] Richard B. Stewart, *Global Standards for National Societies,* in RESEARCH HANDBOOK ON GLOBAL ADMINISTRATIVE LAW 175, 185 (Sabino Cassese ed., 2016).

[69] In the context of global governance, delegation also occurs between global regulatory actors and national administrators. Analogously to the domestic context, the global actors may develop more specific and concrete regulatory norms to reduce discretion. *Id.*

officials in the exercise of their discretion. The change in outcomes is likely to slant toward the interests of those private parties which use the procedures. This function is reflected in the requirement in the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union to "ensure that transparency procedures regarding the development of technical regulations […] allow interested persons of the Parties to participate at an early appropriate stage when amendments can still be introduced and comments taken into account."[70] Similar commitments abound in many international economic regulatory agreements.[71]

Third, the systematic, predictable, and consistent application of these procedures throughout a state's administration can foster an open regulatory system in which private actors can operate with lower uncertainty and risk. In pursuing "freedom to operate", multinational businesses prefer to locate operations in jurisdictions with systems of open and sound regulatory governance.[72] In their cumulative effects, practices of transparency, participation, reason-giving, and review can significantly improve the legibility of a regulatory state, especially to less informed outside actors, and root out informal capture.[73] They can help the overall rationality of regulation and root out discriminatory or protectionist regulatory measures. This is of significant interest to transnational economic actors which seek to continuously maximize allocative efficiency along their global value chains (GVCs).[74] Cumulatively, moreover, these procedures may enhance firms' freedom to operate transnationally by driving processes of overall cross-polity regulatory alignment. By regulatory alignment we mean the promotion in compatibility of regulatory institutions and practices among states in order to facilitate cross-national business and market structures, without requiring strict harmonization or mutual recognition of the standards and regulations of different jurisdictions.[75]

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[70] CETA, Art. 4.6.

[71] *See, e.g.,* US-Colombia FTA, Art. 19.2(b) ("To the extent possible, each Party shall: […] provide interested persons and Parties a reasonable opportunity to comment on [] proposed [regulatory] measures"); EU-South Korea FTA, Art. 12.3.2 (2. Each Party shall: (a) endeavour to publish in advance any measure of general application that it proposes to adopt or to amend, including an explanation of the objective of, and rationale for the proposal; (b) provide reasonable opportunities for interested persons to comment on such proposed measure, allowing, in particular, for sufficient time for such opportunities; and (c) endeavour to take into account the comments received from interested persons with respect to such proposed measure.")

[72] *See* Dan Ciuriak, *Generalized Freedom to Operate,* MEGAREG FORUM PAPER 2016/3 (7 December 2016), http://www.iilj.org/publications/generalized-freedom-operate/

[73] Richard B. Stewart, *The Normative Dimensions and Performance of Global Administrative Law,* 13 INT'L J. CON. L. 499, 500-02 (2015) (discussing the benefits from improved regulatory performance that Global Administrative Law may induce).

[74] Donald Robertson, *Global Value Chains and Business Structures: Megaregional Markets and Regulation*, in CONTESTED MEGAREGULATION: GLOBAL ECONOMIC ORDERING AFTER TPP (Benedict Kingsbury, et al., eds., forthcoming) (manuscript on file with authors).

[75] Benedict Kingsbury, et al., *Megaregulation and Megaregionalism*, in CONTESTED MEGAREGULATION: GLOBAL ECONOMIC ORDERING AFTER TPP (Benedict Kingsbury, et al., eds., forthcoming) (manuscript on file with authors); Iain Osgood, *Sales, Sourcing, or Regulation? New Evidence from the TPP on What Drives Corporate Interest in Trade Policy,* in CONTESTED MEGAREGULATION: GLOBAL ECONOMIC ORDERING AFTER TPP (Benedict Kingsbury, et al., eds., forthcoming) (manuscript on file with authors) (identifying harmonization as an important concern for corporations in trade policy).

The consequences of a domestic regulatory process incorporating Global Administrative Law procedures will depend not only on their supply but also on the nature of the demand for them.[76] This will vary between countries and issue areas, organized economic interests which can identify monetary gains from targeted regulatory change are likely to have a high demand for use of such procedures.

Fourth, regulatory procedures can serve as focal points around which actors sharing material interests or normative agendas in specific issue areas can iteratively build up communities of practice.[77] Whereas these communities used to be relatively specific to a domestic regulatory culture, today they routinely include regulators, firms, and civil society from other jurisdictions and regulatory domains.[78] These communities can evolve into transnationally operating networks that influence domestic regulatory decision-making not only by amplifying specific interests or building new coalitions but also by developing their own standards of appropriate action that frame the understanding of regulatory purpose and agenda.[79] The labor petitions process established pursuant to the 2006 Dominican Republic-Central America Free Trade Agreement (CAFTA-DR), for example, allows organized labor groups to petition the parties' labor ministries in case they are concerned about local enforcement of labor laws.[80] This procedure facilitated development of a new transnational alliance of labor interests to join in concerted action. In 2008 Guatemalan and U.S. labor groups jointly took advantage of the treaty procedure to petition the United States Department of Labor to bring a case against Guatemala for violating its obligations to allow for collective bargaining and ensure acceptable conditions of work.[81] The procedure served as a focal point for coalition building among NGOs and labor unions.

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[76] Walter Mattli & Ngaire Woods, *In Whose Benefit? Explaining Regulatory Change in Global Politics*, in THE POLITICS OF GLOBAL REGULATION 1, 4 (Walter Mattli & Ngaire Woods, eds., 2009).

[77] *See* KARL DEUTSCH ET AL., POLITICAL COMMUNITY AND THE NORTH ATLANTIC AREA: INTERNATIONAL ORGANIZATION IN THE LIGHT OF HISTORICAL EXPERIENCE, (Greenwood Press, 1969); KENNEDY, A WORLD OF STRUGGLE, *supra* note 4; Richard B. Stewart, *The Reformation of American Administrative Law,* 88 HARV. L. REV. 1667, 1675 (1975).

[78] *See, e.g.,* David Bach & Abraham Newman, *Domestic Drivers of Transgovernmental Regulatory Cooperation,* 8 REG. & GOV. 395, 397-398 (2014) (for a brief overview of the scholarship on transgovernmentalism); Louise Curran & Jappe Eckhardt, *Smoke Screen? The globalization of production, transnational lobbying and the international political economy of plain tobacco packaging*, 24 REV. INT'L POL. ECON'Y 87 (discussing transnational firm lobbying in the context of tobacco regulation); Lisa Kastner, *'Much Ado About Nothing?' Transnational Civil Society, Consumer Protection and Financial Regulatory Reform*, 21 REV. INT'L POL. ECON'Y 1313 (2014) (discussing the influence of transnational civil society networks).

[79] James G. March & Johan P. Olsen, *The Logic of Appropriateness*, in THE OXFORD HANDBOOK OF POLITICAL SCIENCE 659 (Robert E. Goodin, et al. eds., 2011)

[80] Central American-Dominican Republic-United States Free Trade Agreement, Aug. 5, 2004, https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text (last visited February 13, 2018) [hereinafter CAFTA-DR], Art. 16.4.3.

[81] The U.S. ultimately brought and consequently lost a state-to-state case. USTR, *In the Matter of Guatemala – Issues Relating to the Obligations Under Article 16.2.1(a) of the CAFTA-DR.* For general information, see https://ustr.gov/issue-areas/labor/bilateral-and-regional-trade-agreements/guatemala-submission-under-cafta-dr.

F. Tilting the Procedural Playing Field in Favor of Certain Interests

International commitments regarding states' regulatory procedures can, similar to McNollgast's analysis in the domestic context, be used to stack the deck in favor of certain interests. These interests are likely to be those which are particularly influential with state executives, even though the legislature may also be lobbied by competing interests, leading to contestation between the two branches and the different coalitions of constituents they represent over the procedures to be adopted.[82] Depending on the specific context, the procedures ultimately agreed on in treaties can systematically affect the outcome in conflicts between economic interests and environmental and social interests, between insiders and outsiders, or combinations of these interests. We identify four ways in which procedures can stack the deck.

First, the procedural set-up can be specifically designed with a view to support or hamper a particular substantive interest. In the patent application process, for example, a procedure to challenge patents before they are granted has been seen as an effective way to prevent the approval of spurious applications.[83] In India, this procedure has been used by social interests advocating for access to medicines.[84] On the other hand, the 2012 economic agreement between Korea and the United States prohibited this pre-grant opposition procedure, thereby empowering patent originators.[85]

Second, interest groups with more resources can be relatively advantaged by demanding and costly procedures. High evidentiary thresholds, requirements for extensive evidence and sophisticated analyses requiring the consultation of experts or commissioned studies, and multiple opportunities to seek review can all drive up the cost of participation.[86] For example, the costs associated with investor-state

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[82] This is what may have happened in the European Union during the TTIP negotiations where the European Parliament took a more critical stance against Investor-State Dispute Settlement than the European Commission. Compare European Parliament, *Resolution of 8 July 2015 containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP)* (2014/2228(INI)) (advocating for the replacement of ISDS with a system that gives foreign investors "no greater rights than domestic investors"), with European Commission, Press Release, *Commission Proposes New Investment Court System for TTUP and other EU trade and investment* (16 September 2015), http://europa.eu/rapid/press-release_IP-15-5651_en.htm (presenting the Commission's reform proposal for ISDS). Successful lobbying from influential groups can, of course, also lead to agreement between the two branches.

[83] Ruth Lopert & Deborah Gleeson, *The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines*, 41 J. L., MED. & ETHICS 199, 203 (2013).

[84] Amy Kapzcynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1599 (2009).

[85] South Korea-United States Free Trade Agreement (Feb. 10, 2011), Art. 18.8.4 [hereinafter KORUS] ("[w]here a Party provides proceedings that permit a third party to oppose the grant of a patent, the Party shall not make such proceedings available before the grant of the patent."). In the first leaked version of the Trans-Pacific Partnership's IP chapter, the suggested version of Article 8.7 also prohibited pre-grant opposition. Knowledge Ecology International, *The complete Feb. 10, 2011 text of the US proposal for the TPP IPR Chapter*, *available at* http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf, Art. 8.7. The Australia-United States Free Trade Agreement (AUSFTA) on the other hand did not prohibit it. Australia-United States Free Trade Agreement (AUSFTA) (May 18, 2004) [hereinafter AUSFTA].

[86] McNollgast, *Positive Political Theory of Law*, *supra* note 21, at 99; *see also* Marc Galanter, *Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change,* 8 LAW & SOC'Y REV. 95 (1974) (discussing the inequitable consequences of multiple review stages).

arbitration arising under international treaties have been credited with establishing an inherent imbalance between 'lawyered-up' investors and respondent states with limited resources.[87]

Third, procedures can directly advantage certain interests by privileging some sources and types of information over others where this information is in the exclusive possession of certain stakeholders.[88] Treaty commitments can also prohibit procedures which would require the release of information which business firms want to protect. In TPP's provisions on the regulation of cosmetics, medical devices, and pharmaceuticals, for example, an identical provision prohibits the Parties from requiring "sale data, pricing, or related financial data" concerning the product in relation to their application of marketing authorization.[89]

Fourth, provisions may remove obstacles that would otherwise exist in national laws to effective participation of environmental and social interests.[90] Relaxed requirements for standing in administrative procedures and judicial review, burdens of proof in favor of environmental protection, and subsidized representation for resource constrained civil society groups can work to support loosely organized interests that face inherent difficulties in mobilizing.[91] The Aarhus Convention, for example, requires states to grant standing for judicial review to any environmental NGO with respect to state's implementation of its access to information obligations under the Convention without having to establish a more specific interest.[92]

G. Review as Deck-Stacking or Democratic Corrective

The effectiveness of procedures for regulatory decision-making can be bolstered or not depending on whether procedures for review of administrative decisions by courts and tribunals are

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[87] Thomas Schultz & Cedric Dupont, *Investment Arbitration: Promoting the Rule of Law or Over-Empowering Investors? A Quantitative Empirical Study,* 25 4 EUR. J. INT'L L. 1147 (2014) (arguing that the international investment regime favors the 'haves' over the 'have-nots').

[88] Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture,* 59 DUKE L. J. 1321, 1328-51 (2010) (presenting a theory of information capture in the US regulatory process).

[89] TPP12, *supra* note 8, Annex 8-C "Pharmaceuticals", para.11; Annex 8-D "Cosmetics", para. 16; Annex 8-E "Medical Devices", para. 12.

[90] For legal strategies to regulate group behavior, see Eric A. Posner, *The Regulation of Groups: The Influence of Legal and Nonlegal Sanctions on Collective Action*, 63 U. CHI. L. REV. 133, 144-55 (1996) (particularly relevant are his discussions of subsidizing groups through group-based rules).

[91] *See generally*, Robert O. Keohane, Stephen Macedo & Andrew Moravcsik, *Democracy-Enhancing Multilateralism*, 63 INT'L ORG. 1, 9-16 (2009) (using US trade policy as an example where multilateral institutions in form of the WTO can restrict the influence of special interest factions in national democratic processes). But in fact environmental agreements often limit the mandated "standing" to challenge environmental measures to "interested parties residing or established in its territory". *See, e.g.,* TPP, Article 20.7.2. This is somewhat analogous to the well-developed debate in the U.S. about the political significance of strict/liberal standing rules. *See generally,* Lisa Schultz Bressman, *Procedures as Politics in Administrative Law*, 107 COLUM. L. REV. 1749 (2007); Richard J. Pierce, Jr., *Lujan v. Defenders of Wildlife: Standing as a Judicially Imposed Limit on Legislative Power*, 42 DUKE L.J. 1170, 1170-71, 1198-1200 (1993).

[92] Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Jun. 25, 1998) 38 I.L.M. 517, 2161 U.N.T.S 447 (entered into force Oct. 30, 2001) [hereinafter Aarhus Convention], Article 9.2 (chausette).

available. Without review, opportunities for input to administrative decision-makers in other countries may have much weaker impacts than in the purely domestic setting. Review may be critical in ensuring compliance with both the substantive and procedural obligations in international agreements and may function either as additional instruments for deck-stacking in favor of particular interest groups or serve as correctives to ensure consideration of the interests of larger publics or the disregarded.[93] Viewing procedures as instruments of control across borders focuses the inquiry on the exact set-up of review bodies in relation to different issue areas and types of substantive obligations.[94]

First, existing domestic review mechanisms may be invoked by private parties seeking review of regulatory action. Review may be an effective way to enforce substantive and procedural obligations in treaties regarding the rights of private actors.[95] Whether the domestic legal system, taking into account any relevant treaty provisions, makes such claims justiciable and gives private actors standing to pursue them are important questions determining the efficacy of these review mechanisms.[96]

Second, some treaties create new rights or mechanisms of domestic review by courts or tribunals that empower private actors, both transnational and domestic. The parties to an agreement can determine the character of the review body (judicial or administrative, existing or new, timing (i.e. *ex ante* or *ex post*), standing, standards of proof, and available remedies. These can be structured in line with State A's interests and that of its constituents.[97] For example, national courts may be required to be open to applications for review in new types of cases and new types of applicants. They may be required to provide specified remedies, as for example in the requirements of the TRIPS agreement for national

[93] Richard B. Stewart, *Remedying Disregard in Global Regulatory Governance: Accountability, Participation, and Responsiveness,* 108 AM. J. INT'L L. 211 (2014).
[94] *See* Kingsbury, *International Courts, supra* note 33, at 203-228 (discussing the variation).
[95] *See, e.g.*, North American Free Trade Agreement, U.S.-Can.-Mex. (Dec. 17, 1992), 32 I.L.M. 289, Art. 1714 [hereinafter NAFTA]. Strong, but relatively standard language, from IP chapters reads ("3. Each Party shall provide that decisions on the merits of a case in judicial and administrative enforcement proceedings shall: (a) preferably be in writing and preferably state the reasons on which the decisions are based; (b) be made available at least to the parties in a proceeding without undue delay; and (c) be based only on evidence in respect of which such parties were offered the opportunity to be heard.4. Each Party shall ensure that parties in a proceeding have an opportunity to have final administrative decisions reviewed by a judicial authority of that Party and, subject to jurisdictional provisions in its domestic laws concerning the importance of a case, to have reviewed at least the legal aspects of initial judicial decisions on the merits of a case. Notwithstanding the above, no Party shall be required to provide for judicial review of acquittals in criminal cases.")
[96] *See generally,* ANDRÉ NOLLKAEMPER, NATIONAL COURTS AND THE INTERNATIONAL RULE OF LAW (2011).
[97] Relatively standard treaty language in US FTAs, for example, reads: "2. Each Party shall ensure that judicial, quasi-judicial, or administrative proceedings are available under its law to provide sanctions or remedies for violations of its environmental laws. (a) Such proceedings shall be fair, equitable, and transparent and, to this end, shall comply with due process of law, and be open to the public except where the administration of justice otherwise requires. (b) Tribunals that conduct or review such proceedings shall be impartial and independent and shall not have any substantial interest in the outcome of the matter." CATFA-DR FTA, Article 17.3. For the importance of analyzing the specific legal question arising in national courts, see Kenneth Keith, '*International Law is Part of the Law of the Land': True or False?, 26 LEIDEN J. INT'L L. 351 (2013).*

courts to be able to issue preliminary injunctions against patent infringements.[98] Benvenisti and Downs have argued that judicial review in national courts can also be a corrective to inequitable interest group influence in global governance.[99] Treaty commitments that require national courts to be open to petitions from the general public may accordingly serve to protect the otherwise disregarded.[100]

Third, many treaties establish new review mechanisms beyond the state. These sometimes interlink with domestic review mechanisms or provide an additional layer of review over states' regulatory or judicial actions. They can either allow private actors to initiate and independently pursue their grievances (e.g. ISDS or regional human rights courts) or take the form of traditional state-to-state dispute settlement which requires governments to espouse the claims of private interests. A deck-stacking feature of the ISDS mechanism, widely found in bilateral investment as well as trade agreements and in TPP, is that it is available only to investors and not to representatives of environmental and social interests, that have unsuccessfully sought to participate.[101] At first sight, the ISDS mechanism runs contrary to the McNollgast logic we develop, because the domestic procedural obligations here are bypassed. But investors can invoke investment treaties' general obligations of fair and equitable treatment against a state which is not keeping its domestic and international procedural obligations.[102] This might include even the specific obligations which a state has made vis-à-vis its domestic regulatory procedures and mechanisms of administrative and judicial review, thereby linking domestic administration, administrative law provisions in international agreements, and international fora for review.[103]

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[98] *See* TRIPS, Art. 50; see Paola Bergallo & Augustina Ramón Michel, *The Recursivity of Global Lawmaking in the Struggle for Argentine Policy on Pharmaceutical Patents*, in BALANCING WEALTH AND HEALTH: THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA 37, 69-71 (Rochelle C. Dreyfuss & César Rodríguez-Garavito, eds., 2014) (detailing the contentious domestic politics of these changes and the ways in which the exact contours of implementation influence the relative power of different interests in the national courts)

[99] BENVENISTI & DOWNS, BETWEEN FRAGMENTATION AND DEMOCRACY, *supra* note 4, at 149-162 (discussing the democratizing potential of national courts); Eyal Benvenisti, *Reclaiming Democracy: The Strategic Uses of Foreign and International Law by National Courts*, 102 AM. J. INT'L L. 241 (2008); Eyal Benvenisti, *Judicial Misgivings Regarding the Application of International Law: An Analysis of Attitudes of National Courts*, 4 EUR. J. INT'L L. 159 (1993).

[100] We are grateful to Eyal Benvenisti for this suggestion.

[101] But, see Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v. The Argentine Republic, ICSID Case No. ARB/07/26, Award, ¶¶ 1110-1221 (declaring Argentina's counterclaim against the investor admissible in principle but failing on the merits).

[102] Benedict Kingsbury & Stephan W. Schill, *Investor-State Arbitration as Governance: Fair and Equitable Treatment, Proportionality, and the Emerging Global Administrative Law*, NYU SCHOOL OF LAW, PUBLIC LAW RESEARCH PAPER NO. 09-46 (September 2009), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1466980.

[103] One recent example is the threatened use of ISDS by a Swiss pharmaceutical company under the Colombia-Switzerland bilateral investment treaty in response to Colombia's attempts to negotiate decreases for a cancer drug. Public Eye, *Compulsory Licensing in Colombia: Leaked documents show aggressive lobbying by Novartis* (12 April 2017), *available at* https://www.publiceye.ch/en/media/press-release/compulsory_licensing_in_colombia_leaked_documents_show_aggressive_lobbying_by_novartis/ (last accessed 31 January 2018).

H. Four Attractions for Negotiators of Procedural Commitments in the Two-Level Game

With all this at hand, we identify four characteristics of procedural commitments that make them particularly attractive to treaty negotiators in Putnam's two-level game. Following Gourevitch, we emphasize the international sources of domestic politics—in this case, domestic regulatory decision-making.[104] The attractions we identify likely contributed to the rise in these types of treaty commitments and suggest that this technology of governance may continue to grow in importance and variety.

First, in treaty negotiations, transnational procedural obligations may be less contentious than substantive commitments because the diplomatic negotiators may underestimate their significance. Even where there is no agreement on detailed substantive obligations, regulatory procedures may steer outcomes in specific directions. Specific substantive policies may more easily be seen as impositions from abroad maladapted for the domestic context and the regulatory system's wider equilibrium.[105] Especially for negotiators from less developed countries, who are often spread quite thin, it may often not be obvious how and in whose favor new procedural obligations would impact the domestic regulatory process, whether the obligations conflict with other commitments, or how much resources will be required for implementation.[106] To the extent that procedures are to function as enforcement mechanisms for substantive obligations, there is of course a need for at least thin agreement on the substantive standard in issue. But it may be much easier to agree on procedures coupled with vague substance than on specific substantive obligations. An example of significant procedural obligations agreed to by developing country negotiators with little appreciation of their performance is the WTO's SPS Agreement, where the substantive impact of the requirement to either regulate in accordance with international standards or to support a regulation with scientific evidence has since become apparent.[107]

Second, in the political dynamics at the domestic or the international tables, administrative procedures may often be less salient in domestic politics, making it easier to obtain agreement. In cases where sharp divisions on substantive commitments persist, procedures may offer a compromise. As Putnam noted, the composition of the interested stakeholders in the domestic-level game will vary across issues, with politicized or politically salient issues drawing more interested participants, thereby making agreement more difficult, especially as the new participants are often less concerned about a scenario in which no agreement takes place at all.[108] For example, TPP negotiators were entangled in sharp disputes over the substantive issue of the exact number of years of exclusive data usage granted to the owners of

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[104] Peter Gourevitch, *The Second Image Reversed: The International Sources of Domestic Politics,* 32 INT'L ORG. 881 (1978).
[105] Stewart, *Global standards, supra* note 68, at 183-84.
[106] Kevin Davis & Benedict Kingsbury, *Obligation Overload* (manuscript on file with authors).
[107] Tim Büthe, *The globalization of health and safety standards: Delegation of regulatory authority in the SPS Agreement of the 1994 Agreement establishing the World Trade Organization*, 71 LAW & CONTEMP. PROB. 219 (2008).
[108] Putnam, *Two-Level Games*, *supra* note 6, 444.

biologics—an issues which had mobilized significant opposition in the domestic discourses of New Zealand, Australia, Chile, Canada, and others.[109] It was therefore to be expected that with the US dropping out, the CPTPP would suspend this provision.[110] In reaction to such sharp substantive disagreements, an astute interest group may be able to increase its share of the negotiated pie by receding from demands for a longer protection period in favor of less salient but similarly valuable procedural objectives such as precluding pre-grant opposition to patents, which nevertheless create significant gains for them in the long-term. On occasion, however, procedural provisions may be salient and highly controversial, especially when they are seen to be closely aligned with substantive outcomes, as exemplified in the furor in Europe over the ISDS provisions in the draft TTIP treaty.[111]

Third, a significant feature of the two-level game is its potential for coalitions between different interest groups in different countries who each think they would benefit from procedural provisions.[112] Coalitions may be built around procedures as opposed to substantive commitments. A commitment to the principle of access to information for example, may generate coalitions between outsider economic interests and local and transnational environmental/social interests.[113] From the perspective of economic actors, transparency obligations can help to flush out cronyism between rivals and government officials and enable them to obtain information about the agency's position in order to more effectively influence its decisions,[114] whereas environmental and social interests may also favor informational provisions which they can use not only to influence regulatory decisions but also to mobilize wider public support.[115] Take as an example the case of *Claude-Reyes et al. v. Chile* before the Inter-American Court of Human Rights, where the court held in favor of the plaintiff, a reform minded lawyer affiliated with NGOs, who claimed that Chile had violated his right of access to public information when the Chilean Foreign Investment Committee refused his request for information about the foreign investors seeking a government concession for a vast forestry project in the Tierra del Fuego archipelago. Here there could well be overlapping interests between domestic forestry developers resisting foreign competition and environmental groups seeking to stop the project altogether. We expect norms of good government other

[109] The final outcome was an odd compromise provision which required either 8 years of data exclusivity or 5 years plus other measures and market circumstances which would together "deliver a comparable outcome in the market". TPP, Art. 18.51.
[110] CPTPP, *supra* note 8.
[111] *See* Alexsia T. Chan & Beverly K. Crawford, *The Puzzle of Public Opposition to TTIP in Germany,* 19 BUS. & POL. 683 (2017).
[112] Putnam, *Two-Level Games*, *supra* note 6, 444 ("Transnational alignments may emerge, tacit or explicit, in which domestic interests pressure their respective governments to adopt mutually supportive policies.")
[113] Iain Osgood, *Sales, Sourcing, or Regulation? New Evidence from the TPP on What Drives Corporate Interest in Trade Policy,* in CONTESTED MEGAREGULATION: GLOBAL ECONOMIC ORDERING AFTER TPP (Benedict Kingsbury, et al., eds., forthcoming) (manuscript on file with authors). *See also*, Ala'i & D'Orsi, *supra* note 1, at 367-68 (noting the "dual use" potential of transparency for both trade liberalization by empowering economic actors and its potential role in government accountability, civil society participation, and addressing due process concerns).
[114] The information, where it relates to activities and business competitors, health commercial value. Most US FOIA requests are by businesses.
[115] This idea is the bedrock of the Aarhus Convention, *supra* note 92.

than transparency such as reason-giving or review to create similar potentials for coalition building, albeit with significant context- and norm-specific variation.

Because generic procedural commitments such as transparency in regulatory decision-making often do not make explicit the substantive ends to which they will be used, they allow for heterogeneous set of interests with disparate, if not contradictory, substantive agendas to build coalitions pushing for provisions on access to information.[116] Obligations in treaties justified as realizations of the principle of transparency, for example, may receive wide support across the spectrum of interest groups which—sometimes uncritically—generally favor more government disclosure. But the procedural provisions in the treaty may often end up being specific rather than generic and exhibit significant variation in terms of intensity, specificity, scope and standing between different issue areas. These varying procedures may favor specific substantive outcomes and interests, although only some of them may be sufficiently strong and targeted to function as instruments of transnational control.

Fourth, treaty commitments for domestic administrative procedures may be particularly attractive to the representatives of states with developed regulatory law and institutions and strong and transnationally active interest groups. Because commitments in international economic agreements are usually reciprocal—what applies to one party applies to all other parties equally—substantive constraints will equally apply to a powerful state.[117] Procedural requirements in treaties that are based, as is often the case, on practices in jurisdictions such as the US and EU may create *de facto* non-reciprocal commitments.[118] The powerful jurisdictions will have already adopted these procedures and their constituencies have become experienced in using them to their advantage.[119] Other jurisdictions will have to adopt and learn the new procedures. This situation represents an application of Büthe & Mattli's notion of institutional complementarity: where international institutions are derived from and congruent with those of one or a few domestic jurisdictions, that circumstance will enhance the power and influence of those jurisdictions and their private actors that have become adept at working the institutional machinery which is being internationalized.[120]

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[116] *See, e.g.,* Michael Mason, *Transparency for Whom? Information Disclosure and Power in Global Environmental Governance*, 8 GLOB. ENVTL. POL. 8 (2008).

[117] There are many examples of treaty obligations regarding trade and regulation that are not reciprocal—bound tariff rates perhaps being the most obvious.

[118] Stewart, *Global standards, supra* note 68, at 191 ("without further support of NGOs and government agencies with the requisite resources and expertise, procedures will do little to remedy power differentials…")

[119] In the case of TPP, for example, the US would have had to change no laws and almost no regulations to be in compliance. The Trans-Pacific Partnership Implementation Act – [DRAFT] Statement of Administrative Action, *available at* https://ustr.gov/sites/default/files/DRAFT-Statement-of-Administrative-Action.pdf (last visited 23 February 2018).

[120] *See* TIM BÜTHE & WALTER MATTLI, THE NEW GLOBAL RULERS: THE PRIVATIZATION OF REGULATION IN THE WORLD ECONOMY (2011) (developing the idea of institutional complementarity to explain national regulators' influence in global rule-making).

I. Limits to the Effectiveness of Procedural Requirements as Instruments of Transnational Control

Our exposition would be incomplete without noting the often-significant limitations of treaty-based procedural commitments as instruments of transnational control. The effectiveness of procedural mechanisms established by treaty crucially depends on their implementation. Without good faith legislative and regulatory changes to give the treaty provisions effect, the procedural machinery set out in the treaty may amount to little. Developing countries may, for example, have an overwhelming number of obligations to comply with and may not be concerned with such procedures.[121] Implementation will also depend on the available support from political principals. This may in part depend on whether the government sees a benefit from the procedures for its own agenda. In the case of TPP and Japan, for example, the external pressure created by the treaty comports with Prime-Minister Abe's own reform agenda.[122] In other cases, political officials may see the procedures as inimical to their ability to maintain control and to target benefits to their favored constituencies. In these cases, it will depend on the interests and abilities of State A to exert pressure on State B to remedy deficiencies in implementation.

Where government leaders in State B oppose the treaty goals and mechanisms, control through procedures may not be able to withstand conflicts with more direct control strategies deployed by those leaders, such as direct oversight, budgetary adjustments, and hiring and firing. In contrast to McNollgast's initial analytical setting, the transnationally operative procedures operate in a space where direct control of regulatory decision-making is lies with a different political principal (that in State B). In cases where ingrained organized interests are close to the regulators or the political principals in State B, new procedures may do little to change outcomes.

Further, host states vary in sophistication and capacity.[123] In cases of low capacity and resources, the establishment of new regulatory procedures may simply miss the inevitable reality of ad hoc administrative action. The treaty commitments may sometimes presuppose a structure of an administrative state which in fact does not exist. The lack of effective domestic mechanisms of review may also hinder the potential of treaty-based procedures as instruments of control. Training and "capacity building" efforts may be crucial for implementation.[124] A further factor is the receptivity to new requirements on part of the regulatory administration and courts. To the extent the new procedures

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[121] Kevin Davis & Benedict Kingsbury, *Obligation Overload* (manuscript on file with authors).
[122] Christina Davis, *Japan: Interest Group Politics, Foreign Policy Linkages, and the TPP*, in MEGAREGULATION CONTESTED: GLOBAL ECONOMIC ORDERING AFTER TPP (Benedict Kingsbury, et al. eds, forthcoming) (manuscript on file with authors)
[123] *See generally,* THE RISE OF THE REGULATORY STATE OF THE SOUTH: INFRASTRUCTURE AND DEVELOPMENT IN EMERGING ECONOMIES (eds. Navroz K. Dubash & Bronwen Morgan, 2013).
[124] See Tran Thi Kieu & Richard A. Bales, *On the Precipice: Prospects for Free Labor Unions in Vietnam*, SAN DIEGO INT'L L. J. (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3110721.

deviate significantly from established routines and regulatory/administrative cultures, there may be significant contestation and resistance.

Finally, the effectiveness of the procedures supplied depends on the existence of demanders able and willing to use them.[125] The nature of the demand for procedures will depend on the ecosystem of interest groups for which these mechanisms may be attractive avenues for exerting influence In some cases, sophisticated networks of organized business interests may generate active and engaged use of procedures.[126] In other cases, especially where potential users are representatives of environmental and social interests plagued by difficulties in organizing and funding, demand may be low, and some potential users may not even know about available procedural avenues for influencing decisions.[127] Transnational networks of environmental, labor, human rights NGOs are, however, developing an increasingly sophisticated understanding of available procedures and are using them within the base available to them.[128]

II. Explaining the Rise of Procedural Requirements in International Economic Agreements

The proliferation of procedural requirements for domestic administration negotiated for in treaties over the past several decades reflects the logics of the McNollgast framework and the political economy of Putnam's two-level game. Yet these logics are not new. The turn in international law toward the regulation of private conduct of firms and individuals and the governance demands of an ever deeper integrated world economy may, together with the two logics, explain the emergence of these types of commitments as a significant legal technology of global regulatory governance.[129] This part of the article outlines this proliferation with reference to our theoretical framework.

Our sketch of the rise of these procedural requirements starts with the 1947 General Agreement on Tariffs and Trade (GATT), spans the 1995 Uruguay Round agreements, and continues in the 2000s with the bilateral trade agreement practices of the United States and European Union.[130] The evolution of

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[125] Mattli & Woods, *In Whose Benefit?*, *supra* note 76, at 4.
[126] So for example with the Enquiry Points mandated pursuant to Article 10 TBT Agreement.
[127] The national enquiry points, for example, are rarely, if ever, used by transnational civil society actors.
[128] Examples of internationally active environmental NGOs using procedures are the Environmental Investigation Agency (https://eia-global.org/about) and the Center for International Environmental Law (http://www.ciel.org/about-us/). *But, see,* César Rodríguez-Garavito, *Ethnicity.gov: Global governance, indigenous peoples, and the right to prior consultation in social minefields*, 18 IND. J GLOB. LEGAL STUD. 263 (2011) (documenting the role of partially internationally mandated procedures for consultation and consent and their ambiguous effects on indigenous peoples' rights).
[129] *See generally*, ANNE PETERS, BEYOND HUMAN RIGHTS: THE LEGAL STATUS OF THE INDIVIDUAL IN INTERNATIONAL LAW (2016).
[130] For purposes of clear exposition, we focus our genealogy on treaties for purposes of clear exposition, but suspect that more informal inter-state agreements also fit our framework. Examples are the procedures governing the Financial Action Task Force (www.fatf-gavi.org) or those of the Basel Committee on Banking Supervision (www.bis.org/bcbs). *See* Michael S. Barr & Geoffrey P. Miller, *Global Administrative Law: The View from Basel,* 17 Eur.

procedural commitments in these treaties is the result of executive branch officials seeking to satisfy the demands of powerful economic constituencies for ever stronger disciplines on states' regulatory practices. Starting with the side-agreements for the North American Free Trade Agreement (NAFTA), there has also been political pressure to include environmental, labor, and other concerns of social protection into economic treaties, and here too procedural commitments have found application, although they are often weak.

A. GATT Article X

The foundational regulatory process innovation of the post-war economic order is Article X of the 1947 GATT.[131] Article X grew out of the United States' desire to create better opportunities for its businesses in the newly constituting system of global commerce, at a time when the reforms of the US Administrative Procedure Act had created a new model of regulatory governance based on public access information, participation, and reason giving.[132] Negotiators of other countries dismissed the need for such procedures in the GATT on the ground that experienced traders knew very well what regulations apply to the products that they traded. John Jackson succinctly explained why this answer was not satisfactory, and why Article X was needed:

> It is an answer which may please those traders that are already engaging in trade in a particular product, since the information which they have has a commercial value to them. But the lack of information inhibits the entry into that market by new traders and limited entry thus decreases the amount of competition for that market. Thus the lack of information is a nontariff trade barrier resulting in joint benefits to the importing nation's government and the established traders.[133]

This account clearly exhibits the logic of procedural commitments as instruments of control at a distance to benefit economic actors from other states, such as the US. These export interests had a major

J. Int'l L. 15 (2006)*;* James T. Gathii, *The Financial Action Task Force and Global Administrative Law*, 197 J. Prof. Law. (2010), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1621877 (last accessed 23 February 2018).

[131] Article X of the Agreement required parties to publish "laws, regulations, judicial decisions, and administrative rulings of general application" which affected the movement of goods or capital "in such a manner as to enable governments *and traders* to become acquainted with them." General Agreement on Tariffs and Trade, art. X.1, opened for signature Oct. 30, 1947, 61 Stat. A-5 T.I.A.S. 1700, 55 U.N.T.S. 187 (entered into force Jan. 1, 1948) [hereinafter GATT]. The genealogy of generic commitments to notify, publish, and provide for participation of private actors in domestic decision-making has been traced even further back to the 1923 International Convention Relating to the Simplification of Customs Formalities which required publication "in such a manner as to enable persons concerned to become acquainted with [customs formalities] and to avoid the prejudice which might result from the application of customs formalities of which they are ignorant. Steve Charnovitz, *Transparency and Participation in the World Trade Organization,* 56 RUTGERS L. REV. 927 (2004), at 929; *see also* Henry Gao, *The WTO Transparency Obligations and China*, J. COMP. L. (forthcoming 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3071676; International Convention Relating to the Simplification of Customs Formalities, Nov. 3, 1923, 19 AM. J. INT'L L. SUPP. 146 (1925) [hereinafter Customs Convention]. The United States was not a party to this Convention.

[132] Ala'i & D'Orsi, *Transparency in International Economic Relations, supra* note 113, at 370.

[133] JOHN H. JACKSON, WORLD TRADE AND THE LAW OF GATT 462 (1969).

role in negotiating the agreement.[134] Despite its long-term transformative potential, Article X was apparently not particularly controversial among the negotiators and regarded as "a procedural provision lacking in substantive force."[135] This history comports with our hypothesis that it may be easier to successfully negotiate for procedural as opposed to substantive obligations.

Life was breathed into Article X as it started to be invoked in conflicts over trade policy. Beginning in the 1980s, the US began to invoke Art. X's transparency commitment against Japan. US businesses finding themselves unable to penetrate the Japanese market despite lower tariffs spurred a focus on Japan's regulatory processes.[136] Of particular interest was the government's practice to issue "administrative guidance" which was selectively shared with mostly domestic firms and effectively excluded US businesses.[137]

B. The WTO Agreements

The procedural machinery was greatly expanded and substantively transformed with the Uruguay Round agreements and the creation of the World Trade Organization including a powerful new dispute settlement system with a standing Appellate Body. With the package of WTO Agreements in 1995—and on the apparent suggestion of an expert group chaired by Swiss banker Fritz Leutwiler—a new principle of participation rights for private actors in domestic regulatory administration gained ground in international economic law.[138] Some even consider the WTO's "transparency and accountability mechanisms" to be its most important aspect—more so than negotiation rounds or even its famous dispute settlement system.[139]

In a 1997 decision, the Appellate Body found that Article X:2 of the GATT embodied a principle of "fundamental importance—that of promoting full disclosure of governmental acts affecting Members and private persons and enterprises, whether of domestic or foreign nationality."[140] It stated that transparency included the instrumental purpose to allow not only the WTO member states but individual

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134 *See* DOUGLAS A. IRWIN, CLASHING OVER COMMERCE: A HISTORY OF US TRADE POLICY 494-96 (2017) (detailing the empowerment of export interests in the US trade policy process in the post-War era compared to earlier periods).
135 Sylvia Ostry, *China and the WTO: The Transparency Issue*, 3 UCLA J. INT'L L. & FOR. AFF. 1, 3-4 (1988) ("During the often contentious negotiations, this provision received little attention and was not substantially altered or affixed with interpretive notes"); Ala'i & D'Orsi, *supra* note 1, at 370.
136 Charnovitz, *supra* note 131, at 947.
137 IRWIN, *supra* note 134, at 602-04 (presenting the contentious debate in the first Reagan administration about policy response to Japan's regulatory barriers for market access by US firms and products). In the second Reagan administration U.S. policy switched to a focus on exchange rates which resulted in the 1985 "Plaza Accord" where Japanese and European officials agreed to seek increases in their currencies relative to the dollar. *Id.,* at 605.
138 Charnovitz, *supra* note 131, 937. GATT, TRADE POLICIES FOR A BETTER FUTURE: PROPOSALS FOR ACTION (1985).
139 Petros C. Mavoridis & Robert Wolfe, *From Sunshine to a Common Agent: The Evolving Understanding of Transparency in the WTO,* 21 BROWN J. WORLD AFF. 117 (2015). For a more detailed discussion, see Stewart & Badin, *supra* note 32, at 569-574.
140 *United States – Restrictions on Imports and Man-Made Fibre Underwear*, Report of the Appellate Body, WT/DS/24/AB/R, at 21 (adopted Feb. 25, 1997)

traders and firms private economic actors the opportunity to "protect and adjust their activities or *alternatively to seek modification of such measures.*"[141] The Appellate Body's linkage of access to information and the ability to engage the regulatory process, displays the logic of procedural entitlements as instruments of transnational control.[142]

The other WTO Agreements create a considerable variety of private procedural rights in domestic decision-making.[143] Some are generic in that they apply across a broad range of issues and do not specify or limit who can invoke them, but in practice are used primarily by business firms. An example are the TBT Agreement's requirements to establish local enquiry points about regulation for all interested persons.[144] This spawned a wide-ranging creation of locally nested points of access for private firms. Others are targeted and reflect deck stacking. Article 31 of the TRIPS Agreement, for example, entitles patent holders to specific rights of notice and participation in governmental decisions to override patents for public purposes.[145] Specifically targeted is also Article 3 of the Agreement on Safeguards which prescribes how members' regulatory authorities are to conduct their domestic investigations to determine whether safeguards are adequate.[146] But it exemplifies the possibilities for procedural deck-stacking as a means to include more diffuse interests into the calculus of regulatory decision-making. "All interested parties", explicitly including importers and exporters presumably to be able to counteract the concerns voiced by the domestic industry seeking protection from foreign competition, are to have the opportunity to

> present evidence and their views, including the opportunity to respond to the presentations of other parties and to submit their views, *inter alia,* as to whether the or not the application of a safeguard measure would be in the public interest.

The regulatory authorities are consequently required to publish a reasoned decision "on all pertinent issues of fact and law".[147] This provision's procedural machinery empowers traders vis-à-vis the

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[141] *Id.* at 21.
[142] Charnovitz, *supra* note 131, at 936.
[143] *Id.* at 936-37 (providing an overview of private procedural rights ranging from Antidumping Agreement to the TBT Agreement).
[144] TBT Agreement, *supra* note 50, Art. 10.1 ("Each Member shall ensure that an enquiry point exists which is able to answer all reasonable enquiries from other Members and *interested parties in other Members* as well as to provide the relevant documents regarding: 10.1.1 any technical regulations adopted or proposed within its territory …")
[145] The agreement for China's accession to the WTO goes further than the WTO agreements, so for example in its commitment to provide a mandatory public comment period. See, Charnovitz, *supra* note 131; Gao, *supra* note 131; China WTO Accession Protocol: WT/L/432, para. 2 ("China shall establish or designate an official journal dedicated to the publication of all laws, regulations and other measures pertaining to or affecting trade in goods, services, TRIPS or the control of foreign exchange and […] shall provide a reasonable period for comment to the appropriate authorities before such measures are implemented, except for those laws, regulations and other measures involving national security, specific measures setting foreign exchange rates or monetary policy and other measures the publication of which would impede law enforcement.")
[146] Agreement on Safeguards, Apr. 15,1994, WTO Agreement, Annex 1A, in THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 275 (1999), Art. 3
[147] *Id.* Art. 5.

domestic industry asking for the safeguard in two ways. It makes the "public interest" the relevant unit of analysis and thereby draws attention to the diffuse but in aggregate significant cost to consumers through higher prices which can result from safeguards. It also requires publication of all parts of the factual and legal analysis which improves traders' ability to identify flaws in the reasoning and makes it harder to fudge the analysis to reach a predetermined result.

C. US and EU Treaty Practice: WTO "Plus" Procedures

The Uruguay Round left developing economies with a strong sense of having been pushed into an unfair deal and resulted in subsequent negotiations marked by deadlock.[148] Particular suspicion plagued the regulatory issues in the Doha negotiating agenda, at a time when further tariff liberalization made these particularly important.[149] Multinational firms pushed for further disciplines on state regulation that impeded trade in goods and services. During the late 1990s and 2000s, the United States and the European Union developed templates for a range of regulation-targeted generic and specific procedural provisions which they included in a series of bilateral trade agreements.[150]

The 2004 US-Chile FTA includes a representative example of a widely used WTO "Plus" provision.[151] It requires the parties to "allow persons of the other Party to participate in the development of […] technical regulations […] on terms no less favorable than those accorded to its own persons" and mandates a process for public comments on planned regulatory action resembling the notice-and-comment rule-making process established in the US Administrative Procedure Act.[152] When in 2014 Chile proposed to introduce mandatory STOP-sign styled front-of-package labels on food and drinks high in calories, sugar, fat, or salt, transnational economic interests—filtering their demands through national industry organizations—made effective use of these procedural entitlements.[153] The U.S. based Grocery Manufacturers Association (GMA), representing the US food and beverage industry, FOODDRINK Europe, the Brazilian-Chilean Chamber of Commerce, and other economic interests submitted extensive comments; domestic NGOs but no foreign environmental/social groups did so.[154] GMA asserted that

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[148] *See* Sungjoon Cho, *A Bridge Too Far: The Fall of the Fifth WTO Ministerial Conference in Cancún and the Future of Trade Constitution*, 7 J. INT'L ECON. L. 219 (2004).
[149] *Id.* at 230-231 (calling the Singapore issues a "conference-buster").
[150] We suspect a similar story could be told for the EU.
[151] See, e.g., Comprehensive Economic and Trade Agreement, art.4.6, Oct. 30, 2016, [hereinafter CETA], *available at* http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf; TPP, article 26.2 (Publication).
[152] United States-Chile Free Trade Agreement, (Jun. 6, 2003) art. 7.7.1, further specified in art. 7.7.2-7; see, Administrative Procedure Act, 5 U.S.C. § 553(c) (2012).
[153] Lorena Rodriquez, *The Implementation of New Regulation on Nutritional Labelling in Chile*, Presentation at the World Trade Organization, *available at* https://www.wto.org/english/tratop_e/tbt_e/8_Chile_e.pdf; See, generally, Council on Foreign Relations, *The Emerging Global Health Crisis: Noncommunicable Diseases in Low- and Middle-Income Countries,* INDEPENDENT TASK FORCE REPORT NO. 72 (2014), at 9-18.
[154] On file with authors.

the proposed regulation violated the requirement in Article 2.2 of the TBT Agreement for regulations not to be "more trade restrictive than necessary."[155]

While we cannot establish causality, after receiving these comments, and other WTO members—including most prominently the EU and US—raised 'concerns' at the WTO's TBT Committee, Chile revised its regulation and changed the phrasing on the labels from "exceso de …" (in excess of certain limits) to "alto en…" (high in).[156] This example shows how inter-state procedural obligations create a pathway for foreign economic actors to potentially influence regulatory decision-making.in another state. They can further use this machinery to help enforce (their interpretation of) substantive international commitments, as the GMA did for the TBT Agreement.

A further example of WTO "Plus" treaty practice comes in the 2016 EU-Vietnam FTA. In its chapter on transparency is the requirement to "provide for mechanisms available for interested persons seeking a solution to problems that have arisen from the application of measures of general application under this agreement."[157] This effectively amounts to a bolstering of the local enquiry points already required by the TBT Agreement. It is significant, because it creates a general right for private actors to complain to the government about asserted problems resulting from alleged faulty implementation or non-compliance with the agreement. Effective use of these mechanisms not only opens an additional interface for private actors to lobby the government but may produce significant information to be used in eventual actions for review, for example through ISDS mechanisms..

Another example involving issue-specific procedures in FTAs concerns government drug reimbursement schedules which specify the drugs that will be covered by government health insurance plans and the reimbursement amount. These schedules are a domain of conflict between originator or proprietary pharmaceutical companies (in contrast to generics) and advocates for wider and cheaper access to medicines.[158] Unless drugs offer an additional clinical benefit over a comparable existing drug, they

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155 *But see*, Robert Howse, *The World Health Organization 20 Years On: Global Governance by the Judiciary*, 27 EUR. J. INT'L. L. 9 (2016).

156 Chile's labeling requirement has been gaining international recognition which explains the interest of large transnational businesses in influencing its exact regulatory contours. *See, e.g,* Andrew Jacobs, *Waging a Sweeping War on Obesity, Chile Slays Tony the Tiger*, N.Y. TIMES, Feb., 8, 2018, at A1.

157 EU-Vietnam Free Trade Agreement (EU-Vietnam FTA, as finally negotiated on Feb. 1, 2016), Chapter 18, Art. 4.4. There is also non-EU or US WTO Plus treaty practice. See, e.g., the ASEAN-Australia and New Zealand FTA (ASEAN-AANZ FTA),). Agreement Establishing the ASEAN-Australia-New Zealand Free Trade Area, Feb. 27, 2009, Chapter 8, art. 11; Annex on Financial Services, art. 5.4.

158 Abbott argues that, "more recently, the PT&IA template advanced by the United States initiates a deeper intrusion into the public health regulatory arena. The new template provides for intervention by pharmaceutical originator companies into government decision-making regarding whether to include particular drugs in national health formularies, and into decisions regarding pricing." Frederick M. Abbott, *The Evolution of Public Health Provisions in Preferential Trade and Investment Agreements of the United States*, in CURRENT ALLIANCES IN INTERNATIONAL INTELLECTUAL PROPERTY LAWMAKING: THE EMERGENCE AND IMPACT OF MEGA-REGIONALS 47, 54 (Pedro Roffe & Xavier Seuba, eds., 2017).

cannot receive a higher price.[159] Originator drug companies consider these listings a "fourth hurdle" to the sale of their products in addition to demonstrating a drug's safety, efficacy, and quality.[160] For advocates of this health care model, it is a legitimate use of the state's authority to concentrate buying power for the purposes of reducing drug prices.

Both US and EU-led bilateral treaties have included strikingly similar, imposing, strong, and precise procedural obligations for states' decision-making about including drugs on these reimbursement schedules.[161] A notable example in chapter 5 of KORUS, which combines substantive obligations to set the reimbursement price fairly, non-discriminatorily, and "based on competitive market-derived prices",[162] with procedural requirements to allow the "manufacturer of the pharmaceutical product" to apply for an increased reimbursement amount,[163] have the regulator make their determinations of reimbursement within a reasonable time,[164] disclose "to applicants […] all procedural rules, methodologies, principles, criteria […], and guidelines used to determine pricing and reimbursement", provide applicants the opportunity to comment and guarantee them "meaningful, detailed written information" regarding the pricing and reimbursement decision, and provide them with the "membership list of all committees related to pricing or reimbursement". KORUS further requires the establishment of an independent review body which can be invoked by "an applicant directly affected,"[165] excluding groups advocating affordable access to medicines and other social interests.[166] This elaborate procedural machinery shows clear signs of deck-stacking in favor of the originator pharmaceutical industry with the purpose to weaken the "fourth hurdle".[167]

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159 Ruth Lopert & Sara Rosenbaum, *What is Fair? Choice, Fairness, and Transparency in Access to Prescription Medicines in the United States and Australia,* 35 J.L. MED. & ETHICS 643, 645 (2007).
160 *Id.*
161 Andreas Dür & Dirk de Bièvre, *Inclusion without Influence? NGOs in European Trade Policy*, 27 J. PUB. POL'Y 79, 93-97 (2007) (documenting the influence of the pharmaceutical industry in the EU's policy debates around access to medicines).
162 KORUS, *supra* note 85, Art. 5.2(b).
163 *Id.* at Art. 5.3.2(b)(2)
164 *Id.* at Art. 5.3.5(a)
165 *Id.,* at Art. 5.3.5(e). KORUS additionally established a "Medicines and Medical Device Committee" which is to meet at least once a year and is co-chaired by health and trade officials. KORUS, Art. 5.7.
166 A sideletter between the US and South Korea further concretizes the structure of the review body: it is to be independent of the health care authorities, is not to be staffed by the authority's employees, and its staff is to be appointed for a fixed period and not be subject to removal by the authorities. KORUS, Pharmaceuticals Products and Medical Devices Confirmation Letter (Independent Review Process), para 2, *available at* http://www.wipo.int/edocs/trtdocs/en/kr-us/trt_kr_us.pdf.
167 While we have no direct evidence of the KORUS process leading to different outcomes, but the internal appeal mechanism of Korea changed the outcomes in 13 percent of appeals. Sung Eun Park, et al., *Evaluation on the First 2 Years of the Positive List System in South Korea,* 104 HEALTH POL'Y 32 (2012). As of October 2015, the KORUS' own review body had not been active. Eun-Young Bae, et al., *Eight-year experience using HTA in Drug Reimbursement: South Korea,* 120 HEALTH POL'Y 612 (2016). With our methods, however, it is not possible to find out whether the shadow of its existence has a disciplining effect on the Korean health authorities' internal process. Robert N. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L. J. 950 (1979). Frederick Abbott notes, the detailed decision-making procedures right for independent review create prospects of "facing time-

The "fast-track" legislation for KORUS also asked for "the elimination of government measures such as price controls and reference pricing which deny full market access for United States products."[168] USTR negotiators reportedly demanded that the "fourth hurdle" be eliminated, but the Korean negotiators refused.[169] KORUS illustrates how, as we discussed above, procedural commitments—in this instance giving originator pharmaceutical companies rights to influence the listing process—can present a possible pathway to agreement, where disagreements over substance otherwise stand in the way.[170] Nonetheless the leading US pharmaceuticals industry group, and the USTR itself, have signaled their dissatisfaction with Korea's implementation of its transparency, reason-giving, and review commitments for the reimbursement process.[171] As mentioned in our discussion of this strategy's limits, the balance of control still lies with the implementing authorities.[172]

Another dimension of the treaty dynamic is that procedural provisions agreed to in one bilateral FTA are often followed, with variations, in subsequent treaties, creating a network of obligations when multilateral mechanisms are blocked.[173] Thus, the procedural provisions in KORUS built on similar, but

consuming litigation involving pharmaceutical industry lawyers [which] will pressure public health authorities to lean towards approval so as to avoid it. Frederick Abbott, *supra* note 158, at 54.

[168] Trade Act of 2002, 19 U.S.C. § 3801 (Public Law 107-210), sec 2102(b)(8)(D).

[169] Lopert & Gleeson, *supra* note 83, at 205.

[170] See *supra* section I.H.

[171] The Pharmaceutical Research and Manufacturers of America (PhRMA), *Comments to 2017 National Trade Estimate Report on Foreign Trade Barriers (NTE),* October 2016, *available at* http://phrma-docs.phrma.org/files/dmfile/PhRMA-2017-NTE-Comments.pdf, pp. 119-120 ("Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination." The Korean Government has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the IRM because the National Health Insurance Service (NHIS) does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. However, this interpretation totally negates the original purpose of the IRM, which we believe should apply to the negotiation process for prices of all reimbursed drugs, particularly patented medicines."); United States Trade Representative, *The 2016 National Trade Estimate Report,* (23 March 2016), *available at* https://ustr.gov/sites/default/files/2016-NTE-Report-FINAL.pdf, p. 284 ("The U.S. medical devices sector continues to cite concerns regarding transparency and the availability of opportunities for meaningful engagement regarding such regulation, including with respect to the October 2013 medical device reimbursement plan based on import pricing or manufacturing cost. The United States has expressed its concern that the reimbursement pricing of medical devices should be determined in a fair, nondiscriminatory, and transparent manner and urged MOHW to engage directly with stakeholders to address their concerns. The United States will continue to monitor these issues closely.")

[172] See, *supra*, I.I. The KORUS pharmaceuticals example also illustrates the potential alignment of insider and outsider interests. The Pharmaceutical Research and Manufacturers of America (PhRMA) is the major industry association of the originator pharmaceutical industry. In South Korea, PhRMA's "local sister association" the Korean Research-based Pharma Industry Association (KRPIA) which in its membership has a significant overlap with the multinational businesses also represented in PhRMA, is likely to benefit from the new procedures. Out of KRPIA's 38 member companies, 17 were also listed members of PhrMA. Compare, http://members.krpia.or.kr/company/member.asp (accessed on 3 December 2017), with http://www.phrma.org/press-release/phrma-welcomes-five-new-member-companies (accessed on 3 December 2017).

[173] *See, e.g.,* Jean Frédéric Morin, et al., *The Trade Regime as a Complex Adaptive System: Exploration and Exploitation of Environmental Norms in Trade Agreements*, 20 J. INT'L ECON. L. 365 (2017).

overall less demanding procedures in the 2005 United States-Australia Free Trade Agreement.[174] For well-organized repeat players such as the multinational pharmaceutical companies, the negotiation for procedural commitments in one agreement can be part of longer-term strategy across a range of agreements. The pervasive influence of the pharmaceutical industry is reflected in the circumstance that in bilateral FTAs negotiated by the EU feature almost identical procedural obligations.[175] Pharmaceutical provisions very like those in the US-Australia Agreement were subsequently adopted in TPP12, regionalizing these and other procedural versions in FTAs. The TPP12 procedures were suspended in CPTPP as New Zealand complained vociferously about adverse budgetary implications for its healthcare system, showing the limits to procedural commitments' ability to escape public attention.[176]

D. Procedures for Environmental and Social Protection

To develop our theory and show its applications, we have thus far focused on procedural commitments for the primary or even exclusive use by economic actors. The WTO Agreements, which feature no affirmative agenda for environmental or social protection, have been used primarily by business interests.[177] The emphasis is strongly on disciplining state regulation of markets, and the FTA practice by the US and EU has carried this agenda forward.

But environmental and labor treaties also regularly include procedural requirements for domestic regulatory decision-making in order to advance their substantive goals.[178] The place of environmental and labor concerns in international economic agreements and the inclusion of procedural provisions to address them have been contested.[179] Starting with NAFTA, however, US trade agreements have included

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[174] Ruth Lopert & Sara Rosenbaum, *What is Fair? Choice, Fairness, and Transparency in Access to Prescription Medicines in the United States and Australia,* 35 J.L. MED. & ETHICS 643, 650 (2007); Lopert & Gleeson, *supra* note 83, at 204.

[175] *See, e.g.,* EU-Vietnam Agreement (2016), Annex 2-A ("Pharmaceutical Products and Medical Devices") (mainly mirroring the obligations in TPP Art. 26-A and the like*);* EU-Singapore Agreement (2015), Annex 2-C ("Pharmaceutical Products and Medical Devices") (mirroring); EU-Korea Agreement (2010), Annex 2-D ("Pharmaceutical Products and Medical Devices").

[176] *Id.* We contacted the Ministry for further information regarding the calculation its costs but did not receive a response.

[177] *See, e.g.,* GREGORY C. SHAFFER, DEFENDING INTERESTS: PUBLIC-PRIVATE PARTNERSHIPS IN WTO LITIGATION (2003) (documenting the complex interactions between private firms and governments in WTO disputes); Daniel C. Etsy, *We the People: Civil Society and the World Trade Organization*, in NEW DIRECTIONS IN INTERNATIONAL ECONOMIC LAW: ESSAYS IN HONOUR OF JOHN H. JACKSON 95 (Marco Bronckers & Reinhard Quack, eds., 2000) (discussing the influence of business interests and civil society at the WTO).

[178] *See, e.g.,* Aarhus Convention, *supra* note 92, Art. 13C ("Information to the Public"); CAFTA-DR, *supra* note 80, Art. 16.3 (concerning procedural guarantees and public awareness regarding the parties labor laws). *But see,* César A. Rodríguez-Garavito, *Global Governance and Labor Rights: Codes of Conduct and Anti-Sweatshop Struggles in Global Apparel Factories in Mexico and Guatemala*, 33 POL. & SOC'Y 204 (2005) (giving an empirical account of the limits of transparency as an instrument of governance).

[179] For discussions on environmental issues, see, e.g., Richard B. Stewart, *International Trade and Environment: Lessons from the Federal Experience*, 49 WASH. & LEE L. REV. 1329 (1992); Robert Howse, *The Appellate Body Rulings in the Shrimp/Turtle Case: A New Baseline for the Trade and Environment Debate,* 27 COLUMB. J. ENVTL. L. 491 (2002); Daniel C. Etsy, *Bridging the Trade-Environment Debate*, 15 J. ECON. PERSP. 113 (2001). For discussions on labor issues, see, e.g., Mary Jane Bolle, Congressional Research Service RS22823, Overview of labor enforcement issues in free trade agreements (2016) (giving a descriptive overview of US practice on trade-labor linkages); Alvaro Santos, *The Lessons of*

chapters on labor and the environment, largely as a political price to be paid to domestic coalitions of what Suzanne Berger has called "turtle defenders and Teamsters"[180] Since then, US and EU FTAs typically include general procedural commitments that can be invoked by environmental and social interests. These arrangements, however, often lack the level of legalization found in the provisions for economic actors, and fail to address the collective action problems faced by diffuse public interests. Enforcement under these agreements ultimately relies on institutionalized variants of diplomatic protection without direct means of legal accountability.[181] The relatively strong provisions in the 2006 US-Peru Forestry Annex establish a high water mark that has not been matched since.

To get the North American Free Trade Agreement (NAFTA) through Congress, President Clinton negotiated two side agreements, one on labor issues and one on the environment. The latter, the North American Agreement on Environmental Cooperation (NAAEC) included a new procedure for private persons and organizations in Canada, Mexico, and the United States to petition a newly created Commission for Environmental Cooperation (CEC) to review a Party's alleged failure to effectively enforce its domestic environmental laws.[182]Upon receiving a valid submission and the implicated government's response, the CEC secretariat can ask the three governments to vote on whether to prepare a factual record. Many proposals do not obtain the first vote; no factual record is created.[183] Further, the Parties appear informally to have agreed not to resort to dispute settlement even if a record reveals persistent failures to enforce environmental laws and have taken steps to ensure that the CEC's Secretariat does not become an advocate for environmental protection.[184] It is accordingly unsurprising that this arrangement has been ineffective.[185]

TPP and The Future of Labor Chapters in Trade Agreements in MEGAREGULATION CONTESTED: GLOBAL ECONOMIC ORDERING AFTER TPP (Kingsbury, et al., eds., forthcoming)

[180] Suzanne Berger, *Globalization Survived Populism Once Before—and It Can Again,* BOSTON REV. (30 January 2018), http://bostonreview.net/class-inequality/suzanne-berger-globalization-survived-populism; See generally, Samuel J. Barkin, *Trade and Environment*, in THE OXFORD HANDBOOK OF THE POLITICAL ECONOMY OF INTERNATIONAL TRADE (Lisa L. Martin, ed., 2015), 445-452.

[181] The reliance on diplomatic protection has, in effect, meant very little enforcement. See, e.g., Sierra Club, *TPP Text Analysis: The Environment Chapter Fails to Protect the Environment*, 29 October 2015, *available at* https://www.sierraclub.org/sites/www.sierraclub.org/files/uploads-wysiwig/tpp-analysis-updated.pdf, at 7-8 ("[T]he state-state dispute settlement mechanism for environmental provisions in all U.S. trade agreements since 2007 has failed to produce a single formal case against documented environmental violations").

[182] North American Agreement on Environmental Cooperation, Sept. 14, 1993, art. 14.1, 32 I.L.M. 1480, 1483 [hereinafter NAAEC]. This illustrates a 'fire alarm' model of enforcement which, contrary to the 'police patrol' model of continuous oversight of agents' compliance, relies on the ability of government to use information already held or easily-discoverable by private actors leading to overall lower administrative costs. Kal Raustiala, *Police Patrols & Fire Alarms in the NAAEC*, 26 LOY. L.A. INT'L & COMP. L. REV. 389, 407 (2004).

[183] Interview with employee of CEC. 25 October 2016.

[184] Victor Lichtinger, Remarks at JPAC 9 November 2017 (Commission for Environmental Cooperation), http://www.cec.org/content/jpac-9-november-2017. There has never been a state-to-state dispute settlement proceeding. *See also,* Council of the Commission for Environmental Cooperation, *Ten-Year Review and Assessment Committee: Ten Years of North American Environmental Cooperation,* at 42.

[185] Geoffrey Garver, *Forgotten Promises: Neglected Environmental Provisions of the NAFTA and the NAAEC*, in NAFTA AND SUSTAINABLE DEVELOPMENT: HISTORY, EXPERIENCE, AND PROSPECTS FOR REFORM (Hoi L. Kong & L.

The 2006 US-Peru FTA's Annex on Forest Sector Governance was the result of significant lobby efforts by environmental interest groups to Democrat lawmakers after the 2006 mid-term elections, which gave them the majority in both chambers of Congress.[186] Innovative and highly targeted, it requires Peru to reform not only its regulatory processes, but also its institutions.[187] Peru is to increase the number of enforcement personnel to protect indigenous areas from illegal logging,[188] develop an "anti-corruption plan" for officials charged with protecting the forests,[189] and create an independent agency, OSINFOR, to supervise verification of all timber concessions and permits.[190] While it is playing a crucial role in tracking illegal logging, it has also been facing public protests with banners claiming that "OSINFOR works for the gringos."[191]

The Forestry Annex includes a complex set of procedures for Peru's forest regulatory practices. To combat illegal logging, Peru is required to implement "a competitive and transparent process to award concessions"[192] and to publicize the approved concession plans.[193] The agreement further requires Peru to take into account comments from private actors when undertaking to strengthen oversight and enforcement mechanisms and to establish a public commenting procedure for any requirements of the Annex.[194] A transnationally operating civil society group—the Environmental Inspection Agency (EIA) has made use of the published information to identify more than one hundred shipments of illegally

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Kinvin Wroth, eds., 2015), at 30 ("the governments' mostly tepid responses to factual records to date suggest this is not a particularly promising means to hold the Parties to account for weak enforcement. The NAAEC does not require a government that is the subject of a factual record to take any action or to respond in any other way up on factual records. Despite calls to make some kind of commitment to follow up on factual records, the council has stated firmly in the past that the follow-up to factual records is a matter of domestic policy of the individual governments.")

[186] United States Peru-Trade Promotion Agreement (signed 12 April 2006, entry into force 1 February 2009), https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text [hereinafter US-Peru FTA], Annex 18.3.4 Annex on Forest Sector Governance. The global regulation of forest conservation and commercialization has generated innovative governance structures, relying in important part on procedures. *See, e.g.,* Gregory Shaffer, *supra* note 2, at 6; Christine Overdevest & Jonathan Zeitlin, *Assembling an Experimentalist Regime: Transnational Governance Interactions in the Forest Sector*, 8 REG. & GOV. 22 (2014). Sikina Jinnah, *Strategic Linkages: The Evolving Role of Trade Agreements in Global Environmental Governance*, 20 J. ENV'T & DEV. 191 (2011) (discussing the novelty of the U.S.-Peru PTA and presenting some, if inconclusive, evidence on the agreement's effects on the trade in endangered bigleaf mahogony). Environmental Investigation Agency, *2007 Annual Report* (Washington D.C.), at 8, https://issuu.com/eia-global/docs/eia.annualreport_p16; S. Rept. 110-249 United States-Peru Trade Promotion Agreement Implementation Act (110th Congress) (describing the forest sector annex).

[187] US-Peru FTA, Arts. 18.7 & 18.8

[188] US-Peru FTA, Annex 18.3.4 Annex on Forest Sector Governance, Section 3(a)(i).

[189] *Id.*, Section 3(a)(ii).

[190] *Id.* Section 3(g)(iii) ("OSINFOR shall be an independent and separate agency"); Matt Finer, et al., *Logging Concessions Enable Illegal Logging Crisis in Peruvian Amazon,* 4 SCI. REPORTS 4719 (2014), at 2 (This was implemented in 2008 when OSINFOR "gained greater independence" by being placed within the Presidency of the Council of Ministers"). See http://www.osinfor.gob.pe/. But Finer and others argue that "lack of oversight and enforcement *prior* to OSINFOR inspections" (emphasis added) makes the established certification regime ineffective. Private actors are not given an independent procedure to ask for review.

[191] Richard Connif, *Chasing the Illegal Loggers Looting the Amazon Forrest,* WIRED (24 October 2017), *available at* https://www.wired.com/story/on-the-trail-of-the-amazonian-lumber-thieves/ (last accessed 4 December 2017).

[192] US-Peru FTA, Annex 18.3.4 Annex on Forest Sector Governance, Section 3(g)(i);

[193] *Id.* Section 3(g)(ii).

[194] *Id.* Sections 19 & 3(h)(i).

logged cedar and bigleaf mahogany to the United States [195] While showing the value of information access, the investigation also revealed that the government systematically approved cutting bigleaf mahogany in places where it did not in fact exist, which allowed traders to pair the granted approvals with illegally cut trees to "launder" them as legal for purposes for US export. This led some to argue that the FTA's governance structure for cutting and trading timber enables rather than restricts illegal logging.[196]

The treaty further commits Peru to permit U.S. officials to join in Peruvian site visits of exporters and producers.[197] This commitment represents a significant innovation in international treaties dealing with natural resources management, facilitating intergovernmental actions to police and correct implementation shortfalls as a complement to privately initiated procedures; our international extension of the McNollgast framework which presumed that such strong oversight mechanisms would commonly be off-limits in relations between sovereign states. The potential for a US government role was further strengthened by the US implementing legislation for the US-Peru FTA, which established an Interagency Committee on Trade in Timber Products from Peru.[198] The Committee, like the CEC Commission, retains wide discretion regarding this investigative and enforcement activities.[199] It is solely for the Committee to decide what action, if any, will be taken once they receive a verification or audit report.[200] In an unprecedented action, in 2016 the Committee found that a shipment of timber to the US from a

[195] Environmental Investigation Agency, *The Laundering Machine: How Fraud and Corruption in Peru's Concession System are Destroying the Future of its Forests* (2012), https://eia-international.org/wp-content/uploads/The-Laundering-Machine.pdf.
[196] Finer, et al., *supra* note 190, at 1; Sierra Club, *supra* note 181.
[197] US-Peru FTA, Annex 18.3.4 Annex on Forest Sector Governance, Section 10(b).
[198] Interagency Committee on Trade in Timer Products From Peru, *Description of the Organization, Functions, and Internal Procedures of the Interagency Committee, available at* https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/pdfs/FTAs/peru/DOC.PDF. (last accessed 4 December 2017) (United States-Peru Trade Promotion Agreement Implementation Act, Public Law No. 110-138, section 501. Section 501 is the primary statutory authority for the Interagency Committee. The Interagency Committee was established by Presidential Memorandum dated May 1, 2009. 74 Fed. Reg. 20865. The five-member Interagency Committee is chaired by the USTR and includes representatives from Department of Justice, Department of Agriculture, Department of Interior, and Department of State. Representatives from the Department of Homeland Security and the U.S. Agency for International Development have observer status.)
[199] *Id.* at IV.C. ("To fulfill its function to monitor Peru's progress, the Committee can demand audits of traders and verifications of shipments from the Peru government. The Committee encourages "the involvement of interested persons" and the public can submit information to assist in establishing any violations of forest protection rules and regulations. Crucially, however, "the submission of information to the Interagency Committee in this regard does not create any substantive or procedural rights with respect to the Interagency Committee's deliberations or determinations." This governance structure ultimately retains all control of managing the process for the government. Private interests are information providers and initiators but have no independent ability to advance the process. The pathway to escalating potential conflict leads via traditional state-to-state dispute settlement.")
[200] *Id.*

specific company was unlawful.[201] In late 2017 the Committee directed the US Customs and Border Protection to deny entry to shipments from a specific Peruvian company for three years.[202]

The Forestry Annex illustrates that environmental groups can succeed in changing resource management by focusing on a specific issue, mobilizing strong congressional support, and securing institutional changes in addition to procedural rights. Subsequent trade agreements, including TPP, have been limited to generic procedural requirements and are much weaker. This history indicates the limitations of governance at a distance, and the stark contrast in strength of legalization between provisions that favor transnationally active firms on the one hand, and those that deal with environmental and labor interests on the other.

III. Variation in Legalization of Transnational Regulatory Procedures: Examples from the TPP

The TPP as signed by the US and 11 other countries in February 2016 was a high point in the use of treaty-based administrative procedures and a major attempt by the US to "export" its regulatory capitalist model of state-market relations and administrative governance across the Pacific. Most of TPP's features were retained as part of CPTPP, which Japan revived in 2017 and which was signed in March 2018. The agreement includes more than one hundred commitments to various regulatory procedures.[203] The content of the CPTPP, which incorporates almost all of the initial TPP agreement wholesale and then suspends a series of provisions listed in an annex, cannot be understood without accounting for the US as the major protagonist of the basic agreement—a treaty among the 11 parties negotiated from a blank slate would certainly look different. Nonetheless, the resilience of the treaty's procedural machinery suggests that this approach has considerable attractions as a technique of international regulatory ordering that does not depend on the United States as its agent.

A focus on variations in the procedural provisions in the 30-chapter TPP—as well as on some of the CPTPP's suspensions—is particularly useful to illustrate our political economy account. Many other variables such as different time periods, treaty templates, and parties, are held constant. We use the analytical machinery developed in Part I to explain the systematic asymmetries in the procedures that TPP requires for economic regulatory decision-making on the one hand, and for social regulation (environment and labor) on the other. This unevenness is likely to be at least partly explained by the McNollGast

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[201] Interagency Committee on Trade in Timber Products from Peru, *Statement Regarding July 2016 Timer Verification Report From Peru* (17 August 2016), *available at* https://ustr.gov/sites/default/files/Timber-Committee-Report-8172016.pdf (4 December 2017). *See generally,* Todd Tucker, *Enforcing Environmental Rules in Trade Shows Politicization's Benefits*, ROOSEVELT INSTITUTE (24 October 2017).

[202] United States Trade Representative, *USTR Announces Unprecedented Action to Block Illegal Timber Imports from Peru* (October 2017), *available at* https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/october/ustr-announces-unprecedented-action. (last accessed 4 December 2017).

[203] [A table of all these commitments will be made accessible upon publication.]

framework and Putnam's two-level negotiating structure, where the relative strength of the procedural commitments negotiated by the more powerful Parties reflect the relative political influence of various constituencies with the political principals.[204] We contrast the intellectual property and environmental procedural provisions of the agreement to illustrate these imbalances.

We analyze variations in the procedural provisions in TPP in terms of their strength, using the concept of international legalization developed by Abbott et al., which classifies international commitments according to three variables, obligation, precision, and delegation.[205] These categories are proxies for how effective the inter-state commitments will be in practice. Without empirically examining the impact of different procedural provisions on substantive regulatory outcomes, we posit that more highly legalized procedural provisions will, on balance, make more of a difference in national regulatory practices.

First, treaties vary in *intensity of obligations*, with less intense obligations being conditional, contingent on national law, or merely hortatory.[206] The intensity of an obligation is reflected in use of different words such as 'shall', 'should', 'may', etc. Linos and Pegram show how such formulations have real effects on state behavior.[207] Second, commitments vary in *precision*—they can be clear and specific or broad and ambiguous.[208] The level of precision influences the range of plausible interpretations and the discretion of the obligee. A third dimension of variation is *delegation*—the extent of discretion granted to third party institutions with respect to the interpretation, application, and implementation, of international commitments. Authority can be delegated both to courts or tribunals for dispute resolution and treaty institutions for implementation. For our purposes it is the delegation of dispute resolution and enforcement to institutions independent of the regulatory agency with procedural obligations that is of

[204] Putnam, *Two-Level Games*, *supra* note 6.
[205] Kenneth W. Abbott et al, *The Concept of Legalization,* 54 INT'L ORG. 401 (developing obligation, precision, and delegation as three dimensions of international legalization). See also, Kenneth W. Abbott & Duncan Snidal, *Hard and Soft Law in International Governance,* 54 INT'L ORG. 421-456 (2000).
[206] Kenneth Abbott et al, *The Concept of Legalization, supra* note 205, at 408-412. Hortatory language features prominently in the TPP. Judge Dillard's statement in his separate opinion in the *Appeal Relating to the Jurisdiction of the ICAO Council* is usefully recalled: "multilateral treaties establishing functioning institutions frequently contain articles that represent ideals and aspirations which, being hortatory, are not considered to be legally binding except by those who seek to apply them to the other fellow." *Appeal Relating to the Jurisdiction of the ICAO Council (India v. Pakistan), Separate Opinion of Judge Dillard, I.C.J. Reports 1972,* p. 107, fn. 1. Because we are primarily concerned with inter-state commitments taking the treaty form, the obligations we analyze already entail a significant degree of legalization on the spectrum between "hard" and "soft" law. The degree of legalization can however vary enormously between different norms within the same or across different treaties—it is this variation we focus on to illustrate our argument. Abbott et al., supra note 51, at 405.
[207] Katerina Linos & Tom Pegram, *The Language of Compromise in International Agreements*, 70 INT'L ORG. 587 (2016) ("If flexibly specifying a task is no different from omitting it altogether, as our data suggest, the costs of compromise are much greater than previously believed.")
[208] Kenneth Abbott et al, *The Concept of Legalization, supra* note 205, 412-415.

interest.[209] Variation in the three dimensions is relevant for legal obligations' effectiveness and hence their potential force as instruments of transnational control.

To illustrate our thesis that, in accordance with the McNollgast/Putnam analysis, well-organized economic interests are able to obtain stronger procedural protections in international economic agreements than environmental and social interests, we first examine the TPP provisions on pharmaceutical products, and then consider the environmental provisions.

A. TPP on Medicines: Strong Procedures to Empower Originator Drug Companies

There are many instruments of global governance relevant for the regulation of pharmaceuticals including the guidelines of the World Health Organization (WHO);[210] cooperation agreements between national regulatory agencies;[211] WTO rules relating to intellectual property rights, foremost in the TRIPS agreement;[212] and importantly also a large set of more recent bilateral and regional economic agreements.[213]

The battle between intellectual property protections and access to medicines played out in the original TPP negotiations, and the suspension of some of its provisions in CPTPP.[214] We expect that in TPP12 procedural commitments would stack the deck in favor of the originator pharmaceutical industry, a well-organized powerful constituency with strong political influence in the two dominant parties—the U.S. and Japan.[215] After the US dropped out, notable provisions in the intellectual property chapter were suspended in CPTPP.[216] These were mostly substantive provisions, whereas the procedural obligations

[209] *Id.* 415-418.
[210] *See, e.g.,* Richard Laing, et al., *25 Years of the WHO Essential Medicines Lists: Progress and Challenges*, 361 LANCET 1723 (2003).
[211] *See, e.g.,* Regulatory Collaboration: *The International Coalition of Medicines Regulatory Authorities (ICMRA),* WHO Drug Information Vol. 29, No. 1 (2015).
[212] *See, e.g.,* GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, A NEOFEDERALIST VISION OF TRIPS (2012).
[213] Frederick Abbott, *supra* note 158(tracing the genealogy of US FTA practice protecting the originator pharmaceutical industry). The relation between access to medicines and international agreements concerning intellectual property has received abundant attention. For an innovative approach to these issues, see BALANCING WEALTH AND HEALTH: THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA (Rochelle C. Dreyfuss & César Rodríguez Garavito, eds., 2014).
[214] Amy Kapczynski, *The Trans-Pacific Partnership—Is It Bad for Your Health*, 373 NEW ENG. J. MED 201 (2015); Deborah Gleeson, et al., *How the Trans Pacific Partnership Agreement Could Undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand*, 112 HEALTH POL'Y 227 (2013) (focusing on the effects of TPP's procedural requirements on health regulation in New Zealand)
[215] According to Abbott, the relative influence of originator and generic pharmaceutical industries plays helps understand variations in U.S. FTA practice. The weaker obligations in the US-Chile and US-Jordan FTAs may be linked to the important generic industries there, rather than a stronger emphasis on public health concerns. Frederick Abbott, *supra* note 158, at 53. The strong influence of the pharmaceutical industry over U.S. trade policy is well documented. *See, e.g.,* SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW (2008); Kaminski, *supra* note 44.
[216] Government of Canada, *Annex II – List of Suspended Provisions*, http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/annex2-annexe2.aspx?lang=eng (last visited 15 February 2018).

largely survived.[217] This comports with our hypothesis about procedural commitments on balance being less politically salient.

The TPP's procedural obligations relevant to pharmaceuticals span the chapters on technical barriers to trade, government procurement, regulatory coherence, transparency, anti-corruption, as well as specific annexes about pharmaceuticals and devices. Considered together, they are intense, specific, and strong in their institutions for implementation.

TPP includes a diverse array of procedural rights for patent applicants and holders, including among others prioritization of earlier applications,[218] the right to amend filings,[219] and information about granted patents.[220] Particularly pronounced are TPP's obligations for domestic opportunities for judicial review. The Parties are, for example, to "ensure that any marketing authorization determination is subject to an appeal or review process that may be invoked at the request of the applicant."[221] Broad in scope are also the requirements to provide "right holders" with "civil judicial procedures concerning the enforcement of any intellectual property right covered in this chapter"[222] TPP specifies the burden of proof in a manner beneficial for the pharmaceutical industry—it creates a presumption of patent validity in patent disputes.[223]

The TPP not only provides for extensive opportunities for review but in some instances, demands specific remedies. The parties must enable patent holders to recover monetary damages from alleged infringers for losses suffered due to negligent or willful behavior and damages include lost profits.[224] The Parties are also required to give their courts the ability to force alleged patent infringers to provide information so as to facilitate patent holders' ability to make a successful claim.[225]

In keeping with recent US FTAs, the TPP requires parties which allow the use of previously submitted safety and efficacy data in market approval applications—which are used by producers of generic drugs to cut approval costs—to set up a procedure linking the medicines registration process with the opportunity for patent review.[226] Modeled on US legislation, this procedure creates a dynamic in which the regulatory agency for approving medicines assists originator pharmaceutical firms with patent

[217] *Id.*
[218] TPP, Art. 18.42.
[219] TPP, Art. 18.43.
[220] TPP, Art. 18.45.
[221] TPP, Annex 8-C.12(c).
[222] TPP, Art. 18.74.1
[223] TPP, Art. 18.72.3.
[224] TPP, Art. 18.74.3-4.
[225] TPP, Art. 18.74.13.
[226] TPP, Art. 18.53.1(b) (requiring Parties to give notice to the patent holder the data of which is being used and adequate time to seek review including preliminary injunctions).

enforcement by automatically notifying them of challenges to their patents.[227] This notification is backed up by guaranteeing "preliminary injunctions or equivalent effective provisional measures" to keep new drugs, in many cases a generic, from entering the market by creating a relatively easily established hurdle at the disposal of originator firms.[228] This system of linkage—which is of high-priority for the originator drug industry—is a strong and precise obligation which illustrates the potential for treaty-based procedural commitments to function as instruments of control at a distance.[229] There might of course be significant slippage between the obligations in the treaty and the functioning of the administrative and judicial processes as they are ultimately implemented. The procedural rights in the treaty are not necessarily a guarantor of different substantive outcomes, but their significance lies in their direct empowerment of private individuals to directly assert their interests. If the procedural rights themselves are flouted, we would expect the private actors to seek redress through the review mechanisms created by the treaty and by lobbying their home country to influence the regulating state.

As Frederick Abbott notes, the linkage system also illustrates the *de facto* imbalance which *de jure* equal and reciprocal international commitments can entail. The delay to the market entry of generic drugs created by the preliminary injunction procedure depends on the efficiency of the local state's administrative or judicial system.[230]

US bilateral agreements with comparatively weaker obligations in the US-Chile and US-Jordan FTAs may be linked to the influence of important generic industries in those countries, rather than stronger support for public health concerns.[231]

B. TPP on Environment: Weak Procedures to Appease Environmental Interests

The evolution of environmental norms in US economic treaties continued in TPP12 which features a total of 136 different environmental provisions only two of which were not copied from

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[227] Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J. L. & MED. 303, 307 (2008) (pointing to the creation of the patent/registration linkage system in the Hatch-Waxman Act).

[228] TPP, 18.53.1(c). *See,* I. GLENN COHEN, THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL ISSUES 308-309 (2013) (discussing the rationale of patent linkage).

[229] PhRMA, *Re: Request for Comments on Negotiating Objectives Regarding Modernization of the North American Free Trade Agreement with Canada and Mexico*, 82 Fed. Reg. 23,699 (May 23, 2017), Public Document Doc-2017-0006 (12 June 2017), at 4.

[230] In countries with lower state capacity, proceedings challenging the granted preliminary injunctions are more likely to be delayed which in fact creates further protection for the originator drug from the generic competitor. Frederick Abbott, *supra* note 158, at 56. ("[l]inkage presents the largest scale problem for the countries with the least well developed legal systems: countries where preliminary injunctions may last for a decade because there is no one that can effectively challenge them.")

[231] *Id.,* at 53. As we noted earlier, TPP12 had also included—and CPTPP subsequently suspended, detailed procedural commitments relating to central health authorities deciding on reimbursement schedules for medicines. *See infra* section II.C.

previous agreements.[232] CPTPP left almost all of the environment chapter intact but suspended an obligation—similar to the US Logan Act—to take measures against trade in wild fauna and flora that violates not a Party's own law but that of the jurisdiction where the original taking occurred.[233] In terms of legalization, the environmental obligations in the treaty were significantly diluted from the corresponding provisions of the 2006 U.S.-Peru agreement, previously discussed.[234] Among the reasons for the scaling back may have been the greater need to compromise among 12 treaty parties and the absence of strong environmental demands in the US Congress's TPP "fast-track" legislative process.

The TPP's procedural obligations relevant to environmental protection span the chapters on technical barriers to trade,[235] investment,[236] government procurement,[237] exceptions,[238] and, of course, the environment. But overall the provisions remain weak and do not give private actors significant rights to protect their interests. The environment chapter requires the parties to "publish information about its programs and activities" relating to the protection of the ozone layer, the protection of the marine environment from ship pollution and the conservation and sustainable use of biological diversity,[239] as well as to generally publish their environmental laws and policies.[240] But in contrast to the pharmaceuticals provisions giving private actors extensive and enforceable access to information rights, TPP's sole specific informational provision requires governments to be informed about fishing subsidies.[241] Even though information asymmetries abound in environmental protection, and many civil society organizations could benefit greatly from assured access to information about environmental conditions and proposed regulatory measures, the TPP's generic information publication requirements fail to ensure that such information will be forthcoming; they give wide discretion to governments as to what information to publish, and lack any private rights of access.[242] Administrative hearings are to be public only "in accordance with [a Party's] applicable laws."[243] A number of procedural provisions do not specify standing

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[232] Jean Frédéric Morin, Joost Pauwelyn & James Hollway, *The Trade Regime as a Complex Adaptive System: Exploration And Exploitation Of Environmental Norms In Trade Agreements*, 20 J. INT'L ECON. L. 365, 389 (2017).
[233] Government of Canada, *supra* note 216.
[234] Sierra Club, *supra* note 181.
[235] TPP, Art. 8.7.10
[236] TPP, Arts. 9.10.3(d); TPP 9.16
[237] TPP, Art. 15.3.2.
[238] TPP, Art. 29.1.2
[239] TPP, Arts. 20.5.2; 20.6.2; 20.13.5.
[240] TPP, Art. 20.7.1.
[241] TPP, Art. 20.16.9 (provide information about the subsidies for fisheries programs).
[242] *See, e.g.,* TPP, Art. 20.7.1 ("1. Each Party shall promote public awareness of its environmental laws and policies, including enforcement and compliance procedures, by ensuring that relevant information is available to the public.") *See also,* TPP 20.3.2 ("The Parties recognise the sovereign right of each Party to establish its own levels of domestic environmental protection and its own environmental priorities, and to establish, adopt or modify its environmental laws and policies accordingly."); TPP 20.3.5 ("The Parties recognise that each Party retains the right to exercise discretion and to make decisions regarding: (a) investigatory, prosecutorial, regulatory and compliance matters; and (b) the allocation of environmental enforcement resources with respect to other environmental laws determined to have higher priorities. …").
[243] TPP, Art. 20.7.4

but leave it to domestic law to establish which interests are "recognized".[244] There are also no obligations for reason-giving, and the remedies provision is only hortatory.[245]

The TPP's provisions regarding enforcement concern both the TPP's obligations, and the Parties own environmental laws and regulations. With respect to the agreement's obligations, TPP provides a public submissions procedure which requires each party to receive and consider written submissions about implementation of the environment chapter.[246] This procedure is only required for "person[s] residing or established in its territory" thereby excluding submission rights from foreign civil society organizations, while the participation provisions in the pharmaceutical context were not so restricted.[247] Once eligible interested persons have made the submission, the Party is required only to "respond in a timely manner [and] in accordance with domestic procedures".[248] This is weak and unspecific. Furthermore, the provision explicitly lists restrictive conditions the Parties may impose for public submissions.[249] Interested persons do not have the right to petition Parties to correct regulatory inaction, this right is reserved only for the other Parties.[250] The inter-Party exchange is administered through the Committee on Environment where private actors have no right of access.[251] In contrast to the U.S.-Peru PTA, where a partially independent secretariat can create a public factual record on the basis of submissions,[252] the TPP does not include any possibility for further public information creation. [253]

The second set of provisions concerns the enforcement of the Parties' existing environmental laws.[254] In comparison to both previous FTAs and the pharmaceutical provisions in the TPP, these procedural obligations are weak and unspecific. [255] A restrictive clause was added, for example, which only gives the right to request investigation of alleged environmental law violations to persons "residing or

[244] *Id.*
[245] TPP, Art. 20.7.5.
[246] TPP, Art. 20.9.
[247] TPP, Art. 20.7.2.
[248] TPP, Art. 20.9.1.
[249] TPP, Art. 20.9.2.
[250] TPP, Art. 20.9.4.
[251] *Id.*
[252] U.S.-Peru PTA, Art. 18.9
[253] Center for International Environmental Law, *The Trans-Pacific Partnership and the Environment: An Assessment of Commitments and Trade Agreement Enforcement,* available at http://www.ciel.org/wp-content/uploads/2015/11/TPP-Enforcement-Analysis-Nov2015.pdf (criticizing the absence of a factual record). The creation of a factual record had been part of the commitments in the NAFTA environment side-agreement, CAFTA-DR, the PTPA, U.S-Columbia PTA and U.S.-Panama PTA. Even in these treaties, the citizen suits have not been able to generate much factual records, of the 87 filed submissions, 22 generated records. *Ibid.*
[254] TPP, Arts. 20.7.2-5.
[255] Compare for example the caveats of TPP Art. 20.7.2 ("Each Party shall ensure that an interested person residing or established in its territory may request that the Party's competent authorities investigate alleged violations of its environmental laws, and that the competent authorities give those requests due consideration, in accordance with the Party's law.") with TPP Art. 18.71 ("Each Party shall ensure that enforcement procedures as specified in this Section are available under its law so as to permit effective action against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies that constitute a deterrent to future infringements.").

established in its territory."[256] Similarly, TPP provides that enforcement proceedings for a country's environmental laws must be public only to the extent this publicity is "in accordance with its applicable laws."[257]

In sum, the numerous TPP procedural provisions relating to the environment do not provide effective instruments for affecting regulatory decisions. They do not empower representatives of environmental interests, do not stack the deck in their favor, and leave pre-existing power imbalances in place. Rather than giving environmental advocates rights of initiative and voice, the agreement vacuously provides that the state parties "may seek advice or assistance from any person or body they deem appropriate in order to examine [disagreements relating to the environment chapter]."[258] Relatedly, in setting up committees, advisory committees and fora for exchange on environmental matters, the Parties "may include persons with relevant experience, as appropriate, including experience in business, natural resource conservation and management, or other environmental matters."[259]

A last weakness regarding environmental enforcement in TPP is its complex and protracted inter-Party dispute resolution process.[260] In cases of disagreement about interpretation or implementation of the TPP environment chapter, the Parties are to resort to consultations. The consultations have *three* stages. First, consultation, then "senior consultation", and then "ministerial consultation", before you can get to SSDS.[261] The practical effect of these elaborate requirements is to foreclose or at least greatly discourage resort to the TPP's SSDS process. In contrast to the Peru treaty, no autonomous secretariat to oversee the enforcement process exists, leading some commentators to question whether "parties seriously intend to comply with environmental commitments in [trade agreements]."[262]

Conclusion

Over the past three decades, the North Atlantic states' regulatory capitalist approach to global economic governance has proliferated and intensified through economic regulatory agreements designed, through procedural as well as substantive commitments, to promote international commerce. Lately this approach has come to draw resistance, not only from some developing countries and China but from home. In the United States and the European Union major critiques of ever increasing international mobility of trade, services, and investment have become politically powerful. The adverse, often locally concentrated, and highly varying impacts on employment and the environment have spurred significant contestation and resistance. China, which benefitted enormously from integrating more closely into the

[256] TPP, Art. 20.7.2; compare, U.S.-Peru PTA Art. 18.4.1.
[257] TPP, Art. 20.7.3; compare, U.S.-Peru PTA Art. 18.4.2(a).
[258] TPP, Art. 20.20.5.
[259] TPP, Art. 20.8.2.
[260] SSDS is available pursuant to TPP Art. 20.23.1
[261] TPP, Arts. 20.20-23.
[262] Center for International Environmental Law, *supra* note 253, at 8.

global market, is now simultaneously pursuing a quite different approach to international economic ordering through its highly ambitious Belt and Road Initiative which focuses on—but reaches much wider than--transportation infrastructures.[263]

A marked difference has existed between the liberal model of private party empowering procedures in EU and US-led agreements on one hand, and in agreements with strong ownership from ASEAN or China.[264] The US has been intent to export procedures that it already has in place domestically, whereas many of the ASEAN governments and China do not want to bind their governments and empower private actors to the same extent. It remains to be seen to what extent China's alternative model for internal and global economic ordering built around a close connection, if not identity, of state and economic actors and the leveraging of government investment in other countries will be the foundation for an entirely different system of transnational control.

Notwithstanding these diverse sources of contestation, the unbundling and re-organization of production and distribution along global value chains through technological innovation, strong growth in cross-border investment and services, and the revolution of the digital economy are here to stay. These dynamic forms of transnational economic activity will generate strong continuing demand for market oriented economic regulation and open procedures for regulatory governance. The question ahead, we think, is how this demand will be satisfied—by which actors, through which institutional arrangements (public, private, or hybrid), and with what distributional consequences. These larger themes should motivate further analysis.

Our goal in this article is to show the importance of treaty commitments for domestic regulatory procedures as important instruments of transnational control of regulatory decision-making. Our analysis of the two-level game dynamics further demonstrates why procedural provisions might be particularly attractive as technologies of transnational governance. The negotiations for these commitments have particular dynamics, but can serve as important venues for political contestation. On our view, the global economic order's procedural infrastructure cannot be uncritically accepted as a means for promoting good government and the rule of law.[265] Procedures are powerful tools for governance at a distance which can be marshalled by different political actors and interests for different ends.

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[263] *See generally,* Mark Wu, *The "China, Inc." Challenge to Global Trade Governance,* 57 HARV. J. INT'L L. 261 (2016); REGULATING THE VISIBLE HAND? THE INSTITUTIONAL IMPLICATIONS OF CHINESE STATE CAPITALISM (Curtis J. Milhaupt & Benjamin Liebman, eds., 2016).

[264] See, e.g., ASEAN-China Free Trade Agreement, Nov. 29, 2004 (the agreement's transparency provision only reads "Article X of the GATT 1994 shall, mutatis mutandis, be incorporated into and form an integral part of this Agreement"; ASEAN-Japan, Apr. 14, 2008; ASEAN-Korea, Aug. 24, 2006.

[265] See, e.g. Charnovitz, *supra* note 131, at 939.

Our analysis also shows that the current pattern of procedural provisions is structurally linked to persisting collective action problems. As a result, business interests almost always prevail over diffuse environmental and social interests in their influence over treaty makers and, through the procedures adopted international agreements, over regulatory administrations. Firms most experienced with the McNollgast/Putnam dynamics are likely, overall, to gain the most from procedural entitlements agreed to in treaties. By showing what treaties can and cannot do in this area, we hope to encourage more refined thinking from academics and civil society groups with respect to these provisions. Vague substantive commitments in the areas of environmental protection or labor relations may often lead to nothing, whereas new procedural commitments designed to allow meaningful and balanced representation by a variety of social interests at both the level of international negotiations and the level of domestic ministry could help redress the imbalance in existing arrangements. More careful design and innovative thinking about specifically empowering communities through subsidized representation or changing access should be included in the toolbox.[266] Our analysis also further supports the growing call for exploring possibilities to open-up the negotiation process to give meaningful participation opportunities for broader social interests.[267]

[266] *See, e.g.,* The WHO Framework Convention on Tobacco Control which has obligations regarding the influence of the tobacco industry in setting and implementing health policies. WHO Framework Convention on Tobacco Control (entered into force 27 February 2005), Art. 5.3; WHO Framework Convention on Tobacco Control, Conference of the Parties, *Guidelines for implementation of Article 5.3 Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry* (adopted by decision FCTC/COP3(7)) (November 2008), http://www.who.int/fctc/treaty_instruments/adopted/article_5_3/en/, para.23, Recommendation 4 ("4.8 Parties should not allow any person employed by the tobacco industry or any entity working to further its interests to be a member of any government body, committee or advisory group that sets or implements tobacco control or public health policy. 4.9 Parties should not nominate any person employed by the tobacco industry or any entity working to further its interests to serve on delegations to meetings of the Conference of the Parties, its subsidiary bodies or any other bodies established pursuant to decisions of the Conference of the Parties.")

[267] *See, e.g.,* Access Now!, W*hy Transparency Matters in Europe's Trade Negotiations* (4 August 2016), https://www.accessnow.org/transparency-matters-europes-trade-negotiations/ (last accessed 23 February 2018). *See also,* Simon Lester, *Transparency in Trade Negotiations: How Much is Enough, How Much is Too Much?,* ICTSD – Bridges Africa 4, Vol. 7 (1 September 2015), *available at* https://www.ictsd.org/bridges-news/bridges-africa/news/transparency-in-trade-negotiations-how-much-is-enough-how-much-is (last accessed 23 February 2018).