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Margaret Chon

**PPPs in Global IP
(Public-Private Partnerships in Global Intellectual Property)**

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**PPPs IN GLOBAL IP
(PUBLIC-PRIVATE PARTNERSHIPS IN GLOBAL INTELLECTUAL PROPERTY)**

By Margaret Chon*

Abstract

Under what conditions may public-private partnerships (PPPs or P3s) involved in multilateral development policy advance public interest goals in global intellectual property (IP)? This paper attempts to assess how non-profit partners within certain development policy PPPs generate and/or implement norms, thereby impacting public policies that promote both innovations as well as access to those innovations. As hybrid actors operating across polyglot transnational networks, the practices of these PPPs illuminate and deepen both the global governance and the IP literatures. They reveal PPPs as regime-straddlers linking the legal domains of trade, IP and development.

* Donald and Lynda Horowitz Professor for the Pursuit of Justice, Seattle University School of Law; 2011-12 Emile Noël Fellow, Jean Monnet Center for International and Regional Economic Law and Justice at New York University School of Law. Many thanks to the faculty, fellows, librarians and students at NYU who helped to support work on this research. In particular, Professors Gráinne de Búrca, Rochelle Dreyfuss and Joseph Weiler, as well as Kathy Strandburg and Visiting Professor Pam Samuelson, gave me valuable advice and encouragement. Seattle University School of Law generously provided research support. This work also benefited from the opportunities to present to law faculties at Cardozo, CUNY, DePaul, Hong Kong, Pace, Marquette, St. John's, the 2012 International Conference on Law & Society, as well as the International Association for Teaching and Research in Intellectual Property (ATRIP). Finally and not least, I deeply appreciate the candor and generosity of my case study respondents. Further reactions to this project are welcome: please e-mail me at mchon@seattleu.edu. This paper is dedicated to the memory of Donna E. Arzt, who nurtured my interest in transnational law.

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I. Introduction and Context

Public-private partnerships (PPPs or P3s) specializing in development policy must contend with the highly intellectual property (IP)-intensive nature of knowledge production. Often produced in the European Union, North America and other developed country markets, IP-protected knowledge goods bear significant global distributional consequences. High uncertainty, risk and cost may be associated with research, development and commercialization of complex creations or innovations (hereinafter simply referred to as innovations), whether for industrialized or developing country sectors—thus these PPPs may respond to particular market failures in the production of these goods.¹ Moreover, governments or intergovernmental organizations (IGOs) may lack sufficient resources to provide full material support or, importantly, distributional mechanisms for these innovations—thus these PPPs also may address government failures in the production and dissemination of public goods for key areas such as agriculture, education or public health.²

Pharmaceutical innovations, for example, are typically privatized through the exclusive rights provided by patents, associated know-how and drug safety regimes. Firms producing these kinds of innovations increasingly collaborate with non-governmental organizations (NGOs) and IGOs via PPPs. PPPs thus address global disease burdens in neglected (typically developing country) markets. These recent solutions to market and government failures have been especially impactful in global health policy, resulting not only in macro changes to the treaty structure of the World Trade Organization (WTO)³

¹ See, e.g. Seth F. Berkley and Wayne C. Koff, *Scientific and policy challenges to development of an AIDS vaccine*, 370 *The Lancet* 94 (2007).

² See Commission of the European Communities, GREEN PAPER ON PUBLIC-PRIVATE PARTNERSHIPS AND COMMUNITY LAW ON PUBLIC CONTRACTS AND CONCESSIONS 2004, available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2004/com2004_0327en01.pdf. (2004); Kenneth Gustavsen and Christy Hanson, *Progress In Public-Private Partnerships To Fight Neglected Diseases*, 28 *Health Affairs* 1745-9 (2009); Jaya Banerji and Bernard Pecoul, Pragmatic and Principled: DNDi's Approach to IP Management, IN **INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES** 1775 (Anatole Krattiger, Richard Mahoney, Lita Nelsen, Jennifer Thomson, Alan Bennett, Kanikaram Satyanarayana, Gregory Graff, Carlos Fernandez and Stanley Kowalski, eds.), MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. (2007), available at: <http://www.iphandbook.org/> [**HEREINAFTER IP HANDBOOK**].

³ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS], Article 31*bis*.

but also micro changes in the institutional structures of non-profit pharmaceutical patent owners, such as universities.⁴ Thus, with almost no fanfare, PPPs have become a central architectural feature of current legal regimes shaping global development policy.⁵ They operate at the nexus of two or more multilateral public policy areas: IP, governed by various treaties including the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),⁶ and the multiple domains affecting development.

Under what conditions may it be possible for PPPs in global IP, with the participation of IGO and NGO partners, to advance public policy goals, that is, encouraging creation and innovation as well as the diffusion of resulting science and technology? Both international relations (IR) and IP literatures provide methodological tools to analyze these institutions. Yet PPPs, especially those dealing in IP, remain under-theorized. This paper maps some possible analytical frameworks.

As a general proposition within IR, global governance increasingly occurs directly and indirectly through transnational networks that are simultaneously “structural and actor-centered.”⁷ And within IP, public law approaches are increasingly intertwined with

⁴ Sania Nishtar, *Public-private 'partnerships' in health—a global call to action*, Health Research Policy and Systems 2:5 (2004), available at <http://www.health-policy-systems.com/content/2/1/5>; National Academy of Sciences, *MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST—COMMITTEE ON MANAGEMENT OF UNIVERSITY INTELLECTUAL PROPERTY: LESSONS FROM A GENERATION OF EXPERIENCE, RESEARCH, AND DIALOGUE* (2011) (advocating adoption of Association of University Technology Manager's Nine Principles); John Fraser, *IP Management and Deal Making for Global Health Outcomes: The New “Return on Imagination” (ROI)*, in *IP HANDBOOK*, *SUPRA* AT 19; Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L. J. 1031 (2005).

⁵ Andrea Wechsler, *WIPO and the Public-Private Web of Global Intellectual Property Governance*, in *EUROPEAN YEARBOOK OF INTERNATIONAL ECONOMIC LAW 2013* (Christoph Hermann & Jörg Philipp Terhechte, eds., Springer 2013); available at: <http://ssrn.com/abstract=2201523>; see also Nirmala Ravishankar, Paul Gubbins, Rebecca J. Cooley, Katherine Leach-Kemon, Catherine M. Michaud, Dean T. Jamison, Christopher J. Murray, *Financing of global health: tracking development assistance for health from 1990 to 2007*, 373 THE LANCET 2113-24 (2009) (tracing growth of Development Assistance for Health (DAH) from \$5.6 billion in 1990 to \$21.8 billion in 2007).

⁶ TRIPS, *supra*.

⁷ Benedicte Bull and Desmond McNeill, *DEVELOPMENT ISSUES IN GLOBAL GOVERNANCE: PUBLIC-PRIVATE PARTNERSHIPS AND MARKET MULTILATERALISM* 20 (2007) [hereinafter Bull and McNeill]; see also Margaret E. Keck and Kathryn Sikkink, *ACTIVISTS BEYOND BORDERS: ADVOCACY NETWORKS IN INTERNATIONAL POLITICS* (1998) (As Keck and Sikkink stated their original research questions: “(1) What is a transnational advocacy network? (2) Why and how do they emerge? (3) How do advocacy networks work? (4) Under what conditions can they be effective—that is, when are they most likely to achieve their goals?”); Marco Schäferhoff, Sabine Campe, and Christopher Kaan, *Transnational Public-Private Partnerships in International Relations: Making Sense of Concepts, Research Frameworks, and*

private ordering mechanisms, such as contract law, often deployed by and through non-state actors. However, although one could readily describe much of global IP today as “administration by hybrid intergovernmental-private arrangements,”⁸ the institutional arrangements receiving most attention in the IR literature usually do not include examples from the domain of IP. And conversely, global governance is not a primary organizational framework within IP literature, which typically dichotomizes regulation into non-overlapping categories of public regulation and private ordering. This latter oversight is somewhat curious since IP is a regulatory domain that quintessentially juggles private interest with public, for the ultimate purpose of encouraging creative and inventive activity to increase social welfare.

This paper attempts to address these gaps in both the IR and the IP literatures, by focusing on P3s in pursuit of multilateral development goals. In particular, it assesses how NGO partners in PPPs push public interest norms within global IP—norms promoting creative and innovative activity, as well as access to the results of such activity through capacity-building, distribution or technology transfer. As an exploratory piece of a larger project, its purpose is to generate new questions about these emerging but already embedded institutions and their numerous impacts. Rather than justifying or testing existing theories, it is primarily descriptive, albeit situated within extant theoretical frameworks of global governance with their own explicit or implicit normative commitments.

Results, INTERNATIONAL STUDIES REVIEW 451 (2009) [hereinafter Schäferhoff et al.] (defining transnational relations as “regular interactions across national boundaries when at least one actor is a nonstate agent” and quoting Robert O. Keohane and Joseph S. Nye, Jr., *Redefining Accountability for Global Governance*, in **GOVERNANCE IN A GLOBAL ECONOMY: POLITICAL AUTHORITY IN TRANSITION** (M. Kahler and D. A. Lake, eds.) (1971)).

⁸ Benedict Kingsbury, Nico Krisch, and Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 LAW & CONTEMP. PROB. 15, 20 (2005) (“Five main types of globalized administrative regulation are distinguishable: (1) administration by formal international organizations; (2) administration based on collective action by transnational networks of cooperative arrangements between national regulatory officials; (3) distributed administration conducted by national regulators under treaty, network, or other cooperative regimes; (4) *administration by hybrid intergovernmental-private arrangements*; and (5) administration by private institutions with regulatory functions.”) (emphasis added) [hereinafter Kingsbury et al., *Emergence*]; see also Benedict Kingsbury, *The Concept of “Law” in Global Administrative Law*, 17 European Journal of International Law (2009); Jose E. Alvarez, **GOVERNING THE WORLD: INTERNATIONAL ORGANIZATIONS AS LAWMAKERS** (2008) (discussing proliferation of intergovernmental organizations, NGOs, and multinational corporations, in addition to state actors, as significant governance actors).

A. IP Frameworks

At least two strands within IP scholarship are relevant. The first is informed by IR theory. Its dominant insights revolve around the formation, implementation and consequences of the TRIPS agreement, specifically on the role of multi-national corporations in this successful effort to increase and harden global IP standards.⁹ In response, developing countries along with aligned NGOs shifted to other more favorable multilateral fora, to advocate more effectively for access to IP-protected knowledge goods for development and other purposes.¹⁰ The on-going “positive agenda for IP,”¹¹ in the vernacular of some advocates, focuses on increasing exceptions and limitations to intellectual property as well as other strategies to protect the public interest in the public goods incentivized by intellectual property.¹² The concept of “regime-shifting”¹³ describes this highly politicized dynamic and also links IP to other global regulatory regimes such as human rights¹⁴ and human or sustainable development.¹⁵

However, regime-shifting also conveys predominantly agonistic relationships between two sets of state actors (particularly along the South-North axis), between civil society

⁹ Peter Drahos and Susan Sell have focused on the formation of the WTO TRIPS as an example of corporate capture of the public treaty-making process as exemplified by titles of their books (**INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?**(2002) and **PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003)**, respectively); see also Chidi Oguamanam, *IP in Global Governance: A Venture in Critical Reflection*, 2 W.I.P.O.J. 26 (2011) (critically examining the impact of the TRIPS framework on aspects of global IP governance).

¹⁰ Duncan Matthews, **INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOs AND SOCIAL MOVEMENTS** 11 (2011) (focusing on the role of advocacy NGOs in implementation of IP standards under TRIPS); Kali Murray and Esther van Zimmeren, *Dynamic Patent Governance in Europe and the United States: the Myriad Example*, 19 CARDOZO J. INT. AND COMP. L. 287 (2011) (comparing EU and US governance approaches to patent law, including the role of civil society).

¹¹ Sean Fiil Flynn, *WIPO's Gurry Coopts "Positive Agenda" for Industry Concerns* (June 18, 2011), available at: <http://infojustice.org/archives/3883>.

¹² The Washington Declaration on Intellectual Property and the Public Interest (August 17, 2011), available at: <http://infojustice.org/washington-declaration>

¹³ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, **A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME** 144 (2012) (citing Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L.J. 1 (2004)); Peter Yu, *A Tale of Two Development Agendas*, 35 OHIO N. U. L. REV. 465 (2009); see also John Braithwaite & Peter Drahos, **GLOBAL BUSINESS REGULATION** 571 (2000) (defining forum-shifting and suggesting that it is a game that only the powerful states can play).

¹⁴ See, e.g., Laurence R. Helfer & Karen J. Alter, *The Influence of the Andean Intellectual Property Regime on Access to Medicines in Latin America*, in **BALANCING WEALTH AND HEALTH: GLOBAL ADMINISTRATIVE LAW AND THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES** (Rochelle Dreyfuss & César Rodríguez-Garavito, eds.) (forthcoming 2012).

¹⁵ Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821 (2006).

and industry and between formal legal regimes, for example, human rights and IP. Fewer inquiries have examined the concurrent proliferation of non-state actors such as NGOs employing *heterarchical* approaches to the generation, interpretation and implementation of global IP norms.¹⁶ Their efforts result not only in regulatory competition but also occasional coordination towards the production of public goods.¹⁷ For example, actors with diverse motivations may nonetheless collaborate within scientific research or other transnational networks to produce public goods both affected by and affecting IP norms.

A second possibly relevant strand of IP scholarship is associated with open access, open innovation and/or peer-produced knowledge, often based on the decentralized architecture of digital networks¹⁸ or possibly agricultural research networks.¹⁹ Resembling other areas of global governance characterized by non-hierarchical approaches to regulation, NGOs such as Creative Commons²⁰ employ a strategy of contracting with downstream actors to expand public interest norms, such as greater distribution of IP-protected knowledge goods. These approaches depend paradoxically upon the exclusive rights of IP as a basis for mandating more open access and use.

¹⁶ Peter Drahos, *An Alternative Framework for the Global Regulation of Intellectual Property Rights*, AUSTRIAN J. OF DEV. STUDIES 21 (2005), available at <http://ssrn.com/abstract=850751> (examining heterarchical regulatory arrangements within global IP through “nodal governance”).

¹⁷ This paper follows the broad definition of public goods as encompassing collective goods. Schäferhoff et al. *supra* at 454 (Collective goods have at least one of the two defining characteristics of public goods, meaning that collective goods are defined as goods whose consumption is nonrival and/or nonexclusive . . . [and] can therefore have the form of club goods—which are nonrival, but exclusive, for instance, a patent, or of common pool resources—which are rivalrous, but nonexclusive, for example, deep sea fishing.”).

¹⁸ See, e.g., Yochai Benkler, **THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM** (2006).

¹⁹ Keith Aoki, **SEED WARS: CONTROVERSIES AND CASES ON PLANT GENETIC RESOURCES AND INTELLECTUAL PROPERTY** (2008); Gregory D. Graff, Susan E. Cullen, Kent J. Bradford, David Zilberman, and Alan B. Bennett, *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECHNOLOGY 989-95 21 (2003); Henry Chesbrough, *Open Innovation: Where We've Been and Where We're Going*, RESEARCH-TECHNOLOGY MANAGEMENT, 20-27 (July–August 2012); Peter Gregory, Robert H. Potter, Frank A. Shotkoski, Desiree Hautea, K. V. Raman, Vijay Vijayaraghavan, William H. Lesser, George Norton And W. Ronnie Coffman, *Bioengineered Crops As Tools For International Development: Opportunities And Strategic Considerations*, 44 EX. AGRIC. 277, 288 (2008)., 90 OREGON L. REV. 1251, 1258-61 (2012).

²⁰ <http://creativecommons.org/>.

Again, some of these decentralized governance modalities occur through the interventions of non-state actors such as NGOs.²¹

B. IR Frameworks

Development policy PPPs originate from the efforts of various non-profit and/or multilateral organizations to achieve sustainable development.²² They include what many categorize as policy-specific PPPs in global health described above, as well as standards-setting organizations (SSOs) operating in the agriculture, environmental and other domains.²³ Both these kinds of development policy PPPs are very different from the previous generations of urban renewal or infrastructure PPPs, which are only noted here (and have far less to do with IP, but may be more familiar to most readers).²⁴

PPPs in global IP illustrate possible new categories to describe inter-regime governance. This paper introduces various concepts:

- *regime-straddling* (contrasted with regime-shifting) within
- *polyglot networks* (of epistemic as well as advocacy, value or instrumental exchange), by

²¹ Antony Taubman, *A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policymakers*, THE OPEN AIDS JOURNAL, 2010 at 12 (discussing open innovation, open source, commons-based peer production and distributed innovation in drug development); see also Brett M. Frischmann, **INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES** (2012) (“commons management can be an efficient means of indirectly supporting public participation in a variety of socially valuable activities, namely activities that involve the production, use, and distribution of public and social goods”); Geertrui Van Overwalle, Individualism, collectivism and openness in patent law: From Exclusion to inclusion through licensing, in **INDIVIDUALISM AND COLLECTIVENESS IN INTELLECTUAL PROPERTY LAW** (Jan Rosen, ed.) (2012).

²² Benedicte Bull, Public-private partnerships: the United Nations experience, in **INTERNATIONAL HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS** Graeme A. Hodge, Carsten Greve and Anthony E. Boardman, eds. (2010) [hereinafter **HANDBOOK OF PPPs**] at 479, 480-83 (summarizing origin of PPPs within the UN system).

²³ Numerous global governance scholars have been fascinated with the implications of standard-setting as a type of private regulation but few have speculated on the role of IP within SSOs that produce knowledge goods. See., e.g., Tim Buthe and Walter Mattli, **THE NEW GLOBAL RULERS, THE PRIVATIZATION OF REGULATION IN THE WORLD ECONOMY** (2011); Georgios Dimitropoulos, Private Implementation of Global and EU Administrative Law: The Case of Certification in the Climate Change Regime: Relationships, Issues and Comparison, in **GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW** 383 (Edoardo Chiti and Bernardo Giorgio Mattarella, eds. 2011); Lisbeth Segerlund, **MAKING CORPORATE SOCIAL RESPONSIBILITY A GLOBAL CONCERN: NORM CONSTRUCTION IN A GLOBALIZING WORLD** 113 (2010) (discussing fair trade labeling and other voluntary standards).

²⁴ Dominique Custos and John Reitz, *Administrative Law: Public Private Partnerships*, 58 AM. J. COMP. L. 555 (2010); Dan Assaf, Conceptualising the use of public-private partnerships as a regulatory arrangement in critical information infrastructure protection, in **NON-STATE ACTORS AS STANDARD SETTERS** 61 (Anne Peters, Lucy Koechlin, Till Forster, and Grett Fenner Zinkernagel, eds.) (2009).

- *hybrid actors* (of public actors aligned temporarily with private and, of particular focus here, of non-profit with for-profit, actors), resulting in possible policy shifts through a widening adoption of new norms created through
- *social licensing* (contrasted with purely commercial licensing) of IP.

Each of these proffered concepts is an amphibious²⁵ or “both/and” variation on transnational networks consisting of familiar actor-based and structural components of global governance. Rather than seamless fusions, each is intended to convey inherently contradictory alliances. In PPPs, the partners may not be “neutrals seeking good governance but rather partisans pursuing their special interests and values with differential power and capabilities.”²⁶ The terms “regime straddling,” “hybrid actor” and even “polyglot network” are intended to challenge some conceptual siloes that proliferate within global governance. They imply détente or code-switching between very different world views and corresponding intentions and actions among so-called “partners.” Interviews with PPP representatives described here uncover these multiple identities and complex dynamics.

Ultimately, development policy PPPs may produce not only a cosmopolitan mix of ideas and activities, already documented by global governance scholars in other contexts,²⁷ but also innovative avenues to the production of global public goods for development—including knowledge goods often incentivized by the exclusive rights of IP. In so doing, they also potentially multiply sites for the expression of public interest norms in global IP.

However, the heterogeneity of PPPs is also their all-too-obvious Achilles heel. As hybrid actors, PPPs attempt to accommodate both commercial and non-commercial interests,

²⁵ Walter W. Powell and Kurt W. Sandholtz, *Amphibious Entrepreneurs and the Emergence of Organizational Forms* (presented at the NYU Colloquium on Innovation Policy (Feb. 16, 2012), forthcoming in *THE STRATEGIC ENTREPRENEURSHIP JOURNAL*) (describing the merger of academic and commercial cultures in venture capital-funded biotech research firms).

²⁶ Abbott and Snidal, *The Governance Triangle: Regulatory Standards Institutions and The Shadow of the State*, in Walter Mattli and Ngaire Woods, eds., **THE POLITICS OF GLOBAL REGULATION** (Princeton University Press 2008) (hereinafter Abbott and Snidal).

²⁷ Sidney Tarrow, **THE NEW TRANSNATIONAL ACTIVISM** 43 (2005) (defining transnational activists as “a subgroup of rooted cosmopolitans, whom I define as individuals and groups who mobilize domestic and international resources and opportunities to advance claims on behalf of external actors, against external opponents, or in favor of goals they hold in common with transnational allies.”).

directly raising the question of whether public interest norms in IP can be expressed when hybrid actors are motivated instrumentally for profit in addition to social mission within networks consisting of simultaneous instrumental and epistemic exchange. Similar questions have been asked of purely commercial actors in the Corporate Social Responsibility (CSR) context.²⁸ One potential view of PPPs is that they act as comforting band-aids on a “thin” public domain,²⁹ and are unlikely to be an inadequate replacement for a robust multilateral structure that truly operates upon the structural causes of global poverty.³⁰ Nor are PPPs a merely neutral global form of civic republicanism. As Nishtar has incisively noted in the global health arena, PPPs inevitably generate multiple ethical challenges, including the clearer specification of norms and principles, non-interference with public sector priorities and reduction of conflicts of interest among public and private partners.³¹

Yet it is very much an open question whether existing public regulatory frameworks, domestic or global, can keep adequate pace with rapid changes in complex global regulatory spaces, especially involving technology.³² The so-called “trade and” (or in IP, the “TRIPS and”) debate suggests that imperfect and uneasy rapprochements between economic and social policies in the trade regime may be possible in some circumstances.

²⁸ United Nations Global Compact, available at: <http://www.unglobalcompact.org/> (providing ten principles for businesses in the areas of human rights, labor, environment and anti-corruption; at the same time emphasizing that PPPs are intended to complement, not substitute for interstate regulation); Jeffrey L. Sturchio and Adel A. F. Mahmoud, *The Evolving Role of the Private Sector in Global Health* (2013), available at: http://www.huffingtonpost.com/jeffrey-l-sturchio/the-evolving-role-health_b_2432823.html?view=print&comm_ref=false; see also Marco Schäferhoff et al., *supra* at 456.

²⁹ John G. Ruggie, Reconstituting the Global Public Domain: Issues, Actors and Practices, *European Journal of International Relations*, 10 (4) 2004: 499-531 (2004) (announcing “the progressive arrival on the global stage of a distinctive public domain – thinner, more partial and more fragile than its domestic counterpart, to be sure, but existing and taking root apart from the sphere of interstate relations.”); see also Sungjoon Cho, *Beyond Rationality: A Sociological Construction of the World Trade Organization*, 52 *Virginia J. Int’l Law* 321, 350, 352 (2012) (“the inclusion of non-WTO norms should be a discursive reflection of the culture, values, and norms of the interpretive community within the WTO . . . [M]arkets may expand the discursive sphere by inviting diverse economic—and social—actors such as traders, environmentalists, consumers, and regulators, to engage in a constructive discourse on particular issues.”).

³⁰ Eyal Benvenisti & George Downes, *The Empire’s New Clothes: Political Economy and the Fragmentation of International Law*, 60 *STAN. L. REV.* 595, 597 (2007) (“[F]ragmentation is a . . . serious problem . . . because it operates to sabotage the evolution of a more democratic and egalitarian international regulatory system and to undermine the normative integrity of international law.”).

³¹ Nishtar, *supra* at 3.

³² Rainier Nickel, *Legal Patterns of Global Governance: Participatory Transnational Governance*, in **CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND INTERNATIONAL ECONOMIC LAW** 157 (Christian Joerges and Ernst-Ulrich Petersmann, eds. 2011).

Both regime-shifting and regime-straddling describe linkages of the IP regime to a larger global regime complex of knowledge production for development in addition to trade, with ubiquitous political questions around the correct distributional balance of exclusive rights with access to these knowledge goods in various regimes. Within a regime-shifting framework, development policy goals may be unintended or ancillary consequences of IP policy. Regime-straddling, however, connotes the consensus-seeking and sometimes ungainly process of compromise involved in producing knowledge goods simultaneously for profit and for non-commercial social welfare gains, as well as intentionally within both the trade and development regimes. This process is mediated by civil society actors, including the NGOs operating within PPPs. Thus the potentially more nimble governance through PPPs and other decentralized institutions are certainly deserving of exploration even if they may be suspect by criteria such as accountability or legitimacy often raised by global governance scholars.

C. Structure of this Inquiry

This paper provides a theoretical map to explore NGO-driven PPPs as regulatory actors within the existing “TRIPS and” context—specifically, their capacity to push public policies via public interest norms in global IP. These norms include building innovation capacity, producing products embodying this innovation and ultimately distributing the resulting knowledge goods through the 3 “As” of technology diffusion: availability, accessibility and affordability.³³ This early stage paper is based on two heuristic case studies,³⁴ for the purpose of generating rather than testing theory.³⁵ It is structured with

³³ Steve Brooke, Claudia M. Harner-Jay, Heidi Lasher and Erica Jacoby, How Public–Private Partnerships Handle Intellectual Property: The PATH Experience, in 1755, **IP HANDBOOK**, *SUPRA* at 1756-57; see also Sandra L. Shotwell, Product Development and IP Strategies for Global Health Product Development Partnerships, in **IP HANDBOOK**, *SUPRA* AT 1247 (2007) (“The mission of global health product development partnerships (PDPs) is to develop *effective, affordable* health products and make them *available and affordable* to those in need.”) (emphasis added).

³⁴ The Appendix to this paper contains a description of methodology and a summary of results. See also Alexander L. George and Andrew Bennett, **CASE STUDIES AND THEORY DEVELOPMENT IN THE SOCIAL SCIENCES** (MIT 2004) at 75 (“purpose of heuristic case study is to inductively identify new variables, hypotheses, causal mechanisms, and causal paths. ‘Deviant’ or ‘outlier’ cases may be particularly useful for heuristic purposes, as by definition their outcomes are not what traditional theories would anticipate.”).

³⁵ Kathy Charmaz, Grounded Theory in the 21st Century: Applications for Advancing Social Justice Studies, in **HANDBOOK OF QUALITATIVE RESEARCH** 507 (Denzin and Lincoln, eds. 3rd ed., 2005); Anselm Strauss and Juliet Corbin, Grounded Theory Methodology: An Overview, in **HANDBOOK OF QUALITATIVE RESEARCH** 273 (Denzin and Lincoln, eds., 1st ed. 1994); see Keck and Sikkink, *supra* at 5 (“Social scientists recognize that generating theory and formulating hypotheses require different methods

an inductive, theory-generating framework intended to flow with the quite varied forms of PPPs within global IP.³⁶ The remainder of this paper is informed by case studies of two PPPs – one operating within global agriculture with an emphasis on policy formation, and the second in global health, with a focus on policy implementation. For ease of reference, the individual NGO representatives of the PPPs are referred to as PPP-A and PPP-B. Some tentative findings as well as questions for potential future research are identified. The paper then concludes by re-situating PPPs in global IP within the global governance literature. While often presented as frictionless institutions, PPPs cover a welter of differing agendas, motivations and stances toward public policy, often attended by a lack of transparency around which partner steers.³⁷ Thus their policy-making effects, whether as norm-generators or implementers demand further inquiry beyond the initial observations gathered here.

II. “Trade and . . . ”: Regime-Straddling Across TRIPS and Development

Virtually every term around which this inquiry is organized lacks a consensus definition, therefore a prefatory ground-clearing exercise is necessary. Disciplinary and ideological differences contribute to the indeterminacy of public-private partnerships and global governance as analytical concepts. As aptly stated by one commentator:

Governance is a contested term, one that has become a catchword in the social sciences. Governance is often interpreted so broadly that its content is said to describe, steer, and produce for a whole variety of social order activities ranging from states (governments) to markets and networks Governance is the type of regulation typical of the cooperation state, where state and non-state actors participate in mixed public-private policy networks. Concerning such new modes of governance, we need to further distinguish between actors

from those for testing theory. Our approach thus resembles what sociologists call “grounded theory,” which is the most systematic attempt to specify how theoretical insights are generated through qualitative research.”).

³⁶ Charmaz, *supra* at 508 (“grounded theorists . . . begin our analyses early to help us focus further data collection. In turn, we use these focused data to refine our emerging analyses. Grounded theory entails developing increasingly abstract ideas about research participants’ meanings, actions, and worlds and seeing specific data to fill out, refine, and check the merging conceptual categories.”).

³⁷ Nishtar, *supra* (outlining numerous ethical and operational challenges).

involved in governance (public and private), on the one hand, and modes of steering, (hierarchical versus non-hierarchical), on the other.³⁸

The basic observation buttressing this project is that the alliances made between public and private actors culminating in the form of PPPs often result in non-hierarchical networks connecting trade with development. Thus PPPs are a subset of global governance, straddling two different legal regimes – economic and social, broadly writ. Furthermore, the non-state actors in PPPs have diverse motivations: the for-profit actors seek to maximize business interest while the non-profit actors seek to further a defined social outcome. The “mixed public-private policy networks” referenced in the definition above are further complicated by these differing motivations on the part of the private actors, as well as the tension generated by a so-called “trade and” or “TRIPS and” linkage.

This section further specifies the critical terms “PPP” and “NGO.” It then iteratively reviews some of the more pertinent observations drawn from two different NGO-driven PPPs.

A. *Regime-Straddling: Development Policy PPPs*

Like other non-state actors, PPPs may participate in transnational governance as

the functional equivalent to the norm-generating setting of the nation-state: [through] participatory arrangements ensuring the involvement of civil society actors, stakeholders and the public in the arguing, bargaining and reasoning processes of transnational regulation . . .³⁹

What are some of the practices of PPPs in global IP that either challenge or support this foundational insight of global governance?

³⁸ Tanja A. Borzel and Thomas Risse, Public-Private Partnerships: Effective and Legitimate Tools of Transnational Governance? in **COMPLEX SOVEREIGNTY: RECONSTITUTING POLITICAL AUTHORITY IN THE TWENTY-FIRST CENTURY** (Edgar Grande and Louis W. Pauly, eds.) 195, 196 (2005) [hereinafter Borzel and Risse].

³⁹ Nickel, *supra* at 161.

The term PPP is described by some observers as “polysemous,⁴⁰ in part because it is a point of deep contestation around the private/public distinction in both political and legal theory. Privatization is strongly associated with the rise of neoliberal approaches to managing political economies and social systems of many democratic states in the late 20th and early 21st centuries.⁴¹ In addition to the political divides generated by this term, PPPs have diverse historical and national origins. Therefore no definitive typology exists. At the highest level of generality, transnational PPPs have been defined as “*institutionalized transboundary interactions between public and private actors, which aim at the provision of collective goods.*”⁴²

PPPs may engage in governance through processes of cooptation, delegation, co-regulation or completely privatized forms of regulation.⁴³ These diverse institutions are sometimes depicted as mutually exclusive “streams” or “fields” or “traditions”⁴⁴ and to organize them according to their main emphases (such as those involved in urban regeneration, policy, infrastructure and development).⁴⁵ PPPs involved in urban regeneration or infrastructure approaches can be excluded from this project because

⁴⁰ Dominique Custos and John Reitz, *Administrative Law: Public Private Partnerships*, 58 AM. J. COMP. L. 555 (2010)

⁴¹ Id. at 566 (“A great deal of the critique of the growth of PPPs in the late 1990s was grounded in the public-private law distinction, revealing that the importance of the distinction had declined but not completely disappeared. Interestingly, in this quasi-resurrection of the late 1990s, a discursive reversal has occurred. On the one hand, since the end of the twentieth century those concerned with the assertion of the public interest and the preservation of the public sphere have stressed the distinction. On the other hand, over half a century earlier, the legal realists who equally meant to protect the public interest and public law argued that the distinction was an obstacle toward that end. In other words, alternatively the champions of the public interest and public law have sought either to expand or to confine the public-private divide. Those who currently object to PPPs make much of the distinction that the legal realists sought to minimize. But they all share an attachment to the public interest.”); see also Steven H. Linder, *Coming to Terms with the Public-Private Partnership: A Grammar of Multiple Meanings*, in **PUBLIC-PRIVATE POLICY PARTNERSHIPS** 19 (Pauline Vaillancourt Rosenau, ed) (2000) [hereinafter Rosenau]; Tony Bovaird, *A brief intellectual history of the public-private partnership movement*, in **HANDBOOK OF PPPs**, *supra*.

⁴² Schäferhoff et al., *supra* at 455 (emphasis added); see also Borzel and Risse, *supra* (“Transnational PPPs . . . [are] institutionalized cooperative relationships between public actors (both governments and international organizations) and private actors beyond the nation-state for governance purposes. By governance purposes, we mean the making and implementation of norms and rules for the provision of goods and services that are considered to be binding by members.”).

⁴³ Borzel and Risse, *supra* at 199-203.

⁴⁴ Guorio Weihe, *Ordering Disorder – On the Perplexities of the Partnership Literature*, THE AUSTRALIAN JOURNAL OF PUBLIC ADMINISTRATION, vol. 67, no. 4, pp. 430–442 at 430 (2008).

⁴⁵ Schäferhoff et al., *supra*; see also Benedicte Bull, *supra*; Kenneth W. Abbott, *Engaging the Public and the Private in Global Sustainability Governance*, available at SSRN: <http://ssrn.com/abstract=1966730> or <http://dx.doi.org/10.2139/ssrn.1966730>.

their characteristics are mostly irrelevant to the PPPs highlighted here.⁴⁶ PPPs addressing specific policy areas, on the other hand, typically cover technology⁴⁷ or health realms directly relevant to IP and development. But policy PPPs can also address wholly unrelated areas such as domestic criminal justice system and the military.⁴⁸ Thus even the category of “policy PPP” may be overly-capacious.

Policy PPPs overlap, nevertheless, with development PPPs. Trends within both the trade and development multilateral regimes have resulted in the formation of *development policy PPPs*, providing a way to capture the types of activity examined here. The trade regime is increasingly challenged by “social” concerns, and IP has been one of its flash points in this regard. In the WTO, for example, the debate over access to patented medicines following the adoption of TRIPS led to proposed changes in its multilateral framework. As a result, WTO member states agreed to amend the compulsory licensing provisions of TRIPS in the form of proposed Article 31 *bis*,⁴⁹ in order to allow developing countries without manufacturing capacity to issue compulsory licenses to import patented pharmaceuticals under certain conditions. This highly politicized debate about the relationship of trade and IP to development continues today through various TRIPS-plus plurilateral negotiations, such as the proposed Trans-Pacific Partnership (TPP).⁵⁰ Transnational advocacy NGOs often align with intellectual property-importing states to underscore these linkages between the trade/IP regimes and the health and human rights regimes. The WTO is also partnered with various U.N. agencies such as UNCTAD through the joint International Trade Centre, which focuses on promoting export

⁴⁶ UNDP, PPPUE/Capacity 2015 training, PPP definitions (2009), available at: www.undp.org/pppue/about/brochure/chapter0.htm (e.g., “Public private partnerships (PPPs) are a generic term for the relationships formed between the private sector and public bodies often with the aim of introducing private sector resources and/or expertise in order to help provide and deliver public sector assets and services. The term PPP is used to describe a wide variety of working arrangements from loose, informal and strategic partnerships to design build finance and operate (DBFO) type service contracts and formal joint venture companies. [Source: 4Ps, UK local government procurement agency]”).

⁴⁷ Joseph E. Stiglitz and Scott J. Wallsten, *Public-Private Technology Partnerships: Promises and Pitfalls in Rosenau, supra*.

⁴⁸ See generally Rosenau, *supra*.

⁴⁹ Amendment of the TRIPS Agreement, available at: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (not in effect until accepted by 2/3 of WTO member states); Cynthia M. Ho, **ACCESS TO MEDICINES IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENT AND RELATED RIGHTS** (Oxford University Press, 2011).

⁵⁰ <http://www.ustr.gov/tpp>

development for small businesses in developing countries.⁵¹ And its agreement with the World Intellectual Property Organization (WIPO, a UN agency as of 1967) compels the latter to help implement TRIPS Article 68.⁵²

During the same period that the trade regime was infused with social concerns in the form of development, multilateral development agencies affiliated with the United Nations (U.N.) system began a sharp turn to the private sector, not just for funding purposes but also seeking partnerships in development.⁵³ At the outset of Kofi Annan's tenure as U.N. Secretary General, he signaled this shift in several key speeches and meetings, such as his 1997 appearance at the World Economic Forum at Davos.⁵⁴ Response to his 1999 speech to the World Economic Forum was apparently so enthusiastic that the U.N. established the U.N. Global Compact, a "strategic policy initiative for businesses that are committed to aligning their operations and strategies with ten universally accepted principles in the areas of human rights, labor, environment and anti-corruption."⁵⁵ The Millennium Development Goals declared later that same year included Goal 9, which invited partnerships for development.⁵⁶

Although some U.N. multilateral agencies such as UNICEF already had a long history of partnering with business, other U.N. agencies formed new partnerships as a result. And following the World Summit on Sustainable Development (WSSD) at Johannesburg in 2002, two hundred partnerships were launched—an historic moment that is seen by several scholars as the ushering in of the current era of development PPPs.⁵⁷ This has caused one commentator to observe that "[j]ust as Rio was as much about the legitimizing of NGOs in global governance as it was about the environment,

⁵¹ International Trade Center, available at: <http://www.intracen.org/>.

⁵² Agreement Between the World Intellectual Property Organization and the World Trade Organization, Dec. 22, 1995, 35 I.L.M. 754 (1996), available at: http://www.wipo.int/treaties/en/agreement/trtdocs_wo030.html; TRIPS Article 68 ("Council for Trade-Related Aspects of Intellectual Property Rights").

⁵³ Weihe, *supra* at 430 (2008); Benedicte Bull, Public-private partnerships: the United Nations experience, in **HANDBOOK OF PPPs**, *supra* at 479, 480-83; see also Ananya Mukherjee Reed and Darryl Reed, *Corporate Social Responsibility, Public-Private Partnerships and Human Development: Towards a New Agenda (and Beyond)* at 2 (Paper presented at the Conference "Public Private Partnerships in the Post-WSSD Context," Copenhagen Business School, August 14-15, 2006).

⁵⁴ Bull and McNeill, *supra* at 8.

⁵⁵ <http://www.unglobalcompact.org/AboutTheGC/index.html>; see *id.*

⁵⁶ UN Millennium Development Goals Goal 9 ("Develop a Global Partnership for Development"), available at: <http://www.un.org/millenniumgoals/global.shtml>.

⁵⁷ Bull, *supra* at 480-83; Weihe, *supra* at 434.

Johannesburg was about the legitimacy of the role of business in development.”⁵⁸ Decidedly more market-oriented from its inception, the World Bank has also clearly embraced the partnership concept. Although its charter prevents it from engaging directly in partnerships with business (it can only lend directly to states),⁵⁹ it has developed subsidiary agencies such as the International Finance Corporation and other institutional arrangements within the “World Bank Group” to engage with PPPs. Indeed much of the extant literature on PPPs derives from the efforts of the UN and the World Bank to deploy PPPs on behalf of their various goals of development and/or poverty reduction.

In different areas involving development policy, then, various multilateral institutions possibly cast the proverbial shadow under which PPPs operate. However, it is very much an open question whether this is a shadow of hierarchy or non-hierarchy. In the agricultural area, U.N. agencies such as the FAO and UNCTAD participate with PPPs. In the global health area, U.N. agencies such as UNICEF, UNDP and WHO are prominently involved with various PPPs. In both agriculture and health, the World Bank’s subsidiaries and the U.N. General Assembly play a role in convening, encouraging and supporting the formation of PPPs. The UN’s resolutions also define the parameters of PPPs: one UN document, for example, states that:

[p]artnerships [between the UN and business] are . . . voluntary and collaborative relationships between various parties, both State and non-State in which all participants agree to work together to achieve a common purpose or undertake a specific task, and to share resources, responsibilities, risks and benefits.⁶⁰

In all areas implicating IP policy with respect to development, the WTO TRIPS Agreement provides the basic framework, along with certain of WIPO’s activities such as

⁵⁸ Bull and McNeill, *supra* at 10 (quoting Zadek).

⁵⁹ *Id.* at 11.

⁶⁰ U.N. General Assembly, Enhanced cooperation between the United Nations and all relevant partners, in particular the private sector, UN A/60/214 (August 10, 2005); see also U.N. General Assembly, We the peoples: civil society, the United Nations and global governance: Report of the Panel of Eminent Persons on United Nations–Civil Society Relations, UN A/58/817 (June 11, 2004).

its Development Agenda.⁶¹ This is despite the fact that neither the WTO nor WIPO has strong identities as development institutions.⁶²

It is fair to state that many of the PPPs working in this realm are neither just policy PPPs nor just development PPPs, but rather an amalgam referred throughout here as *development policy PPPs*. A widely-known example of such a development policy PPP is the Global Alliance for Vaccines and Immunizations (GAVI Alliance), which was formally announced at the World Economic Forum in 2000. This PPP was jointly endorsed by the then-head of the WHO, along with the President of the World Bank President and the Director of UNICEF; it was seeded with a \$US 750 million commitment from the Bill and Melinda Gates Foundation (the “Gates Foundation”).⁶³ The GAVI Alliance describes its work as follows:

As a public-private partnership, GAVI represents the sum of its partners' individual strengths, from WHO's scientific expertise and UNICEF's procurement system to the financial know-how of the World Bank and the market knowledge of the vaccine industry.⁶⁴

Furthermore,

Two key factors set the GAVI Alliance apart from other actors in the field of international health aid:

The partnership model: as a public-private partnership, GAVI capitalises on the sum of its partners' comparative advantages;

The business model: by funding the delivery of new vaccines, GAVI shapes the vaccine market.⁶⁵

As with many PPPs, the relationship of various partners in this arrangement to each other is not spelled out in great detail, at least based on the publicly available literature.

⁶¹ Development Agenda at WIPO, available at: <http://www.wipo.int/ip-development/en/agenda/>. It does not appear that WIPO has embraced the P3 concept as much as some of the other U.N. agencies such as UNCTAD that are centered on development.

⁶² Margaret Chon, *Global Intellectual Property Governance (Under Construction)*, 12 THEORETICAL INQUIRIES IN LAW 349, 365 (2011)

⁶³ Bull and McNeill, *supra* at 78.

⁶⁴ GAVI Alliance, The Partnership Model, available at: <http://www.gavialliance.org/about/partners/the-partnership-model/>

⁶⁵ GAVI Alliance, GAVI's Partnership Model, available at: <http://www.gavialliance.org/about/gavis-partnership-model/>

GAVI, for example, does not pinpoint its exact status with respect to multilateral agencies. The World Health Organization website states:

Some so-called public-private partnerships could be more accurately described as public sector programmes with private sector participation. Collaborations in this category include Roll Back Malaria, Safe Injection Global Network, and Stop TB (all of which have secretariats in WHO) and the Global Alliance for Vaccines and Immunization, which has its secretariat at UNICEF. There are also legally independent “public interest” (but actually private sector) entities such as the Global Fund to Fight HIV/AIDS, TB and Malaria.⁶⁶

The GAVI Alliance’s own website lists UNICEF merely as an “alliance member” and locates GAVI’s Secretariat offices in Geneva and Washington, D.C., with no reference to UNICEF.⁶⁷ UNICEF does hold permanent seats on the 27 member board, along with WHO, The World Bank and the Gates Foundation; seats are also available for other partners as well as independent or unaffiliated individuals.⁶⁸ Regardless of its exact internal governance structure, the GAVI Alliance is a type of development policy PPP; it is an “institutionalized transboundary interaction”⁶⁹ involved in global vaccine distribution through procurement and possibly drug development for developing countries.⁷⁰ It works in partnership with multilateral agencies and private foundations as well as business partners.

⁶⁶ World Health Organization, Public-Private Partnerships for Health, available at: <http://www.who.int/trade/glossary/story077/en/> (emphasis added)

⁶⁷ GAVI Alliance, GAVI Secretariat, available at: <http://www.gavialliance.org/about/governance/secretariat/>

⁶⁸ GAVI Alliance, Partners in the Alliance, available at: <http://www.gavialliance.org/about/partners-in-the-alliance/>

⁶⁹ Schäferhoff et al., *supra* at 455.

⁷⁰ GAVI Alliance, What We Do, available at: <http://www.gavialliance.org/about/mission/what/> (“GAVI has brought a single-minded focus to the urgent task of closing three critical gaps in the provision of vaccines:

1. between children for whom immunisation is a given and the 23.2 million children worldwide with no access to vaccines;
2. between the introduction of a new vaccine in rich countries and the average 10-15 years required for the same vaccine to reach low-income countries;
3. between the need for new vaccines in developing countries and the lack of research and funds to provide them.”).

However, the GAVI Alliance is not necessarily representative or typical of PPPs even in other health development policy areas. Global health PPPs are heterogeneous along various axes.⁷¹ The WHO itself acknowledges that:

The term public-private partnerships covers a wide variety of ventures involving a diversity of arrangements, varying with regard to participants, legal status, governance, management, policy-setting prerogatives, contributions and operational roles. They range from small, single-product collaborations with industry to large entities hosted in United Nations agencies or private not-for-profit organizations. The objectives of public-private partnerships include:

Developing a product, e.g. the Medicines for Malaria Venture and the International AIDS Vaccine Initiative.

Distributing a donated or subsidized product, to control a specific disease, e.g. initiatives to distribute leprosy medicines. Concerns have been expressed about these initiatives as not tackling the health problems of highest priority, as perceived locally.

Strengthening health services, e.g. the Gates Foundation/Merck Botswana Comprehensive HIV/AIDS partnership.

Educating the public.

Improving product quality or regulation.⁷²

As this somewhat critical description suggests, within the health development policy area, PPPs may specialize in various activities. Some PPPs engage primarily in policy formation or norm-setting⁷³ as opposed to others engaged mainly in policy- or norm-implementation:⁷⁴

Policy form[ulation] relates to the development of norms and standards that are supposed to regulate state or business behavior. Policy implementation encompasses implementing rules and standards, and also the provision of

⁷¹ Bernhard Liese, Mark Rosenberg and Alexander Schratz, *Programmes, partnerships, and governance for elimination and control of neglected tropical diseases*, 375 *The LANCET* 67, 70 (2010) (“Despite early calls for integration and the apparent similarities of neglected tropical diseases, their control initiatives are heterogeneous. They differ in terms of origins, geographic coverage, epidemiological goal, stakeholders involved, funding, and governance structure. Table 2 presents an overview of initiatives that we have selected to show key differentiating organisational and control features.”).

⁷² World Health Organization, *Public-Private Partnerships for Health*, available at: <http://www.who.int/trade/glossary/story077/en/index.html>.

⁷³ Bull and McNeill, *supra* at 17 (“These partnerships establish both formal and informal dialogue and knowledge-sharing between the UN and the private sector, with the aim to have an impact on policy.”).

⁷⁴ Schäferhoff et al., *supra* at 457-58.

services as a particularly widespread function of PPPs in the areas of development and humanitarian aid.⁷⁵

In the latter category fall PPPs

aimed at overcoming market imperfections, information failures and political hurdles to provide essential goods and services, and these represent a significant degree of interaction and dialogue between the multilateral agencies and the private sector.⁷⁶

Thus, a pragmatic (but fluid) dichotomy can be established between development policy PPPs that focus on policy formation or norm-setting (typically advocacy organizations, such as some who work on the TRIPS and global health linkage) and those whose mission is primarily around policy implementation.⁷⁷ And a further distinction within policy implementation PPPs can be made between access and product development (PDPPPs), at least within the global health realm.

[PDPPPs] are nonprofit entities that sponsor others to perform or directly perform themselves at least one of the following R&D activities: basic research (such as target identification, validation and proof of concept), animal, preclinical and clinical testing, licensing, and manufacturing. The successful PDPPP may also be responsible for distribution. PDPPPs are distinguished from Access PPPs, which are nonprofit entities concerned primarily with expanding access by pulling together manufacturers, funding agencies (such as GAVI, USAID) and developing countries to enable the purchase and distribution of existing drugs, vaccines, and other medical products.⁷⁸

These PDPPPs may be focused on very specific outputs and therefore may not view themselves comfortably within a policy discourse of regulatory entrepreneurship.

⁷⁵ *Id.*

⁷⁶ Bull and McNeill, *supra* at 9 (describing these PPPs as “operationalizing” policy).

⁷⁷ Schäferhoff et al., *supra* at 457

⁷⁸ Jon F. Merz, Intellectual Property and Product Development Public/Private Partnerships (Final Report, May 16, 2005 to the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health) at 2; Sandra L. Shottwell, Product Development and IP Strategies for Global Health Product Development Partnerships, **IP HANDBOOK, SUPRA** at 1247 (“The not-for-profit product development partnerships (PDPs) often seek for-profit partners to access essential technology, expertise, and resources. These may be early-stage companies, leveraging philanthropic and government resources to develop a platform technology or established companies building out from existing markets or testing new technologies.”).

Nonetheless, as institutions that *implement* policy, they directly and indirectly shape norms and policies in their areas of operation. For example, Nishtar has observed that “[p]reviously policies around vaccination were grounded in the general princi[ple of] equitable access[; h]owever new initiatives and their vertical systems have less of a focus on sustainability, may not contribute to strengthening of the health system and have the potential of redirecting national health policies”⁷⁹

And what of the public interest in IP? One definition of development policy PPPs in global health suggests that:

[T]he IP-based right to exclude certain uses of protected materials can be used to encourage direct allocation of private resources towards public interest outcomes, in the absence of market incentives: this is the essence of IP management in public-private partnerships.

Exclusive rights can be licensed to preclude commercial use of protected materials, to promote non-commercial creative exchange and adaptation.⁸⁰

We’ll return shortly to this key definition.

B. *Polyglot Networks and Hybrid Actors: The Multiple Roles of Non-Profit Partners within PPPs*

Like PPPs, non-profit NGOs and other non-state actors are the subjects of considerable definitional ambiguity.⁸¹ Keck and Sikkink’s typology of network actors is a useful starting point for thinking about the special nature of NGOs in PPPs. According to them, non-state actors within transnational global governance networks fall within

⁷⁹ Nishtar, *supra* at 4.

⁸⁰ Taubman, *supra* at 9-10 (“[For example, t]he judicious application of the right to exclude can be used to safeguard the open quality of a shared innovative domain for agricultural biotechnology excluding open access to derivative technologies). [Or, s]tandards bodies use IP licensing structures to ensure open access to standards while encouraging technology developers to pool their technologies for mutual benefit, such as by defining fair, reasonable and non-discriminatory (FRAND) terms and conditions for licenses.”)

⁸¹ As observed, “[a]ny attempt to define NGOs in positive rather than negative terms is problematic, beyond the observation that they tend to be private citizens’ groups established to further certain common objectives of their members. The objectives pursued by NGOs differ considerably.” Menno T. Kamminga, *The Evolving Status of NGOs under International Law: A Threat to the Inter-State System?*, in **NON-STATE ACTORS AND HUMAN RIGHTS** 93-111 (Philip Alston, ed. 2005); see also Philip Alston, *The ‘Not-a-Cat’ Syndrome: Can the International Human Rights Regime Accommodate Non-State Actors?*, in **NON-STATE ACTORS AND HUMAN RIGHTS** 3 (Philip Alston, ed. 2005); Steve Charnovitz, *Nongovernmental Organizations and International Law*, 100 *ASIL* 348 (2006), reprinted in **NON-STATE ACTORS AND INTERNATIONAL LAW** (Andrea Bianchi, ed.) 147, 149 (2009).

three different categories based on their motivations: (1) those with essentially instrumental goals, especially transnational corporations and banks; (2) those motivated primarily by shared causal ideas, such as scientific groups or epistemic communities; and (3) those motivated primarily by shared principled ideas or values (transnational advocacy networks) . . .

What distinguishes principled activists of the kind we discuss in this volume is the intensely self-conscious and self-reflective nature of their normative awareness. No mere automatic “enactors,” these are people who seek to amplify the generative power of norms.⁸²

This tri-partite categorization of non-state actors into instrumental, epistemic and advocacy networks implies that these three types have non-overlapping agendas. It implicitly negates the possibility that an institutional arrangement might be intentionally comprised of all three types, or that they may be nested or otherwise linked via complex relationships.⁸³ Within this strand of IR scholarship, advocacy actors engaged primarily in policy formation (or norm-setting) – i.e., NGOs—have a privileged position with respect to the generation of norms aligned with the public interest,⁸⁴ compared to other kinds of non-state actors. While these advocacy NGOs (“value actors motivated by principled beliefs rather than any direct stake in an issue”⁸⁵) have grabbed the scholarly headlines, PPPs operating with the global IP space are a combination of instrumental (both for-profit and non-commercial), epistemic (scientific) and advocacy (principled) networks. Thus PPPs can be composed of very different communities of practice.⁸⁶ Despite speaking different discourses, the participants must communicate their way to a common understanding. Thus PPPs exemplify *polyglot networks*, a term that conveys that these particular transnational networks can be comprised of a mix of activities, goals and purposes. Yet these PPPs share a strong social mission with the advocacy NGOs receiving the lion’s share of scholarly attention so far.

⁸² Keck and Sikkink, *supra* at 30 and 35.

⁸³ See, e.g., Jyh-An Lee, *The Greenpeace of Cultural Environmentalism*, 16 WIDENER L. REV. 1, 38 (2010).

⁸⁴ Keck and Sikkink, *supra* (“principled activists [with an] intensely self-conscious and self-reflective nature of their normative awareness”).

⁸⁵ Abbott and Snidel, *supra*.

⁸⁶ Damien Chalmers, Administrative Globalisation and Curbing the Excesses of the State, in **CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND INTERNATIONAL ECONOMIC LAW** 351, 376 Christian Joerges and Ernst-Ulrich Petersmann, eds. 2011).

In the institutional setting of a PPP, NGOs are in the position to act instrumentally through their deployment of the commercial value of IP for non-commercial ends. Thus NGOs sometime leverage IP for social mission either defensively (“to preclude commercial use of protected materials”⁸⁷) or offensively (“to promote non-commercial creative exchange and adaptation”⁸⁸). As Taubman states in his definition above, “this is the essence of IP management in public-private partnerships.”⁸⁹ The admixture of different instrumental goals is a main reason that PPPs should be viewed as *hybrid actors*, consisting not only of public and private actors in polyglot policy networks,⁹⁰ but also of differently motivated private actors (for profit partnering with not-for-profit actors).

Acknowledging this hybridity also involves recognizing some of the debate within the governance literature as to whether NGOs should be classified with for-profit firms as ‘private’ actors.⁹¹ This tension between commercial and non-commercial goals relative to the ideal types within a single institution has been observed by sociologists of science,⁹² but not captured more widely within the context of transnational network governance.

In their instrumental actor roles, NGOs provide non-profit checks and balances to their for-profit partners within PPPs. But they also can play multiple other roles within PPPs. As epistemic network actors, NGOs within PPPs can provide technical expertise and technology transfer to either their private or public partners.⁹³ And as advocacy network actors, they may act as proxies for others (possibly of minority perspectives) within pluralistic global policy settings. One tentative finding from my interviews is these newer sorts of PPPs may not see themselves primarily as advocacy organizations. But

⁸⁷ Taubman, *supra*.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ Kingsbury, et al., *Emergence, supra* (describing hybrid intergovernmental-private arrangements); Borzel and Risse, *supra* at 196 (describing mixed public-private policy networks).

⁹¹ Schäferhoff et al., *supra* at 454 (“Definitions, however, differ on the term ‘private actor.’ One group of authors opts for a broad understanding of this term, and includes both business and civil society organizations. A second group applies a narrower definition, referring to for-profit organizations only, which means that the participation of a for-profit actor becomes a definitional criterion for transnational PPP.”).

⁹² Siobhán O’Mahony & Beth A. Bechky, *Boundary Organizations: Enabling Collaboration Among Unexpected Allies*, 53 ADMIN. SCI. Q. 422, 432–33 (2008).

⁹³ Duncan Matthews, *supra*.

advocacy can take place in many different ways. Importantly, PPP advocacy may not be in the form of consultation or participation in intergovernmental norm-setting, although indeed advocacy can take that shape. Instead, NGOs may express their principles through advocacy internal to the PPP. For example, a non-profit partner might help to its mission of reducing the cost of an IP-protected good when negotiating with its for-profit partners, thus disclosing the hybrid nature of PPPs as transnational actors.

C. A Brief Data Dive I

What findings support the proposal that more nuanced terminology would help to describe the roles of NGOs in PPPs?

I first asked each respondent to describe the PPP's origin story, including what he thought of two extant definitions of PPPs. In response to a broad definition of "private sector" (including non-profit organizations) in one of the definitions, I distinguished the private for-profit sector from the private non-profit sector. PPP-A immediately responded with:

That's interesting that . . . when you say, private sector, you mean NGOs –in this case, non-profits, non-governmental, acting in the public sphere. Normally, I find this to be hybrids in-between. The way I see PPPs commonly used, at least in development schema is as a private-for-profit company engaging in the public sector often government, with the mediation or participation of an NGO or a non-profit organization, to achieve what is ultimately a public goal because it's often paid for with public funds, but with participation, whether it's, at least in resources, time or access to markets, etc., of the private sector or companies who also will benefit and get certain private good out of this process . . .

I want to make sure that you are not including private companies in that definition.

I clarified by responding that my focus is on NGOs, specifically, how they are entering the PPP space and to what extent they are driving it. I emphasized that I didn't want to exclude the for-profit partner, but I also didn't want to focus on the for-profit partner.

[Understood.] Although to some extent, I'm sensing, usually the gorilla in the room is the private partner.

Similarly, PPP-B's representative responded with:

Public sector organizations like [us] seek[] resources from external sources (the private sector) to further our goals.

I asked whether he considered the NGO partner in PPP-B as being public or private. His response was:

I see us as being public. We are aligned with the NIH, [in] that essentially we do fairly early research and development, push it forward, but ultimately the people who will commercialize it are the private sector organizations.

Both respondents immediately felt that the classification of NGO as being public versus private was a critical issue. Their responses to me were similar: to push back on the suggestion that the NGO partner could be lumped in with other private partners. This suggests that the NGOs hold a distinctive identity vis-a-vis the for-profit private actors with which they partner. The term 'hybrid' came up in the interview with PPP-A. In the interview with PPP-B, my respondent went so far as to insist that his PPP was 'public' rather than 'private.' He also contrasted his PPP's social mission (and duty to its stakeholders) with the partners' for-profit mission (and corresponding duty to its shareholders). At the end of the same interview, he elaborated that his view of the PPP was defined along the lines of corporate ownership and governance:

[o]n the checklist on the public side: we don't have any stockholders, our board of directors has governance authority but they don't have an ownership interest; we're obligated through IRS regulations to be very transparent; . . . we're a 501(c)(3) by virtue of being a medical organization.

In other words, both respondents had a strong impulse to characterize what they were doing as 'public' rather than 'private.' It is not clear whether this is because of their explicit social mission, their perception of non-profit status as automatically aligned with the public interest, their belief or sense that they in fact were genuinely acting in the public interest or that they were helping to create the kinds of public goods that public sector organizations often do. Further research might disentangle these possible explanations.

Most of the listed partners on PPP-A's website are non-profit actors or public actors; although agribusiness firms participate in the activities, they are rarely mentioned on the site. Perhaps PPP-A eschews any affiliation with for-profit partners, raising the question of whether this is a specific representational strategy to maintain its identity as an NGO-driven PPP. Yet in the interview PPP stated:

It amazes me that we have four of the largest food companies in the world participating alongside producer groups, NGOs, with public bodies, a whole span of characters that normally don't get together.

PPP-B's website, by contrast, lists numerous private for-profit partners, and non-profit partners, as well as public sector partners.

The Appendix illustrates the sheer number of partners with which even these modestly-sized PPPs must engage. In the case of PPP-A, these partners are divided into founding partners and others, both with respect to funding and non-funding activities. These include direct partnerships with NGOs, including many located in developing countries. This illustrates the hybrid nature of the NGO's partnership with public agencies, including its temporal evolution from founding to later-added partners. For PPP-B, the hybrid quality derives from its many "collaborations" with for-profit firms as well as other NGOs in the global health development policy area. Further research might distinguish between the essential and peripheral partnerships and collaborations.

D. Polyglot Networks and Hybrid Actors: Interest Convergence, Mutual Dependency and/or Comparative Competences

The most common explanation for the emergence of PPPs is functional. Under this view, PPPs are claimed to provide an effective governance solution in response to a perceived or real governance gap.⁹⁴ However, some scholars claim instead that public and private self-interest rather than government failure drive the formation of PPPs.⁹⁵ In these

⁹⁴ Schäferhoff et al., *supra* at 456 (describing Gramscian, constructivist, functionalist, interest overlap theories, and stating that "[I]n brief, PPPs [are claimed to] evolve because of a functional demand for effective governance solutions").

⁹⁵ *Id.* ("Many studies have contested this functional explanation. A study on the WSSD partnerships shows that they cannot be found in areas where institutional failure and governance gaps are exceptionally pronounced, but rather in areas in which the partnerships correspond to the interests and capacities of northern donors and international organizations. Therefore, this study argues that the WSSD partnerships are not demand-driven but supply-driven, because they reflect the interests of powerful

accounts, PPPs emerge when partners have overlapping interests and each can expect benefits from the partnership.⁹⁶ For instance, public actors may obtain resources not otherwise available, private firms may find new markets and NGOs can extend their influence, reputation and consultancy work.⁹⁷ A variation of this non-functionalist view explains that PPPs emerge in conditions of mutual resource dependency where partners can pool both material and ideational benefits, and share burdens or risks.⁹⁸ Another approach emphasizes the comparative competences each actor may bring to a PPP, and views actor competencies as power resources.⁹⁹ These various non-functionalist theories could be summarized as being based, respectively, upon concepts of interest convergence, mutual dependency and/or comparative competence. Despite the differences in these theories, each emphasizes the self-interest of the NGO as a driving motivation for joining and working within a PPP format.

Hybrid actors such as PPPs may provide a “connecting tissue”¹⁰⁰ between less represented global sectors and sectors of relative power. From a policy formation (or norm-setting) perspective, this may result in “mutually constitutive norm generation”¹⁰¹ within the polyglot network—in which different world views then combine to transform transnational norms. And from a policy (or norm) implementation perspective, NGO literature posits that PPPs may be more effective than markets or states acting in isolation from each other, especially where the provision of a public good requires many different inputs. This may be especially true if a strong convergence exists among the interests of the various actors¹⁰² and/or obvious comparative advantages exist of

northern actors but fail to incorporate the needs of developing countries . . . [and] underline the notion that such functionalist explanations are problematic, because they rely on the normative assumption that actors generally aim at solving global challenges and set up PPPs for this reason. The examined PPPs were not formed to serve the function of closing governance gaps but to advance the interests of actors.”).

⁹⁶ Abbott and Snidal, *supra*.

⁹⁷ Schäferhoff et al., *supra* at 456-57.

⁹⁸ Borzel and Risse, *supra* at 198, 209 (describing this model and observing that this can lead to policy problem-solving or to “policy-shifting. . . as international organizations come to rely on INGOs.”).

⁹⁹ Abbott and Snidal, *supra*.

¹⁰⁰ Steffik and Kissling, *supra* at 137; cf. Keck and Sikkink, *supra* at 214.

¹⁰¹ Keck and Sikkink, *supra* at 214.

¹⁰² Schäferhoff et al.; see also Christopher Paun, *Between Collaboration and Competition Global Public-Private Partnerships Against Intellectual Property Crimes* 23 (2011) (identifying five factors that influence the formation, maintenance, termination, and reform of PPPs, including (1) common ground, (2) absolute and/or relative gains of resources, (3) management of the PPP and its discretion, (4) representation of stakeholders, and (5) policy pursued by the PPP).

different actors with complementary tasks towards a mutually beneficial goal.¹⁰³ Because of their social mission, NGOs acting through PPPs may be effective in delivering certain public goods for development purposes.¹⁰⁴ And provision will be more prevalent where NGOs care deeply about the beneficiaries.¹⁰⁵ These potential complementary competences between the non-profit and for-profit private partners¹⁰⁶ support both the concepts of polyglot networks and actor hybridity introduced earlier.

With respect to pure advocacy NGOs, some observers claim that specific opportunities further incentivize NGO participation within the WTO and other multilateral organizations. These include the ability of the NGO to bring a new issue to the attention of the policy-maker, to influence research processes leading to definition of policy problem, to influence policy formation, to monitor compliance and to further organizational self-interest through funding.¹⁰⁷ So-called “push factors” such as these extrapolate easily to NGOs focusing on policy implementation, since they cover specific and iterative policy tasks across different institutional settings.

Aside from specific motivations for NGOs to pursue their agendas via PPPs, civil society actors such as NGOs possibly provide an additional forum for resolving social conflicts and/or a “transmission belt between local and global public spheres, thus enabling and supporting a higher deliberative quality of global regulatory governance – at least in theory.”¹⁰⁸ In that regard, by incorporating civil society perspectives together with other perspectives, PPPs are said to “increase both the effectiveness (problem-solving capacity) and the legitimacy (democratic accountability) of international governance.”¹⁰⁹

¹⁰³ Abbott and Snidal, *supra*.

¹⁰⁴ Besley, Timothy J. and Ghatak, Maitreesh, Public-Private Partnership for the Provision of Public Goods: Theory and an Application to NGOs, The Development Economics Discussion Paper Series, The Suntory Centre (August 1999), available at SSRN: <http://ssrn.com/abstract=1126986>

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*; see also Abbott and Snidal.

¹⁰⁷ Jens Steffik and Claudia Kissling, Why Co-operate? Civil Society Participation at the WTO, in **CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND INTERNATIONAL ECONOMIC LAW** 135 (Christian Joerges and Ernst-Ulrich Petersmann, eds. 2011) 142-43 (From the perspective of IGOs, suggesting also some pull factors for including NGOs in multilateral activities, including the ability of NGOs to pinpoint new issues, bring additional expertise, implement policy, monitor compliance with international norms or agreements, and enhance the legitimacy of IGO. *Id.* at 139-141).

¹⁰⁸ Nickel, *supra* at 178.

¹⁰⁹ Borzel and Risse, *supra*, at 195.

E. A Brief Data Dive II

Although these answers were in response to a “how” question (how PPPs originate), they give some insight into the “whys” of PPPs. They point to the possibility that all extant theories (functionalist, non-functional as well as transnational network) of NGO participation are non-mutually-exclusive.¹¹⁰ With respect to government gaps, the question was put as to whether the PPP provided an opportunity for stakeholders to engage in private forms of public policy-making or regulation.¹¹¹ The NGO representative from PPP-A stated:

The vacuum is clear. We're not seeing the capacity anywhere, not even U.S. and Europe. . . No state can do it alone. How would Ghana engage Australia? In fact part of this work has stimulated an understanding that the U.N. has . . . to better understand issues of sustainability because no one government has a way of getting to it. It wasn't emerging and maybe could not emerge because of the scope.

In response to the question of whether PPPs influenced research processes leading to the definition of a policy problem, PPP-B responded with a more indistinct view of whether governance gaps existed, to which his organization may have responded:

That's an interesting one . . . we engage with organizations and specifically principal investigators in the developing world that then have connections to their own government . . . and through those connections we develop momentum within a country to examine new opportunities.

With respect to non-functional theories, both PPP-A and PPP-B clearly delineated the specific interests and competencies they could bring to the PPP table as non-profits, and similarly readily articulated the business interest of their for-profit partners. For example, PPP-A stated that the impetus to form a PPP was from both sides:

on the one side, [there was a] clear vision of public need for a definition of sustainability; at the same time . . . private business side was struggling to find tools to operate within that space . . . [including] some who saw it as a competitive advantage.

Similarly PPP-B stated:

¹¹⁰ Questions 5-11 in Appendix, *infra* re: impetus.

¹¹¹ *Id.*, question 21.

Our mission is essentially to introduce products to reduce the burden of disease; so in a sense, by telling a for-profit organization there's value here for you, jump in, let's make a difference together. ...

As far as its own competencies, each NGO representative agreed that it presented a 'non-profit' perspective within the NGO; however, interestingly, both hesitated when asked whether the NGO advocated for a particular perspective. PPP-A stated:

Not that we're advocating a particular view of [sustainability], but [the concept] itself needed a clear measure or definition.

Similarly PPP-B observed:

My vision of what [the PPP] does is not necessarily advocate but provide value for the organization to move forward . . . if advocacy is (I'm wagging my finger): you have an obligation to meet the needs of these people, I don't think we're doing that. I think we're saying, there's an opportunity here for you, social obligation aside, there's an economic opportunity for you so that we can both meet the (our) organizations' mission.

Both respondents unhesitatingly endorsed their roles of epistemic actor ("was an impetus to join the PPP an opportunity to contribute technical expertise?") and instrumental actor (an impetus . . . to address the issue from a not-for-profit approach as opposed to a "for-profit approach?). No doubt the epistemic actor and instrumental actor "hats" feel more comfortable for these particular NGOs than does the advocacy hat.

PPP-A was more lukewarm about whether interest convergence existed among partners, stating that some for-profit partners might experience a net short-term loss; PPP-B, by contrast, was certain that the PPP presented not just a win-win, but a

win-win-win because in the process then our stakeholders the people who are impacted by disease in the field benefit as well.

He was quite adamant about the importance of "mutual benefit" to both the for-profit and non-profit partners, emphasizing this several times. Both respondents were enthusiastic about the suggestion that one impetus to join the PPP was "to share policy goals" and because it was the "best way to manage to get to a shared policy goal"

(although PPP-B demurred on the term “policy” and substituted the term “norm” instead). Finally, when asked about whether being part of a PPP contributed to the NGO’s organizational goals, such as increased funding,¹¹² both agreed immediately. PPP-A stated:

Having a pretty good acceptance of what [we]’re doing allows us to have a seat at the table, as long as some of the goals have a clear public interest . . .

With respect to acting as a “connective tissue” or “transmission belt” between local and global policy concerns, both strongly assented to this role. PPP-A stated:

Absolutely, yes, yes, yes. Connective tissue clearly. Ultimately we feel that there are a number of actors in this process and the ones that have the least voice are the ones essentially at the bottom of the pyramid. The producers in the agricultural sphere, these billions of people who participate in the supply chains . . . the information about them, that is gathered with them, and shared with them as participants in this process enables . . . [us] to eliminate this disconnect between our ability to understand what is happening . . . now they are able to understand cost of production and risks, for example, and become more powerful actors either in negotiation with firm or policy actors, government – [and to be able to say that] we are experiencing these levels of soil erosion, education impact, gender inequality . . . it makes it possible for them . . . [to] demonstrate [these issues] in a more clear and credible way.

Less emphatically but nonetheless affirmatively, PPP-B grabbed onto the “transmission belt” metaphor:

You talk about the download speed and the upload speed, and they’re very different, . . . we provide very good information to our developing world partners, principal investigators, the regulatory authorities that they are connected to, but we don’t provide a mechanism for those regulatory authorities to go to the WHO . . . that’s again not really our sweet spot in terms of what we do.

This section of the survey instrument provides further support for the notion of polyglot networks. Non-profit actors within these PPPs toggle between their epistemic and instrumental non-profit actor roles, especially in relation to their instrumental for-profit partners and their developing country partners. This also reinforces the notion of PPPs

¹¹² *Id.*, question 18.

being hybrid actors; it is quite clear that the NGOs possess a very strong identity apart from their business partners: they see themselves allied with non-profit and public interests. Finally, these answers suggest that each of the non-functionalist theories of PPPs has some traction. Within the self-identified motivations of the participating NGOs as well as the motivations they attribute to their business partners, they express a clear sense of comparative competences. Slightly more ambiguous is the NGOs' tepid endorsement of their roles as advocacy actors.

F. Polyglot Networks and Hybrid Actors: Effectiveness and Legitimacy

The question of how to evaluate PPP effectiveness very much depends upon whether the PPP is engaged primarily in policy formation (or norm setting) as opposed to policy or norm implementation. Effectiveness in policy formation may depend mostly upon successful inclusion of stakeholders.¹¹³ In the policy implementation area, however, it may depend more upon demonstrated output, outcomes and impacts. These are all possible dependent variables in future empirical work.¹¹⁴ Some scholars are skeptical that output effectiveness can be measured directly even in the case of policy implementation, and suggest inputs as proxies for effectiveness. Input metrics might include whether the NGO is successful in contributing towards various regulatory tasks such as agenda-setting, negotiation, implementation, monitoring and/or enforcement.¹¹⁵

¹¹³ Schäferhoff et al. at 452.

¹¹⁴ Schäferhoff et al. at 457 (Drawing on game theory, situation-structuralists explain the varying institutional forms of international regimes through different types of strategic settings or situation structures. A common tenet of situation-structuralists is, for instance, the distinction between coordination and collaboration situations. Coordination situations require only relatively lowly formalized and centralized regimes. Once actors agree upon a needed regulation, say, the distribution of radio frequencies, the regulation becomes self-enforcing, as no incentives for defection exist. Collaboration situations represent a more severe form of collective action problems, as actors face incentives for defection—a state may have incentives to subsidize its industry despite an international agreement that prohibits industry subsidies. . . . PPPs in which the participating actors have incentives to defect may be based on precise rules and compliance mechanisms, whereas PPPs that pose fewer problems for cooperation rely on less formalized institutional designs.”).

¹¹⁵ Abbott and Snidal, *supra* (“It is difficult to assess effectiveness in any of these senses by measuring real-world impact: too many variables influence the outputs and effects of regulation, and the counterfactuals are too complex. We therefore ask instead what attributes, capacities and skills – what inputs or “competencies” – an institution needs to operate successfully throughout the regulatory process. By identifying competencies that are necessary to effectiveness, we can conclude that schemes lacking one or more of those competencies are likely to be ineffective. However, the competencies we identify are not sufficient: a scheme that possesses all of them might still be paralyzed by infighting . . . the regulatory process comprises five main stages: placing an issue on the regulatory agenda (Agenda-setting), negotiating, drafting and promulgating regulatory standards (Negotiation), implementing standards

Although the question of what features of institutional design lead to success is well beyond the scope of this paper, notable approaches towards evaluating effectiveness bear brief mention here. They typically are based in compliance theory, whether from a rational choice, constructivist or management perspective. A sanguine view, for example, is that the incorporation within private regulation of so-called rule targets and stakeholders can lead to better outcomes and greater deliberative democracy via learning communities or methods.¹¹⁶ Related claims are made by proponents of experimentalist governance.¹¹⁷ Others are far less optimistic about the ability of private actors and the larger institutional context in which they operate to serve the “public interest” or “common interests” rather than being captured mainly by private interests.¹¹⁸

With respect to legitimacy, the evaluative landscape is similarly complex. Input legitimacy may be a means of reducing the democratic deficit within global governance structures. By their mere participation, civil society actors are viewed as legitimating both the multilateral structure as well as more decentralized global governance structures.¹¹⁹ However, despite their identity as non-governmental or non-profit organizations, NGOs do not automatically represent the broader public interest. They may instead represent their own “private” principles, intertwined with their non-profit

within the operations of firms or other targets of regulation (Implementation), monitoring compliance (Monitoring), and promoting compliance and responding to non-compliance (Enforcement).”).

¹¹⁶ Borzel and Risse, *supra* at 210; see also Schäferhoff et al., *supra* at 462 (“The central mechanism for achieving compliance is that actors will suffer a costly loss of reputation in cases of detected rule-violations, which will complicate future cooperation. A critical regime function is thus to increase the reputational consequences of noncompliance by incorporating monitoring systems that make the compliance records of other actors transparent and create assurance against free-riding. Sticking with the example of the Global Compact, scholars argue that the initiative harnesses the power of reputation, and stress the central role of international NGOs as part of the institutional context. NGOs are crucial, because they monitor corporate behavior, pursue examples of corporate hypocrisy, engage in public shaming, and boost consumer pressure.”).

¹¹⁷ Gráinne de Búrca, *New Governance and Experimentalism: An Introduction*, 210 WISC. L. REV. 2011, 232; Charles Sabel and William Simon, *Minimalism and Experimentalism in the Administrative State*, 100 Georgetown L. J. 53 (2011); Charles F. Sabel and Jonathan Zeitlin, *Experimentalism in Transnational Governance: Emergent Pathways and Diffusion Mechanisms* (unpublished paper presented at the panel on “Global Governance in Transition,” annual conference of the International Studies Association, March 16-19, 2011); Christine Overdevoest and Jonathan Zeitlin, *Assembling an Experimentalist Regime: EU FLEGT and Transnational Governance Interactions in the Forest Sector* (unpublished paper, 2011); James Brassett, Ben Williamson and Richard Smith, *Experimentalist Governance, Deliberation and Democracy: A Case Study of Primary Commodity Roundtables* (Working Paper, 2010).

¹¹⁸ Abbott and Snidal, *supra*.

¹¹⁹ Borzel and Risse, *supra* at 211-12.

mission. Even where NGOs share clear public interest goals with their public or for-profit partners in PPPs, they may represent only a segment of society's interests.¹²⁰ Relatedly, the NGO foundations, particularly the giant ones such as the Gates Foundation, have a very different posture with respect to the spheres of development policy PPPs. These foundations plausibly could be viewed as one of the major hierarchical actors in this area – and thus must be treated as independent categories in their own rights. This is discussed more in a later section on funding governance. Furthermore, numerous political theorists have identified sources of the legitimacy deficit within transnational networks, including lack of accountability,¹²¹ or transparency, which are of critical importance in this regard.

In any event, a trade-off may exist between input legitimacy and effectiveness, such that greater input by civil society actors such as PPPs may come at the cost of greater fragmentation and a reduction of the more nimble functioning that is supposed to be one of the merits of governance structures.¹²²

G. A Brief Data Dive III

I asked a series of ten questions regarding how PPPs operate, for example, whether they bring new issues to the attention of policymakers.¹²³ Because I had not intended to generate information around the specific questions of effectiveness and legitimacy, the observations here are not systematic.

PPP-A represents a policy formation PPP; it also engages in some policy implementation. The responses of the NGO partner representative reflect this PPP's strong input into the early stages of norm generation. Furthermore, he was extraordinarily aware that the inclusion of stakeholders was critical, although he candidly admitted the difficulties in doing so:

¹²⁰ Abbott and Snidal, *supra*.

¹²¹ Ruth W. Grant and Robert O. Keohane, *Accountability and Abuses of Power in World Politics*, AMERICAN POLITICAL SCIENCE REVIEW (February 2005) ("Accountability, as we use the term, implies that some actors have the right to hold other actors to a set of standards, to judge whether they have fulfilled their responsibilities in light of these standards, and to impose sanctions if they determine that these responsibilities have not been met.").

¹²² Schäferhoff et al., *supra* at 466-67.

¹²³ Appendix, *supra*, questions 13-23.

Resources . . . obviously, even setting up a meeting is a resource on the tangible side. But I think the bigger challenge is the lack of understanding or the level of understanding. The stakeholders . . . have a very disparate levels of understanding of these issues.

Thus he pointed out the additional challenge relating to the “epistemic” aspect of its scientific role, which bears upon effectiveness and legitimacy of policy formation through PPPs.

By contrast, PPP-B represents a policy implementation PPP; correspondingly his answers reflect some confusion about why certain questions regarding policy formation were being asked of him.

Yet when asked whether the PPP allowed the NGO partner to create an additional forum for raising and/or resolving policy conflict (a predictable characteristic of policy formation PPPs, according to the literature), PPP-A responded:

I don't know that it's a forum we are creating, so I would say no. It certainly provides a basis around which a forum can function.

Whereas PPP-B responded:

I think the burden is on the developing country to prioritize . . . so I think that we create mechanisms, we provide information, we provide opportunities.

These somewhat counterintuitive responses seem to switch the roles of norm setter and implementer. In any event, both respondents discussed the importance of including stakeholders at various points during the interview. Each was also quite careful when using the term “policy” in relation to their activities, and PPP-B was practically averse to the notion that his PPP was directly involved any part of a policy-making process. As a result, I suggested and he agreed on the term “collateral consequence” to describe the indirect impact of its activities on policy. Both respondents were quite clear in stating that institutional competence and legitimacy for steering public policy lies primarily with public agencies or partners and not with the NGOs or their private partners. No direct questions were asked about output, outcomes and impacts – some of this

information is available on the websites and indicates that the PPPs in fact have produced public goods of value. More research is needed to specify this further.

H. Polyglot Networks and Hybrid Actors: Expressing Public Interest Values in IP

The terrain of possible IP practices confronting PPPs is where the proverbial rubber hits the road in expressing public interest values. Recall the definition provided earlier:

[T]he IP-based right to exclude certain uses of protected materials can be used to encourage direct allocation of private resources towards public interest outcomes, in the absence of market incentives: this is the essence of IP management in public-private partnerships.

Exclusive rights can be licensed to preclude commercial use of protected materials, to promote non-commercial creative exchange and adaptation.¹²⁴

In scientific R&D, the complex processes of innovation in a firm¹²⁵ may not significantly differ from those in PPPs or non-profit sectors such as universities or NGOs. Some universities have moved towards more social licensing principles, partly in response to their mission as non-profit institutions and partly in humanitarian response to pressures from advocacy NGOs.¹²⁶ Indeed, different policy development PPPs may decide upon radically different business (or sustainability) plans, reflecting different attitudes towards IP – some may embrace its revenue-generating potential as a type of “honey” to attract for-profit partners, others may see it as a necessary evil,¹²⁷ and still

¹²⁴ Taubman, *supra* at 9-10 (“For example, t]he judicious application of the right to exclude can be used to safeguard the open quality of a shared innovative domain for agricultural biotechnology excluding open access to derivative technologies). [Or, s]tandards bodies use IP licensing structures to ensure open access to standards while encouraging technology developers to pool their technologies for mutual benefit, such as by defining fair, reasonable and non-discriminatory (FRAND) terms and conditions for licenses.”)

¹²⁵ **KNOWLEDGE INTEGRATION AND INNOVATION: CRITICAL CHALLENGES FACING INTERNATIONAL TECHNOLOGY-BASED FIRMS** (Christian Berggren, Anna Bergek, Lars Bengtsson, Jonas Söderlund, and Michael Hobday, 2011) (“as firms increasingly need to integrate and co-ordinate knowledge by means of project groups, diversified organizations, inter-organizational partnerships, and strategic alliances. Innovation processes have progressively become interdisciplinary, collaborative, inter-organizational, and international, and a firm's ability to synthesize knowledge across disciplines, organizations, and geographic.”).

¹²⁶ Association of University Technology Managers (AUTM), In the Public Interest: Nine Points to Consider in Licensing University Technology (March 2007); AUTM Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (200?).

¹²⁷ Richard Jefferson, CAMBIA, available at <http://www.cambia.org/daisy/cambia/home.html>.

others may even decide to dedicate all scientific knowledge to the public domain.¹²⁸ Negotiating IP choices towards the technology transfer end game of “availability, accessibility and affordability”¹²⁹ requires tremendous savvy about licensing, particularly when multiple inputs are involved in a complex R&D process. The form viral license characteristic of open source software licenses or Creative Commons licenses, in the copyright context, cannot be models in the kinds of scientific collaboration characteristic of most policy development PPPs. The licenses must be negotiated on an individual basis, taking into account not just the social mission of the NGO but the need for quality control and maintenance of sufficient financial incentives for any for-profit partner to be involved. Social licensing in this context thus proceeds with many caveats. Furthermore, in the context of SSOs, IP is generated in the form of standards, which can be licensed on an open, limited commons or proprietary basis.¹³⁰ In addition, the standards can be embedded in certification marks, which then can be licensed on a non-discriminatory basis to those who meet the standards.¹³¹

In this area, hybrid actors must navigate many challenges. The profit-seeking partner of a PPP might be in the driver’s seat of a particular partnership, to the detriment of the bargaining power of the NGO partner, and consequently to public interest norms. Negotiation by NGOs with for-profit partners seeking to maximize return on investment inevitably involves a confrontation between economic and social values. Furthermore, polyglot networks pose some possible obstacles to social licensing by their very nature. As epistemic actors with deep scientific expertise, NGOs within PPPs may fall into the same trap of technocratic self-justification as their for-profit partners or other experts. More harshly, in their role as advocacy actors, NGOs in PPPs may be driven by primarily by their internal priorities or need for self-representation as providers of humanitarian aid rather than by the priorities of those on whose behalf they act. As Anne-Marie Slaughter has succinctly observed, “corporate and civic actors may be driven by profits

¹²⁸ Panel at Global Health and IP class, Seattle University School of Law, April 2011 (statement of general counsel of Allen Institute for Brain Science).

¹²⁹ Steve Brooke, Claudia M. Harner-Jay, Heidi Lasher and Erica Jacoby, *supra*.

¹³⁰ Taubman, *supra* (FRAND, etc.)

¹³¹ Margaret Chon, *Marks of Rectitude*, 77 FORDHAM L. REV. 2311 (2009).

and passion, respectively.”¹³² Possibly aware of the reputation of some NGOs of being driven more by enthusiasm than evidence, the NGO respondents here tried to distance themselves from their “advocacy” hats. However, the data suggests that NGOs in PPPs may engage in an internal advocacy of public interest values within the PPP, toward social licensing goals. They also engage directly and indirectly with external constituents.

I. A Final Data Dive: The Multiple Roles of Social Licensing

In some ways, this part of the survey was the biggest surprise. I asked my respondents very open-ended questions about whether they furthered public interest values in IP, including whether the PPP impacted innovation, access, the production of other global public goods (such as reducing disease burden) and whether the PPP bargained around existing global IP frameworks such as TRIPS.

PPP-A and PPP-B are situated very differently with respect to social licensing. PPP-A has developed metrics and possible incipient standards for measuring sustainability. He has not yet implemented an IP strategy, but is about to make a decided shift towards including IP as part of the PPP’s institutional strategy. The reasons he gave for deploying IP more intentionally in the near future relate to the organization’s long term sustainability. In discussing this, PPP-A stated:

We like the wiki concept, the Internet concept, no one owns it, no one should have any rights over it except to ensure a level of quality, other people don’t take it over. . .

This is a public good, where one borrows the book, and we’re providing the knowledge . . . [but] we want to maintain more control than the wiki model.

With respect to certification marks and trademarks, he stated:

I don’t think there’s a need for yet another . . . we’re now up to over 400 eco-labels. Having another mark . . . to me, this is label overwhelm. . . . I do think

¹³² Slaughter, *supra* at 10 (“[G]overnment actors can and should interact with a wide range of nongovernmental organizations (NGOs), but their role in governance bears distinct and different responsibilities. They must represent all their different constituencies, at least in a democracy; corporate and civic actors may be driven by profits and passion, respectively. ‘Governance’ must not become a cover for the blurring of these lines, even if it is both possible and necessary for these various actors to work together on common problems.”).

we want to stick to what we know is missing, what we do best, that is to provide a credible basis for measurement.

And with regard to innovation and access, he was very clear about the fact that his organization contributes to both IP public interest goals. However, he was equally clear that the PPP works within and not around the existing multilateral frameworks:

We want to make sure that the kinds of things we're doing are relevant things – that's why we have broad stakeholder (hundreds) participation; at the same time, another stakeholder is the treaties. Benchmarking against them, meaning that if we want to convey something about labor and sustainability, . . . what has the ILO said about these things? . . . We make sure we align with them or don't contravene them.

PPP-B had much more to say with respect to social licensing because IP has been a central part of its current organizational sustainability plan for some time. With respect to whether the PPP impacts access to the innovation:

IP –as you know, there's an inherent tension there, essentially – it's an exclusive right and we're using it to further a public good.

So I think we promote knowledge of the underlying art, but we don't really broadly disseminate rights to practice the art – so I think the answer is yes, we disseminate knowledge but we're somewhat choosy with respect to who gets the rights we license.

With respect to whether the PPP impacts innovation itself, this representative expressed some frustration with the constraints posed by having to negotiate with the commercial aspects of IP within a non-profit mission:

Right now, IP tends to be cost-neutral in the sense that the users pay for them. That results in a huge burden for us when our ultimate goal is to reduce the price at market entry, so there's a certain tension there.

I feel like we're paying more than we should and so I would really like to change that, but are we doing anything to change it? No we're not. . .

Whenever we get someone's ear that might make a change in, for example, the cost structure of obtaining IP, we do so, but we don't organize fora.

Like PPP-A, PPP-B was very clear that he works within and not around the current multilateral system:

Do we promote IP rule-following? I think that what we do is we demonstrate to our commercialization partners [that] we don't have to destroy the current IP framework: you benefit, we benefit, your stockholders benefit, our stakeholders benefit. And . . . it doesn't require breaking any existing rules, it just requires mutual knowledge and understanding and leveraging.

Most interesting to me was his response to whether his PPP's activities encouraged discursive or material commitments from states. He eventually responded that his PPP and similar ones have influenced public policy-makers in the following way:

There's a greater emphasis on job creation and I think there is greater job creation in the product development process . . . even though we're a global health non-profit, we have to attract the best talent. That involves competing with for-profit organizations. We're more likely to be here, we've seen in this region, for example, organizations get purchased and their assets go elsewhere but their jobs don't remain here. We're more dependable in that regard. We're more likely to be here in ten years than a for-profit organization. And so I think that attracts policy-makers in terms of demonstrating that with a bit of seed money, and I think really that the vision of funding organizations has changed. We see a grant from the NIH essentially as seed money to test out our technology and push it down that pipelines and that seed money creates social benefits in a lot of ways: reducing the burden of disease, potentially on the international policy front assisting countries in a way that reduces their burden of disease and creates jobs in our own backyard that appeals to the NIH and Congress in general.

Both PPPs demonstrate the potential and reality of contracting in or out of public interest values.¹³³ PPP-A knows *ex ante* that quality control will be a priority in any future attempt to distribute broadly the standards and evaluative tools it has developed. PPP-B currently deploys social licensing as part of its organizational strategy, limited by its need to ensure quality control and in the face of commercial pressures from its for-profit partners. Strikingly, the social licensing strategies are as much about the need to

¹³³ Custos, *supra* at 576 (suggesting contractual provisions to preserve due process and other public values as one way to counter-balance the outsourcing of public sector activities to the private sector in the infrastructure PPP context.)

ensure downstream quality control as they are about adhering to non-commercial ends. Similarly, a robust global governance literature documents the disciplining effect of intra-supply chain contracts to promote public policy goals under the shadow of state regulation.¹³⁴ And not surprisingly, optimal social licensing strategies may be constrained by the need for financial sustainability and political support. Both PPPs expressed this latter concern, but PPP-B put it more directly:

Just as [with] cancer, I always see . . . initiation and propagation, I also see this with organizations – why are they initiated or founded, and why are they propagated. [This PPP] was initiated or founded with a sense of developing products to alleviate the burden of disease. The second part though requires sustainability – how can an organization continue to sustain itself and is there a method of sustaining oneself that is independent from the constant grant cycle?

Participants within a PPP engage in distributive bargaining around their respective bundle of competencies as predicted by governance theorists.¹³⁵ But the social licensing strategies to promote availability, accessibility and affordability (the three “A”s) of IP technology diffusion may matter much more to the non-profit NGO than to its other, especially for-profit, partners. And correspondingly, the NGO may not have sufficient leverage over the other PPP participants by virtue of whatever power resources it brings to the table to push its partners towards social licensing goals outside of a short-term trajectory (funding cycles for public agencies or private foundations; profit cycles for commercial partners; budget concerns of governments¹³⁶). While this study did not attempt to measure the efficacy of the social licensing efforts in a detailed way, the

¹³⁴ Fabrizio Cafaggi, *Private regulation, supply chain and contractual networks: The case of food safety*, European University Institute, EUI Working Paper RSCAS 2010/10 (2010) at 26 (“Not only do consumers have low level of participation in contractual design and standard-setting within the food supply chain approach, but they also have very weak enforceability powers before courts. The accountability of these regimes is mainly based on the enforcement strengths of NGOs and, to a limited extent, competitors. The strengths and capacities of NGOs may vary across industries and countries.”).

¹³⁵ Abbott and Snidal, *supra*.

¹³⁶ Matt Erskine, United States Department of Commerce, *Creating High-Quality Jobs in Growing Industries through Public-Private Partnerships* (April 5, 2012), available at: <http://www.commerce.gov/blog/2012/04/05/creating-high-quality-jobs-growing-industries-through-public-private-partnerships>.

partial dependence upon IP as a source of funding for PPPs points to the need in future work for a hard look at sustainability,¹³⁷ or put another way, funding governance.¹³⁸

As recently noted:

The participants in private governance institutions must find resources to fund or otherwise support each stage of the regulatory process themselves. Furthermore, the way the costs of these burdens are allocated among the participants can have a significant impact on the effectiveness of the regulation. In smaller, self-governing communities, Elinor Ostrom has observed that that the costs and benefits associated with successful regulatory regimes tend to be proportionate for the participants. If participants' costs bear no relation to their benefits, they may either opt out or cheat, causing the system to unravel. The same dynamic is observed at the international level.¹³⁹

Given these tensions, private governance institutions have developed a number of mechanisms to generate higher prices and other forms of funding.¹⁴⁰ These efforts mirror the strategies of multilateral organizations acceding to PPPs in the first place.¹⁴¹ The sheer amount of private funding of development now rivals that of public

¹³⁷ Bull, *supra* at 90.

¹³⁸ Tracey M. Roberts, *Innovations in Governance: A Functional Typology of Private Governance Institutions*, DUKE ENVIRONMENTAL LAW & POLICY FORUM 101, 150 (2012) (“Rules, and the institutions developed to enforce them are public goods, and the process of developing rules and effectuating them can be expensive. Public goods are by definition non-rival (if public goods are provided to anyone, everyone can enjoy their benefit without diminishing others’ enjoyment of them) and non-exclusive (those who pay for the goods cannot exclude others from their enjoyment). In general, not everyone will contribute to the creation and maintenance of public goods to the extent of their enjoyment of those goods because they may free-ride on the efforts of others. Consequently, the private market will supply less of the public goods than would be socially optimal. Formal governments regulating within their own jurisdictional boundaries have several advantages in funding, most particularly, the latter stages of the regulatory process: implementation, monitoring and enforcement. As many have noted, formal governments have the authority and the power to coerce implementation and compliance through threat of criminal sanction or monetary fines. Possibly more importantly, governments use their taxing power to overcome the free rider problem and cover the costs of developing, effectuating, and enforcing new rules. In contrast, in private governance institutions, participants must find resources to cover costs at each of the regulatory stages; consequently, internal tensions among participating interest groups may continue to occur throughout the regulatory process.”)

¹³⁹ *Id.* at 154; see also Nishtar, *supra* at 4-5; Barbara K. Bucholtz, *Doing Well by Doing Good and Vice Versa: Self-Sustaining NGO/Nonprofit Organizations*, XVII JOURNAL OF LAW AND POLICY 403 (2009).

¹⁴⁰ Rosenau, *supra* at 12, 14 (Figures 1 and 2, positing intrasectoral versus intersectoral funding mechanisms as contributing towards strong versus weaker partnership forms).

¹⁴¹ Marco Schäferhoff, Christina Schrade, Gavin Yamey, *Financing Maternal and Child Health—What Are the Limitations in Estimating Donor Flows and Resource Needs?*, 7 PLOS MEDICINE (July 2010, available at: www.plos.org Needs?)

funding.¹⁴² Sustainability of funding is an issue for all development policy PPPs, especially in developing country global sectors.¹⁴³ The role of foundation NGOs are not part of this project although obviously their impact in this realm of development policy needs to be traced in order to assess how their specific type of actor hybridity may shape development norms.¹⁴⁴ Yet they are so different in kind and influence from the other NGOs at the center of this study as to be almost different species altogether.¹⁴⁵

III. Some Concluding Observations: Regime-Straddling Revisited

Some global governance theorists posit that we are “facing another ‘great transformation’ of international relations and intergovernmental politics”¹⁴⁶ partially through the turns to the economic and social realms described here. As with many other regulatory regimes, the IP regime is increasingly transnational, privatized and at the same time pressured to balance social with economic values. This process has resulted in multiple jurisgenerative fora. Acknowledging the full range of institutional arrangements linking IP to other global regulatory regimes is critically important to a more comprehensive understanding of this growing transnational regulatory mode of

¹⁴² Nirmala Ravishankar, Paul Gubbins, Rebecca J. Cooley, Katherine Leach-Kemon, Catherine M. Michaud, Dean T. Jamison, Christopher J. Murray, *supra*; see also Jean-Paul Fitoussi, Joseph E. Stiglitz and The Paris Group, **THE G20 AND RECOVERY AND BEYOND: AN AGENDA FOR GLOBAL GOVERNANCE FOR THE TWENTY-FIRST CENTURY**, eBook available at <http://www.ofce.sciences-po.fr/pdf/documents/ebook2011.pdf> 122 (Feb. 2011) (“The total amount of funds channeled towards developing countries by . . . ‘private’ actors was recently estimated to be around \$ 50 billion a year, 40 per cent of total [development assistance] aid. The increasing number of aid actors makes problems of coordination and harmonization, already serious among traditional donors, still more acute and potentially harmful to effectiveness.”).

¹⁴³ Liese and Rosenberg, *supra* at 73 (“A major driving force in these advocacy efforts has been the Global Network for Neglected Tropical Diseases—an alliance of mostly USA-based or UK-based organisations working to control these diseases by 2020, with support from two grants from the Bill & Melinda Gates Foundation. Although harmonisation efforts so far have thus concentrated on advocacy and technical challenges, almost no attention has yet been given to national governance and sustainability challenges. Financing is largely off-budget for many recently established programmes for neglected tropical diseases, almost all in Africa, and special semi-autonomous implementation arrangements are common. *Such arrangements result in a high amount of donor dependence, high transaction costs, and difficulties with sustainability.*”) (emphasis added).

¹⁴⁴ William New, *Pharma Executive To Head Gates’ Global Health Program*, INTELLECTUAL PROPERTY WATCH (Sept. 14, 2011).

¹⁴⁵ World Health Organization, CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION (2012), available at: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf.

¹⁴⁶ Nickel, *supra* at 157.

IP. Yet dominant theoretical frameworks in IP are still those in which the distinction between public regulation in the public interest and/or for the production of public goods contrasted with private exclusive rights generated by IP seems to have hardened rather than dissolved. Global governance theory beckons with the possibility to interrupt this often constraining dichotomy within IP. As one of my respondents put it, “to what extent can [the public sector] lasso the private approaches, the more agile, faster . . . in every sense of the word, more active?”

Of course, many unintended side effects are associated with these distributed governance approaches.¹⁴⁷ Rather than a great transformation, we may be witnessing the advent of a “global multistakeholder bazaar”¹⁴⁸ characterized by the retreat of multilateral organizations, fragmentation if not shattering of state-centric legal frameworks and a corresponding shrinkage of public goods.¹⁴⁹ The capacity of developing countries, already challenged by the unequal distributional impact of globalization, will be stretched even further to be present, much less active within these multiple regulatory nodes. This may advantage

‘experts and enthusiasts,’ the two groups outside government that have the greatest incentive and desire to participate in governance processes. The network form, with its loose, informal, and nonhierarchical structure, only exacerbates this problem. The governance dilemma thus becomes a tri-lemma: we need global rules without centralized power but with government actors who can be held to account through a variety of political mechanisms.¹⁵⁰

This governance “tri-lemma” (global rules, heterarchical oversight and accountability) via government, markets and civil society constitutes a central issue in what has been called the “politics of problem-solving”¹⁵¹ in the production of global public goods¹⁵² “within the praxis and arrangement of administrative power.”¹⁵³ In generating global

¹⁴⁷ Schäferhoff et al., *supra* at 464.

¹⁴⁸ *Id.*

¹⁴⁹ Liese and Rosenberg, *supra* at 74.

¹⁵⁰ Anne-Marie Slaughter, **A NEW WORLD ORDER**, *supra* at 10.

¹⁵¹ Chalmers, *supra* at 352 and 366.

¹⁵² Nico Krisch, *Pluralism and Global Public Goods* (paper presented at NYU IILJ Colloquium, February 29, 2012).

¹⁵³ Chalmers, *supra* at 359.

public goods such as the knowledge or knowledge goods incentivized by IP in particular, even well-intended non-profit NGOs who partner with for-profit partners in PPPs could turn into “[c]ommunities of practice marked by specialization, unrepresentativeness and strong internal bonds of mutual justification.”¹⁵⁴

This paper has uncovered various areas that deserve further exploration in any future research. The nature of “private” in these PPPs is contested and ambiguous. The relationship of partners to each other and to actual control of the PPP is critical. Effectiveness of policy implementation PPPs depends upon demonstrated output, outcomes and impacts—all of which could be the focus of future empirical work. Furthermore, a further disentangling of the impact of PPPs on various IP norms, and their concomitant cumulative policy consequences, is important. Whether social licensing can be successfully deployed primarily for non-commercial goals – or whether it will be held hostage to other licensing concerns such as quality control and/or commercial return on investment—is a significant open question bearing on the scope and reach of PPPs with respect to development goals. And the underlying question of sustainability of these innovative institutional models is a key variable with regard to their long-term impact. Finally, this paper reveals what could be viewed as a three-level framework with respect to governance questions: intra-PPP governance (which may be analogous to governance within firms), intra-network governance arrangements and, finally, the relation of these decentralized governance models to both national and international forms of public law and hierarchy such as multilateral institutions. On the one hand, each PPP may be comprised of a multi-stakeholder governance system; at the other end of the spectrum, PPPs may be nested within other collaborative networks, as partnerships within partnerships. Each of these levels could be profitably explored in more depth.¹⁵⁵

Hybrid actors in the form of PPPs link the IP to the development regimes as regime-straddlers via polyglot networks. Both IP and governance theories lag behind practice on the ground in these and other areas. Thus this paper provides some signposts to a

¹⁵⁴ Id. at 376.

¹⁵⁵ I am indebted to Rochelle Dreyfuss for this apt observation.

fuller understanding of the transnational social processes contributing to glocality¹⁵⁶ or assemblages,¹⁵⁷ as well as to the on-going geological formation of international law.¹⁵⁸

¹⁵⁶ Benjamin R. Barber, *Why Interdependence?* (“Glocality” is a useful neologism that captures the needs of citizens whose participation remains vibrantly local but whose responsibilities must also be global.”), available at: <http://interdependencemovement.org/blog/?p=3504> (February 2012); Sally Engle Merry, *International Law and Sociolegal Scholarship: Toward a Spatial Global Legal Pluralism*, 41 *STUD. L. POL. & SOC’Y* 149, 151-52 (2008) at 151-52.

¹⁵⁷ Saskia Sassen, *Bordering Capabilities Versus Borders: Implications for National Borders*, 30 *MICH. J. INT’L L.* 567, 570 (Spring 2009).

¹⁵⁸ J.H.H. Weiler, *The Geology of International Law – Governance, Democracy and Legitimacy* (2004) Max-Planck-Institut für ausländisches öffentliches Recht und Völkerrecht, available at: http://www.zaoerv.de/64_2004/64_2004_3_a_547_562.pdf.

Appendix: Case Studies

	PPP-A	PPP-B
Type of Development PPP	Policy formation	Policy implementation
Development Focus	Agriculture, Environment, Gender and Labor (sustainable agriculture)	Health (product development)
NGO Mission	“to co-create, in open partnership, a common language of sustainability measures for agriculture that are widely-shared because they are widely valued.”	“to develop novel, advanced products for the diagnosis, prevention and treatment of neglected diseases of poverty. . . . to bring[] diverse talents and resources together and appl[y] them to solve intractable global health problems. Our emphasis on the final goal line — products on the market — sets us apart from other not for profit research groups. We strive to apply the world's best science to the world's worst diseases, and to do so through collaborations and teamwork.”
Type of IP	Data, metrics and standards with which to measure sustainability in agricultural production, leading to or supporting use of certification marks	Patents for drug development for neglected diseases
Public Partners (partial list; U.S.-based unless otherwise indicated; some omitted due to ambiguity in status)	FOUNDING <ul style="list-style-type: none"> • UNCTAD • Centre de coopération internationale en recherche agronomique pour le développement (CIRAD) [France] • Centro Agronómico Tropical de Investigación y Enseñanza (CATIE) 	“Collaborators” <ul style="list-style-type: none"> ○ Centers for Disease Control and Prevention ○ Colorado State University ○ Federal University of Goias [Brazil] ○ Iowa State University ○ LMIV/NIH ○ LSU Veterinary School of Medicine

Private Partners

(partial list; same caveats as above; includes both for-profit and non-profit partners)

<p>[Costa Rica]</p> <p>NON-FOUNDING</p> <ul style="list-style-type: none"> • International Trade Centre (UNCTAD-WTO) • Ministry of Agriculture of Tanzania • International Finance Corporation (World Bank Group) • Consultative Group on International Agricultural Research World Agroforestry Centre (World Bank) 	<ul style="list-style-type: none"> ○ National Institute of Infectious Diseases [Japan] ○ Oswaldo Cruz Foundation-FIOCRUZ [Brazil] ○ UK Consortium on AIDS and International Development ○ Universidade Federal da Bahia [Brazil] ○ Universidade Federal de Uberlandia [Brazil] ○ Walter Reed Army Institute of Research
<p>FOUNDING</p> <ul style="list-style-type: none"> • IISD [Canada] • Centro Agronómico Tropical de Investigación y Enseñanza (CATIE) [Costa Rica] • Sustainable Markets Intelligence Center (CIMS) [Costa Rica] <p>NON-FOUNDING</p> <ul style="list-style-type: none"> • Harvard University Institute for Quantitative Social Science (IQSS) • Financial Alliance for Sustainable Trade • Colombian National Federation of Coffee Growers, the Regional Centre for Social and Economic Studies (CRECE) [Colombia] • ISEAL Alliance [UK] • Instituto de Estudios Peruanos (IEP) [Peru] 	<p>“Collaborators”</p> <ul style="list-style-type: none"> ○ Academia Sinica [Taiwan] ○ Anandaban Hospital [Nepal] ○ Bio Veto Test [France] ○ Case Western Reserve University ○ Chembio Diagnostics Systems, Inc. ○ CTK Biotech, Inc. ○ DiaMed ○ EASE-Medtrend [China] ○ Immune Design Corporation ○ Inbios ○ Medicago ○ Merial ○ NanoPass [Israel] ○ Research Triangle International ○ Seattle Biomed (SBRI) ○ St George's University of London ○ UK Consortium on AIDS and

Public Partners (Funders)	<p>FOUNDING</p> <ul style="list-style-type: none"> • UNCTAD <p>NON-FOUNDING</p> <ul style="list-style-type: none"> • International Trade Centre (UN-WTO) • Swiss Department of Economic Affairs • USAID • Belgian Development Agency 	<p>International Development “Collaborators”</p> <ul style="list-style-type: none"> ○ Army Research Office ○ Biomedical Advanced Research and Development (BARDA) ○ Defense Advanced Research Project Agency (DARPA) ○ NIH/NIAID
Private Partners (Funders)	<p>FOUNDING</p> <ul style="list-style-type: none"> • IISD [Canada] <p>NON-FOUNDING</p> <ul style="list-style-type: none"> • Ford Foundation • NORAD Solidaridad Network [Latin America] • Agricultural Cooperative Development International and Volunteers in Overseas Cooperative Assistance (ACDI/VOCA) 	<p>“Collaborators”</p> <ul style="list-style-type: none"> ○ American Leprosy Mission ○ Bill and Melinda Gates Foundation ○ Eli Lilly Company ○ Global Alliance for TB Drug Development ○ MJ Murdock Charitable Trust ○ Program for Appropriate Technology in Health (PATH)
Other Partners? (e.g., status not determinable)	Yes	Yes
Brief Answers to Structured Interview Questions:		
I. What are PPPs and How Do They Originate?		
1) Are NGOs public or private?	Hybrid	Public or hybrid; aligned

	with the NIH	
2) Do you differentiate not-for-profit from for-profit (non-commercial from commercial) within PPP?	Yes	Yes but mutual benefit critical (benefit to the NGO's social mission and to for-profit's shareholders)
3) Are your final goods public or private?	Public	Public
4) What is the role of public sector in PPPs?	Facilitator, or mitigator of worst-case scenarios	Source of seed money to test technology and push it down the pipeline
5) Impetus for PPP formation from public or private?	Both – some firms saw competitive advantage	Non-profit side first – mission driven and then found for-profit partners “to hand off our technology” and maintain organizational sustainability
6) <i>Impetus to form or join PPP from NGO perspective: opportunity to - contribute technical expertise?</i>	Yes	Yes
7) – to represent or advocate for a particular perspective?	Partly (plays more epistemic than advocacy role)	Partly (epistemic but advocates for mission of addressing neglected diseases)
8) – to address market failure or market niche?	Yes	Yes
9) – to address the issue from a not-for-profit approach as opposed to a “for-profit” approach?	Yes	Yes
10) – to share policy goals with other partners, both public and private?	Yes	Yes
11) - to find a “win-win” solution: gain of	Mostly yes, although some	Yes; win-win-win

efficiencies or resources?	net rent losses in the short term for some actors	(stakeholders win in addition to public and private partners)
12) – to find a best way to manage toward a shared policy goal?	Yes – space to achieve consensus among partners with very different views	Yes – although distinguishes between norms and policy; PPP creates norms, not policy
II. How PPPs Operate: <i>Do PPPs allow the NGO to -</i>		
13) – bring new issues to the attention of policy-makers?	Yes	Not so much; a by-product of what we do as a PDPPP
14) – influence research processes leading to the definition of the policy problem?	Yes – e.g., zeroing in on education metrics as a proxy for child labor	Yes—e.g., indirectly by influencing researchers in developing countries
15) – influence policy formation?	Yes – indirectly	Yes – indirectly. Not a primary focus.
16) If yes, who is steering?	Policy-maker should be public agency; NGO would prefer less power to steer	Policy-maker should be public agency; developing country stakeholder should create policy
17) – monitor compliance?	Yes, but would prefer open licensing to third parties so that compliance can be monitored by many, so long as tools are used appropriately	On scientific tasks but not on the regulatory front
18) – further other organizational goals such as obtaining funding for the NGO?	Yes	Yes
19) – contribute to an additional forum for raising and/or resolving policy conflict?	No	Yes; provides opportunity for developing country to develop priorities within own policy infrastructure
20) – act as a transmission belt or	Yes	Yes; provides good info to

connective tissue between local and global concerns?		developing country partners; less of a mechanism for them to go to WHO or other global regulatory authorities
21) – enable other stakeholders to engage in private regulation, e.g., standard-setting?	Yes	Not yet –may participate in patent pool
22) If yes, does NGO attempt to include other interested stakeholders in the policy process?	Yes	n/a
23) If yes, difficulties in doing so?	Yes – resources, knowledge level of other stakeholders	n/a
<p>III. How PPPs Impact Public Interest Norms in IP: <i>Does the PPP impact:</i></p>		
24) --Innovation?	Yes, but less tangibly than in copyright or patent	No; cost issues only discussed internally
25) --Access to innovation?	Yes	[No]; choosy about licensees in order to ensure quality but can out-license creatively
26) --Production or co-production of other global public goods?	Yes	Yes; reducing disease impact but as an IP (life sciences) organization rather than a public health organization
27) --Work-around existing treaty frameworks?	No – deliberately benchmarks to treaty standards	No – works within IP laws
28) Final thoughts?	Does not care to link directly to certification or trademarks.	Influences norms within public partner; NIH sees value in NGOs, applied science (versus basic science) and job creation

Likes the wiki concept, but may need to license knowledge to provide revenue stream and at same time broaden transparency

Not sure about identity as a “private” actor with 501(c)(3) status as opposed to a public actor with transparency