Dear Innovation Policy Colloquium Participants,

Thank you for taking the time to read this draft. A few notes regarding the genesis of this project. I initially wrote this as a book chapter for an edited volume on intellectual property and human rights. The book project has fallen through, however. In light of this, and what I think are original insights that may be best disseminated by publication as a stand-alone piece, I am now re-writing this piece as a full-length Article. The draft that follows is a version of the book chapter. My goal is to expand upon this version, including by carrying out additional research and re-framing the chapter to engage more deeply with literature on institutional culture and international organizations.

I also plan to expand my research beyond written sources to interviews with staff of WTO and WHO, and possibly also WIPO. I will very likely seek a travel and research grant to go to Geneva and do further archival research.

In light of this, any suggestions for how to expand data-collection efforts and frame or re-structure the Article are very much welcome.

Best,

Laura Pedraza-Fariña

Essential Medicines and Culture Clash: How Competition between the WTO and WHO Shaped Global IP Regimes

Laura G. Pedraza-Fariña[1]

International intellectual property law in the twenty-first century has undergone a foundational shift from a property-centric to a human-rights view as it relates to medicine. Existing explanations for this shift focus almost exclusively on the power struggle between developing and developed countries, and on the influence of a social movement organized around a shared critique of intellectual property rights as hindering access to essential medicines. Yet these explanations leave out the central role of two international organizations, the World Trade Organization (WTO) and the World Health Organization (WHO), and in particular of their permanent staff, who, as I explore in this Article, have been profoundly influential in shaping international intellectual property law at the intersection of trade and global health.

This Article argues that competition between the clashing professional cultures of WHO and WTO staff is a significant missing piece that helps explain the emergence of a human-rights perspective on intellectual property rights. Relying on internal memoranda, public speeches, commissioned reports, and interviews with key stakeholders, this Article traces the history of the involvement of the WHO in intellectual property, trade and global health debates through its interaction with the WTO. It begins by detailing how the signing of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement sidelined the WHO's involvement in intellectual property law, granting jurisdictional control to the WTO, and privileging an economic, trade-based understanding of intellectual property. It then describes how the WHO—through the work of the Essential Drugs Program staff—gained increasing influence over international intellectual property law both by repurposing the concept of essential medicines to include patented medicines and by framing intellectual property rights on essential medicines as implicating the fundamental human right to health. These twin strategies were successful because they capitalized upon an emerging social movement that criticized expansive intellectual property rights, thus catalyzing the creation of a powerful coalition among WHO staff, developing countries, and non-governmental organizations. The clash of these two internal cultures—one privileging an economic, trade-based approach to intellectual property, the other emphasizing a human rights framework—re-enact a long-standing debate about the proper role and scope of intellectual property rights.

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Table of Contents

I. Introduction

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement brought international intellectual property law within the regulatory domain of the World Trade Organization (WTO).[2] Locating the TRIPS agreement within the administrative umbrella of the WTO has been widely regarded as a triumph of the interests of developed countries and the global pharmaceutical industry headquartered there.[3] But no sooner had TRIPS entered into effect that opposition to the Agreement began to coalesce.[4] Capitalizing on its observer status before the Council for TRIPS, the World Health Organization (WHO) began questioning the advantages of TRIPS to developing countries, asking for (and commissioning) empirical research on the potential technology transfer benefits of TRIPS, and advocating for an interpretation of TRIPS flexibilities that framed access to essential medicines as a core component of the human right to health that could trump intellectual property entitlements.[5]

Between 1995 and 2010, the relationship between WHO and WTO staff was openly antagonistic, as staff in the two organizations disagreed over the role of public health principles in interpreting the TRIPS Agreement. In recent years, however, the WHO and the WTO (together with WIPO) have moved from a strategy of competition to one of collaboration. Surprisingly, this new partnership encapsulates the WHO's position—highlighting the importance of a public health perspective in both negotiation and implementation of intellectual property agreements, and emphasizing that "intellectual property rights do not and should not prevent Member States from taking measures to protect public health."[6]

The role of WTO and the WHO in shaping international intellectual property law thus offers a puzzling paradox. Despite vigorous opposition from powerful interests, including most developed countries and the WTO Secretariat itself, the WHO has increasingly assumed a wider role in the area of trade and access to medicines. What explains the WHO's jurisdictional expansion? Two competing views have shaped current

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[2] *See generally* GRAEME B. DINWOODIE & ROCHELLE COOPER DREYFUSS, A NEOFEDERALIST VISION OF TRIPS (2012); CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY (2011); DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT (2002); CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS (2001); Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 278 (1997).

[3] *See, e.g.,* HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO, 43-49 (2007); Dinwoodie & Dreyfuss, *supra* note 2, at 21-30; Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOYOLA L.A. L. REV. 323, 356-58 (2004); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY LAW (2003); Dreyfuss & Lowenfeld, *supra* note 2 at 277 ("[T]he enforcement system of the new WTO was probably one of the most attractive features of the GATT to the intellectual property community.").

[4] Observers note that opposition to the TRIPS Agreement was notably absent during the negotiation stage, largely because most developing countries' delegations lacked relevant expertise, and because consumer groups and NGOs were "reactive and ineffectual." JOHN BRAITHWAITE & PETER DRAHOS, 202 GLOBAL BUSINESS REGULATION (2000). *See also* DUNCAN MATTHEWS, INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS 2 (2011) (noting that "pubic interest non-governmental organizations (NGOs) were generally absent from the debate" during TRIPS negotiations, and remarking that "developing countries simply did not have the knowledge necessary to negotiate effectively on the detailed content of the text of the TRIPS Agreement").

[5] *See* Hestermeyer, *supra* note 3 at 76-78.

[6] *Id.*

understandings of how political forces influence the boundaries of international intellectual property, and have been deployed to explain this paradox. The first, a public choice one, emphasizes the active role of both governments and non-state actors in expanding the number of international organizations that participate in intellectual property law and policy making.[7] The second, a social movements perspective, focuses on the emergence and influence of a social movement around a particular critique of intellectual property rights.[8]

But these perspectives offer an incomplete analysis of the political economy of international intellectual property. A full understanding of this political economy must conceptualize international organizations as more than recipients of lobbying efforts by special interest groups (as do public choice theories) or as targets of social movements.

A new wave of scholarship on international organizations has begun to challenge the conceptualization of IOs as mere state agents.[9] This "cultural turn" within IO scholarship seeks to reconceptualize IOs as bureaucratic entities with specific internal cultures, subcultures, and autonomous goals.[10] This Article contributes to this nascent literature in three ways. First, it advances theoretical debates about the role of culture in international organizations by drawing attention to the importance of cultural competition *among* international organizations. Extant accounts of organizational culture within IOs focus on how internal culture impacts the actions of individual IOs.[11] But culture matters not only to understand how IOs internalize and act upon external demands, but also to understand how they interact with each other in areas of overlapping jurisdiction. Second, drawing from literature in the sociology of the professions and the sociology of expertise, this Article conceptualizes institutional culture as institutional expertise, residing in communities of experts within IOs but embedded within larger epistemic networks.[12] Conceptualizing

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[7] For example, using public choice theory, Laurence Helfer has described the "regime shifting" strategy of developing countries and NGOs who lobby an expanding array of international organizations "seeking ways to recalibrate, revise, or supplement" TRIPS. International organizations whose "institutions, actors, and subject matter mandates are more closely aligned with" developing countries' and NGOs concerns—such as WHO on the topic of access to essential medicines—are predicted to be important targets in a regime-shifting strategy. Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 6 (2004).

[8] Using framing theory, Amy Kapczynski has analyzed how a social movement coalesced around a particular critique of intellectual property rights (the access to knowledge, A2K, movement). In this account, the WHO's increasing involvement in intellectual property policy is in part a result of pressure from the A2K movement Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 807-808 (2008).

[9] *See, e.g.*, PAUL BLUSTEIN, THE CHASTENING: INSIDE THE CRISIS THAT ROCKED THE GLOBAL FINANCIAL SYSTEM AND HUMBLED THE IMF (2001); MICHAEL BARNETT, EYEWITNESS TO A GENOCIDE: THE UNITED NATIONS AND RWANDA (2002); Gayl D. Ness & Steven R. Brechin, *Bridging the Gap: International Organizations as Organizations*, 42 INT'L ORG. 245 (1988); MICHAEL BARNETT & MARTHA FINNEMORE, RULES FOR THE WORLD (2004); RAWI ABDELAL, CAPITAL RULES: THE CONSTRUCTION OF GLOBAL FINANCE (2007); CATHERINE WEAVER, HYPOCRISY TRAP: THE WORLD BANK AND THE POVERTY OF REFORM (2008); JEFFREY M. CHWIEROTH, CAPITAL IDEAS: THE IMF AND THE RISE OF FINANCIAL LIBERALIZATION (2010); GALIT SARFATY, VALUES IN TRANSITION: HUMAN RIGHTS AND THE CULTURE OF THE WORLD (2012).

[10] *See, e.g.,* Stephen Nelson & Catherine Weaver, *Organizational Cultures*, *in* OXFORD HANDBOOK OF INTERNATIONAL ORGANIZATIONS (Jacob Katz Cogan, Ian Hurd, and Ian Johnstone, eds. 2016).

[11] *See, e.g.,* Sarfaty*, supra* note 9 (emphasizing the importance of *internal* conflict between internal communities within the World Bank); Barnett, *supra* note 9; Stephen Nelson, *Playing Favorites: How Shared Beliefs Shape the IMF's Lending Decisions*, 68 INTERNATIONAL ORGANIZATION 297 (2014).

[12] Ruth Okejdii in her analysis of the relationship between WIPO and WTO takes a similar approach, by emphasizing that international organizations develop "institutional identities" that can, independently of state and non-state actors pressure, influence their policy-making. Ruth Okediji, *WIPO-WTO Relations and the Future*

culture as professional expertise allows the framing of institutional competition as one of competition among different professional communities. Third, this Article argues that understanding *how* and *why* IOs interact with each other is crucial to understanding the development of international law in overlapping regulatory domains. These overlapping regulatory domains, for example health and intellectual property/trade, health and the environment, are increasingly important. In fact, given the mounting fragmentation of the international legal regime, one would be hard pressed to find international legal issues that cannot be framed as belonging to the intersection of two or more international organizations.[13] This Article develops these three points through a case study of the evolving relationship between the WTO and the WHO in their overlapping domains of patents and access to medicine.

Drawing on work from the sociology of expertise and the sociology of the professions, this Article analyzes the interactions between the WTO and the WHO as analogous to those among distinct communities of experts. When domains of expertise overlap, expert communities are predicted to compete with each other for dominance by framing overlapping issues as uniquely suited to solution by their expert skills. At the intersection of intellectual property and public health, and despite an initial arrangement that favored the WTO, the WHO successfully expanded its domain of expertise over intellectual property norms by framing the regulation of essential medicines as implicating the fundamental human right to health.

The remainder of this Article proceeds as follows. Part 2 provides a brief overview of the field of sociology of expertise as applied to institutional actors. It then shows how both WTO and WHO can be conceptualized as two distinct expert communities. Part 3 charts the evolution of WTO and WHO policy with regard to access to essential medicines. It focuses on how WHO used human rights rhetoric as a framing device to expand its domain of expertise (and thus its influence) over intellectual property law. Part 4 concludes by analyzing the normative implications of this expert community approach for the debate about fragmentation in international law.

II. An Expert Community Approach

An important sociological tradition has studied the institutional organization of expertise in society.[14] This institutional approach to expertise analyzes how organized groups of experts interact with each other and with society at large.[15] For example, sociologists have studied how psychiatrists have competed with psychologists and social workers in the field of mental health by seeking control over the drafting of the Diagnostic and Statistical Manual of

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of Global Intellectual Property Norms, 39 NETHERLANDS YEARBOOK OF INTERNATIONAL LAW 69, 79 (2008) ("The contested orthodoxy with which WIPO administered its mandate is one that originated not with the states but with WIPO independently; WIPO structured that orthodoxy around its institutional identity.")

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14 For a review of the literature, *see* Elizabeth H. Gorman & Rebecca L. Sandefur, *"Golden Age," Quiescence, and Revival: How the Sociology of Professions Became the Study of Knowledge-Based Work*, 38 WORK & OCCUPATIONS 275 (2011).

15 *See, generally* ANDREW ABBOTT, THE SYSTEM OF PROFESSIONS: AN ESSAY ON THE DIVISION OF EXPERT LABOR (1988); E. FREIDSON, PROFESSIONALISM: THE THIRD LOGIC (2001).

Mental Disorders (DSM).[16] My own work has used sociology of expertise as a lens to analyze the behavior of the Federal Circuit (a specialized court with almost exclusive jurisdiction over patent appeals in the United States), and its interaction with generalist courts and the specialized agency in charge of patent issuance (Patent and Trademark Office, PTO).[17]

Early research on the sociology of expertise identified jurisdictional competition as the single most important driving force in the interaction between and among expert communities.[18] Having complete jurisdictional control means having the power to define and classify a problem, to define and apply the correct treatment, and to evaluate the treatment's success.[19] Because a particular problem is often amenable to study and solution by multiple expert groups and approaches, competition takes place at the overlap, where multiple expert groups can make a case for jurisdiction over a particular problem.[20]

Expert communities compete for jurisdictional control by framing overlapping problems as best solved through a particular expert community's own knowledge system.[21] Thus, an expert community will often compete for jurisdiction by "reduc[ing] the work of competitors to a version of their own."[22] The extension of the field of international trade law into the area of services and intellectual property is an example of such a re-framing.[23] Under this account, all of intellectual property is trade-related because minimal intellectual property protections are required to support well-functioning global markets.[24]

The traditional sociological account of expertise sees the ultimate goal of any community of experts as exerting absolute control and autonomy over its jurisdiction. Competition for autonomy and control is endless: some communities of experts disappear as a result of this competition, and new ones emerge to take their place. Absolute control and autonomy is seldom possible, however, and studies have described a series of intermediate arrangements that arise from jurisdictional competition. For example, one community may become subordinate to another, or there may be a division of labor between two or more communities.[25] All of these arrangements are ultimately unstable and subject to renewed jurisdictional competition: subordinate communities are constantly seeking to assert more

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[16] *See, e.g.,* STUART A. KIRK & HERB KUTCHINS, THE SELLING OF DSM: THE RHETORIC OF SCIENCE IN PSYCHIATRY 10 (1992) (describing the drafting of the DSM as part of a strategy by psychiatrists "to assert leadership in developing an official language about mental disorders.").

[17] Laura Pedraza-Farina, *Understanding the Federal Circuit: A Model of Expert Decision-making*, 30 BERKELEY TECH. L.J. (forthcoming 2015).

[18] *See, e.g.,* Abbott *supra note* 15, at 2 ("It is the history of jurisdictional disputes that is the real, the determining history of the professions.")

[19] *Id.*

[20] *Id.* at 39-40. *See also* Pedraza-Farina, *supra* note 17, at ____.

[21] Abbott, *supra* note 15, at 40; Pedraza-Farina, *supra* note 17, at ____. An important second mechanism of jurisdictional competition (codification or rule-making) will not be discussed in this Article. Codification allows expert communities to delegate tasks to subordinate communities while retaining control over the abstract principles that make the rules.

[22] Abbott, *supra* note 15, at 36

[23] *See* G. VELASQUEZ & P. BOULET, GLOBALIZATION AND ACCESS TO DRUGS: PERSPECTIVES ON THE WTO/TRIPS AGREEMENT 20 (1999).

[24] *See, e.g.,* Andrew T.F. Lang, *Legal Regimes and Professional Knowledge: The Internal Politics of Regime Definition*, *in* REGIME INTERACTION IN INTERNATIONAL LAW: FACING FRAGMENTATION 113, 119 (Margaret A. Young, ed. 2012) ("[T]he politics of international trade came to be played out in part as a struggle over which governmental measures could and should be redescribed as distortions of trade, and therefore as legitimate subjects of discipline through international trade law").

[25] Abbott *supra* note 15, at 69-79.

independence and control; the boundaries of particular divisions of labor are never fixed. A key element in jurisdictional settlement is legitimation by relevant audiences and the broader public. In other words, the authority of the profession's knowledge to address a particular social problem should "shape, indeed, the very public idea of the tasks that the profession does."[26]

Yet, knowledge-sharing and cooperation, which should be anomalous from this point of view, are surprisingly common practices. More recent studies in the sociology of expertise have begun to study how people from distinct expert communities—with different and often conflicting commitments to interpretive frameworks and research tools—come together to define and work on shared problems.[27] One important finding from these studies is that collaboration can take place without consensus, even on fundamental issues.[28]

Recent studies of expert communities have also begun shifting their focus from studying expert communities and organizations to analyzing expert networks that reach beyond particular expert communities. These studies argue that a full understanding of expertise requires examining the set of relationships (or the network) among individuals, institutions, concepts and techniques that enable a particular community of experts to claim control over a set of problems.[29]

Membership into a particular expert group (or network)—whether formal or informal—is achieved through a process of socialization into particular expert practices, values and world-views. It is these values and worldviews that are pitted against each other in jurisdictional contests. Under a sociological view of expertise, having individually mastered a set of abstract principles and their application to concrete problems through repeated practice is only part of what it means to become an "expert."[30] Expertise also requires "enculturation:" interactively immersing oneself into expert culture.[31] Both becoming and continuing to be an "expert" requires embeddedness in the relevant expert community: "expertise can be lost if time is spent away from the group."[32]

Several international law and international relations scholars have analyzed the rise of "the managerial mindset"[33] in international organizations.[34] For example, Marti Koskennniemi argues that the language of expertise—claiming neutrality and universality—obscures important structural biases arising from specialization that tend to favor "some solutions,

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[26] Abbott *supra* note 15, at 71. *See also* E. JOHANNA HARTELIUS, THE RHETORIC OF EXPERTISE 1 (2011) ("Expertise is not simply about one person's skills being different from another's. It is also grounded in a fierce struggle over ownership and legitimacy.).

[27] *See, e.g.*, Gil Eyal & Grace Pok, *From a sociology of professions to a sociology of expertise*, *available at* http://cast.ku.dk/papers_security_expertise/Eyal__2011_From_a_sociology_of_professions_to_a_sociology_of_expertise.pdf/.

[28] *See, e.g.,* Adele E. Clarke and Susan Leigh Star, *The Social Worlds Framework: A Theory/Methods Package, in* THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES 113, 125-127 (Edward J. Hackett, Olga Amsterdamska, Michael Lynch & Judy Wajcman eds., 2008).

[29] *See, e.g.,* Eyal, *supra* note 27, at 868-71.

[30] *See generally* HARRY COLLINS & ROBERT EVANS, RETHINKING EXPERTISE (2007)

[31] Collins & Evans, *supra* note 30, at 23-24.

[32] Collins & Evans, *supra* note 30, at 3.

[33] Marti Koskenniemi, *The Fate of Public International Law*, 70 MODERN L. REV. 1, 27-30 (2007).

[34] *See generally id.*; Martti Koskenniemi, *The Politics of International Law – 20 Years Later*, 20 EUR. J. INT'L L. 7 (2009); David Kennedy, *The Politics of the Invisible College: International Governance and the Politics of Expertise*, 5 EUR. HUMAN RIGHTS L. REV. 463 (2001).

some actors, some interests" at the expense of others.[35] David Kennedy has argued that international scholars should focus on making visible the "politics of expertise" by examining the background assumptions that underlie the professional vocabularies of international organizations.[36] These accounts describe how professional experts and their technical dialects have replaced the political processes traditionally associated with international institutions. They share a pessimistic and critical view of the professionalization of international institutions: technocratic governance is seen to obscure real political and distributional choices by presenting its decisions as irrevocably following from the rational application of professional tools and logic. But analyses of the professionalization of international institutions have insufficiently focused on the dynamics of expert competition and collaboration. It is through this competitive relationship in overlapping regulatory domains that norms can be both negotiated and contested. Competition among expert international institutions can thus mitigate the perils associated with technocratic governance.

The remainder of this Article analyzes one such instance of competition—that between the WTO and the WHO at the intersection of intellectual property and global health.

A. WTO and WHO as Expert Communities within Networks of Trade and Public Health Expertise

The claim for conceptualizing WTO and WHO as expert institutions that are part of distinct expert networks is straightforward: these two international organizations are key members in two distinct networks of expertise—one that revolves around international trade and a second one that revolves around international public health. Until relatively recently, these two networks did not routinely interact.

The WTO was established on April 15, 1994 at the conclusion of the Uruguay Round of trade negotiations.[37] Its function is to administer WTO trade agreements (including TRIPS), provide a forum for trade negotiations and handle conflicts arising from any of these agreements through a unified dispute settlement mechanism.[38] Many commentators have analyzed the reasons for the shift from WIPO to GATT/WTO as a forum to negotiate a comprehensive intellectual property agreement.[39] Primary among them was the ability to bring the relatively hard-line WTO dispute settlement mechanism to bear on issues of intellectual property enforcement.[40] Under this mechanism, Member States have an automatic right to the creation of a panel following the filing of a complaint. Panel reports can only be rejected by a consensus of all Member States against adoption. Appeals can only be filed with a standing Appellate Body. Failure to abide by panel and Appellate Body decisions can have important economic consequences—leading to suspension of concessions or obligations under the same or a different agreement under WTO supervision.[41]

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[35] Koskenniemi, *supra* note 34, at 11.
[36] Kennedy, *supra* note 34, at 465.
[37] Agreement Establishing the World Trade Organization, Apr. 15, 1994, Art. IV.5, 33 I.L.M. 1125 (1994).
[38] *Id.*
[39] *See, e.g.,* Sell, *supra* note 3; Dinwoodie & Dreyfuss *supra* note 2, at 21-45; Helfer *supra* note 7, at 18-23; Hestermeyer *supra* note 3, at 39-49.
[40] *See, e.g.,* Helfer *supra* note 7, at 22.
[41] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, Article 22, 33 I.L.M. 1125 (1994) [hereinafter DSU]. Although sanctions are usually imposed under the agreement violated, the DSU allows the imposition of sanctions under a different WTO agreement when

The dispute resolution panels and the standing Appellate Committee are crucial components of the international trade system, as they both interpret and apply WTO law. Importantly for the purpose of this Article, it is experts in trade who must staff both these bodies. In fact, WTO law requires that panel and Appellate Body members be experts in trade law. Article 8(1) of the Dispute Settlement Understanding (DSU) requires panels to be composed of "well-qualified governmental and/or non-governmental individuals." In turn, being "well-qualified" for panel membership requires having expertise in trade law.[42] The same is true of Appellate Body membership: "The Appellate Body shall comprise persons of recognized authority, with demonstrated expertise in law, international trade and the subject-matter of the covered agreements generally."[43] In addition to panel and Appellate Body membership, the WTO Secretariat is also composed mostly of professionals with expertise in trade law.[44] Finally, the WTO has a large administrative infrastructure, composed of over 35 committees, working parties, and review bodies.[45] The work of these committees is often "hidden from view" and has not been fully documented in the academic literature.[46] But it is potentially in these committees that the "'background norms' of international economic governance are produced in less formal ways."[47] Because committees often lend technical support to Member States, they can be conceptualized as "sites in which government delegations are exposed to knowledge produced in expert communities."[48] In turn, the expert communities in WTO committees are organized around trade principles.[49]

From a sociology of expertise perspective, the WTO—and the network of trade experts in which it is embedded—is likely to constitute a community with a shared set of values, assumptions, and tools with which to address social problems. It is unsurprising that this expert community has used the language of trade—and of trade benefits—to seek jurisdiction over an expanding array of social problems.[50]

In contrast, the WHO sits within a distinct network of expertise in global health.[51] Its Executive Board[52] is composed of 34 members, each serving for a three-year term, and each

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sanctions within the same agreement are "not practicable or effective"—an option known as "cross-retaliation." *Id.* Article 22.3 (b)-(c).

[42] Article 8(1) defines "well qualified" as "including persons who have served on or presented a case to a panel, served as a representative of a member or of a contracting party to GATT 1947 or as a representative to the Council or Committee of any covered agreement or its predecessor agreement, or in the Secretariat, taught or published on international trade law or policy, or served as a senior trade policy official of a Member." Representatives of member states or contracting parties are generally trade experts. *See also* Gabrielle Marceau, *WTO Dispute Settlement and Human Rights*, 13 EJIL 753, 765-66 (2002) ("[P]anellists and members of the Appellate Body are trade experts . . . .")

[43] Article 17(3) of the DSU.

[44] https://www.wto.org/english/thewto_e/secre_e/intro_e.htm. "The professional staff is composed mostly of economists, lawyers and others with a specialization in international trade policy."

[45] Andrew Lang & Joanne Scott, *The Hidden World of WTO Governance*, 20 EJIL 575, 575 (2009).

[46] *Id.*

[47] *Id.* at 612.

[48] *Id.*

[49] *Id.* at 612-13.

[50] *See, e.g.,* Richard B. Stewart & Michelle Ratton Sanchez Badin, *The World Trade Organization and Global Administrative Law, in* CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION (Christian Joerges & Ernst-Ulrich Petersmann eds., 2009).

[51] The field of global health includes not only basic and applied medical research, but also epidemiology, pharmacoeconomics, health economics and health regulation research.

[52] The main functions of the Board are to give effect to the decisions and policies of the Health Assembly, to advise it and generally to facilitate its work.

"technically qualified in the field of health."[53] The WHO Secretariat is "staffed by some 7000 health and other experts and support staff on fixed-term appointments."[54] The WHO's traditional core areas of research (and thus of expertise) are pandemics and infectious disease control; non-communicable diseases; and identifying underlining social determinants of health.[55] It was not until relatively recently, that WHO expanded its expertise base to include an intellectual property and trade component. In 2006, WHO created a new Secretariat on Public Health, Innovation and Intellectual Property (PHI).[56] The new Secretariat represents the culmination of a series of WHO resolutions calling for a deeper understanding of the effects of the TRIPS Agreement on access to essential medicines, technology transfer, and global innovation. The PHI supports analyses of trade and health issues, and provides technical support to countries wishing to take advantage of TRIPS flexibilities.[57] Importantly, it has catalyzed the training of a new cadre of experts at the intersection of intellectual property and public health.

The next sections chart the WHO's expanding jurisdiction into the IP/public health intersection, its relationship with the WTO, and its key use of human rights language.

III. Access to Essential Medicines and the Role of Human Rights Rhetoric

A. Negotiating TRIPS—Shifting Jurisdiction to WTO by Framing Intellectual Property as a Trade Issue

The framing of intellectual property rights as a trade issue during the Uruguay Round of trade negotiations, as well as the expansion of the types of social problems that came to be seen as "trade problems," has been well-documented and examined in the academic literature.[58] During negotiations of the TRIPS Agreement, developed countries (and in particular the United States, EU countries, and Japan) framed trade in counterfeit goods as creating important trade distortions.[59] This argument placed intellectual property as the key issue for international trade liberalization in the knowledge economy: lack of global minimum standards of IP protection threatened the liberalization project and had the potential to erase any benefits bargained for in the GATT. The United States had already singled out the problem of weak protection for U.S. intellectual property as a priority in

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[53] http://www.who.int/governance/eb/en/

[54] http://www.who.int/governance/en/

[55] *See* http://www.who.int/about/what-we-do/en/. *See also* Tim K. Mackey & Bryan A. Liang, *Promoting global health: utilizing WHO to integrate public health, innovation and intellectual property*, 17 DRUG DISCOVERY TODAY 1254, (2012).

[56] Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action, WHA59.24 (May 27, 2006) [hereinafter WHA59.24].

[57] http://www.who.int/phi/about/en/

[58] *See, e.g.,* Sell, *supra* note 3; DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND INTERPRETATION (2008); Okediji, *supra* note 9; Molly Land, *Rebalancing TRIPS,* 33 MICH. J. INT'L L. 433, 451 (2012) ("Situating intellectual property disputes within a trade dispute resolution mechanism has led to jurisprudence that is both internally incoherent and inconsistent with the goals of intellectual property balancing and the proper interpretation of the TRIPS Agreement.").

[59] TRIPS Agreement, at 320 ("Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.");

bilateral trade negotiations and as a target for trade retaliation.[60] Industry groups, mobilized and organized through an "Intellectual Property Committee," played an important role in the United States' efforts to link intellectual property to trade, their efforts bolstered by Congressional concerns about domestic trade deficits, especially with Japan (a country with a relatively closed market).[61]

Prior to the TRIPS Agreement, intellectual property and trade were two distinct areas of the law practiced by distinct expert communities with little overlap.[62] Therefore, this framing represented a jurisdictional expansion of the community of experts in trade and the (at least partial) subordination of WIPO to WTO as the forum for addressing global intellectual property disputes and policies.[63] Indeed, Ruth Okediji has argued that the 1996 WTO-WIPO Agreement can be interpreted as codifying a hierarchical relationship between the two international organizations, in which WIPO takes a subordinate position.[64]

The creation of the WTO and the expansion of the field of international trade law into the area of services and intellectual property also brought into conflict two areas of the law–global public health and intellectual property.[65] In the specific area of intellectual property law, the TRIPS Agreement has clear consequences for global public health and for access to medicines more specifically: once fully implemented (by 2016 for least developed countries) patent holders will be able to set the price of new medicines worldwide.[66] The TRIPS Agreement, however, gives jurisdictional primacy on the regulation of medicine pricing to the community of experts in trade law over the public health community.[67] Public health experts are not regularly included in (nor consulted by) trade delegations.[68] And despite the WHO's consistent participation in meetings of the TRIPS Council through its *ad hoc* observer status, both the EU and US trade delegations to the TRIPS Council have argued that much of WHO's advice on how to balance intellectual property and public health considerations is outside its mandate.[69]

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[60] Omnibus Trade Act of 1988.

[61] *See, e.g.,* Sell, *supra* note 3; A. Koury Menescal, *Those Behind the TRIPS Agreement: The Influence of the ICC and the AIPPI on International Property Decisions,* 2 INTELL. PROP. Q. 155 (2005). *See also* Margot E. Kaminski, *The Capture of International Intellectual Property Law Through the U.S. Trade Regime,* 87 SO. CAL. L. REV. 977 (2014) (arguing that institutional capture of the Office of the U.S. Trade Representative (USTR) by industry groups through its IP Advisory Committee—consisting only of IP-intensive industries— has led the USTR to advocate for levels of intellectual property protection that in some cases exceed those available domestically in the U.S.).

[62] *See* Hestermeyer *supra* note 3, at 46 n. 194 (citing statements by trade and intellectual property practitioners attesting to their lack of expertise in each others' practice domains); Dreyfuss & Lowenfeld, *supra* note 2, at 278 (noting that "the trade community and the intellectual property community do not know each other well").

[63] Laurence Helfer has described this movement from WIPO to the WTO as the forum to negotiate a global intellectual property agreement as part of a "regime shifting" strategy by developed nations seeking a more favorable forum. Helfer *supra* note 7, at 19-23.

[64] Okediji, *supra* note 9, at 98-100; Agreement between the World Intellectual Property Organization and the World Trade Organization, Dec. 22, 1995, 35 I.L.M. 754 (1996).

[65] *See generally,* Ellen R. Shaffer, Howard Waitzkin, Joseph Brenner & Rebeca Jasso-Aguilar, *Global Trade and Public Health*, 95 AM. J. PUBLIC HEALTH 23, 23 (2005).

[66] *See* Richard Laing, Brenda Waning, Andy Gray, Nathan Ford & Ellen 't Hoen, *25 Years of the WHO Essential Medicines Lists: Progress and Challenges*, 361 LANCET 1723, 1727 (2003).

[67] *Id.*

[68] *See, e.g.,* Shaffer, Waitzkin, Brenner & Jasso-Aguilar, *supra* note 65, at 23; Kaminski, *supra* note 61, at 1000-03.

[69] *See* Laing *et al.*, *supra* note 66, at 1728.

B. After TRIPS: WHO-WTO Conflict and Competition in the Pre-Doha Period

Shortly after the signing of the TRIPS Agreement, the WHO began a broad consultative process to develop a new global health policy framework that took into account the globalization challenges of the twenty-first century.[70] The result of this process was the document "Health for All: Policy for the 21st Century (HFA),"[71] which explicitly tied health to economic development and emphasized health as a global priority in the new U.N. development agenda.[72] HFA provides a conceptual framework for WHO's future work on global health. In addition to linking health to development, HFA contained two important conceptual developments that would later be used as frames to argue for WHO jurisdiction at the intersection of trade and intellectual property. First, it emphasized the importance of recognizing health as a fundamental human right. Conceptualizing health as a fundamental right ("the right to health") was not new—the WHO constitution already did so.[73] But HFA made explicit that WHO should "implement health aspects of international human rights treaties," thus bringing human rights law and its interpretive framework to bear on the content and scope of the WHO's mandate.[74] On December 1997, a month before the publication of HFA, WHO began an informal consultation process with the Office of the High Commissioner of Human Rights on human rights and health.[75]And in 2000 WHO started work towards a strategy document which incorporated health and human rights into the policy and program work of the WHO.[76] Health and human rights are currently considered relevant to each of the WHO's four strategic directions.[77]

Second, HFA highlights the liberalization of global trade as a key twenty-first century variable with important consequences for health outcomes that remain to be explored. And it emphasizes the WHO's role in evaluating the potentially negative impact of trade policies on health, and in advocating for alignment between trade policies and HFA's goals. This was clearly the position taken by WHO staff: in a publication meant "to be read in conjunction with HFA,"[78] co-authors Fernando S. Antezana, then- Assistant Director-General of the WHO, Claire M. Cholat-Traquet, then Director of the Division of Development of Policy, Programme and Evaluation, and Derek Yach, then member of the Policy Action

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[70] WHA48.16 (May 1995).

[71] Health-for-all policy for the twenty-first century, WHA51.7 (May 16, 1998) [hereinafter Health-for-all].

[72] The new development consensus emerged from a series of eight U.N. world conferences that took place between 1990 and 1996. The conferences were: World Summit for Children (1990); United Nations Conference on Environment and Development (1992); World Conference on Human Rights (1993); International Conference on Population and Development (1994); World Summit for Social Development (1995); Fourth World Conference on Women (1995); Second United Nations Conference on Human Settlements (Habitat II) (1996); World Food Summit (1996).

[73] Constitution of the World Health Organization, Preamble: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."

[74] Health-for-all, *supra* note 71. *See also* Fernando S. Antezana, Claire M. Chol-Traquet & Derek Yachc, *Health for All in the Twenty-First Century*, 51 WORLD HEALTH STAT. QUART. 3 (1998) ("The foundational role of certain values is emphasized in the new policy. . . The values are: recognition that the enjoyment of the highest attainable standard of health is a fundamental human right ("the right to health") . . .")

[75] Collaboration within the United Nations System, EB 101.17 (Nov. 17, 1997).

[76] *See* Sofia Gruskin & Daniel Tarantola *Health and Human Rights, in* PERSPECTIVES ON HEALTH AND HUMAN RIGHTS 3, 24 (2005)

[77] *Id.*

[78] Antezana, Chol-Traquet & Yachc, *supra* note 74, at 1 ("the Health-for-All Policy for the 21st century should be read in conjunction with this volume.")

Coordination Team, interpret HFA as "call[ing] for urgent attention to be given to several emerging *negative* aspects of globalization, [including] the implementation of trade agreements that may limit access of the poorest countries to essential drugs and technologies for health."[79] HFA serves as the policy backdrop for a series of efforts by the WHO (and specifically by departments within the Secretariat, most notably the Essential Medicines Division) to bring discussions of the impact of trade on health—and in particular on access to essential medicines—within the confines of the WHO.

Since the passage of the HFA, the WHO has increasingly assumed a wider role in the area of trade and access to medicines. This new role includes providing advice and technical assistance to developing countries on the implementation of TRIPS Agreement flexibilities to ensure the broadest possible access to essential medicines, and commissioning independent reports on the impact of TRIPS on technology transfer and access to technology and essential medicines, among others. The WHO's new role has now become part of its institutional identity and structure: the PHI Secretariat is explicitly tasked with working at the "interface between public health, innovation, research, transfer of technology and intellectual property."[80]

The WHO's involvement in intellectual property policy, and its public health perspective, has been met with opposition from powerful interests, including the WTO Secretariat itself. This opposition was particularly prominent prior to the signing of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health ("Doha Declaration").[81] Both the United States and the European Union have consistently opposed granting the WHO influence in the interpretation of international intellectual property agreements,[82] characterizing WHO's involvement in patents on medicines as "tangential" to its core public health mission.[83] And several studies report an "acrimonious" relationship between WTO and WHO staff, stemming in part from their divergent interpretative stances regarding the TRIPS Agreement.[84]

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[79] *Id.* at 5. [emphasis added].

[80] http://www.who.int/phi/about/en/

[81] WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1,41 I.L.M. 746 (2002) [hereinafter Doha Declaration]. Paragraph 4 of the Doha Declaration on TRIPS and Public Health reaffirms Members' rights to take measures "to protect public health": "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

[82] Cable from the United Kingdom to the U.S. Department of Commerce, Secretary of State, and to the Mission to the European Union in Brussels, November 1, 2007, available at https://www.wikileaks.org/plusd/cables/07LONDON4102_a.html (stating that UK delegates from the Intellectual Property Office and the Department of Health agree with the Untied States that the WHO should not have "*any* role in determining international agreements on intellectual property.")

[83] *Id.* ("UK DH (Department of Health) wants the WHO's emphasis to remain on public health and not become involved with *tangential* issues.") (emphasis added). Similarly, at a USPTO-sponsored event in India, the U.S. Ambassador to India expressed the view that the WHO "had no role to play regarding intellectual property." Ho, *supra* note 2, at 346.

[84] *See, e.g.,* FATOUMATA JAWARA & AILEEN KWA, BEHIND THE SCENES AT THE WTO: THE REAL WORLD OF INTERNATIONAL TRADE NEGOTIATIONS 212-215 (2003) (describing the collaboration between the WTO and WHO leading to a joint 2002 publication as "long and acrimonious"); Jean Frédéric Morin & E Richard Gold, *Consensus-seeking, distrust and rhetorical entrapment: The WTO decision on access to medicines*, 16 EUR. J. INT'L REL. 563, 574-75 (2010) (based on interviews conducted with key actors between 2006 and 2007 authors remark that

What explains the WHO's continued jurisdictional expansion in the face of such initial opposition? In part, this expansion has undoubtedly been fueled by developing country and NGO coalitions that have looked to the WHO and its public health mission as a forum friendlier to their interests.[85] But a separate story complements that of regime shifting and social movements: departments within the WHO, with their own expert culture and priorities, themselves lobbied for "expanding" the WHO's jurisdiction. They did so by framing access to essential medicines as a human right that should take priority over commercial interests. This framing took place in different fora: at Council for TRIPS meetings; at Executive Board and World Health Assembly negotiations; through WHO publications; through formal and informal training sessions; and through commissioned and broadly disseminated reports by independent public health experts that highlighted the public health dimension of intellectual property.

An important way in which the WHO advanced its policy agenda as outlined in the HFA before the WTO—and competed for jurisdiction in the area of trade, intellectual property, and health—was through its *ad hoc* observer status before the Council for TRIPS. Organizations with observer status before WTO bodies do not have the right to "circulate papers or to make proposals . . . nor to participate in decision-making."[86] But they do have available other, less formal, avenues to influence policy-making. For example, its observer status allowed the WHO to attend meetings of the Council and receive copies of all documents submitted to it.[87] In turn, simply being present at Council meetings placed WHO representatives in a position to provide informal technical advice to Member States "both inside WTO negotiating rooms and in the all important hallways outside."[88]

The TRIPS Council also invites intergovernmental organizations with observer status to file information on "their technical cooperation programs relating to the implementation of the TRIPS Agreement."[89] The WHO has filed updates of its activities relevant to TRIPS implementation almost every year since obtaining observer status in the year 2000. Three key aspects of these reports are worth noting. First, beginning with its first submission to the Council in the year 2000, the WHO has emphasized that the concept of health as a human right serves as a guiding principle that puts access to essential medicines on at least equal footing with intellectual property protection for innovators—and as a priority policy for the WHO.[90] WHO communications also make clear that strong intellectual property protection will sometimes be at odds with public health goals.[91] Second, justified by its emphasis on the

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"[m]any interviewees noted tensions between the WTO and the WHO and attributed a bias toward developed and developing countries to each, respectively.").

[85] *See, e.g.,* Matthews, *supra* note 4.

[86] General Council, Guidelines for Observer Status for International Intergovernmental Organizations in the WTO, WT/L/161 (July 25, 1996).

[87] *Id.*

[88] Laurence Helfer, *Mediating Interactions in an Expanding International Intellectual Property Regime*, 36 CASE W. RES. J. INT'L L. 123, 130 (2004).

[89] https://www.wto.org/english/tratop_e/trips_e/intel9_e.htm

[90] *See, e.g.,* IP/C/W/202 (Aug. 31, 2000) ("[A]ccess to health and therefore essential drugs is a human right."); IP/C/W/305/Add.3 (Sept. 25, 2001) ("The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, as defined in the Constitution of the World Health Organization. Progressive realization of that right involves access to health facilities, prevention, care, treatment and support, including access to medicines.").

[91] *See, e.g.,* WHO, Globalization, TRIPS and access to pharmaceuticals, WHO Policy Perspectives on Medicines, No. 3, March 2001, at 2 (noting that "current [intellectual property] standards – historically derived from those of developed countries – are not necessarily appropriate for countries struggling to meet health and

fundamental nature of the right to health, the WHO has strongly endorsed the use of *any* TRIPS flexibilities by developing countries (including compulsory licenses) to ensure the availability of essential medicines to those who need them.[92] Third, the WHO has advocated for the inclusion of public health experts in national and international discussions regarding intellectual property laws, and has spearheaded the creation of a cadre of experts in public health and trade, housed within the WHO.[93]

Debates within the World Health Assembly have also played a crucial role in the competition for jurisdiction over international intellectual property norms. The WHO's mandate to monitor the impact of the TRIPS agreement on public health derives from two World Assembly resolutions: WHA 52.19[94] and WHA 54.11.[95] The resolutions base the WHO's institutional authority in the area of intellectual property and trade on WHO's long-standing role in "promoting the essential drugs concept."[96] The drafting of WHA Resolution 52.19 (the "Revised Drug Strategy"), however, was the site of significant controversy between developed and developing countries' blocs regarding the balance and hierarchy between public health and commercial considerations. An initial draft proposed by the WHO's Executive Board called on Member States to "ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies."[97] The U.S. delegation feared that this language could "undermine intellectual property rights (IPR) guaranteed under the WTO TRIPS Agreement, and could eventually have wide-ranging IPR implications."[98] The European Union raised similar concerns.[99] Ultimately, the 1999 Final Revised Drug Strategy removed language that suggested public health interests should take precedence over commercial, intellectual property ones, urging Member States instead "to ensure that public health interests are paramount in pharmaceutical and health policies."[100]

This controversy, including the intensifying AIDS crisis, which was a key background element in the debate, has been well documented in the literature.[101] But a feature that has not been sufficiently explored is the role of expert groups within the WHO, and of the rhetoric of expertise itself, in framing intellectual property and trade as a health issue. The WTO and the WHO (as well as NGOs and individual member states) have used

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development needs.")

[92] *See, e.g.,* IP/C/W/202 (Aug. 31, 2000) ("WHO supports any measure which will improve access to all essential drugs, including mechanisms to promote competition, such as: price information; generic policies; reduced duties, taxes, mark ups; parallel imports; application of WTO/TRIPS safeguards, such as compulsory licensing, exceptions which can promote generic competition (Bolar provisions) and the extension of the transitional period."); Globalization, TRIPS and access to pharmaceuticals*, supra* note 91, at 1 (arguing that it is "imperative that health officials work closely with other parts of government, such as the trade department, and use top-level legal, trade and pharmaceutical expertise when legislation is being drafted.").

[93] *See, e.g.,* Globalization, TRIPS and access to pharmaceuticals*, supra* note 91, at 2, 6 ("A network of legal experts who have specialized knowledge and understanding of the public health and pharmaceutical impact of international trade agreements is being developed as a resource for developing countries.").

[94] Revised Drug Strategy, WHA 52.19 (May 24, 1999) [hereinafter Revised Drug Strategy].

[95] WHO Medicines Strategy, WHA 54.11 (May 21, 2001).

[96] Revised Drug Strategy, *supra* note 94, at 1.

[97] EB101.R24, Agenda Item 9 (Jan. 27, 1998).

[98] U.S. Department of State cable, Revised Drug Strategy at WHO: Atmospherics of the Debate, and Recommended Plan of Action (May 27, 1998) http://keionline.org/node/920. [hereinafter U.S. Department of State cable].

[99] European Commission (DG 1) note on the WHO's Revised Drug Strategy, http://www.cptech.org/ip/health/who/eurds98.html; Department of State cable, *supra* note 98.

[100] Revised Drug Strategy, *supra* note 94.

[101] *See, e.g.,* Hestermeyer, *supra* note 3, at 11-15; Ho, *supra* note 2, at 326-335.

the rhetoric of expertise as a weapon to minimize the involvement of the "competitor" institution and as a shield to deflect any critiques to their own policies. For example, at the WHO, the Action Programme on Essential Drugs (DAP)—a group of experts with backgrounds largely in health, and tasked with implementing WHO's essential drugs policy—has been a key player in evaluating the effect of TRIPS on development, production, marketing and pricing of essential drugs. The "essential drugs" concept was introduced by the WHO in the 1970s and has been a cornerstone of the WHO's efforts in global public health: "to ensure equity of access to essential drugs, rational use, and quality."[102] Following the passage of TRIPS, DAP began a series of projects designed to evaluate the impact of trade agreements on access to essential medicines policies. The work of the DAP was informed by the concept of access to essential drugs as an integral part of the right to health and by its long history of public advocacy around the central role of essential medicines in national health systems.[103]

As part of its efforts to evaluate the impact of TRIPS on access to drugs, DAP commissioned and contributed to a report "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement."[104] Although not an official WHO publication, the report was listed as a key WHO policy guidance document in its year 2000 submission to the Council for TRIPS.[105] And it figured prominently in debates around the 1999 Revised Drug Strategy. The report concludes that the wholesale adoption of the minimal standards of intellectual property protection established by the TRIPS Agreement—without taking advantage of potential exceptions and flexibilities—would interfere with developing countries' abilities to make essential drugs accessible at affordable prices.[106] In particular, it argued for compulsory licenses for drugs on WHO's essential medicines list, and for parallel importation policies for patented drugs.[107] The primacy of these public health considerations was justified "because [essential] drugs play a significant social role in that they are an integral part of the realization of a *fundamental human right* - the right to health."[108] A second publication, "Globalization, TRIPS, and Access to pharmaceuticals," also argued that the minimum standards of patent protection embedded in TRIPS are "historically derived from those of developed countries," and thus are not "necessarily appropriate for countries struggling to meet health and development needs."[109] The publication urged developing countries to take advantage of TRIPS flexibilities and to ensure that Ministries of Health are included in the drafting of national patent legislation.

The position taken by the DAP, including through its publications, drew sharp criticism from the United States and European Union members.[110] This critique was framed in the rhetoric of expertise—tying expertise to apolitical, neutral, factual, and ultimately "legitimate" knowledge. In a 1998 cable concerning Revised Drug Strategy negotiations, the

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[102] WHO Director-General, Dr. Gro Harlem Brundtland, Presentation at the ad hoc working group on the Revised Drug Strategy, Geneva, 13 October 1998 (reproduced in full in Velasquez & Boulet, *supra* note 23.
[103] *See generally* Laing *et al. supra* note 66.
[104] Velasquez & Boulet *supra* note 23.
[105] IP/C/W/202 (Aug. 31, 2000).
[106] Velasquez & Boulet *supra* note 23, at 40-41 ("It is thus very clear that the Uruguay Round negotiations were largely dominated by industrialized countries and that developing countries were constrained to accept commitments sometimes running counter to their economic and social development.").
[107] *Id.* at 41-42.
[108] *Id.* at 17-18.
[109] Globalization, TRIPS, and Access to Pharmaceuticals, *supra* note 91, at 2.
[110] *See, e.g.,* European Commission (DG 1) note on the WHO's Revised Drug Stategy, http://www.cptech.org/ip/health/who/eurds98.html; Department of State cable, *supra* note 98.

U.S. State Department objected to allowing "health experts, rather than trade experts at WTO," to interpret trade agreements.[111] The cable portrayed discussions at WHO on access to pharmaceuticals as plagued by "lack of clarity or internal secretariat expertise concerning trade-related issues."[112] It was this lack of expertise that needed to be corrected in future negotiations, by allowing WTO members to speak before the World Health Assembly to "clarify interpretations of TRIPS or WTO agreements."[113] In turn, the DAP's position was "an outrageous and biased attempt to mold international opinion."[114] On one side stood the ideological, biased views of DAP; on the other that of (trade) experts—a neutral, apolitical and fact-based view.

In a speech before the World Health Assembly following the 1999 Revised Drug Strategy debates, the WHO took a similar approach—but this time emphasizing the need for expertise in health when interpreting international norms and standards involving pharmaceuticals, and the lack of relevant health expertise at the WTO.[115] The WHO Director General's speech, while calling for collaboration between the WTO and WHO, also hinted at a contested relationship between the two organizations.[116] Indeed, one of the initial attempts at WTO-WHO collaboration, despite leading to a joint publication,[117] is reported to have been rife with conflicts between staff at the two organizations regarding the primacy of trade versus public health interests in the interpretation of TRIPS flexibilities.[118] And a study that has interviewed staff at both organizations describes the WHO-WTO relationship prior to the Doha Round as filled with tension and distrust.[119] Thus, an underlying dynamic in the contested interaction between the WHO and the WTO prior to the Doha Declaration is the competition of expert groups for jurisdiction in the area of intellectual property and health.

The signing of the Doha Declaration was a watershed moment for the WHO with important consequences for its relationship with the WTO.[120] In essence, the declaration constituted an explicit acknowledgement on the part of WTO Member States that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[121] The Declaration allowed the WHO to cement its jurisdiction over the intersection of trade and health: it legitimized the WHO's role as a key voice in trade issues

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[111] Department of State cable, *supra* note 98.
[112] *Id.*
[113] *Id.*
[114] *Id.*
[115] WHO Director-General, Dr. Gro Harlem Brundtland, Presentation at the ad hoc working group on the Revised Drug Strategy, Geneva, 13 October 1998 (reproduced in full in Velasquez & Boulet, *supra* note 23, at 70). ("WHO's role must be viewed as the only representative organization worldwide with a mandate and technical expertise for setting health-related norms and standards. . . . [T]here clearly are important trade issues which require a public health perspective. WTO does not have that expertise.")
[116] *Id.* at 71 (noting that in a meeting with the then-Director General of the WTO, Mr. Ruggiero, "I urged that WTO take a more active role in understanding the health perspective and I confirmed that WHO will work seriously to analyse the trade perspective.").
[117] WHO & WTO Secretariats, *WTO Agreements and Public Health* (2002).
[118] Jawara & Kwa *supra* note 84, at ____.
[119] Morin & Gold *supra* note 84, at ____.
[120] *See generally* Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, J. INT'L ECON. L. (2002); World Trade Organization, Technical Cooperation Activities: Information from Other Intergovernmental Organizations, WHO, IP/C/W/376/Add.3, November 1, 2002 at 1 (stating that the Doha Declaration "marks a watershed in international trade, demonstrating that a rules-based trading system is compatible with public health interests.").
[121] Doha Declaration, at ¶ 4.

both by singling out public health as a key justification for invoking TRIPS flexibilities and by mobilizing public support for the issue of access to essential medicines (and thus for the WHO's work in this area). The WHO itself viewed the Doha Declaration as "enshrin[ing] the principles WHO has publicly advocated and advanced over the years, namely, the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and promote access to medicines."[122]

The next section focuses on the evolving WTO-WHO Relationship following the signing of the Doha Declaration.

C. From Competition to Collaboration– WTO-WHO Relationship in the Post-Doha Period and the Role of Human Rights Rhetoric

In the years following the Doha Declaration, the World Health Assembly issued a series of resolutions that explicitly addressed the link between intellectual property (and patents in particular), innovation and public health. These resolutions called on the WHO to provide guidance to developing countries in ensuring access to essential medicines when implementing the TRIPS Agreement, and in particular when drafting national patent laws.[123] The declarations also stressed the need for research on the impact of international trade agreements on public health and access to essential medicines.[124] Beginning with WHA 56.27, "Intellectual Property Rights, Innovation, and Public Health," the WHO recruited a series of groups of experts to analyze intellectual property and trade from a public health perspective. The first of these expert committees, the "Commission on Intellectual Property, Rights, Innovation and Public Health", created a very influential report, "Public Health, Innovation, and Intellectual Property Rights."[125]

The Commission's report framed the legitimacy of a public health perspective in trade and intellectual property in the language of human rights. Noting that arguments for and against particular intellectual property policies with regards to access to essential medicines are often conducted from economic, medical, and scientific perspectives, the Commission emphasized that "it should not be forgotten that there is an underlying moral issue"—to ensure universal access to existing life-saving medicines.[126] States moral obligations are "backed by a legal imperative:" States human rights obligations under the International Covenant on Economic, Social and Cultural Rights (ICESCR). In particular, the Commission focused on articles 12.1 of the ICESCR, "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," and article 15 of the Covenant, "the right to benefit from the fruits of scientific progress." In this view, the preamble of WHO's Constitution, calling for "[t]he enjoyment of the highest attainable standard of health,"[127] should be interpreted as reflecting—at a minimum—States' obligations under the ICESC. Although resource constraints may prevent States from the immediate fulfillment of the right to health, States' obligations to ensure the "progressive

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[122] IP/C/W/424/Add.2, at 2 (October 2004).

[123] *See, e.g.,* Intellectual property rights, innovation and public health, WHA56.27 (May 26, 2003); WHA59.24, *supra* note 56; Global strategy and plan of action on public health, innovation and intellectual property, WHA61.21 (May 24, 2008) [hereinafter WHA61.21].

[124] *Id.*

[125] COMMISSION ON INTELLECTUAL PROPERTY RIGHTS INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS, CIPH/2006/1 (2006).

[126] *Id.* at 8.

[127] *Id.* at 9.

realization" of the right require that States "give consideration to the health implications of their policies."[128]

Crucially, the Commission engages with current interpretations by human rights bodies of the content of the right to health, to argue for concrete "core" obligations contained in Article 12.1—that is, essential levels of protection that governments, no matter the level of resources at their disposal, are obligated to fulfill. Specifically, relying on General Comment No. 14 on Article 12, the Commission emphasizes that "the provision of essential biomedical innovations" constitutes a "core" obligation of the right to health. [129] Finally, the Commission adopts, as a framework for its analysis of the impact of international trade agreements on public health, the *human rights* framework set forth in General Comment No. 14.[130] This framework emphasizes four dimensions of the right to health: availability, acceptability, accessibility and quality.[131] This frame of analysis is repeated in different WHO documents that followed the Commission's report,[132] including the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property ("Global Strategy")—providing a powerful justification for incorporating the perspective of public health experts in any debates involving trade and intellectual property.

Following the Commission's report, the World Health Assembly established an intergovernmental working group "to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission."[133] The PHI Secretariat was established in September 2006 to facilitate the work of the intergovernmental working group. By providing administrative support for public health, trade, and intellectual property initiatives, and by creating a new cadre of experts at the intersection of public health, law and trade under the aegis of the WHO, the PHI Secretariat institutionalized WHO's jurisdiction in the area of intellectual property and trade.

The Global Strategy—drafted by the intergovernmental working group—cites the Commission's report as "provid[ing] an analysis of the problems and mak[ing] recommendations that form a basis of future actions," thus entrenching a human rights framework and justification for the WHO's involvement in access to medicines policies.[134] It also links Member States obligations vis-à-vis public health and intellectual property to their obligations under International Human Rights instruments.[135] The Global Strategy makes it explicit that lowering the price of essential medicines in order to increase access is a priority goal for the WHO.[136] In practice, these resolutions support fully employing TRIPS flexibilities to foster competition, including through generic production of essential medicines under patent protection, and through interpreting TRIPS in a manner consistent

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[128] *Id.* at 10.

[129] *Id.* General Comment 14 explicitly links the core obligation "to provide essential drugs" to the WHO Essential Drugs List ("To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs."). General Comment 14, *The right to the highest attainable standard of health,* Economic and Social Council, E/C.12/2000/4 (2000) ¶ 43(d).

[130] Public health, innovation and intellectual property rights *supra* note 125, at 11-12; General Comment 14 *supra* note 129, at ¶ 12.

[131] *Id.*

[132] *See, e.g.,* WHA61.21, *supra* note 123.

[133] WHA59.24, *supra* note 56, at 34.

[134] Global Strategy, *supra* note 123, at 4 ¶6.

[135] *Id.* at 3 ¶ 3("More efforts should be made to implement States' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.")

[136] *Id.* at 4 ¶ 11 ("The price of medicines is one of the factors that can impede access to treatment.").

with the broadest possible access to essential medicines.[137] The human rights framework of analysis, which emphasizes that essential medicines should be affordable, accessible, and available in sufficient quantities, plays a crucial role in justifying the WHO's position.[138]

In addition, the global strategy calls for the WHO Secretariat to "strengthen efforts to coordinate effectively work relating to intellectual property and public health among the secretariats and governing bodies of relevant regional and international organizations."[139] Although the WHO had previously worked with the WTO in the drafting of the 2001 report on Trade and Public Health, those involved in the early collaboration efforts reported that conflict, not collaboration, characterized that early exchange.[140]

The WHO and WTO would not embark on another joint venture until 2010[141]—this time at the initiative of the WHO following the mandate set forth in the Global Strategy framework. Since 2010, the WTO, WHO and WIPO have organized a series of symposia around the theme of access to medicines, innovation, and patents. This trilateral cooperation led to a joint publication: "Promoting Access to Medical Technologies and Innovation."[142] One key point stands out when comparing the 2002 WHO-WTO publication to the 2013 trilateral study: the importance given to a human rights perspective. The 2002 publication only mentioned the human rights dimension of access to essential medicines once—and even then only when articulating the perspective of the UN Commission on Human Rights on access to HIV/AIDS treatment.[143] In contrast, the 2013 publication explicitly adopted human rights as a policy framework, emphasizing that "[e]nsuring access to essential medicines constitutes a core human right obligation of states."[144]

The stark contrast between the two publications is most salient in their introductions. The 2002 publication opens by emphasizing the virtues of trade liberalization, including its positive impact on public health: "Expanding trade is a central component of the increasing connectedness among countries. . . . importantly also, there is a positive link between freer trade and economic growth, which can lead to reduced poverty and higher standards of living, including better health."[145] In contrast, the trilateral study begins by

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[137] *See, e.g., id.* at 13 ¶33 ("There is a crucial need to strengthen . . . capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health."); WTO, Technical Cooperation Activities: Information from Other Intergovernmental Organizations, WHO, IP/C/W/549/Add.4, October 24, 2010 at ¶ B.7 ("Patents have an impact on price, as the exclusive rights granted to the patent holder allow the holder to keep generic medicines out of the market and to enjoy monopoly prices for a defined period of time. Generic competition in the market however is one of the most efficient mechanisms to bring prices down.")

[138] *Id.*

[139] Global Strategy, *supra* note 123, at ¶ 34(5.1)(h).

[140] *See supra* note 84.

[141] The first event in the trilateral cooperation program among WHO, WTO and WIPO was a joint technical symposium: "Access to Medicines: Pricing and Procurement Practices," http://www.wipo.int/meetings/en/2010/wipo_wto_who_ge_10/a. *See also* IP/C/W/549/Add.4, at ¶ 9 (Oct. 24, 2010) ("[T]he Director-General of WHO exchanged letters with the Directors-General of the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) to enhance collaboration and coordination of the respective activities in this field.").

[142] WTO, WIPO & WHO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (2012) [hereinafter "Promoting Access"].

[143] WTO Agreements and Public Health, *supra* note 117, at ¶ 202.

[144] Promoting Access, *supra* note 142, at 40.

[145] WTO Agreements and Public Health, *supra* note 117, at ¶ 2.

highlighting that "[h]ealth is a fundamental and universal human right. The attainment by all peoples of the highest possible level of health is the foundational objective of the WHO."[146]

The initial conflict between the WHO and WTO was due, at least in part, to different interpretative stances regarding TRIPS and public health. Using the human right to health as a guiding framework, the WHO generally favored generic competition whenever necessary to ensure sufficient access to essential medicines. In contrast, the WTO, some WHO member states (the U.S. and EU), and the International Federation of Pharmaceutical Manufacturers Association, took the position that strong IP rights were not only consistent with public health goals, but also necessary for the development of essential medicines.[147] In this view, weakening of IP rights (while leading to access to particular medicines in the short term) would tend to have an overall detrimental effect on innovation and public health goals.[148] While the 2002 WHO-WTO report reflects this latter view, the trilateral cooperation study is much more in line with the former position, initially adopted by the WHO.[149]

In the ten years between the initial WTO-WHO collaboration and the trilateral cooperation report, conceptualizing access to essential medicines as a human right progressed from a marginal to a mainstream position. NGOs and developing countries undoubtedly played a crucial role in the acceptance of a human rights perspective.[150] But so did the interaction between the WHO and the WTO. Despite an initial allocation of power that favored the WTO, and thus free trade as a key organizing principle, the WHO successfully expanded its expert domain by framing the regulation of essential medicines as a fundamental human rights issue. Human rights rhetoric increased the WHO's legitimacy as a policy actor before key audiences, allowing the WHO to forge powerful alliances with NGOs and developing countries.[151]

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[146] Promoting Access, *supra* note 142, at 18.

[147] *See, e.g.,* European Commission (DG 1) note on the WHO's Revised Drug Strategy, *supra* note 110 ("intellectual property is a means to "achieve health protection", e.g. via effective patent protection); Jawara & Kwa, *supra* note 84, at 211-215 (discussing the views of key WTO staff, including the head of its intellectual property division); Ellen F. M. 't Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 3 CHICAGO J. INT'L L. 27, 43 (2002) (describing the position of the International Federation of Pharmaceutical Manufacturers regarding compulsory licenses for essential medicines).

[148] Richard Adelstein, *Equity and Efficiency in Markets for Ideas*, 17 CONN. J. INT'L L. 249, 260 (2002) ("Dismantling the system of patent monopolies to allow more poor people access to AIDS drugs now might leave us with no way to mobilize resources against the next great global epidemic.").

[149] These two opposing views mirror the two "polarized views of patents" analyzed by Cynthia Ho as underpinning international debates around TRIPS. In this account, patents are either "a privilege granted by the state and inherently subject to limitation" or an "uber-right" deserving "stronger patent protection than traditional property rights during a limited time." Those who adhere to the latter view consider that "patents are consistent with promotion of public heath because patents promote innovation that results in improved treatments benefitting all." Ho, *supra* note 2, at 326-27, 351-52.

[150] *See, e.g.,* Kapczynski, *supra* note 8, at 852 ("The access to medicines campaign . . . both understood and built claims against strong patent laws through frameworks of international human rights discourse . . . .").

[151] Through its "public interest roundtable process" the WHO has developed a close working relationship with several NGOs, including Medecins sans Frontieres. IP/C/W/202, 31 August 2000 (describing the WHO/Public Interest NGO Roundtable process to monitor the impact of TRIPS on essential drug prices). *See also* Helfer, *supra* note 7, at 42 (describing how "Brazil, South Africa, and Zimbabwe, together with public health NGOs such as the Consumer Project on Technology (CPT), Medecins sans Frontieres (MSF), Health Action International (HAI), and Oxfam, were the principal catalysts for the WHO's critical review of TRIPs."); Kapczynski, *supra* note 8, at 852; Sell, *supra* note 3, at 146-50 (describing how the NGOs Health Action International and Consumer Project for Technology collaborated with the WHO Executive Committee to draft the 1998 Revised Drug Strategy).

IV. Conclusion

The issue of access to essential medicines and technology stands at the intersection of multiple regulatory domains, and involves public health, intellectual property, trade and human rights policy. This Article argued that a full understanding of the development of policies that regulate access to essential medicines requires examining the interaction between two key international organizations—the WHO and WTO—conceptualized as expert communities with two distinct domains of expertise. Competition between the WHO and WTO for jurisdiction over access to medicines policies has played a key but understudied role in the development of international norms regarding international intellectual property, and in the interpretation of the TRIPS Agreement. In turn, human rights rhetoric has mediated this jurisdictional competition. By framing access to essential medicines and to the fruits of scientific discovery as a fundamental human right, the WHO has been able to gain and solidify its jurisdiction over intellectual property policy.

Many questions remain to be explored. Most importantly, what led WTO professionals to embrace collaboration with the WHO and WIPO and to co-author a report that takes a human rights perspective to access to medicines the WTO previously appeared to reject? It is possible that pressures from other stakeholders, such as developing countries and NGOs, combined with high-profile public health emergencies (such as the HIV/AIDS crisis) led the WTO to change its position to avert the deepening of a legitimacy crisis.[152] In this context, an alliance with the WHO may have served to increase the WTO's own institutional legitimacy—without a real consensus on a human rights framework of analysis for access to medicines policies.[153] It is also possible that both organizations have found common ground in their position vis-à-vis TRIPS-plus Agreements.[154] Thus, the WTO's embrace of a trilateral cooperation with WIPO and the WHO may represent a strategic alliance to increase its own relevance, which many see as dwindling in the past decade—characterized by a deadlock in multilateral trade negotiations and a renewed interest in

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[152] *See, e.g.,* LORI M. WALLACH & PATRICK WOODALL, WHOSE TRADE ORGANISATION, A COMPREHENSIVE GUIDE TO THE WTO (2005) (criticizing the WTO for its "startling lack of transparency, public disclosure or accountability"); B. Stewart & Michelle Ratton Sanchez Badin, *The World Trade Organization: Multiple dimensions of Global Administrative Law*, 9 INT'L J. CONS. L. 556, 559 (2011) (noting that a key WTO challenge is to "bolster[] its institutional legitimacy against attacks by critics faulting it for secretive decision making and disregard of non-trade interests and values.").

[153] This instance of collaboration would represent an example of "collaboration without consensus." *See supra* note 28.

[154] Both WHO and WTO expert bodies have expressed concern about the proliferation of bilateral trade agreements that enhance the minimum intellectual property protections set forth in the TRIPS Agreement and eliminate some of its flexibilities, in particular with respect to public health. *See* Promoting Access, *supra* note 142, at 43 ("Developing countries should carefully assess possible adverse consequences on access to medicines when adopting TRIPS-plus provisions); Public health, innovation and intellectual property rights, *supra* note 125, at Recommendation No: 4.26 ("Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries."); CONSULTATIVE BOARD TO DIRECTOR-GENERAL SUPACHAI PANITCHPAKDI, THE FUTURE OF THE WTO: ADDRESSING INSTITUTIONAL CHALLENGES IN THE NEW MILLENNIUM ("Sutherland Report") ¶ 87 (2004) (recognizing that serious problems arise from preferential trade agreements (both bilateral and regional), including those containing "comparatively ambitious and one-sided provisions on intellectual property"). For an overview of "TRIPS-Plus" Standards *see* Ho, *supra* note 2, at 225-228. As of this writing, the Trans-Pacific Partnership (TPP) is the most recent regional trade agreement negotiation that threatens to substantially increase the scope of patent protection beyond TRIPS minimum requirements. *See, e.g.,* Sean M. Flynn, Brook K. Baker, Margot E. Kaminski & Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105 (2013).

bilateralism and regionalism.[155] Alternatively, this new cooperation may also reflect the rise of a new network of experts at the intersection of public health, trade, intellectual property and human rights that share many of the same commitments.

The analysis presented here also has implications for the debate about fragmentation in international law, and in particular for the concern voiced by multiple commentators that the fragmented and specialized structure of international governance closes spaces for politics. In a recent article, Andrew Lang asks whether "a fragmented legal order opens up spaces for political contestation even as it reflects and consolidates a move to the technical."[156] If we conceptualize fragmentation as leading to competition among different expert communities, the answer is a qualified yes. As I illustrated in this Article, the rhetoric of expertise can obscure political choices, by dressing them up as neutral expert opinions. But competition among expert communities can re-open a space for political dialogue. In the spaces of shared (or potentially shared) regulatory domains—where jurisdictional competition takes place—political accountability can re-insert itself. When two or more expert communities compete for jurisdiction over a particular task, they effectively pit their framing devices against each other as the most effective means to solve particular problems—seeking to gain legitimacy in the eyes of relevant audiences: consumers of their services and law-makers with the power to alter rules in their favor.[157] In arguing for the superiority of their expert frameworks, expert communities are incentivized not only to justify the superiority of their approach, but also to undermine claims of neutrality presented by their competitors and bring to light any indeterminacies that underlie the other community's expert knowledge. Thus, jurisdictional fights can bring the public back in: winning requires public involvement to legitimate a particular approach as preferable to the alternatives.

[155] *See, e.g.,* Symposium, Structural Issues at the World Trade Organisation, 14 WORLD TRADE REV. 1 (2015) (describing and analyzing the hurdles surrounding the Doha Round of multilateral lawmaking at the WTO).
[156] Lang, *supra* note 24, at 134.
[157] *See supra* Part III.A.