ANNUAL REVIEWS

Annual Review of Law and Social Science

How to Study Global Lawmaking: Lessons from Intellectual Property Rights and International Health Emergencies

Tatiana Andia[1] and Nitsan Chorev[2]

[1]Department of Sociology, University of Los Andes, Bogotá, Colombia; email: tandia@uniandes.edu.co

[2]Department of Sociology, Brown University, Providence, Rhode Island, USA; email: nitsan_chorev@brown.edu

Annu. Rev. Law Soc. Sci. 2023. 19:215–34

First published as a Review in Advance on July 17, 2023

The *Annual Review of Law and Social Science* is online at lawsocsci.annualreviews.org

https://doi.org/10.1146/annurev-lawsocsci-111522-091304

Keywords

intellectual property, global law, global health, methodological nationalism, international agreements

Abstract

International agreements on Intellectual Property (IP) have proven to be a good example to study global lawmaking. Beginning by looking at the 1990s Trade-Related Intellectual Property Rights (TRIPS) agreement and into the negotiation and implementation of regional and national trade agreements, this article reflects on the intricate relationship between international IP agreements and public health. The comprehensive analysis of these international rules and their effect provides valuable insights into the dynamic interplay between domestic and international factors in shaping health policies. Building upon the IP case, we categorize existing scholarship on global lawmaking into three methodological approaches: (*a*) methodological internationalism, (*b*) methodological nationalism, and (*c*) the interplay between domestic and international factors. We close with a call for researchers to advocate and integrate into their methods a co-constitutive approach that considers the simultaneous shaping of domestic and international elements.

INTRODUCTION: ON INTERNATIONAL AGREEMENTS AND PUBLIC HEALTH

Back in 1948, as a central part of a new world order, 23 nations signed the General Agreement on Tariffs and Trade (GATT). The Agreement's overall purpose was to promote international trade by reducing or eliminating trade barriers. Additional rounds of trade negotiations led countries to reduce quotas, duties, and other trade barriers—but intellectual property rights (IPRs) were not part of the negotiations, and countries maintained significant autonomy in designing and implementing Intellectual Property (IP) policies (Chorev 2007a). Hence, although some countries had laws protecting IP in pharmaceuticals, until the 1990s, many countries did not grant patents in pharmaceuticals, given the effects that patents might have on the price of drugs and access to health. This is not to say that there was no international diffusion, including by coercive means, of IP norms from one jurisdiction to another, but IPRs were not internationally coordinated.

It was only with the establishment of the World Trade Organization (WTO) in 1995, which succeeded GATT, and the agreement on Trade-Related Intellectual Property Rights (TRIPS) that for the first time rules that affect national policies on IP were included as part of an international legal regime (Chorev & Shadlen 2015). TRIPS intended to impact several knowledge-based sectors, but the health sector was a major one and a key reason many developing countries unsuccessfully attempted to keep IP off the trade negotiations agenda. TRIPS required all WTO members to grant patents in all fields of technology, including pharmaceuticals; it established long terms for patents—20 years—from the date of application; and it offered only a narrow range of allowable exemptions to patent rights (Athreye et al. 2020).

Developing countries were somewhat successful in negotiating specific aspects of the agreement. This included transition periods that vary according to countries' level of development, and that have been further extended for least-developed countries three times (in 2005, 2013, and 2021), with a new 2034 deadline, and whether patents could be granted retroactively (Matthews 2002, Reichman 2009, Watal & Taubman 2015). Moreover, in 2001, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health. The Doha Declaration clarified the rules and removed ambiguity as to what actions were acceptable under TRIPS; the Declaration also underscored countries' rights to implement their new international IP obligations in health-supportive ways. In doing so, the Doha Declaration aimed to facilitate the use of "flexibilities" present in TRIPS to narrow the use of IPRs in support of public health (Chorev & Shadlen 2015).

Although central, TRIPS was not the only international agreement that introduced IP protection around that time. Both the United States and the European Union have negotiated, including with developing countries, numerous bilateral and regional trade agreements that included IP provisions, which typically exceed those in TRIPS (Chorev & Shadlen 2015). These provisions are often described as TRIPS-Plus.[1] As in many other policy arenas, such as investment or environmental law among many others, the overlap between multilateral, regional, and bilateral agreements in addition to the activities of local and international nongovernmental organizations (NGOs) and of pharmaceutical domestic manufacturers and transnational corporations created what the literature on global lawmaking often describes as patterns of mutually connected institutions, norms, and processes across a range of legal sites (Walker 2015).

The potential impact of IP rules under TRIPS and other agreements on health is complex but nonetheless clear. Simply put, where pharmaceutical firms have patents on drugs, they can limit

[1] For a comprehensive analysis of the spread of IP in multilateral, regional, and bilateral trade agreements, see Shadlen et al. (2020).

the competition they would otherwise face and raise drug prices. Drug prices, in turn, can create financial challenges for providing access to medicines (Chorev & Shadlen 2015).[2] Accordingly, both legal scholars and health activists have carefully analyzed the TRIPS agreement and its potential and actual implications on access to medicines, especially in countries with limited resources.[3]

Legal scholars and health activists were joined by sociologists, anthropologists, political scientists, and others who studied the origins, diffusion, and challenges to TRIPS and other IP agreements. How did the TRIPS agreement come about in the first place? What were the domestic responses once TRIPS was signed, and how do we explain variation in that response? What factors led to resistance to the TRIPS agreement, and under what conditions was such resistance successful? And why this ongoing focus on IP?

In this review, we offer a novel categorization of the scholarship on IPRs and public health emergencies, which, we hope, will move our scholarly agenda forward, not only in the field of IPRs and access to medicines but also in our understanding of global law more broadly. Our categorization is based not on the research question but rather on the methodological orientation. We identify three dominant approaches in the literature on IPRs and health. The first approach, which was dominant earlier on, follows what we call methodological internationalism. Scholars following that approach focus on the international level as the central (often, only) site of analysis and on member states as the central (often, only) participating actors. The second approach, which became the dominant one in line with political developments following TRIPS, deserted the international level as the site of analysis in favor of methodological nationalism, in which a concern with domestic developments led to a focus on domestic factors, at the expense of exogenous influences. Although many focus on the state as the main (often, only) actor, over time the list of actors considered relevant has widened to include domestic actors also outside the state. The third, and most recent, approach considered the interplay between domestic and international actors, institutions, and conditions. We believe that a productive next move is an analysis of the interplay between the two levels that does not approach the domestic and the international as two already-constructed entities that then influence each other, but rather considers the concurrent co-constitution of the international and the national. In the rest of this review, we first describe the three methodological approaches used in the study of international agreements and public health emergencies and then discuss the possibility and promise of the co-constitutive approach.

ERA I: METHODOLOGICAL INTERNATIONALISM

The first question scholars raised about TRIPS regarded the agreement's origins: How did TRIPS come about in the first place? And why was it followed by the Doha Declaration?

---

[2] On the general question of "private appropriation of knowledge in the form of intellectual property monopolies," see Zeller (2007, p. 86). Others have shown that the same IPRs have been used to appropriate traditional knowledge, as in the case of industrial reformulations of ayurvedic plant-based Indian traditional medicine (Gaudillière 2014, Pordié & Gaudillière 2014). For "solutions" and/or alternative mechanisms, see 't Hoen et al. (2011) and Pogge (2012).

[3] For example, see Abbott & Reichman (2007), Aginam et al. (2013), Athreye et al. (2020), Barton (2004), Chaudhuri (2005), Coriat (2008), Coriat et al. (2006), Drahos (2001), Guan (2016), La Croix & Ming (2008), Lanjouw (1998, 2002), Lanoszka (2003), Löfgren & Williams (2013), Malbon & Lawson (2008), Nichols (2018), Oliveira et al. (2004), Reichman & Dreyfuss (2007), Roffe & Spennemann (2006), Slade (2016), Thomas (2002), Wade (2003), and Yu (2012). Regarding access to HIV/AIDS medicines, see Castro & Westerhaus (2007), Correa (2006), and 't Hoen et al. (2011). For articles that suggest that patents are not the main barrier for access to HIV/AIDS medicines in Africa, see Attaran & Gillespie-White (2001); on the general "neoliberal turn" of trade agreements, including in the realm of intellectual property rights, see Gathii (2011).

Drahos (1995, p. 7) nicely describes the scholarly fascination with TRIPS by suggesting that the agreement was a "remarkable achievement." He explains,

> It is remarkable because one country, the US, was able to persuade more than 100 other countries that they, as net importers of technological and cultural information, should pay more for the importation of that information. Assuming rational self-interest on the part of these other states, their willingness to sign off on TRIPS constitutes a real-world puzzle worth studying. (Drahos 1995, p. 7)

In turn, the Doha Declaration was often seen as a remarkable achievement for precisely the opposite reason: remarkable because poor countries were able to force the United States to soften its interpretation of the original agreement.

Producing some of the most influential accounts of TRIPS and the Doha Declaration, scholars approached these questions by focusing first on the positions and strategies of the negotiating governments at the international level (Drahos 1995, Helfer 2004, Sell 2003, Weiss 2005, Weissman 2004). As in many other areas of global lawmaking, such as environmental agreements, this scholarship pays attention to states' conflicting interests with a special focus on North–South relations (Mitchell 2003).

Although some authors, such as Helfer (2004), rejected the notion of states as unitary actors, they still offer an analysis with governments at the center. He suggests that, following a "regime shifting" strategy, the United States and the European Communities moved discussions on IPRs from the World Intellectual Property Organization (WIPO) to the GATT. The strategy was used because these states enjoyed significant negotiating leverage in the GATT, and later the WTO, as the negotiators with the largest domestic markets, and thanks to their ability under the GATT/WTO to link IP protection to other issues as part of a package deal.

With the Doha Declaration, scholars began to look not only at wealthy members of the WTO that supported TRIPS but also at countries that opposed it. They came to appreciate the fact that, in response to TRIPS, developing countries did not stay passive but "sought to clarify the rules of international patent law, to affirm the rights established during the TRIPS negotiations, and to minimize vulnerability to opportunism by powerful states" (Shadlen 2004, p. 76). Abbott (2002) contends that although the Doha Declaration did not address all of developing countries' concerns regarding the impact of IP protection on access to medicines, it was a significant milestone. Seven years after publishing her seminal book on the TRIPS negotiations, discussed below, Sell (2011a,b) considers the "ups and downs, victories and defeats" that followed. In doing so, she considers the actions of several governments, including "developing countries[, which] became much more fully engaged in intellectual property norm-setting activities" (Sell 2011b, p. 449). Similarly, Helfer's (2004, p. 53) discussion on "regime shifting" recognizes that developing states also "adopted a strategy of regime shifting. . .from the WTO and WIPO into international regimes governing biodiversity, PGR [plant genetic resources], public health, and human rights." Drahos (2001) considers the position of developing countries, including potential trade-offs between international and bilateral trade agreements. At the same time, Drahos (2007) helpfully realizes that IPR negotiations are a continuous process rather than a chain of independent negotiations. Moving beyond the common North–South dichotomy, Hopewell (2015a) suggests that the new political influences of China, India, and Brazil at the WTO have different origins, leading to different strategies and demands in the course of the negotiations.

This focus on negotiations and on negotiating countries is common also in studies on bilateral and regional trade agreements. This is exemplified in Chander & Sunder's (2018) study of a leaked draft of the Regional Comprehensive Economic Partnership, involving China, India, and 14 other countries, and in Araujo's (2013) study of the European Union's bilateral and regional trade negotiations.

While maintaining a focus on interstate dynamics, others have considered the normative and institutional context of the negotiations. Rather than an expression of interstate power balance, Parra-Salas (2013) sees the legal harmonization across countries, as in the case of TRIPS, as a result of an exchange of legal norms, where some countries act as exporters and others act as importers of legal provisions. Others integrate the role of international institutional arrangements into the analysis of how countries negotiate. For example, Chorev (2005) shows how legal harmonization has been achieved in part due to WTO dispute settlement procedures.

Moving beyond a narrow state-centric focus, some scholars, while maintaining their empirical gaze on the international level, have recognized actors other than governments. If early studies focused on the political power of national industries (e.g., Helfer 2004), later on, other actors were also considered, including civil society (both NGOs and international NGOs), multinational corporations and associations, and international bureaucracies (Chorev 2007a, 2012a; 't Hoen 2002). This focus on nongovernmental and other actors coincides with the interest of sociolegal studies in other fields in the role that transnational advocacy networks played in global lawmaking (Keck & Sikkink 1998), and with scholarship on the development of private regulatory standards (Bartley 2007).

The view of the international level as occupying actors other than nation-states is in part an outcome of the proliferation of international public–private partnerships, including in the realm of health. Designed to be less politicized, these organizations often provide a more direct voice to nongovernmental actors (industries, NGOs, and people living with diseases) but less influence to governments from the Global South (Buse & Walt 2000, Chorev et al. 2011). Hopewell (2015b) shows how civil society actors that sought to engage with and influence the WTO in the course of the TRIPS negotiations have been transformed in the process. Hopewell argues that they have become both more technocratic and more reformist—with NGOs advocating positions that accord with the neoliberal trade paradigm. She concludes that global civil society is not in fact independent or autonomous but shaped and influenced by the institution it targets. Chorev (2012a, 2013) similarly moves beyond reducing the international to interstate relations by looking at the influence of international bureaucracies. In one of her case studies, Chorev discusses the World Health Organization's proactive response against TRIPS (Chorev 2013). Finally, Demortain (2015, p. 1249) identifies the role of broader regulatory logic, suggesting that "regulating pharmaceuticals. . .happens incrementally, through gradual changes and hybridization of the existing regime, much more than all-out replacement of the regime."

All these studies follow an analytical approach that we call methodological internationalism. Sociologists have called methodological nationalism the tendency to assume that "nation/state/society is the natural social and political form of the modern world" (Wimmer & Glick Schiller 2002, p. 302), leading to the fact that "the social sciences have become obsessed with describing processes within nation-state boundaries as contrasted with those outside, and have correspondingly lost sight of the connections between such nationally defined territories." Correspondingly, methodological internationalism refers to the tendency to assume that the international level is the natural economic and political form of the modern world; that nation-states are the most adequate entities for studying the international world, as Wimmer & Glick Schiller (2002, p. 304) observe; and that, when studying nation-states as actors at the international level, it is adequate to reduce the "nation-state" to the interests and positions as presented by the government in the course of negotiations. As a result, methodological internationalism invites analyses that empty the international level of most actors other than government representatives, and that describe (rather than explain) governments' interests and positions. To the extent that other actors (international NGOs, international bureaucrats, and so on) do appear, they still function almost solely in the international realm.

Methodological internationalism left scholars with an analysis of the "front stage"—a description of what was achieved by way of international negotiations, but with no access to the original construction of positions or the later modification of those positions. Some scholars, therefore, complemented their analysis of international negotiations with a study of domestic interests. Indeed, one of the most influential analyses of TRIPS, by Sell (2003), combines an international analysis of the negotiations with a political-economic analysis of the United States. Sell shows that new structural conditions, including enhanced capital mobility, strengthened the political influence of US-based transnational firms in knowledge-intensive sectors such as computers, software, and pharmaceuticals. These firms favored tougher IPRs and pressured the US government to introduce IPRs as part of the trade negotiations. In subsequent writings, Sell (2007, p. 41) continues to explore the way that "global brand name pharmaceutical firms have sought to ration access to medicines and have used their economic and political clout to shape United States trade policy." In particular, she documents their ability to get "extremely restrictive TRIPS-Plus. . .intellectual property provisions into regional and bilateral free trade agreements" (p. 41). Roemer-Mahler (2013) complements Sell's (2003) argument by showing that conflict between commercial and political interests within the pharmaceutical industry has shaped the trajectory in which global pharmaceutical IP governance has developed. Paying attention to clashes among US corporations, Chorev (2007a) shows that private interests in the United States that supported trade liberalization and/or the strengthening of IPRs pushed Congress to delegate authority to the WTO, exactly in order to weaken the political influence of those in the United States who opposed liberalization. Paine & Santoro (1992) describe how the US-based pharmaceutical company Pfizer helped transform IP from a lawyer's specialty to an international trade issue by forming a tripartite coalition among American, Japanese, and European industries and through close cooperation with the US government.

Other scholars look at how positions of states other than the United States have been constructed at the domestic level. Verger & van Paassen (2013) look at Ecuador and Peru. Postigo (2016) explores government–business relations that informed the positions of Thailand and Malaysia in international trade negotiations. Importantly (as we discuss below), Postigo (2016) considers the way trade negotiations shaped government–business relations in East Asia. Townsend et al. (2018) describe Japan's interests in negotiating IPRs in the Trans-Pacific Partnership agreement and the Regional Comprehensive Economic Partnership. Others, including Ryan (1998), Matthews (2002), and Pugatch (2004), offer a more global political-economic perspective.

In many of these studies, the political influence of pharmaceutical and other companies is undertheorized, with some important exceptions. In a recent piece, Kapczynski (2023) makes explicit the different forms of power that the pharmaceutical industry exercises, such as property power through patents and industrial secrets that limit competition, ideational power that makes others believe that only they can innovate, and structural dependence of governments. Others identify additional means through which the position of the US government gets constructed. For example, Kaminski (2014) argues that private parties captured the office of the US Trade Representative, affecting the IP law that is then exported to other countries through international trade agreements.

Scholars who look at the domestic interests that inform government positions originally assumed that governments are dominated by corporate interests. As with the assumption that Western governments get what they want in international negotiations, the assumption that corporations control these governments also had to be relaxed with the Doha Declaration. Hence, Sell & Prakash (2004) compare the business victory in the establishment of TRIPS with the subsequent NGO campaign against enforcing TRIPS to ensure access to essential HIV/AIDS medicines. A rich scholarship has identified NGOs' essential role in shaping international politics, directly but more often by influencing the position of individual member states. Notable NGOs

include the Consumer Project on Technology and Health Action International, who were among the first to raise concerns over the impact of IP protection on access to affordable medicines in the developing world in the mid-1990s, as well as Médecins sans Frontières and Oxfam (Matthews & Munoz-Tellez 2006, Muzaka 2009). Scholars also looked at the role of actors other than multinational companies and health activists. In an edited volume, Kapczynski & Krikorian (2010) explore the origins of access to knowledge (A2K) activism. They describe how with the expansion of IPRs, the A2K movement attempted to conjure forth an alternative ethic of the conditions of creativity and freedom in the information age. They emphasize, however, that A2K is not a mass movement; it is not confrontational; many of its advocates are not very radical; and, as a whole, it is rather utilitarian. Andia (2011) analyzes domestic struggles over IPRs in Colombia, where the opposition consisted of NGOs as well as local pharmaceutical producers. Andia shows that this coalition was relatively successful in resisting TRIPS-Plus provisions in bilateral trade agreements but unsuccessful in resisting non-IP/trade marketing approval provisions, such as data protection. As with the literature on corporate influence, most of the literature undertheorizes the ability of social movements to make a difference. One exception is Kapstein & Busby (2016), who, by comparing AIDS activism with climate activism, argue that global market structures matter for movements' outcomes.

In sum, the early scholarship on TRIPS focused almost exclusively on international-level activities and actors. Domestic factors, when considered, were used to understand governments' interests and positions in international negotiations. In addition, the scholarship focused almost exclusively on governments and domestic interests of the United States and similarly powerful countries, with only secondary attention to other countries. All this shifted quite radically with a growing interest in the impact of TRIPS and the Doha Declaration, once in place.

ERA 2: METHODOLOGICAL NATIONALISM

Methodological internationalism has been quite effectively used for describing TRIPS, as well as subsequent international, bilateral, and regional negotiations (even if in the next section we suggest that it offers only a partial understanding of international dynamics). What has quickly become clear, however, is that methodological internationalism offers no tools for understanding the impact of international dynamics on domestic events. When domestic impacts were considered, they were frequently assumed rather than empirically investigated—with the common assumption being that TRIPS would have a common, negative impact on health outcomes in developing countries.

Following TRIPS, all WTO member states were obligated to amend their IP rules in line with the agreement. Some scholars suggested that TRIPS would lead to a "homogenized model" of uniformly patent-driven innovation systems (Rao 2006) and studied the convergence of TRIPS across states (Morin & Gold 2014, Ostry 2000). Empirical studies, however, quickly found a surprising variation in the way TRIPS was introduced into domestic laws and regulations—regarding both the use of patent protection and the use of flexibilities as a form of resistance. To understand that divergence, scholars stopped looking at member states as unitary actors confronting each other at the international level (the gist of what we call methodological internationalism) and began to more systematically address political, economic, and social processes at the domestic level that lead to divergence in the acceptance or contestation of international obligations.[4]

[4]Most of the literature focuses on TRIPS implementation and shies away from measuring its actual impact on health-related issues such as drug prices, given "the conceptual and methodological challenges of assessing

Once scholars recognized major divergence in TRIPS implementation, they also recognized that the extent and substance of TRIPS implementation cannot be explained by looking at the relative power of member states. Considering TRIPS and other international agreements as exogenous forces, scholars instead focused on local specificities that lead to variation in how states respond to a presumably similar force.

In looking at domestic forces to understand the puzzle of divergence, one common approach considered national governments as the sole actors responding to TRIPS. For example, Harris (2011) attributes governments' limited use of compulsory licensing to the fact that it is a difficult process, but also to fear of retaliation, and to the introduction of additional restrictions to compulsory licensing via bilateral trade agreements.[5] Dontje (2015, p. 407) predicts that presumed TRIPS violations will be resolved among states, "through WTO jurisdiction based upon the familiarity of the WTO tribunals with intellectual property disputes." Sampat & Shadlen (2015), who look at the effect that government decisions have on the issuing of patents, find that in both Brazil and India the measures designed to limit secondary patents and thereby limit the negative impact of TRIPS have little direct effect, and as a result, these types of patents are frequently approved. By treating the nation as a coherent unit, represented by its government, these scholars—particularly those who recognize some divergence but see it as an exception to the rule—use an approach to the domestic level that is in fact consistent with methodological internationalism.

Also, scholars who are interested in what enables some countries to use TRIPS flexibilities despite the fear of retaliation often refer to countries (e.g., Brazil) in a way that implies a government acting on behalf of a unitary entity [see, for example, Cohen & Lybecker (2005), who offer a game-theoretic approach to analyze Brazil's threat of using compulsory licensing]. Some explicitly single out governments as the main actors. For example, Cassier & Marilena (2003) argue that a combination of state policies—a favorable pre-1996 IP policy for drugs (non-patentability of pharmaceutical products and processes), a successful public health policy (a decree on universal access to antiretroviral therapy), and an industrial policy that allows the copying of existing drugs—enabled Brazil's enhanced local pharmaceutical production even after TRIPS. The existence of capable state-owned pharmaceutical laboratories also helped. In a more critical analysis, Biehl (2004, 2007) argues that the 1996 Brazilian law that made AIDS medication universally available to all registered HIV/AIDS cases fitted into President Cardoso's plan to internationalize Brazil's market. The signing and compliance with TRIPS in Brazil faster than in other developing countries was meant to attract foreign investment.

Governments-as-actors negotiate—and in other ways try to influence each other's actions—through means other than international negotiations. Scholars have identified the many ways by which governments' response to TRIPS has been shaped by both direct and indirect actions of other governments. When in 1998, in response to a South African law that was designed to facilitate low-cost access to AIDS drugs, 39 multinational pharmaceutical companies sued the South African government for allegedly circumventing TRIPS (Barnard 2002), the South African government also confronted pressure from other governments, especially the United States (Bond 1999). The position of the US government eventually changed, in large part in response to the mobilization of US AIDS activists and the Congressional Black Caucus (see Klug 2008). Government-on-government pressure impacted TRIPS implementation elsewhere as well. For

---

the effects of patent provisions in trade agreements on drug prices, including the choice of variables to focus on, how to operationalize these variables, and the importance of timing in analyzing the effects of TRIPS-Plus provisions" (Shadlen et al. 2020, p. 76).

[5] Compulsory licensing refers to when, in the name of public health, a government allows the production of a patented drug without the consent of the patent owner.

example, the US Trade Representative regularly keeps India on its list of countries whose IP regimes are of concern, in part due to a section in Indian law that prohibits patents on variants of existing compounds that do not show enhanced efficacy, which the transnational pharmaceutical industry and the US–India Business Council regard as establishing an unacceptably high barrier to patenting (Sampat et al. 2012).

Even studies that emphasize governments as the main actors normally acknowledge that governments are not fully autonomous and are responsive to external pressures, particularly from pharmaceutical companies on the one hand and health activists on the other. For example, Ford et al. (2007) argue that Brazil and Thailand were able to achieve universal antiretroviral therapy thanks not only to supportive legislation for free access to treatment and a public sector with the capacity to manufacture medicines but also to a strong civil society that supported government initiatives to improve access (see also Ford 2004). Chaves et al. (2008) similarly argue that social movements were instrumental for Brazil's progressive position with regard to IPRs. Offering a rare historical perspective, they track the trajectory of health-related social movements back to the Public Health Movement that had secured the recognition of the right to health in the Brazilian constitution. Also in South Africa, Bond (2003), Klug (2005, 2008, 2012), Friedman & Mottiar (2005), and others analyze the crucial role of the Treatment Action Campaign in the fight against HIV/AIDS, including in the context of TRIPS.

Importantly, the government itself is hardly a unitary actor—a fact that only a few scholars consider. Flynn (2013) argues that, in Brazil, not "the government" but, specifically, the government's National AIDS Program led the struggle in contesting a corporate-driven international IP regime. One important distinction among government agencies might be between political and administrative government bodies, with the latter including bodies such as the patent office, which plays a particularly important role in implementing TRIPS (Drahos 2008). Of course, subgovernment agencies are also exposed to government-to-government influence. For example, Drahos (2008, 2010) highlights the importance of technical assistance to developing countries provided by the European Patent Office, the Japan Patent Office, and the US Patent and Trademark Office.

Government agencies offer different positions on policy issues in part because of the influence of civil society actors, experts, and other actors (Andia 2016). Helfer & Alter (2014) introduce to the literature on IP a rather unusual actor, the Andean Community, which through the Andean Tribunal influenced the way IP administrative agencies interpreted IP law in a pro-consumer fashion and empowered governments to resist external pressures. Not only did governments, local pharmaceutical producers, and civil society activists play a role, but professions did as well. Cassier (2013), who looks at how legal cases, patent oppositions, and regulatory provisions changed the nature of IP laws in Brazil and India, suggests that this was made possible also thanks to the diffusion by lawyers of legal counter-expertise across developing countries.

But it may not be enough to identify the role of non-state actors in influencing the state without also analyzing the conditions that make such influence possible. In an edited volume exploring the national implementation of TRIPS in 11 Latin American countries, editors Dreyfuss & Rodríguez-Garavito (2014) conclude that differences across countries reside in the efficacy of local contestation, which in turn depends on factors such as expertise, institutional competence, and normative commitments, as well as the structure of civil society and political opportunity structures. Shadlen (2009, p. 42) suggests that Brazil, but not Mexico, adjusted the IP system to ameliorate the effects that drug patents can have on prices and access because, in Brazil, the Ministry of Health was able to build a coalition in support of IP reform thanks to "the existence of an economically and politically more autonomous local pharmaceutical sector [than in Mexico]." Divergence in policies, then, "is attributable to distinct interests and [therefore distinct possibilities for] alliances" across state and non-state actors (p. 42).

Just the way that governments can bypass international venues and influence each other directly, nonlocal non-state actors may also try to shape domestic outcomes. We have already seen that multinational pharmaceutical companies have tried to directly influence IP laws in South Africa—by suing the government! On the other side of the political map, not all health activists were local. According to Barnard (2002), when Big Pharma ultimately withdrew its case against South Africa, it was thanks to a multimedia, global campaign against them, led by the South African Treatment Action Campaign and the international Médecins sans Frontières. But drawing on a critical reading of the literature on transnational advocacy networks, which introduces the possibility of power dynamics between global and local actors (Morin 2010), others have suggested the possibility of differences in the priorities of the global access to medicines movement and local health activists. As Godoy (2015) shows, the causes that mobilize transnational access advocates may rely on assumptions and considerations that mesh poorly with the on-the-ground realities as understood by local activists. Andia (2015) similarly identifies a potential mismatch between the global Kaletra campaign, which challenged Abbott Laboratories' monopolistic hold on a critical HIV/AIDS medicine, and local activism in Colombia and Ecuador. Andia (2015) suggests that the extent of a mismatch depends on the origins of global activists' positions, which in turn depend on the type of relationships established between international advocates and domestic actors. In this context, Morin's (2010) insight as to how movements die is relevant. Drawing on the case of HIV/AIDS movements, Morin suggests that the first actors that called attention to the legal problem of IPRs and that capitalized on the HIV/AIDs crisis in Africa were also the first to feel constrained by their own frame, which limited their ability to seek broader solutions.

These actors do not act in a political-economic vacuum, but few scholars have paid attention to the institutional or structural conditions that impact variation. One exception is Shadlen (2017). Looking at Argentina, Brazil, and Mexico, Shadlen (2017, p. 6; see also Sampat & Shadlen 2015) finds,

> Countries' initial responses. . .varied as a consequence of how industrial legacies interacted with export profiles to affect the possibilities for building coalitions around the issues of when and how pharmaceutical patents should be introduced. How these initial conflicts regarding the introduction of patents were resolved, in turn, conditioned policy choices in the 2000s, around how the new pharmaceutical patent systems function.

Although TRIPS attracted much of the analysis, it has not been the only event with implications for IPRs. Sell (2010) shows that even after the Doha Declaration, brand-name pharmaceutical companies continued with their efforts to limit the scope of flexibilities and in other ways to expand the protection of IPRs. As soon as a certain issue or venue is exhausted (in the sense that a specific dispute is resolved, whether in favor of patent maximalists or patent minimalists), new issues emerge and new venues are explored in an attempt to reverse previous unfavorable outcomes. One example is the fight against counterfeits. According to Chorev (2015), debates over whether anti-counterfeit measures apply to medicines were in fact another nested dimension of the previous debate over IPRs. Looking at the case of Kenya, where the Industrial Property Act in 2001 was followed by the Anti-Counterfeit Act in 2008, Chorev identifies a range of actors—including pharmaceutical companies, activists, and state agencies—but at the same time suggests, more in line with those interested in structural conditions, that the contours of the latter struggle have been greatly shaped by and in the previous one.[6]

[6]On the credibility behind the alarm regarding fake drugs, see Hodges & Garnett (2020); on anti-counterfeit initiatives in the United States, see Blakeney (2013).

In turn, TRIPS's influence extends beyond access to medicines. Another stream of literature has considered TRIPS's impact on additional issues, including industrialization and innovation. Kyle & McGahan (2012) find that although patent protection in wealthy countries is associated with increased research and development (R&D) efforts, the introduction of patents in developing countries has not been followed by greater R&D investment in the diseases that are most prevalent there. Yet, Arora et al. (2008, p. 20) find that among India-based pharmaceutical companies, patent reform in line with TRIPS was followed by "an increase in both R&D investment and measured inventive output." Similarly, Horner (2014) finds that, contrary to expectations, the Indian pharmaceutical industry has continued to grow post-TRIPS, in part thanks to an increasingly collaborative relationship with multinationals.[7] The implication in both studies is that at least some private sectors—depending on their capabilities and broader institutional settings—may successfully adapt to new national regulations. Even more explicitly, Ryan (2010) claims that patent reforms provided incentives for Brazilian biomedical technology entrepreneurs to make risky investments in innovation; the reforms also facilitated technology markets among public–private technology innovation networks. A comparative analysis suggests, however, that India and Brazil see different types of pharmaceutical innovation in response to TRIPS. According to Schüren (2013, p. 237), domestic conditions—specifically, "the active (or absent) engagement of the state"—explain that variation. Shadlen (2007) moves beyond an abstract notion of government-led financial incentives, which supposedly allow some firms, if not all, to adapt through upgrading, to a more concrete analysis of how the new global political-economic IPR order turned the incentives of pharmaceutical companies in India against investing in production of generic versions of new drugs for AIDS treatment. The dire implication is that the fighting over TRIPS might be meaningless if the companies that were supposed to produce generic drugs for poor countries have turned elsewhere.[8]

Relatedly, another venue of research that emerged in conversation with IPR is the question of pharmaceutical production of generic drugs in low- and middle-income countries. One of the consequences of the TRIPS agreement in the context of the AIDS pandemic was a push for local pharmaceutical manufacturing also in countries with limited manufacturing capabilities. The literature on the political economy of pharmaceutical production in Brazil (Sweet 2013); China (Le & Samson 2021); India (Chaudhuri 2005); and Kenya, Tanzania, and Uganda (Chorev 2020), as well as Cuba, Egypt, Indonesia, Malaysia, Pakistan, South Africa, South Korea, and Turkey, considers the "aftermath of TRIPS" to be a constitutive moment (Williams & Löfgren 2013, p. 1). Shadlen & da Fonseca (2013, p. 562) explain how health policies may lead to interest in pharmaceutical industrialization. Looking at Brazil, they show that "activist policies directed toward the health sector can trigger efforts to stimulate capability development in the pharmaceutical industry."[9] A push for local pharmaceutical production in resource-poor countries was

[7]The debate on TRIPS's impact on production and innovation of medicine in India, Brazil, and other countries that were forced into patent reform echoes a broader debate on the issue that is similarly unresolved. Walsh et al. (2003) investigate whether increases in patenting of "research tools" in the drug discovery process hinder drug discovery itself. They suggest (*a*) that drug discovery has not been impeded by the increase in patenting of research tools; (*b*) likewise, university research has not been hindered by concerns about patents (except in the case of genetic diagnostics); and (*c*) this is, notwithstanding some delays and restrictions, due to access to negotiation to patented research tools. However, Orsi et al. (2006) offer a less optimistic view about the effects of patenting. They argue that patenting in upstream technologies (i.e., basic research, or tools for research) is threatening the future of basic research itself and has dangerous consequences all the way down to public health care.

[8]For a "social-historical" approach to innovation, see Pedraza-Fariña (2013).

[9]Yet, elsewhere Shadlen (2011, p. 146) also suggests that "the array of initiatives to encourage incremental innovations [that] has fostered the acquisition of innovative capabilities in the Brazilian pharmaceutical

motivated by both the cost of importing drugs and the promise of benefiting from international aid devoted to purchasing such drugs (Chorev 2020). With time, the discussion moved from what may be possible under TRIPS (Chaudhuri et al. 2010) to what has been achieved. Chorev (2020) examines the role of foreign aid in supporting local pharmaceutical production both before and after TRIPS; Mackintosh et al. (2016, p. 3) offer "a loud challenge to pessimism about African industrial development and health care commitment."

In sum, in contrast to the Era 1 scholarship that focused almost exclusively on activities and actors at the international level, the Era 2 scholarship shifted its attention to domestic processes and, as a result, to domestic actors, including not only governments but also pharmaceutical companies, civil society activists, and others—and the interactions and competition between them. This literature moved beyond the usual suspects and considered the role of individual government agencies, professions such as lawyers, and international actors in domestic settings. Divergence in implementation was explained not only by variation in actors and their actions but also by institutional and structural differences among countries. Finally, scholars have studied not only health policies but related issues, including pharmaceutical production and innovation. Most of these studies pay attention to the more marginal actors in international analyses—developing countries that were less influential in international negotiations but mattered greatly when it came to implementing TRIPS.

The major contributions of this scholarship notwithstanding, it ironically moved away from methodological internationalism only to fall back into the pitfall of methodological nationalism. Of course, TRIPS itself is considered an exogenous force, but once in place, the literature considers the international agreement as a given and looks only at actors and factors present within the confines of the nation-state boundaries. The dangers of methodological nationalism are on full display: These analyses consider each country's response as if it was independent from other countries' responses, with no attention to processes of diffusion, and these analyses fail to consider how countries' responses may impact the international level in turn.

ERA 3: INTERPLAY AND CONCURRENT CO-CONSTITUTION

In response to the methodological internationalism of the first era and the falling back into methodological nationalism of the second era, scholars began to pay greater attention to the interplay between the two realms—based on the insight that policy outcomes necessitate the inclusion of both domestic and international factors (Chorev 2007b), as well as attention to their interaction and mutual constitution.

Shadlen's (2007) analysis is an excellent illustration of how international conditions—here, the introduction of TRIPS—change domestic ones, beyond the legal obligations themselves. Shadlen convincingly argues that by altering the financial incentives of generic pharmaceutical companies in countries capable of supplying essential medicines, such as India, IP regulations changed these companies' interest in what drugs to produce. Consequently, "those actors capable of taking the economic, legal, and political steps necessary to increase the supply and availability of essential drugs have diminished interest in doing so, and those actors with an interest in expanding treatment may lack the capacities to address the problem of undersupply" (Shadlen 2007, p. 559). Similarly, looking at domestic pharmaceutical patent policies in India and Turkey, Eren-Vural (2006) finds sources of convergence that are associated with the increased structural power of transnational capital, but also sources of divergence, which have to do with the dynamics of

---

sector. . .have altered actors' policy preferences and thus contributed to the erosion of the coalition in support of. . .the health-oriented approach to examining pharmaceutical patents."

interclass politics in each country. Like Shadlen, then, Eren-Vural considers how TRIPS impacted the domestic terrain. Andia (2015) broadens the types of international influence on local dynamics that are of interest by analyzing the relations between domestic and international NGOs. Looking at how the global Kaletra campaign played out in Colombia and Ecuador, she shows that activism operated in an "inverse boomerang" pattern, by which an international NGO reached out to local allies to expand its global coalition, in the process prioritizing its own agenda over competing domestic considerations.

Still, we argue that studies that look at either how the domestic shapes the international or how the international shapes the domestic only get half the story. A more complete analysis necessarily requires a dynamic interplay between the domestic and the international. When Kapczynski (2009, p. 1643) reports that "rather than reject TRIPS, India has entered fully into the Agreement, while also creatively interpreting its terms," she suggests that India's IP reform was directly shaped by, but also shaped, TRIPS. In a more theoretically explicit way, Chorev (2012b) finds that in the process of implementing TRIPS, countries learned from each other how to deviate from what dominant actors considered the correct implementation.

The accumulated process of deviation eventually forced a new interpretation of the global norms—as formalized by the Doha Declaration. It is therefore a dynamic interplay between the international and the national—in which interests and strategies of domestic actors are not independent of the international processes, whereas international outcomes reflect not only international negotiations but also actions by governments and other actors at the domestic level.

But even the analyses that are sensitive to the interplay between the domestic and the international normally fail to capture the intersecting conditions that simultaneously constitute actors, their interests, and their strategies at the domestic and international levels. To overcome both methodological internationalism and methodological nationalism, it is not enough to look at how the international impacts the national that, then and only then, impacts the international (Chorev 2012b, Halliday & Carruthers 2009). Rather, we need to identify the political-economic processes in which both the domestic and the international are concurrently co-constituted in the process of global lawmaking. We need to understand how the domestic is being constituted by international negotiations at the same time that the international is being constituted by those domestic alterations. International negotiations over IPRs were constituted by domestic economic interests, geopolitical arrangements, and health concerns at the same time that these same international discussions led to the creation of new actors and the transformation of existing positions and interests. What this means is that we should stop thinking in terms of sequences.

Consequently, we should stop thinking in terms of making, ratification, and implementation of global laws as distinct and consecutive events that happen on different scales at different times. Instead, we need to understand that the factors that shape global law, ratification, and future implementations are made simultaneously at both levels. Here we draw broad insights from recent sociological approaches that, we believe, could inform not only the study of histories and politics but the study of law as well. We have in mind, in particular, sociological approaches that have moved beyond metropole-centric analysis of history to postcolonial and decolonial approaches (Go 2016, 2020; Hammer & White 2018; Itzigsohn & Brown 2015, 2020; Quisumbing King 2019; Zuberi 2004). Although not centrally concerned with relations between domestic and international laws, by positing that the social world is a network of interactions, including across scales, between actors who are themselves formed in those interactions, these approaches are useful in offering the tools needed for conceptualizing and studying what we call concurrent co-constitution. In this, we complement but also move beyond Conti's (2021) call for a relational turn in comparative law, by moving from comparative law to global law and, relatedly, calling to pay particular attention to relations of power.

There are certain analytical lacunas that a co-constitutive view of actors and structures fills. First, it allows for an open-ended view of interests. This approach refuses to take interests as given but instead asks about their construction and transformation. Second, it allows for an open-ended view of power. A co-constitutive approach clarifies the process and outcomes of negotiations by looking at power dynamics and strategies. One strategy to get what one wants is to alter the interests of those most likely to oppose. This approach therefore can explain the disproportionate influence of countries from the Global North, but also the ability of countries from the Global South to successfully resist impositions in some cases. Finally, and importantly, a co-constitutive approach allows us—in fact, forces us—to incorporate the historical dimensions of the present. Both interests and power dynamics are rooted in historical processes—including, in the context of North–South relations, in colonialism—that established the differentials in innovation and industrial capabilities, health conditions, and other characteristics that the literature is rightly concerned about.

CONCLUSION

The literature on IPRs and international health emergencies is emblematic of the methodological challenges social scientists and sociolegal scholars face when studying global phenomena. Methodological internationalism emphasizes processes that take place at the international level at the expense of equally important events that happen at the domestic level and that shape and are shaped by member states and other actors' positions in international negotiations. In turn, methodological nationalism is concerned with domestic factors and actors in a way that overshadows the impact exogenous influences may have. Considering this, we propose to further advance the recent scholarship that considers the interplay between domestic and international actors, institutions, and conditions by paying attention to the concurrent co-constitution of the international and the national.

In addition to these methodological considerations, and given that most of the scholarship on IPRs and international health emergencies is concerned with the impact that IP protection may have on access to medicines, we propose to move beyond IPRs, particularly patents, to identify other constraints that may impede the supply and affordability of medicines and other health technologies. The COVID-19 pandemic powerfully demonstrates that IPR protection is not the only barrier that limits access to vaccines and other health technologies across the globe. Authors have considered factors that affected the supply and affordability of vaccines and other products, such as limited manufacturing capacity, disruptions in supply chains, export restrictions (Le & Samson 2021), and import tariffs and nontariff restrictions (Banik et al. 2021). Others have looked at nonpatent IPR barriers to the global scale-up of access to COVID vaccines and treatments (Flynn et al. 2021). Focusing on other topics besides pharmaceutical patents could help us find complementary causes and solutions to access barriers. For example, Brennan et al. (2016) discuss the issue of excessive pricing in the United States, and rather than focusing on patents and competition, they suggest the use of a domestic US law that gives the government power to buy generic versions of medicines cheaply.

Moreover, as some authors have suggested for a while now, we may be paying too much attention to pharmaceuticals over other relevant health aspects. For instance, Biehl (2004, p. 105; 2007) argues that because Brazil's AIDS policy was associated with a form of health delivery that was pharmaceutically mediated, "it changed the concept of public health from clinical care and prevention to medicamentation." Elsewhere, Biehl (2008) suggests that the pharmaceuticalization of AIDS and of public health more broadly crystallizes new inequalities. It is worth considering how a broader understanding of what better global health means could be incorporated in the analysis of events taking place at both the domestic and the international levels.

How, then, should we study global lawmaking? Drawing on the rich literature on IPRs and international health emergencies, we call for a concurrent co-constitutive methodological approach that considers the concurrent shaping and reshaping of both domestic and international factors. But we also call for the expansion of what we study as global lawmaking. International treaties, agreements, and declarations are crucial to understand, but they should not come at the expense of alternative paths through which the global is made and remade.

DISCLOSURE STATEMENT

The authors are not aware of any affiliations, memberships, funding, or financial holdings that might be perceived as affecting the objectivity of this review.

LITERATURE CITED

Abbott FM. 2002. The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO. *J. Int. Econ. Law* 5:469–505

Abbott FM, Reichman JH. 2007. The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *J. Int. Econ. Law* 10:921–87

Aginam O, Harrington J, Yu PK, eds. 2013. *The Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines*. Elgar Intell. Prop. Glob. Dev. Ser. Northampton, MA: Edward Elgar

Andia T. 2011. The invisible threat: trade, intellectual property, and pharmaceutical regulations in Colombia. In *Intellectual Property, Pharmaceuticals, and Public Health: Access to Drugs in Developing*, ed. KC Shadlen, S Guennif, A Guzmán, N Lalitha, pp. 77–109. Northampton, MA: Edward Elgar

Andia T. 2015. The inverse boomerang pattern: the global Kaletra campaign and access to antiretroviral drugs in Colombia and Ecuador. *Stud. Comp. Int. Dev.* 50:203–27

Andia T. 2016. *Bureaucrats against the state: the making of pharmaceutical policy in Latin America*. PhD Diss., Brown Univ., Providence, RI

Araujo BA. 2013. Intellectual property and the EU's deep trade agenda. *J. Int. Econ. Law* 16:439–74

Arora A, Branstetter L, Chatterjee C. 2008. *Strong medicine: patent reform and the emergence of a research-driven pharmaceutical industry in India*. Presented at Location of Biopharmaceutical Activity, H John Heinz III School of Public Policy Management, Carnegie Mellon University, Pittsburgh, PA. **http://conference.nber.org/confer/2008/si2008/IPPI/branstetter.pdf**

Athreye S, Piscitello L, Shadlen KC. 2020. Twenty-five years since TRIPS: patent policy and international business. *J. Int. Bus. Policy* 3:315–28

Attaran A, Gillespie-White L. 2001. Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa? *JAMA* 286:1886–92

Banik N, Chakraborty D, Dash S. 2021. *IPR waiver in vaccines and opportunities for India: What does the data show?* Work. Pap., Asia-Pac. Res. Train. Netw. Trade, Bangkok

Barnard D. 2002. In the High Court of South Africa, Case No. 4138/98: the global politics of access to low-cost AIDS drugs in poor countries. *Kennedy Inst. Ethics J.* 12:159–74

Bartley T. 2007. Institutional emergence in an era of globalization: the rise of transnational private regulation of labor and environmental conditions. *Am. J. Sociol.* 113:297–351

Barton JH. 2004. TRIPS and the global pharmaceutical market. *Health Aff.* 23:146–54

Biehl JG. 2004. The activist state: global pharmaceuticals, AIDS, and citizenship in Brazil. *Soc. Text* 22:105–32

Biehl J. 2007. *Will to Live: AIDS Therapies and the Politics of Survival*. Princeton, NJ: Princeton Univ. Press

Biehl J. 2008. Drugs for all: the future of global AIDS treatment. *Med. Anthropol.* 27:99–105

Blakeney M. 2013. Covert international intellectual property legislation: the ignoble origins of the Anti-Counterfeiting Trade Agreement (ACTA). *Mich. State Int. Law Rev.* 21:87–114

Bond P. 1999. Globalization, pharmaceutical pricing, and South African health policy: managing confrontation with U.S. firms and politicians. *Int. J. Health Serv.* 29:765–92

Bond P. 2003. *Against Global Apartheid: South Africa Meets the World Bank, IMF, and International Finance*. London: Zed Books. 2nd ed.

Brennan H, Kapczynski A, Monahan CH, Rizvi Z. 2016. A prescription for excessive drug pricing: leveraging government patent use for health. *Yale J. Law Technol.* 15:275–354

Buse K, Walt G. 2000. Global public-private partnerships: part I—a new development in health? *Bull. World Health Organ.* 78:549–61

Cassier M. 2013. Pharmaceutical patent law in-the-making: opposition and legal action by states, citizens, and generics laboratories in Brazil and India. In *Ways of Regulating Drugs in the 19th and 20th Centuries*, ed. J-P Gaudillière, V Hess, pp. 287–317. London: Palgrave Macmillan

Cassier M, Marilena C. 2003. Patents, innovation and public health: Brazilian public-sector laboratories' experience in copying AIDS drugs. In *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries: Issues and Challenges*, ed. JP Moatti, B Coriat, Y Souteyrand, T Barnett, J Dumoulin, J Flori, pp. 89–108. Paris: ANRS

Castro A, Westerhaus M. 2007. Access to generic antiretrovirals: inequality, intellectual property law, and international trade agreements. *Cad Saúde Pública* 23:S85–S96

Chander A, Sunder M. 2018. The battle to define Asia's intellectual property law: TPP to RCEP. *UC Irvine Law Rev.* 8:331–62

Chaudhuri S. 2005. *TRIPS and changes in pharmaceutical patent regime in India*. Work. Pap. 535, Indian Inst. Manag. Calcutta, Joka, India

Chaudhuri S, Mackintosh M, Mujinja PGM. 2010. Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. *Eur. J. Dev. Res.* 22:451–68

Chaves GC, Vieira MF, Reis R. 2008. Access to medicines and intellectual property in Brazil: reflections and strategies of civil society. *Sur Int. J. Hum. Rights* 5:170–98

Chorev N. 2005. The institutional project of neo-liberal globalism: the case of the WTO. *Theory Soc.* 34:317–55

Chorev N. 2007a. *Remaking US Trade Policy: From Protectionism to Globalization*. Ithaca, NY: Cornell Univ. Press

Chorev N. 2007b. A fluid divide: domestic and international factors in US trade policy formation. *Rev. Int. Political Econ.* 14:653–89

Chorev N. 2012a. *The World Health Organization between North and South*. Ithaca, NY: Cornell Univ. Press

Chorev N. 2012b. Changing global norms through reactive diffusion: the case of intellectual property protection of AIDS drugs. *Am. Sociol. Rev.* 77:831–53

Chorev N. 2013. Restructuring neoliberalism at the World Health Organization. *Rev. Int. Political Econ.* 20:627–66

Chorev N. 2015. Narrowing the gaps in global disputes: the case of counterfeits in Kenya. *Stud. Comp. Int. Dev.* 50:157–86

Chorev N. 2020. *Give and Take: Developmental Foreign Aid and the Pharmaceutical Industry in East Africa*. Princeton Stud. Glob. Comp. Sociol. Princeton, NJ: Princeton Univ. Press

Chorev N, Andia T, Ciplet D. 2011. The state of states in international organizations: from the WHO to the Global Fund. *Review* 34:285–310

Chorev N, Shadlen KC. 2015. Intellectual property, access to medicines, and health: new research horizons. *Stud. Comp. Int. Dev.* 50:143–56

Cohen JC, Lybecker KM. 2005. AIDS policy and pharmaceutical patents: Brazil's strategy to safeguard public health. *World Econ.* 28:211–30

Conti JA. 2021. Relational sociology and comparative law. *Am. J. Comp. Law* 69(4):636–63

Coriat B, ed. 2008. *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems, and Free Access*. Northampton, MA: Edward Elgar

Coriat B, Orsi F, d'Almeida C. 2006. TRIPS and the international public health controversies: issues and challenges. *Ind. Corp. Change* 15:1033–62

Correa CM. 2006. Implications of bilateral free trade agreements on access to medicines. *Bull. World Health Organ.* 84:399–404

Demortain D. 2015. The tools of globalization: ways of regulating and the structure of the international regime for pharmaceuticals. *Rev. Int. Political Econ.* 22:1249–75

Dontje A. 2015. Rethinking trips: the future of pharmaceutical patents. *Wis. Int. Law J.* 33:380–409

Drahos P. 1995. Global property rights in information: the story of TRIPS at the GATT. *Prometheus* 13:6–19

Drahos P. 2001. BITs and BIPs: bilateralism in intellectual property. *J. World Intellect. Prop.* 4:791–808
Drahos P. 2007. Four lessons for developing countries from the trade negotiations over access to medicines. *Liverp. Law Rev.* 28:11–39
Drahos P. 2008. "Trust me": patent offices in developing countries. *Am. J. Law Med.* 34:151–74
Drahos P. 2010. *The Global Governance of Knowledge: Patent Offices and Their Clients*. Cambridge, UK: Cambridge Univ. Press
Dreyfuss RC, Rodríguez-Garavito C, eds. 2014. *Balancing Wealth and Health: Global Administrative Law and the Battle over Intellectual Property and Access to Medicines in Latin America*. Oxford, UK: Oxford Univ. Press
Eren-Vural I. 2006. Domestic contours of global regulation: understanding the policy changes on pharmaceutical patents in India and Turkey. *Rev. Int. Political Econ.* 14:105–42
Flynn M. 2013. Origins and limitations of state-based advocacy: Brazil's AIDS treatment program and global power dynamics. *Politics Soc.* 41:3–28
Flynn S, Nkrumah E, Schirru L. 2021. *Non-patent intellectual property barriers to COVID-19 vaccines, treatment and containment*. Res. Pap. 71, PIJIP/TLS Res. Pap. Ser.
Ford N. 2004. Patents, access to medicines and the role of non-governmental organisations. *J. Generic Med.* 1:137–45
Ford N, Wilson D, Chaves GC, Lotrowska M, Kijtiwatchakul K. 2007. Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand. *AIDS* 21:S21–S29
Friedman S, Mottiar S. 2005. A rewarding engagement? The Treatment Action Campaign and the politics of HIV/AIDS. *Politics Soc.* 33:511–65
Gathii JT. 2011. The neoliberal turn in regional trade agreements. *Wash. Law Rev.* 86:421–74
Gaudillière J-P. 2014. Herbalised Ayurveda? *Asian Med.* 9:171–205
Go J. 2016. *Postcolonial Thought and Social Theory*. New York: Oxford Univ. Press
Go J. 2020. Race, empire, and epistemic exclusion: or the structures of sociological thought. *Sociol. Theory* 38:79–100
Godoy AS. 2015. Market myths and assumptions: examining the transnational politics of access to medicines campaigning in Central America. *Stud. Comp. Int. Dev.* 50:187–202
Guan W. 2016. IPRs, public health, and international trade: an international law perspective on the TRIPS amendment. *Leiden J. Int. Law* 29:411–40
Halliday TC, Carruthers BG. 2009. *Bankrupt: Global Lawmaking and Systemic Financial Crisis*. Stanford, CA: Stanford Univ. Press
Hammer R, White AIR. 2018. Toward a sociology of colonial subjectivity: political agency in Haiti and Liberia. *Sociol. Race Ethn.* 5:215–28
Harris D. 2011. TRIPs after fifteen years: success or failure, as measured by compulsory licensing. *J. Intellect. Prop. Law* 18:367–400
Helfer LR. 2004. Regime shifting: the TRIPs Agreement and new dynamics of international intellectual property lawmaking. *Yale J. Int. Law* 29:1–83
Helfer LR, Alter KJ. 2014. The influence of the Andean intellectual property regime on access to medicines in Latin America. See Dreyfuss & Rodríguez-Garavito 2014, pp. 247–62
Hodges S, Garnett E. 2020. The ghost in the data: evidence gaps and the problem of fake drugs in global health research. *Glob. Public Health* 15:1103–18
Hopewell K. 2015a. Different paths to power: the rise of Brazil, India and China at the World Trade Organization. *Rev. Int. Political Econ.* 22:311–38
Hopewell K. 2015b. Multilateral trade governance as social field: global civil society and the WTO. *Rev. Int. Political Econ.* 22:1128–58
Horner R. 2014. The impact of patents on innovation, technology transfer and health: a pre- and post-TRIPs analysis of India's pharmaceutical industry. *New Political Econ.* 19:384–406
Itzigsohn J, Brown K. 2015. Sociology and the theory of double consciousness: W.E.B. Du Bois's phenomenology of racialized subjectivity. *Du Bois Rev.* 12:231–48
Itzigsohn J, Brown K. 2020. *The Sociology of W.E.B. Du Bois: Racialized Modernity and the Global Color Line*. New York: NYU Press
Kaminski M. 2014. The capture of international intellectual property law through the U.S. trade regime. *South. Calif. Law Rev.* 87:977–1052

Kapczynski A. 2009. Harmonization and its discontents: a case study of TRIPS implementation in India's pharmaceutical sector. *Calif. Law Rev.* 97:1571–649

Kapczynski A. 2023. The political economy of market power in pharmaceuticals. *J. Health Politics Policy Law* 48:215–39

Kapczynski A, Krikorian G, eds. 2010. *Access to Knowledge in the Age of Intellectual Property*. New York: Zone Books

Kapstein EB, Busby JW. 2016. Social movements and market transformations: lessons from HIV/AIDS and climate change. *Int. Stud. Q.* 60:317–29

Keck ME, Sikkink K. 1998. *Activists Beyond Borders: Advocacy Networks in International Politics*. Ithaca, NY: Cornell Univ. Press

Klug H. 2005. Campaigning for life: building a new transnational solidarity in the face of HIV/AIDS and TRIPS. In *Law and Globalization from Below: Towards a Cosmopolitan Legality*, ed. B de Sousa Santos, CA Rodríguez-Garavito, pp. 118–39. Cambridge, UK: Cambridge Univ. Press

Klug H. 2008. Law, politics, and access to essential medicines in developing countries. *Politics Soc.* 36:207–45

Klug H. 2012. Access to medicines and the transformation of the South African state: exploring the interactions of legal and policy changes in health, intellectual property, trade, and competition law in the context of South Africa's HIV/AIDS pandemic. *Law Soc. Inq.* 37:297–329

Kyle MK, McGahan AM. 2012. Investments in pharmaceuticals before and after TRIPS. *Rev. Econ. Stat.* 94:1157–72

La Croix S, Ming L. 2008. The effect of GDP growth on pharmaceutical patent protection, 1945–2005. *Bruss. Econ. Rev.* 52:355–75

Lanjouw J. 1998. *The introduction of pharmaceutical product patents in India: "Heartless exploitation of the poor and suffering"?* NBER Work. Pap. 6366

Lanjouw J. 2002. A new global patent regime for diseases: U.S. and international legal issues. *Harvard J. Law Technol.* 16:85–124

Lanoszka A. 2003. The global politics of intellectual property rights and pharmaceutical drug policies in developing countries. *Int. Political Sci. Rev.* 24:181–97

Le VA, Samson L. 2021. Are IPRs and patents the real barriers to COVID-19 vaccine supplies? *Manch. J. Int. Econ. Law* 18:192–204

Löfgren H, Williams OD. 2013. *New Political Economy of Pharmaceuticals: Production, Innovation and Trips in the Global South*. London: Palgrave Macmillan

Mackintosh M, Banda G, Tibandebage P, Wamae W, eds. 2016. Introduction: African industrial development, values and health care. In *Making Medicines in Africa: The Political Economy of Industrializing for Local Health*, pp. 1–4. Int. Political Econ. Ser. London: Palgrave Macmillan

Malbon J, Lawson C, eds. 2008. *Interpreting and Implementing the TRIPS Agreement: Is It Fair?* Northampton, MA: Edward Elgar

Matthews D, Munoz-Tellez V. 2006. Bilateral technical assistance and TRIPS: the United States, Japan and the European communities in comparative perspective. *J. World Intellect. Prop.* 9:629–53

Matthews DN. 2002. *Trade-related aspects of intellectual property rights: Will the Uruguay round consensus hold?* Work. Pap. 99/02, Cent. Stud. Glob. Reg., Coventry, UK

Mitchell RB. 2003. International environmental agreements: a survey of their features, formation, and effects. *Annu. Rev. Environ. Resour.* 28:429–61

Morin J-F. 2010. The two-level game of transnational networks: the case of the access to medicines campaign. *Int. Interact.* 36:309–34

Morin J-F, Gold ER. 2014. An integrated model of legal transplantation: the diffusion of intellectual property law in developing countries. *Int. Stud. Q.* 58:781–92

Muzaka V. 2009. Dealing with public health and intellectual property for pharmaceuticals at the World Trade Organization. In *Health for Some: The Political Economy of Global Health Governance*, ed. SJ MacLean, SA Brown, P Fourie, pp. 183–95. London: Palgrave Macmillan

Nichols S. 2018. Expanding property rights under investor-state dispute settlement (ISDS): class struggle in the era of transnational capital. *Rev. Int. Political Econ.* 25:243–69

Oliveira MA, Bermudez JAZ, Chaves GC, Velásquez G. 2004. Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health? *Bull. World Health Organ.* 82:815–21

Orsi F, Sevilla C, Coriat B. 2006. Upstream patents and public health: the case of genetic testing for breast cancer. In *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, ed. M Mazzucato, G Dosi, pp. 327–45. Cambridge, UK: Cambridge Univ. Press

Ostry S. 2000. Convergence and sovereignty. In *Coping with Globalization*, ed. JA Hart, A Prakash, pp. 52–76. London: Routledge

Paine L, Santoro M. 1992. *Pfizer: global protection of intellectual property*. Case 392-073, Harvard Bus. School, Cambridge, MA

Parra-Salas LE. 2013. Propiedad intelectual, competencia y aspectos regulatorios del medicamento: determinantes internacionales y política pública. *Rev. Gerencia Políticas Salud* 13(26):159–61

Pedraza-Fariña LG. 2013. Patent law and the sociology of innovation. *Wis. Rev.* 2013:813–73

Pogge T. 2012. The Health Impact Fund: enhancing justice and efficiency in global health. *J. Hum. Dev. Capab.* 13:537–59

Pordié L, Gaudillière J-P. 2014. The reformulation regime in drug discovery: revisiting polyherbals and property rights in the Ayurvedic industry. *East Asian Sci. Technol. Soc. Int. J.* 8:57–79

Postigo A. 2016. Institutional spillovers from the negotiation and formulation of East Asian free trade agreements: government-business relations in the policymaking of bilateral free trade agreements. *Rev. Int. Political Econ.* 23:379–417

Pugatch MP. 2004. *The International Political Economy of Intellectual Property Rights*. New Horiz. Intell. Prop. Northampton, MA: Edward Elgar

Quisumbing King K. 2019. Recentering US empire: a structural perspective on the color line. *Sociol. Race Ethn.* 5:11–25

Rao CN. 2006. Para 6 of WTO Doha Declaration: non-solution of TRIPS problem. *Econ. Political Wkly.* 41:301–3

Reichman JH. 2009. Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options. *J. Law. Med. Ethics* 37:247–63

Reichman JH, Dreyfuss C. 2007. Harmonization without consensus: critical reflections on drafting a substantive patent law treaty. *Duke Law J.* 57:85–130

Roemer-Mahler A. 2013. Business conflict and global politics: the pharmaceutical industry and the global protection of intellectual property rights. *Rev. Int. Political Econ.* 20:121–52

Roffe P, Spennemann C. 2006. The impact of FTAs on public health policies and TRIPS flexibilities. *Int. J. Intellect. Prop. Manag.* 1:75–93

Ryan MP. 1998. The function-specific and linkage-bargain diplomacy of international intellectual property lawmaking. *Univ. Pa. J. Int. Econ. Law* 19:535–43

Ryan MP. 2010. Patent incentives, technology markets, and public-private bio-medical innovation networks in Brazil. *World Dev.* 38:1082–93

Sampat BN, Shadlen KC. 2015. TRIPS implementation and secondary pharmaceutical patenting in Brazil and India. *Stud. Comp. Int. Dev.* 50:228–57

Sampat BN, Shadlen KC, Amin TM. 2012. Challenges to India's pharmaceutical patent laws. *Science* 337:414–15

Schüren V. 2013. What a difference a state makes: pharmaceutical innovation after the TRIPs agreement. *Bus. Politics* 15:217–43

Sell SK. 2003. *Private Power, Public Law: The Globalization of Intellectual Property Rights.* Cambridge Stud. Int. Relat. Cambridge, UK: Cambridge Univ. Press

Sell SK. 2007. TRIPS-Plus free trade agreements and access to medicines. *Liverp. Law Rev.* 28:41–75

Sell SK. 2010. *The global IP upward ratchet, anti-counterfeiting and piracy enforcement efforts: the state of play*. PIJIP Res. Pap. 15, Am. Univ. Wash. Coll. Law, Washington, DC

Sell SK. 2011a. TRIPS: fifteen years later. *J. Intellect. Prop. Law* 18(2):1–29

Sell SK. 2011b. TRIPS was never enough: vertical forum shifting, FTAS, ACTA, and TTP. *J. Intellect. Prop. Law* 18:447–78

Sell SK, Prakash A. 2004. Using ideas strategically: the contest between business and NGO networks in intellectual property rights. *Int. Stud. Q.* 48:143–75
Shadlen KC. 2004. Patents and pills, power and procedure: the North-South politics of public health in the WTO. *Stud. Comp. Int. Dev.* 39:76–108
Shadlen KC. 2007. The political economy of AIDS treatment: intellectual property and the transformation of generic supply. *Int. Stud. Q.* 51:559–81
Shadlen KC. 2009. The politics of patents and drugs in Brazil and Mexico: the industrial bases of health policies. *Comp. Politics* 42:41–58
Shadlen KC. 2011. The political contradictions of incremental innovation: lessons from pharmaceutical patent examination in Brazil. *Politics Soc.* 39:143–74
Shadlen KC. 2017. *Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America*. Oxford, UK: Oxford Univ. Press
Shadlen KC, da Fonseca EM. 2013. Health policy as industrial policy: Brazil in comparative perspective. *Politics Soc.* 41:561–87
Shadlen KC, Sampat BN, Kapczynski A. 2020. Patents, trade and medicines: past, present and future. *Rev. Int. Political Econ.* 27:75–97
Slade A. 2016. The objectives and principles of the WTO TRIPS agreement: a detailed anatomy. *Osgoode Hall Law J.* 53:948–98
Sweet CM. 2013. The political economy of pharmaceutical production in Brazil. In *The New Political Economy of Pharmaceuticals*, ed. H Löfgren, OD Williams, pp. 29–47. London: Palgrave Macmillan
't Hoen E. 2002. TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha. *Chicago J. Int. Law* 3:27–46
't Hoen E, Berger J, Calmy A, Moon S. 2011. Driving a decade of change: HIV/AIDS, patents and access to medicines for all. *J. Int. AIDS Soc.* 14:15
Thomas C. 2002. Trade policy and the politics of access to drugs. *Third World Q.* 23:251–64
Townsend B, Gleeson D, Lopert R. 2018. Japan's emerging role in the global pharmaceutical intellectual property regime: a tale of two trade agreements. *J. World Intellect. Prop.* 21:88–103
Verger A, van Paassen B. 2013. Human development vis-à-vis free trade: understanding developing countries' positions in trade negotiations on education and intellectual property rights. *Rev. Int. Political Econ.* 20:712–39
Wade RH. 2003. What strategies are viable for developing countries today? The World Trade Organization and the shrinking of "development space." *Rev. Int. Political Econ.* 10:621–44
Walker N. 2015. *Intimations of Global Law*. Cambridge, UK: Cambridge Univ. Press
Walsh JP, Arora A, Cohen WM. 2003. Effects of research tool patents and licensing on biomedical innovation. In *Patents in the Knowledge-Based Economy*, ed. WM Cohen, SA Merrill, pp. 285–340. Washington, DC: Natl. Acad. Sci. Eng. Med.
Watal J, Taubman A, eds. 2015. *The Making of the Trips Agreement: Personal Insights from the Uruguay Round Negotiations*. Geneva: World Trade Organ.
Weiss L. 2005. Global governance, national strategies: how industrialized states make room to move under the WTO. *Rev. Int. Political Econ.* 12:723–49
Weissman R. 2004. Long, strange trips: the pharmaceutical industry drive to harmonize global intellectual property rules, and the remaining WTO legal alternatives available to third world countries. *Univ. Pa. J. Int. Econ. Law* 25:1079–132
Williams OD, Löfgren H. 2013. The new political economy of pharmaceuticals: conformity and resistance in the Global South. In *The New Political Economy of Pharmaceuticals*, ed. H Löfgren, OD Williams, pp. 1–28. London: Palgrave Macmillan
Wimmer A, Glick Schiller N. 2002. Methodological nationalism and beyond: nation-state building, migration and the social sciences. *Glob. Netw.* 2:301–34
Yu PK. 2012. Intellectual property and human rights in the nonmultilateral era. *Fla. Law Rev.* 64:1045–100
Zeller C. 2007. From the gene to the globe: extracting rents based on intellectual property monopolies. *Rev. Int. Political Econ.* 15:86–115
Zuberi T. 2004. W.E.B. Du Bois's sociology: *The Philadelphia Negro* and social science. *Ann. Am. Acad. Political Soc. Sci.* 595:146–56