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Intellectual Property, Access to Medicines, and Health: New Research Horizons

Introduction to Special Issue in *Studies in Comparative International Development*, on "Intellectual Property, Access to Medicines, and Health"

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Abstract

In this introduction we briefly review the literature on intellectual property rights and access to medicines, identifying two distinct generations of research. The first generation analyzes the origins of new intellectual property rules, in particular the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the significance of TRIPS to developing countries. The second generation examines national-level experiences, as countries adjust their laws and practices to conform to TRIPS. Based on the insights provided by the articles in the special issue, we contribute to the second generation by considering a pair of overarching sets of issues. First, we highlight the domestic political challenges that affect how countries go about implementing their new obligations under TRIPS. We argue that alliances and coalitions are necessary to underpin the use of policy instruments designed to conform to TRIPS while taking into account local conditions and needs, , and we present insights that allow us to understand why alliances and coalitions are difficult to construct and sustain in this area. Second, we explain why policies that many countries adopt in response to TRIPS often do not generate their desired or intended outcomes. In the last section of the introduction we review the articles that appear in this special issue.

Introduction[1]

Global changes have national consequences. Changes in international rules affect national policies and practices, which in turn affect the people's lives and livelihood. This special issue addresses these relationships by examining how changes in the rules of the international trade system can affect national development policies that bear on health.

International trade rules may bear on health through a complex causal chain linking access to health to access to medicines, access to medicines to price of drugs, and price of drugs to intellectual property (IP) protection. The World Health Organization (WHO) estimates that one-third of the people living in developing countries are unable to receive or purchase essential medicines on a regular basis. [2] In pursuit of better health care outcomes, one of the many challenges governments face is improving access to medicines. And the price of drugs, in turn, can create challenges for improving access to medicines. While health, access to medicines, and the price of drugs are, of course, a function of many factors, one important issue regards the role of intellectual property (IP). Where pharmaceutical firms have patents on drugs, they can, potentially, limit the competition they face and raise the price of drugs.

This causal chain linking IP to health has become increasingly important and received a great deal of attention on account of major changes at the global level that mark the start of the 21st Century. Specifically, when the World Trade Organization (WTO) was founded in

[1] The special issue is a result of two workshops hosted by the Watson Institute for International Studies, Brown University. The first, on "Global Governance and Civil Society," took place in October 2012; the second, on "Access to Medicines in the Global South," took place in January 2014. We would like to thank Peter Evans for suggesting and co-organizing the workshops, and for his continuous support throughout this process. We would also like to thank Barbara Stallings for her support and guidance in bringing the collection of papers together in this special issue of the journal. Matthew Flynn, Anne Roemer-Mahler, Valbona Muzaka, and two anonymous reviewers provided invaluable comments on this introduction, for which we are grateful.

[2] http://www.who.int/trade/glossary/story002/en/

1995, it included the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). For the first time rules that affect national policies on IP were included in the international trade regime.

TRIPS fundamentally reshaped the debate over access to medicines. Prior to TRIPS, countries had significant autonomy in designing and implementing their IP policies. Concerned about the effects that IP in pharmaceuticals might have on the price of drugs and health, for example, many countries did not allow patents in this area.[3] TRIPS requires all countries to grant pharmaceutical patents. The extension of the international patent system to mandate coverage of pharmaceuticals, a major and unprecedented shift, has sparked widespread interest and concern over what impact it would have on access to medicines, especially in countries with limited resources.[4]

Scholarship on the politics of IP and the IP-medicines-health nexus can be thought of in terms of two generations of research. The overwhelming amount of research on the topic, which constitutes the first generation, has examined changes to the global architecture: where the new IP rules came from and the significance of the changes in international rules for developing countries' array of available policy options. A principal contribution of this research has been to show how IP became defined and treated as "trade-related" in the 1980s and 90s and, subsequently, integrated into the international trade regime. To explain this shift, analysts have focused principally on the lobbying activities of firms and trade

[3] Patents, which are a form of IP, constitute private property rights over knowledge and inventions.

[4] Among the many works addressing these concerns, see Lanjouw (2002), Lanoszka (2003), Barton (2004), Chaudhuri (2005), Roffe et al (2005), Corriat et al (2006), Coriat (2008), Malbon and Lawson (2008), La Croix and Liu (2008), Aginam, Harrington, and Yu (2013), Lofgren et al (2013).

associations from pharmaceuticals (and other IP-sensitive sectors) that sought greater protection on a global scale.[5]

The results of these efforts include TRIPS, of course, but more generally the prominent place that IP plays in the foreign economic policies of the world's leading powers. After all, TRIPS is hardly the only international agreement on IP that affects developing countries – it is not even the only "trade-related" international agreement on IP that affects developing countries. Throughout this period both the USA and the European Union have negotiated bilateral trade agreements that also include IP provisions, provisions that typically exceed those in the WTO.[6]

Intrinsically linked to scholarship on the making of new international rules, and also part of the first generation, is research on what these rules imply for developing countries' policy choices (Reichman 1996; Correa 2000b; Watal 2001; Commission on Intellectual Property Rights 2002; Weissman 1996). Here it is important to underscore that TRIPS constitutes a set of minimal standards to which countries comply, leaving opportunities for cross-national variation in how they do so. That is, within the constraints established by the new global regime, countries have "flexibilities."[7] For example, in the area of pharmaceuticals, TRIPS requires countries to grant pharmaceutical patents – but it left some discretion regarding the timing of when they began to do so and other issues related to

[5] Countless studies have highlighted the role of transnational pharmaceutical firms in pushing for stronger patent protection. See, among others, Paine and Santoro (1992), Drahos (1995), Ryan (1998), Braithwaite and Drahos (2000), Matthews (2002), Sell (2003), Pugatch (2004), Sell (2010a), Muzaka (2011), Roemer-Mahler (2013).

[6] Among the many works that contrast the IP provisions in the WTO and regional and bilateral trade agreements, see Fink and Reichenmiller (2005), Shadlen (2005), El-Said (2005 and 2007), Mercurio (2006), Morin (2006 and 2009), Sell (2007 and 2010), Krikorian and Szymkowiak (2007), Deere (2008).

[7] Examination of countries' flexibilities within the new international IP environment is consistent with – and part of – broader analyses of "policy choice" in the context of new global economic regimes (UNDP 2003; Gallagher 2013).

implementation of this new obligation.[8] Likewise, once patents are granted, TRIPS requires minimal standards of protection, but, again, how countries go about complying with these new standards can vary from country to country in ways that affect, de facto, the balance of power between the actors who own the patents and the actors that seek to use proprietary knowledge.

In the period since TRIPS came into affect, research on the international regime and policy implications has focused largely on the "Doha Declaration on the TRIPS Agreement and Public Health," which was adopted by the WTO Ministerial Conference of 2001. The Doha Declaration itself did not alter the TRIPS Agreement; it is a simple seven-paragraph document that affirms what was already in TRIPS. Yet by clarifying the rules and removing ambiguity as to what steps were acceptable under TRIPS, and most importantly by underscoring countries' rights to implement their new international IP obligations in health-supportive ways, the Doha Declaration aimed to facilitate the use of flexibilities. Related to the Doha Declaration was a subsequent agreement that addressed specific problems of countries with insufficient manufacturing capabilities, by addressing the conditions under which drugs could be exported from countries where they are patented to specifically designated countries.[9]

Complementing and building on the research on international IP rules and their implications, a second generation of research examined national-level implementation and the "on the ground" effects of these grand changes. Here, analytic attention shifts from the constraints that the global political economy presents to the actions taken by countries in response. This is a natural progression. After carefully analyzing the processes by which new

[8] Countries that did not grant pharmaceutical patents as of the start of TRIPS had until 2005 to do so. Countries varied in how much of this transition period they utilized.

[9] We refer here to the "Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," adopted in August 2003. For analyses of these events, see, among others, Chorev (2012), Shadlen (2004), Abbott and Reichman (2007).

international rules were created, it is logical for scholars to examine how and the extent to which these were implemented at the national level, especially given the built-in flexibilities in the international agreement.

The literature on TRIPS implementation includes a proliferation of case studies, both single-country and cross-national, providing fresh observations of what is happening on the ground in various parts of the world. We do not purport to review this whole body of works here, rather we wish to point to some of the various explanatory factors that have been invoked. For example, Deere's (2008) cross-national analysis of TRIPS implementation points to the role of wide range of factors, including international pressures, state capacities, inter-agency coordination, and government volition. Drahos's (2010) analysis of patent offices in the developing world considers the role of technical assistance as a source of socialization. May (2004) and Matthews and Munoz-Tellez (2006) also examine the role of technical assistance in shaping national policies. Matthews's (2011) analysis of IP policymaking in Brazil, India, and South Africa focuses on the role of non-governmental actors. Nunn (2009) traces the driving force of social mobilization in the Brazilian approach to pharmaceutical patents, while Flynn (2015) emphasizes the important role that health activists in the state bureaucracy played in pushing the Brazilian government to utilize TRIPS flexibilities. Eren-Vural's (2007) analysis of India and Turkey and Shadlen's (2009) comparison of patent policies in Brazil and Mexico both emphasize the importance of industrial structure for coalition formation.[10] Ultimately, work on national-level IP politics remains incipient and eclectic. In contrast to the first generation of research discussed above, which offers a clear narrative of governments responding to business lobbying and reshaping

[10]In addition to the works cited in the text, many edited volumes with chapters on individual cases of IP policymaking have been published. A non-comprehensive list includes Coriat (2008), Haunss and Shadlen (2009), Shaver (2010), Shaver and Rizk (2010), Shadlen, Guennif, Guzman, and Lalitha (2011), Lofgren and Williams (2013), Dreyfuss and Rodriguez-Garavito (2014).

international rules, as well as a consensus on the existence of flexibilities within the new international rules, the second generation of research, to this point, offers a much less coherent explanation of the factors influencing patterns of TRIPS implementation. Nor has the IP literature examined the effects of these policy choices.

The articles in this special issue contribute in important ways to this emerging second generation of scholarship. We consider two overarching sets of issues: the making of policies in response to the new international environment, and the consequences of their implementation. With respect to both inquiries, the articles offer new perspectives concerning the processes leading to the enactment of flexibilities and the impact those have once enacted. Thus, in contributing to this second generation of scholarship on IP, and access to medicines, and health, the special issue provides fresh theoretical and empirical insights that contribute to our understanding of the politics of global policies more broadly.

The remainder of this introductory chapter consists of three sections. We begin by discussing the principal insights that the authors bring with regard to IP policymaking, TRIPS implementation, and the use of flexibilities. We then discuss their analyses with regard to the effects of policy measures taken. In the final section we offer brief summaries of each article in the special issue.

Using Flexibilities: Rethinking Conditions and Strategies

Implicit in the first generation of research is an expectation that, were the international context less restrictive, countries would utilize more creative policies and take advantage of available policy space to improve access to affordable medicines. Yet in IP policy, as in other areas of economic policy, levels of under-utilization are remarkable (Correa 2000a; Oliveira et al. 2004; Musungu and Oh 2006). These observations are typically treated with laments, that governments lack awareness to exploit TRIPS flexibilities, or that bilateral pressures and bilateral trade agreements inhibit the use of flexibilities, or that the nature of technical

assistance creates biases against doing so. IP is technical indeed, and external pressures and biased technical assistance are well documented, but these factors cannot adequately explain the level of flexibility utilization. After all, many governments have resisted (and continue to resist) pressures for stronger IP at the global level, so lack of awareness is an unconvincing explanation. Nor do external pressures, trade agreements, and technical assistance adequately account for the variation. Not all countries have trade agreements with the US,[11] and not all countries will be vulnerable to threats of trade sanctions or other types of external pressures. Thus, while international politics certainly play an important role, the analyses in this collection point to the domestic political challenges to utilizing TRIPS flexibilities. In particular, the articles suggest that alliances and coalitions are necessary to underpin the use of flexibilities, and these are difficult to construct and sustain.

In thinking about the challenges to constructing and sustaining coalitions in support of the use of TRIPS flexibilities, consider the positions of three critical actors in "access to medicines" campaigns: global health activists, local health activists (including other NGOs), and domestic pharmaceutical firms. The sites of contention were often in the Global South, where governments had to catch up with IP laws long established in industrial countries, while global activists were often organized in the Global North – although there were certainly important instances of South-South collaborations too (Veras 2014). The global activists' approach has been informed by a commitment to retaining and using TRIPS flexibilities. The movement largely coalesced around the battles over flexibilities in the late 1990s, particularly in the run-up to the 2001 Doha Declaration ('t Hoen 2002; Kapczynski 2008; Kapstein and Busby 2013). The claim that expanded flexibilities is essential for improving access to medicines has subsequently turned into the cornerstone of global

[11] Furthermore, as discussed below, it is not clear that developing countries have underutilized TRIPS flexibilities because they have bilateral trade agreements with the US and EU, or that countries have such trade agreements because they have underutilized TRIPS flexibilities.

activism, and its source of legitimation. To be sure, the global health activists studied by the authors here are keenly aware of the fact that improving health depends on multiple issues, not just access to medicines, and that access to medicines is not solely a function of IP policies. The state of patents and patent protection may have significant effects on access to medicines in any given country, but so too do the proximity of health clinics and countless other things. Yet while global health activists would hardly deny the importance of the other obstacles that resource-poor countries, in particular, face in their attempt to provide the population needed medicines, the overriding focus has been on IP. The campaigns are informed by a conviction that relaxing IP rules are a necessary, if not sufficient, condition for improved access to medicines. Or, to put it differently, that the use of flexibilities – including compulsory licensing, parallel importation, and minimal protection of test data, as well as strict rules for patentability – are instrumental for improving access to medicines and improving public health outcomes.

Our point here is not to debate this causal logic; few would dispute that the path to access to medicines passes through IP, nor would many disagree that more than IP alone affects access to medicines. Our point, rather, is to show how this orientation and emphasis can affect the process of alliance formation in domestic settings. The challenge is that while local health activists may share global activists' goal of improving access to affordable and high-quality medicines, they may embrace different approaches and strategies to achieve that goal. For example, local health activists may prioritize lowering prices, which they may believe can be accomplished without the explicit use of IP flexibilities, or they may regard the quality and state of countries' health care systems as more essential for improving access to medicines than utilizing flexibilities and relaxing levels of patent protection. In some cases, local activists may not even share the concern with improving access to medicines. As Godoy shows, in Costa Rica, El Salvador, and Guatemala, activists with a different approach

to health came to resent – or at least greet with caution – the global activists' IP-oriented approach. Local activists feared that a focus on TRIPS flexibilities placed too much trust in the efficiency of market competition, could lead to an overly industrial-biomedical "pharmaceuticalization" approach to health, and would likely undermine the basic health care approach they preferred.

Why this gap between global and local approaches? It is not difficult to understand global activists' emphasis on IP. More than many public health initiatives, ideas about the IP-access-health link are easier to diffuse across international boundaries and seem easier to implement. They are easy to diffuse because they draw on an accessible message that effectively creates "villains" in the form of multinational pharmaceutical companies oblivious to nothing but their profits. They are easy to diffuse also because of the promise of the relative simplicity of implementation. After all, IP changes seem to only require a legislative act, in contrast to initiatives that may also require resources, the presence of competent bureaucrats, skilled health workers, or improvements to health care infrastructure. IP policy changes also tend to be discrete events. Actors focus on specific elements of a country's IP law to change, legislators make changes, and when the law is changed it is difficult (though certainly not impossible) to reverse. Alternative measures, such as reforms to healthcare systems, in contrast, involve multiple parts that need to be coordinated and more likely require significant follow-up. Initiatives such as the development of local pharmaceutical production might be even more challenging, as shown by Russo and Banda. The point, then, is that alliances between global and local health activists may be unstable, not because of the former's naivety about what is happening on the ground or the latter's indifference to IP, but simply because of a set of factors that may drive both sets of actors to prioritize different sets of issues. In short, alliances between global and local activists – two sets of actors that both care about health – may be anything but naturally occurring outcomes. Rather, they need to

be established and, at times, they may fail to materialize due to distinct interests, priorities, and strategies.

Our papers also suggest that there may be geographical and temporal patterns to the likelihood of alliances between global and local activists. Andia's article hints at the possibility that such alliances are more likely to happen in countries that are "trend setters," where local activists recruit global activists, than among the countries that are followers, where global activists recruit local participants. Chorev, in turn, suggests the possibility of a diminishing interest of civil society in IP issues, especially as conflicts become more arcane and difficult to comprehend, as was the case with the Anti-Counterfeit Act in Kenya.

Nor do local pharmaceutical firms, when those exist, always fit easily or naturally into global campaigns in support of the implementation and use of flexibilities. Again, this may appear surprising, as we expect local pharmaceutical firms in developing countries to oppose stronger patent rights, but these firms may not place such emphasis on patents per se. After all, most pharmaceutical firms in most countries focus on selling older drugs that are beyond the period of potential patent protection. For such drugs, patents, or lack of patents, are irrelevant. Even where local firms used to produce and market their own versions of drugs that would otherwise have been patented (if the country were to have a pharmaceutical patent regime), few do so any longer because of TRIPS. Remember, the issue here is the use of flexibilities once countries have implemented TRIPS, and not TRIPS implementation per se, i.e. how to go about creating provisions that mitigate the effects of pharmaceutical patents, but not whether or not to allow pharmaceutical patents. Quite simply, TRIPS compelled countries to introduce pharmaceutical patents and, in turn, compelled firms to adjust to this new status quo. If local firms' own business models do not depend on TRIPS flexibilities, then their participation in alliances to use such flexibilities may not be forthcoming. Furthermore, some of the measures that might be supported by local health activists may

incur the wrath of local firms. Health activists may seek price controls, for example, which could obviously impinge on firms' profits. Likewise health activists may lower barriers to drug imports, to lower prices. Health activists may also seek more stringent and rigorously enforced health regulations, such as requirements to attain certification of production facilities or demonstrate bioequivalence of follow-on drugs, regulations to which compliance can be costly for local firms. In other cases, as Russo and Banda imply, local pharmaceutical firms may at time rely for technical and other support on international support, including from multinational pharmaceutical companies.

The articles provide illustrations of these conflicting interests and tensions. Godoy shows, for example, that local drug manufacturers had other considerations, outside of pharmaceuticals, that made them support the Central America Free Trade Agreement (CAFTA) in spite of the "TRIPS-plus" provisions in the agreement that, we might expect, would trigger opposition. Chorev shows that the local pharmaceutical industry in Kenya supported flexibilities in the debate over the Intellectual Property Act but sided with multinational pharmaceutical companies in the court case regarding the Anti-Counterfeit Act. In debates over the Anti-Counterfeit Act, Kenyan pharmaceutical firms found themselves more closely allied with the transnational pharmaceutical sector than health activists, since they, too, prefer to keep less expensive imported drugs out of the local market. In other work, Shadlen (2011) examines the tensions in the alliance between local activists and local pharmaceutical firms in Brazil, as the local pharmaceutical sector in Brazil has provided more consistent support for the government's stance on compulsory licensing than on the inclusion of the health agency in pharmaceutical patent examination.

The extent to which alliances between transnational activists and local actors exist may have important implications for policy outcomes. Godoy suggests that the adoption of CAFTA in Costa Rica, El Salvador, and Guatemala could be regarded as a failure of global

activists but not as a failure of local health activists, who never really mobilized against the agreement. Andia shows that the paths taken in reducing the price of Kaletra in Ecuador and Colombia was different from the paths in Brazil and Thailand precisely because in the first pair of countries local activists were not as supportive of the measures as in the latter pair. Although it is beyond the scope of their papers, it is also easy to imagine that the laws governing secondary patenting in Brazil and India, studied by Sampat and Shadlen, have been influenced by the interplay between global and local forces; similarly, the industrial policies affecting local pharmaceutical production, the subject of Russo and Banda's piece, may be influenced by the support (or lack thereof) of local health activists. The punchline is that the support of local activists is important at the level of policy-making, but possibly even more so at the stage of implementation. As Godoy suggests, "the transnational gaze is always fleeting; ultimately, unless local activists take up an issue, any gains made during the period of the transnational campaigning may be short-lived."

These observations mean that we need to be much more attentive not only the local-specific interests of the many actors involved in making and implementing policies in any given setting, but also to the specific political economic contexts in which activists and other relevant actors function, for it is these contexts that will shape actors' position and the possibility of alliances. Much of the scholarship treats the politics of IP as if it were a universe of its own, as if the conflicts over different aspects of IP policy (international, regional, national) occurred in a silo. But IP is always a part of broader set of issues, part of a broader political economy. Indeed, this is one of the first lessons of the early research reviewed above: IP was made "trade-related" and thus addressed in the context of trade negotiations. Yet subsequent discussion has had a tendency to focus on IP on its own terms. Consider, for example, the abundant literature on IP in regional and bilateral trade agreements, referred to above. We know that regional and bilateral trade agreements typically

include IP provisions that, because they exceed those in the WTO, are typically regarded with alarm. Yet these agreements are about much more than IP. What much of this work seems to overlook is that "TRIPS Plus" trade agreements also include benefits, in terms of enhanced market access for non-traditional exports, which also exceed what is available in the WTO (Shadlen 2005). That is not to say that the agreements, on the net, are "good" (i.e. that the benefits for developing countries outweigh the costs), but simply to draw our attention to the fact that agreements of this sort are founded on trade-offs. In the context of making trade-offs the actors opposed to the IP provisions may prevail, or their concerns may get subordinated.[12] It is incumbent on political analyses to understand how actors concerned with IP interact with other actors with different concerns.

Broadening the analytic lens to look beyond IP per se is useful for consideration of domestic laws too. After all, the Anti-Counterfeit Act in Kenya, for example, was concerned with many more commodities and products than medicines, which necessarily affected the support and opposition to it in Parliament as well as civil society. Grounding the analysis of IP in this way, we believe, will not only allow us to better understand actors' positions, actions and possible successes in the struggles over intellectual property rights, but will also improve dialogue between scholars of IP and scholars of international political economy and development. While IPE and development scholarship provide useful analytical tools for sharpening the analysis of IP; the empirically rich IP scholarship is a particularly fertile ground for applying and development new arguments and theories relevant for IPE and development.

Using Flexibilities: Rethinking the Effects

In spite of the challenges to building and sustaining alliances, many countries have taken steps to utilize TRIPS flexibilities and resisted attempts to curtail the use of

[12] Frischtak (1995) also points to the new trade-offs and challenges that inform IP policymaking in "open economies."

flexibilities. Many countries now have laws that permit and facilitate compulsory licensing, for example, or that place restrictions on secondary patenting. Indeed, many "TRIPS Plus" provisions have been relaxed, as many of the articles in this special issue illustrate. However, these articles also suggest that, even when all the pieces are lined up and the alliances come together, the implementation of TRIPS flexibilities may not have the desired outcomes. Andia finds that even though in both Colombia and Ecuador compulsory licensing was permitted by law, and in Ecuador a compulsory license was issued, both countries continued to purchase the patented version of the drug Kaletra, rather than generic versions. Moreover, Andia argues that the compulsory licenses themselves cannot explain the price reductions that these countries secured. Sampat and Shadlen's analysis of secondary patenting in Brazil and India also forces us to think about how effective touted TRIPS flexibilities may be in practice. Both countries' patent laws include provisions that could potentially minimize secondary patenting, but these authors find that India has a surprisingly low rejection rate of secondary patents, and that where applications for secondary patents are rejected, rarely is this directly attributable to the specific mechanisms in place to achieve this goal. The grant rate for secondary patents appears to be lower in Brazil, but, again, the direct effects of the specific measure put in place to achieve this goal are less than one might expect.

One reason for this gap between intentions and outcomes, of course, is the complexity involved in improving access to medicines and health. As discussed above, these outcomes are affected by myriad factors, so that even successfully implemented TRIPS flexibilities may have only marginal effects on overall outcomes. Even if we look not at the overall goal of improved access to drugs but the more immediate goals, such as lowering the price of a particular drug or the rate of secondary patenting, complexity may contribute to the minimal impacts these studies report. Measures that may make sense in theory are often hard to use in practice. Producing drugs locally to get around IP barriers imposed by TRIPS may seem

logical, but as Russo and Banda show, in practice it is enormously complex. Minimizing the grant of secondary patents may seem simple, but Sampat and Shadlen's analysis of the experiences of India and Brazil indicate that it is anything but.

Another reason why the effects of TRIPS flexibilities are often less than expected is because the terrain of debate has been narrowed. Chorev's study on the anti-counterfeit debate in Kenya, where activists were able to successfully challenge some provisions of the Anti-Counterfeit Act, suggests that the stakes of at least some of the disputes over flexibilities may simply be lower than what health activists believe. In a similar vein, Sampat and Shadlen's analysis shows that Brazil granted fewer secondary patents than India, but nevertheless had more drugs covered by patents, because of earlier decisions made in the 1990s with regard to when and how to comply with TRIPS and introduce pharmaceutical patents. To put it simply, while TRIPS and the initial fight over flexibilities had important implications, subsequent policy choices might not be as consequential.

Our analysis of effectiveness has important implications for contemporary analysis of IPE. Much of the post-Uruguay Round political conflict has been about the existence and use of "policy space," i.e. what sorts of measures countries can put in place, and what sorts of barriers (de jure and de facto) countries face in using this policy space. We have focused on this debate over IP, but analogous issues and debates emerge in a variety of issue areas (Gallagher 2013, Abbott 2009, Maskus 2010). Implicit in discussions of policy space is the expectation, or at least hope, that such measures, if taken, would have their desired effects. But they may not. These articles offer two ways of thinking about the gap between the outcomes intended by policy changes and the actual outcomes yielded by policy changes.

One possible interpretation offered here is that TRIPS flexibilities may not yield the benefits that are expected because they are challenging to implement and enforce. This view is consistent with a long tradition of scholarship. We know from the distinction between "law

in books" and "law in action" and from the institutional analysis of policy-making that new laws do not often bring about the intended outcomes. Laws create opportunities; they set boundaries of permissible and non-permissible action. But opportunities need to be seized; and sometimes actors expected to seize opportunities for action lack the interests for doing so, or the necessary resources for doing so; or actors who would be disadvantaged by the enforcement of a law counter-mobilize. In such cases, we should indeed expect to witness gaps between the outputs that laws allow and the outputs that we observe.

A second interpretation, also offered here, is that "counter-hegemonic globalization" measures, of which TRIPS flexibilities are an example, can only have minimal impact even when implemented and enforced, independently of the social forces on the ground. Domestic laws may simply not be effective means to mitigate the effects of the new status quo introduced by TRIPS and other international agreements. The much-touted TRIPS flexibilities are not functional substitutes for measures that are now prohibited by TRIPS. Pharmaceutical markets and health care systems are likely to operate differently – fundamentally differently –in a world marked by TRIPS, with pharmaceutical patents, even if countries actively used their flexibilities in terms of restricting the grant of some patents, threatening and issuing compulsory licenses, allowing parallel imports, embarking on local production, and so on. The world has changed, and the use of flexibilities cannot restore the pre-TRIPS order. Chorev's article speaks clearly and explicitly to this issue: over time, the stakes become smaller. This means that the potential achievements of some legal changes are small. If the room for dispute has narrowed, then we need to reconsider our expectations of just how much significant change on the ground we should expect to observe as a result of policy reforms.

Summary of papers

The authors contributing to this special issue are all concerned with the question of access to medicines, but draw on different case studies and come to distinct conclusions.

Chorev is interested in the trajectory leading from one IP-related dispute to another. She studies the struggles over the legislation of two laws in Kenya, the Industrial Property Act, 2001, which included a number of important flexibilities and was as a result supported by health activists, and the Anti-Counterfeit Act, 2008, which, activists argued, threatened some of the flexibilities gained in the Industrial Property Act. Looking at the debates over each law, the paper argues that, contrary to the activists' claims, the stakes of the second dispute were much lower – indeed, secondary – than the stakes in the earlier dispute. The paper argues that this is typical to international disputes and explains why that is the case.

Godoy explains why transnational health activists were not able to successfully mobilize local activists in Central America against the escalation of IP requirements in the context of CAFTA's ratification debates. The article spells out the tension between the considerations and interests motivating the agenda of global activists, local health activists, and local pharmaceutical producers. The analysis situates local actors within the specific political and economic contexts, identifying, rather than assuming, these actors' goals and strategies. In doing so Godoy reveals the potential mismatches between with the goals and strategies of the various actors involved in the political economy of pharmaceutical IP in Central America.

Andia is interested not only in the political processes leading to the introduction of flexibilities (compulsory licensing) in various countries, but in the political processes affecting the utility of the policies once in place. Comparing price reductions of the brand-name antiretroviral drug Kaletra in Colombia and Ecuador, Andia also emphasizes the tensions between global and local activists in policy formation. Yet Andia also shows that the

extent to which local actors are invested in a law influences its successful implementation even more so than its enactment.

Sampat and Shadlen use original datasets of governments' decisions regarding secondary patenting to assess the effects of flexibilities on access to medicines. Their analyses of pharmaceutical patent examination in Brazil and India offer comparisons of the distinct filing and examination patterns in these countries, placing the countries' practices with regard to secondary patents in the context of their larger trajectories of TRIPS implementation. They find that, in both countries, the effects of the measures to address secondary patenting were outshadowed by the effects of earlier choices regarding the introduction of pharmaceutical patents in the first place.

In the final paper, Russo and Banda explore another aspect of access to medicines – the local manufacturing of drugs. They describe the opportunities and obstacles of drug manufacturing in Mozambique and Zimbabwe and assess how political-economic conditions may lead countries in different paths.

References

Abbott, Fredrick M. 2009. "Innovation and Technology Transfer to Address Climate Change: Lessons From Global Policy Development on Intellectual Property and Public Health." Prepared for International Center for Trade and Sustainable Development, ICTSD. Geneva.

Abbott, Fredreick M. and Jerome H. Reichman. 2007. The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions. *Journal of International Economic Law* 10(4): 921-987.

Aginam, O. 2013. *The Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines*. Edward Elgar Publishing.

Barton, John H. 2004. “TRIPS And The Global Pharmaceutical Market. *Health Affairs* 23 (3): 146-154.

Braithwaite, John, and Peter Drahos. 2000. *Global Business Regulation*. Cambridge University Press.Chaudhuri, Sudip. 2005. *The WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries*. New Delhi: Oxford University Press (India).

Chorev, Nitsan. 2012. “Changing Global Norms through Reactive Diffusion The Case of Intellectual Property Protection of AIDS Drugs.” *American Sociological Review* 77 (5): 831–53..

Commission on Intellectual Property Rights. 2002. *Integrating Intellectual Property Rights and Development Policy*. Commission on Intellectual Property Rights.Coriat,Benjamin, Fabienne Orsi and Cristina d’Almeida. 2006. “TRIPS and the international public health controversies: issues and challenges,” *Industrial and Corporate Change* 15 (6): 1033-1062.

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

Correa, Carlos M. 2000a. “Reforming the Intellectual Property Rights System in Latin America.” *World Economy* 23 (6): 851–72.

———. 2000b. *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*. Zed Books.

Deere, Carolyn. 2008. *The Implementation Game:The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*. Oxford University Press.

Drahos, Peter. 1995. “Global Property Rights in Information: The Story of TRIPS at the GATT.” *Prometheus* 13 (1): 6–19.

———. 2010. *The Global Governance of Knowledge: Patent Offices and Their Clients*. Cambridge University Press.

Dreyfuss, Rochelle Cooper, and César Rodríguez-Garavito. 2014. *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America*. Oxford University Press.

El Said, Mohammed. 2007. “Surpassing Checks, Overriding Balances and Diminishing Flexibilities - FTA-IPRs Plus Bilateral Trade Agreements: From Jordan to Oman.” *Journal of World Investment & Trade* 8: 243.

El-Said, Mohammed. 2005. “The Road from Trips-Minus, to Trips, to Trips-Plus.” *The Journal of World Intellectual Property* 8 (1): 53–65.

Eren-Vural, Ipek. 2007. “Domestic Contours of Global Regulation: Understanding the Policy Changes on Pharmaceutical Patents in India and Turkey.” *Review of International Political Economy* 14 (1): 105-142.

Fink, Carsten, and Patrick Reichenmiller. 2005. “Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements”. The World Bank.

Flynn, Matthew B. 2015. *Pharmaceutical Autonomy and Public Health in Latin America: State, Society, and Industry in Brazil’s AIDS Program*. Routledge.

Frischtak, Claudio R. 1995. “Harmonization versus Differentiation in International Property Rights Regimes.” *International Journal of Technology Management* 10 (2/3): 200–213.

Gallagher, Kevin P. 2013. *The Clash of Globalizations: Essays on the Political Economy of Trade and Development Policy*. Anthem Press.

Haunss, Sebastian, and Kenneth C. Shadlen. 2009. *Politics of Intellectual Property: Contestation Over the Ownership, Use, and Control of Knowledge and Information.* Edward Elgar Publishing.

Kapczynski, Amy. 2008. "The Access to Knowledge Mobilization and the New Politics of Intellectual Property." *The Yale Law Journal* 117 (March): 804–85.

Kapstein, Ethan B., and Joshua W. Busby. 2013. *AIDS Drugs for All: Social Movements and Market Transformations*. Cambridge University Press.

Krikorian, Gaëlle P., and Dorota M. Szymkowiak. 2007. "Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine." *The Journal of World Intellectual Property* 10 (5): 388–418.

Lanjouw, Jean. 2002. "Intellectual Property and the Availability of Pharmaceuticals in PoorCountries." Working Paper No.5, Center for Global Development.

La Croix, Sumner and Ming Liu (2008). "Patents and Access to Essential Medicines," In Keith Maskus, ed. *Intellectual Property Rights and Technical Change.* Vol. 1, Frontiers of Economics and Globalization. New York: Elsevier.

Löfgren, Hans, and Owain David Williams. 2013. *The new political economy of pharmaceuticals : production, innovation and TRIPS in the global south.* London*:* Palgrave Macmillan.

Lanoszka, Anna. 2003. "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries." *International Political Science Review* 24 (2): 181–97.

Malbon, Justin, and Charles Lawson, eds. 2008. *Interpreting and Implementing the TRIPS Agreement: Is It Fair?* Edward Elgar Publishing.

Maskus, Keith. 2010. “Differentiated Intellectual Property Regimes for Environmental and Climate Technologies.” OECD Environment Working Papers, 17. OECD Publishing.

Matthews, Duncan. 2002. *Globalising Intellectual Property Rights: The Trips Agreement*. Psychology Press.

———. 2011. *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements*. Edward Elgar Publishing.

Matthews, Duncan, and Viviana Munoz-Tellez. 2006. “Bilateral Technical Assistance and TRIPS: The United States, Japan and the European Communities in Comparative Perspective.” *The Journal of World Intellectual Property* 9 (6): 629–53.

May, Christopher. 2004. “Capacity Building and the (re)production of Intellectual Property Rights.” *Third World Quarterly* 25 (5): 821–37.

Mercurio, Bryan Christopher. 2006. “TRIPS-Plus Provisions in FTAs: Recent Trends”. SSRN Scholarly Paper ID 947767. Rochester, NY: Social Science Research Network. http://papers.ssrn.com/abstract=947767.

Morin, Jean-Frederic. 2006. “Tripping up TRIPS Debates: IP and Health in Bilateral Agreements.” *International Journal of Intellectual Property Management* 1 (1): 37–53.

_____. 2009. “Multilateralizing TRIPs-Plus Agreements: Is the US Strategy a Failure?” *The Journal of World Intellectual Property* 12 (3): 175–97.

Musungu, Sisule F., and Cecilia Oh. 2006. “The Use of Flexibilities in TRIPS by Developing Countries : Can They Promote Access to Medicines? / Sisule F. Musungu, Cecilia Oh”. South Centre and World Health Organization. http://apps.who.int//iris/handle/10665/43503.

Muzaka, Valbona. 2011. “Linkages, Contests and Overlaps in the Global Intellectual Property Rights Regime.” *European Journal of International Relations* 17 (4): 755-776.

Nunn, Amy. 2009. *The Politics and History of AIDS Treatment in Brazil.* New York: Springer.

Oliveira, Maria Auxiliadora, Jorge Antonio Zepeda Bermudez, Gabriela Costa Chaves, and Germán Velasquez. 2004. “Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation That Favours Public Health?” *Bulletin of the World Health Organization* 82 (11): 815–21.

Paine, Lynn Sharp, and Michael A. Santoro. 1992. “Pfizer: Global Protection of Intellectual Property”. Harvard Business School Case 392-073. Cambridge, Mass. http://www.hbs.edu/faculty/Pages/item.aspx?num=12370.

Pugatch, Meir Perez. 2004. *The International Political Economy of Intellectual Property Rights*. Edward Elgar Publishing.

Reichman, Jerome. 1996. “From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement.” *New York University Journal of International Law & Politics* 29 (January): 11–93.

Roemer-Mahler, Anne. 2013. “Business Conflict and Global Politics: The Pharmaceutical Industry and the Global Protection of Intellectual Property Rights.” *Review of International Political Economy* 20 (1): 121-152.

Roffe, Pedro, Geoff Tansey, and David Vivas-Eugui, ed. 2006. *Negotiating Health: Intellectual Property and Access to Medicines*. London: Earthscan Publishing.

Ryan, Michael Patrick. 1998. *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*. Brookings Institution Press.

Sell, Susan K. 2003. *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge University Press.

———. 2007. “TRIPS-Plus Free Trade Agreements and Access to Medicines.” *Liverpool Law Review* 28 (1): 41–75.

———. 2010a. “The Rise and Rule of a Trade-Based Strategy: Historical Institutionalism and the International Regulation of Intellectual Property.” *Review of International Political Economy* 17 (4): 762–90.

———. 2010b. “TRIPs Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP.” *Journal of Intellectual Property Law* 18: 447.

Shadlen, Kenneth C. 2004. “Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO.” *Studies in Comparative International Development* 39 (3): 76–108.

———. 2005. “Exchanging Development for Market Access? Deep Integration and Industrial Policy under Multilateral and Regional-Bilateral Trade Agreements.” *Review of International Political Economy* 12 (5): 750–75

———. 2009. “The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies.” *Comparative Politics* 42 (1): 41–58.

———. 2011. “The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil.” *Politics & Society* 39 (2): 143–74.

Shadlen, Kenneth C., Guennif, Samira, Alenka Guzmán, and N. Lalitha. 2011. *Intellectual Property, Pharmaceuticals And Public Health: Access to Drugs in Developing Countries*. Edward Elgar Publishing.

Shaver, Lea. 2010. Access to Knowledge in Brazil: *New Research on Intellectual Property, Innovation and Development*. Bloomsbury Academic.

Shaver, Lea, and Nagla Rizk. 2010. *Access to Knowledge in Egypt: New Research on Intellectual Property, Innovation and Development*. Bloomsbury Academic.

Subramanian, Ramesh, and Lea Shaver. 2011. *Access to Knowledge in India: New Research on Intellectual Property, Innovation and Development*. Bloomsbury Academic.

't Hoen, Ellen. 2002. "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha." *Chicago Journal of International Law* 3 (1): 27–46.

Veras, Juliana. "Making Tenofovir Accessible in the Brazilian Public Health System: Patent Conflicts and Generic Production." *Development World Bioethics* 14 (2): 92-100.

Watal, Jayashree. 2001. *Intellectual Property Rights in the WTO and Developing Contries*. Kluwer Law International.

Weissman, Robert. 1996. "Long, Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries." *University of Pennsylvania Journal of International Law* 17 (4): 1069.