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India, Brazil, and public health: Rule-making through south–south diffusion in the intellectual property rights regime?

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Abstract

This article analyzes the domestic drivers of regulatory state formation in India and Brazil and its consequences for the global rules governing pharmaceutical patents. We first analyze Indian and Brazilian politics of regulatory state formation; then, in light of the extent to which the two countries have built regulatory capacity and capability in the field of patent regulation, we explore whether and how they have been able to influence the existing intellectual property regime in health. We look into India's Section 3(d) and Brazil's prior consent requirement. Whereas India's Section 3(d) regulation has gained international regulatory influence by diffusing to other developing countries, the same cannot be said for Brazil's prior consent regulation, which has been caught by policy-reversals. The transition toward regulatory states in emerging countries is a bulky road and does not progress in linear ways. However, once regulatory capacity and capability have been solidified, domestic policy innovations can become internationally influential.

Keywords: Brazil, India, intellectual property, public health, rule-making, south–south diffusion.

1. Introduction

In the light of current power transitions and an increasingly politicized international economy, a key question is whether shifts in economic power also entail shifts in the substance of international regulations. The intellectual property (IP) regime is a particular case in point, as several of its norms have faced significant opposition by emerging economies. This article shows that with the strengthening of their regulatory state, India and Brazil have succeeded in translating preference divergence into domestic policy initiatives that depart from the current IP regime in the field of pharmaceutical patents (henceforth health-IP regime). Yet, the article also reveals that the translation of domestic policy-initiatives into internationally relevant innovation, that is, rule-making, may still be difficult. On the one hand, it appears particularly challenging for emerging powers to develop stable preferences in a context of domestic contestation, institutional weaknesses related to their still developing status, and the effects of shifts in government. On the other hand, international influence depends on the ability to win support from other states, including both other contesters and the defenders of the status quo. Herewith, the article contributes to the Special Issue's overarching interest in the conditions under which emerging countries develop into rule-makers in global trade regulation.

The article focuses on two key domestic initiatives enacted by India and Brazil, which have the potential of altering the current health-IP regime: Section 3(d) on scope of patentability in India and prior consent in Brazil. While there may be other relevant examples of the use of flexibilities under the TRIPS (e.g. Marsoof 2018), these

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selected cases are particularly well suited to illustrate the domestic challenges involved in applying such flexibilities, in particular the processes whereby regulatory capacity and capability are developed.

Brazil and India opposed stronger IP protection during the Uruguay Round negotiations on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), since, among other things, TRIPS substantially limited their policy-space in areas such as access to health (e.g. by limiting the use of generic pharmaceuticals). Developing countries, including India and Brazil, were coerced to agree to the TRIPS due to the World Trade Organization (WTO)'s single undertaking and the inherent bargains that linked IP protection to improved market access for textiles and agriculture (Deere Birkbeck 2008), as well as due to economic pressure of developed countries. Still, some concessions were made, such as notably TRIPS' transition periods of 10 years, as well as certain other flexibilities, which permitted different domestic implementation, for instance, with regard to public health emergencies and compulsory licensing. These flexibilities were reinforced by the 2001 Doha Declaration on TRIPS and public health (WTO 2001), which developing countries formulated as an essential prerequisite for launching the new Doha round of trade negotiations. This was the starting point for first changes in the TRIPS agreement that ultimately came into force in 2017 with the inclusion of art. 31bis into the treaty (New 2017). Post-TRIPS, India and Brazil have continued to lead coalitions of developing countries aimed at limiting and calibrating the impact of the changes brought about by the TRIPS Agreement. These efforts have involved launching agendas on diverse issues, such as access to medicines, the linkage between human rights and health, the protection of traditional knowledge, and access to biological resources (Kapczynski 2008). For example, one of Brazil's most important initiatives with regards to safeguarding flexibilities in TRIPS was the launching in 2004 (together with Argentina) of a Development Agenda at the World Intellectual Property Organization (WIPO) aimed at counteracting the influence of industrialized countries in setting a pro-patents position in the organization (May 2007). However, these successes, which at first sight appear significant, had important limitations. In order to make use of the flexibilities in the agreement, countries need both resources and an understanding of what is allowed or not under TRIPS rules and/or where grey areas exist. This understanding refers to what the editors of this special issue (Lavenex, Serrano & Büthe 2021) define as the institutional strength of the regulatory state, consisting of both regulatory capacity and capability.

Regulatory capacity relies on the ability to bundle expertise and resources domestically and in pertinent international venues (Lavenex, Serrano & Büthe 2021). In the health-IP regime, improving regulatory capacity is closely related to an expansion and professionalization of their respective patent offices. Professionalization refers, in particular, to the training and expansion in the number of patent examiners, even if the patent system also includes judges and patent attorneys. As Drahos (2010, pp. 215–216) notes, in practice, patent examiners are crucial gatekeepers, since patent portfolios of multinational corporations are built on the basis of their decisions. This capacity-building process was neither linear nor absent of contradictions. Indeed, political battles in the two countries' public administrations ensued, given that the expansion of their patent offices had social costs.

In this context, it is important to note that better regulatory capacity does not automatically translate into regulatory influence, as this requires regulatory capability as well. Following Cafaggi and Pistor (2015) and the framework article of this Special Issue, we understand regulatory capability as the ability to recognize one's interests and articulate regulations that advance those interests. As we show later, in India and Brazil, regulatory capability has been strongly shaped by the support of transnational networks of activists and an epistemic community of Southern intellectuals and legal scholars (see also Scott 2015; Shaffer *et al.* 2015). We also show that this capability has been more resilient in India than in Brazil, where recent political turmoil has had its toll and lead to a decreased regulatory capability.

The literature evaluating the role of emerging countries in the health-IP regime, especially India and Brazil, has extensively documented the latter's multilateral initiatives, in particular, but not exclusively around the 2001 Doha Declaration (see e.g. Drahos 1997; Correa 2000; Panagariya 2002; Bass 2002; Wade 2003; Helfer 2004; Yu 2004; Kapczynski 2008). Domestic efforts complementing and supporting these international initiatives have received less attention, so has their eventual horizontal diffusion to other (developing) countries. Seeking to fill this void, this article focuses on two key domestic laws, which have in effect modified the health-IP regime: Brazil's prior consent law and India's Section 3(d). We argue that these discrete efforts to tailor IP policies domestically when implementing TRIPS, so as to maximize the "flexibilities" allowed by the agreement, widen the policy-space available to other developing countries, clarify what is possible or not under the TRIPS rules,

and indirectly reshape the regime itself. They are also two crucial examples of the ways rising powers are using their expanded and expanding regulatory capabilities. This explains why India and Brazil have been so important for the health-IP system. Domestic implementation of this type is particularly important if it sets models to be followed by other developing and emerging economies. Most notable in this international promotion, which is the focus of the last section of this article, has been India's Section 3(d), which sets limits to secondary pharmaceutical patents. In so far as this rule has diffused horizontally to other (developing) countries, it can be considered a case of international rule-making – even if it has not changed the wording of the multilateral regulations as such.

The evidence was collected through extensive fieldwork including two longer research stays in the countries and 36 interviews with key stakeholders, including judges, diplomats, NGOs, legal firms, and government officials, in India and Brazil who were directly involved in these policy changes, and their permanent representations to the WTO in Geneva. The analysis offers support for the thesis proposed in the theoretical framework for this Special Issue (Lavenex, Serrano & Büthe 2021), that the strength of the regulatory state is the key conduit through which the growing resources in emerging economies give their governments leverage in global regulatory governance. We also show, however, that regulatory state formation is not automatic but occurs only where these rising powers make the political choice to invest in building regulatory capacity and capability. Providing an understanding of the domestic and international drivers of such political choices by the Indian and Brazilian governments is the goal of this article. For this reason, we seek to answer two key questions: *How far have India and Brazil developed regulatory capacity and capability in dealing with pharmaceutical patents? And, which effects has this had on their ability to shape the health-IP regime?*

After offering a brief outline of the theoretical framework and this article's research design in section II, we examine the development of regulatory capacity plus capability of India and Brazil and how this has led to domestic policy innovation (section III). Section four turns to the question: how far these domestic innovations, section 3(d) in India and prior consent in Brazil, impact the global health-IP regime. While the wording of multilateral rules has remained unchanged, their substance has been altered through the south–south diffusion of Section 3(d) of the 2005 Indian Patents Act, which sets substantial limits on the scope of patentability. The fifth section concludes.

2. Regulatory state formation and international rule-making

The theoretical framework proposed in the introduction to this Special Issue (Lavenex, Serrano & Büthe 2021) emphasizes the interplay between domestic and international politics as fueling or inhibiting the creation of regulatory capacity and capability, and thus determining the strength of the regulatory state in emerging countries. Building on earlier work by Krasner (1977) on rule-making, rule-breaking, and rule-taking; and Walter (2008) on mock compliance, Lavenex, Serrano and Büthe (2021) hypothesize that lacking regulatory capability and capacity, emerging countries will remain passive rule-takers, if their preferences converge with the status quo – or be resentful rule-fakers, if their preferences diverge. Moreover, they posit that institutional strength does not translate automatically into regulatory activism. In cases where domestic preferences do not diverge from the status quo that reflects the established powers' preferences, countries will join and support the existing regime as rule-promoters. Only in cases where the rising powers, having developed regulatory capacity and capability, have preferences diverging from the status quo, and when these are then accommodated by the established powers, that rule-making ensues. In contrast, if their divergent preferences are not accommodated, they will become rule-breakers or spoilers.

The selection of Brazil and India follows this Special Issue's focus on the BICs (Brazil, India, and China), as these three countries are central in the economic power transition currently taking place. They are also generally considered most able to challenge the global IP system in its present form (Löfgren & Williams 2013; Serrano & Burri 2019).[1] India and Brazil in the health-IP regime are both representative of cases where rising powers are investing in regulatory state formation and exhibit divergent domestic preferences from the international status quo. Methodologically, the study relies on 36 interviews with key stakeholders involved in the development of the two policy innovations as well as primary and secondary sources collected during research stays in India and Brazil between 2012 and 2014 and in 2016.[2] Given that recent changes, in particular, in Brazil, are significant, we

have complemented the interview-material with primary and secondary sources extending the period of the study up to the end of 2019.

Before offering a detailed overview of the two cases in the next section, we briefly evaluate below the status quo ante and how the institutional strengthening of their regulatory states (capacity and capability) took place, as well as whether this has allowed them to become rule-makers or not. We develop these three aspects in more detail in the individual country-cases.

2.1. Status quo ante

We start by evaluating the ex-ante position of India and Brazil, that is, before the power transition took place. Their position can be better understood as one of resenting rule-takers or "rule-fakers," as the legalization of the IP regime, which reached its highest degree with the adoption of the TRIPS as part of the founding agreements of the WTO, was met with widespread resistance. As was already mentioned, during the Uruguay Round negotiations (1986–1994), Brazil and India, which were still relatively small economies at the time, assumed a leading role in opposing stronger IP protection (Watal & Taubman 2015).

2.2. Regulatory capacity

As we have already mentioned, regulatory capacity relies on being able to foster expertise and resources domestically and in pertinent international venues on a particular policy-field (Lavenex, Serrano & Büthe 2021). Even if the realm of health-IP protection includes actors as diverse as judges or health professionals, patent offices are the most relevant actors when it comes to building regulatory capacity. Increasing capacity meant the development of legal expertise and of skilled authorities through the professionalization and expansion of patent offices. This creation of autonomous professional and specialized patent offices was one of the main institutional requirements introduced by TRIPS. Capacity building was supported by training from the patent offices of the United States and European Union, cooperating closely under the Trilateral Patent Offices program, which also includes Japan (often known as the Trilaterals). The WIPO supports these efforts by providing further training and a multilateral setting for direct interaction.[3]

The clearest example that both agencies, IPO (India) and INPI (Brazil), improved their regulatory capacity was their recognition as International Searching and International Preliminary Examining Authorities under the Patent Cooperation Treaty (PCT) (henceforth, ISA status). Brazil (in 2009) and India (in 2013) became the second and third emerging-country patent offices (after China and excluding South Korea) to gain ISA status. In comparison, only Chile, Egypt, Russia, Turkey, and Ukraine have such a status among developing countries. ISA status means the offices are able on the basis of published patent documents and technical literature to establish a written opinion of the potential for patentability. These opinions are often followed by other patent offices that determine whether they grant the patent or not for their respective jurisdiction and this ultimately gives offices with ISA status a central role in the system, given that it involves having strong regulatory capacities (in terms of manpower and expertise) and provides strong offensive and defensive capabilities, essentially allowing it to be part of the lead pack of patent offices (Drahos 2010). Even if compared to leading patent offices, such as those of the United States (USPTO) or the European Union (EPO), India's and Brazil's development of regulatory capacity may appear limited, the latter has expanded over time with the hiring of a substantial number of new patent examiners and increases in budget, and by setting-up cooperation agreements with other leading patent offices. We provide some more concrete information about the professionalization of India's and Brazil's patent offices in terms of their rising number of (pharmaceutical) patent examiners and partnerships in the next section.

2.3. Regulatory capability

We have defined regulatory capability as being able to recognize one's interests and to develop regulations to support them (Cafaggi & Pistor 2015, Lavenex, Serrano & Büthe 2021). While networks of patent offices were particularly relevant in building regulatory capacity in India and Brazil, we find that networks of activists and academics played at least a similarly important role in assisting the development of regulatory capability. The role of transnational networks has been often ignored in the literature. Avant *et al.* (2010) are among the few (other exceptions include Büthe & Mattli 2011) to recognize that corporations, professional associations, and advocacy

groups can be "active agents who want new structures and rules (or different rules) to solve problems, change outcomes, and transform international life" (Avant *et al.* 2010, p. 1). Transnational networks of NGOs and other activists use information, ideas, and strategies to alter the value context within which states make policies (Keck & Sikkink 1998). As such they have "epistemic and legitimation functions" shaping not only transnational policy decisions but also regime rules, principles, and decision-making procedures (Hall & Biersteker 2002). Epistemic communities may either reinforce or challenge current global governance arrangements by providing training, legitimating functions, research, and even serving as agents of policy principals, testing new ideas or providing alternative frameworks (Biersteker 2011).

Campaigns and coalitions of developing countries with NGOs not only led to a breakthrough at the international level through the Doha declaration,[4] but supported domestic actors exploring laws aimed at weakening patent protection. In India, this domestic ecosystem consisted of a few highly specialized legal firms and think-tanks with strong links to academics, often from the Indian diaspora in North American and European universities, as well as NGOs. In Brazil, it consisted of networks of academics, diplomats, think-tanks, NGOs, and judges, which had also developed links to peers in both industrialized and other developing countries.

2.4. Rule-making

Following the framework paper (Lavenex, Serrano & Büthe 2021), we define rule-making as the capacity to establish new rules that become accommodated by established powers and alter the status quo. In the case of the health-IP regime, TRIPS flexibilities allow for scope variation. While the established powers have sought to minimize these flexibilities and their expansion, developing countries have sought to maximize policy-space available under TRIPS, by pushing against the limits set by the agreement both at the multilateral level and through the horizontal diffusion of innovative domestic practices. Rule-making thus need not be at a change of multilateral rules (although it can, as in fact was the case with the Doha Declaration in 2001), but can also occur through the diffusion of policy innovations in domestic legislation. Accommodation of such new domestic interpretations to the TRIPS agreement (a change in the rules), by established powers, may either take the form of tolerating these policies (weak accommodation), or an unsuccessful challenge at the WTO's dispute settlement body (see Okediji 2004), as long as they accept the appellate body decisions (strong accommodation).

3. Regulatory state formation and policy innovation in India and Brazil

Below we evaluate the concrete ways in which the strength of the regulatory state developed in India and Brazil, and the extent to which this regulatory capacity and capability have allowed them to put forward policy innovations that depart from the international status quo.

3.1. India

TRIPS required a transformation of the Indian Patent Office (IPO), which went from having low capacities in terms of staff and resources, to a relative professionalization over the course of two decades. With higher funding and increased personnel, it improved its regulatory capacities. Patent offices, such as that of India (and Brazil), lacking experience in pharmaceutical patent protection (they did not recognize them before TRIPS), sought cooperation from established patent offices, mainly from the US (USPTO) and EU (EPO), to fill these gaps. In effect, "(t)he USPTO much like the EPO builds capacity in developing countries that favors the patenting strategies of its respective companies. It is a form of encoded capacity-building in which the aim is to form an interpretive community through patient years of assistance and training" (Drahos 2010, p. 216). This modernization began changing the prevailing culture at the IPO. In effect, pre-TRIPS, India had redesigned its colonial-era patent practices through its 1970 Patents Act to suit its development needs (Drahos 2010). The 1970 Patents Act is often seen as the cornerstone for the development of India's generics industry. TRIPS provisions limited these regulatory levers and, not surprisingly, were denounced by members of the Indian pharmaceutical industry as attempts by US and EU pharmaceutical companies to put them out of business.

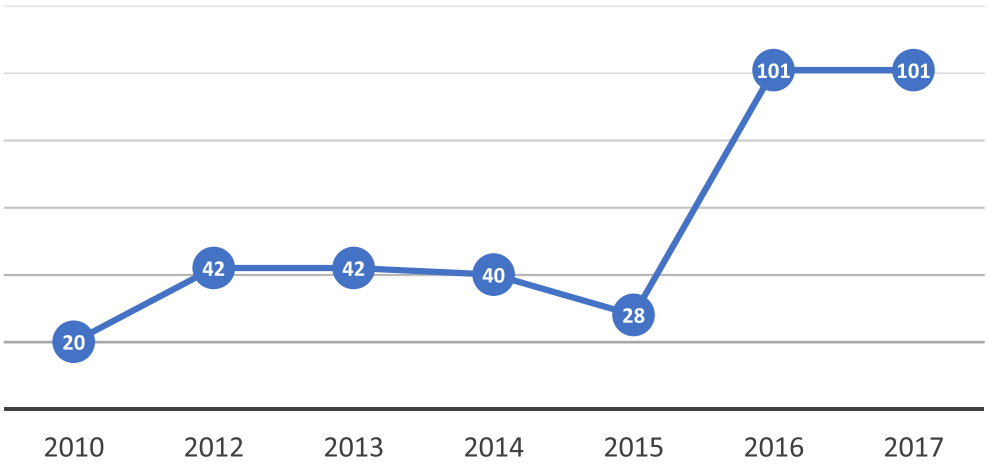
Despite its professionalization, which saw the IPO reach ISA status in 2013, and a rising number of patent examiners, important challenges remain. According to a report by one of India's main business newspapers

(Mint) on the basis of a parliamentary standing committee, Indian patent examiners have the worst working conditions among international patent offices, having "the highest number of per-capita workload delivered at the lowest pay."[5] The report notes that Indian patent examiners handle about 20 applications per month compared to 7 by EPO's, 8 by USPTO's, and 7 by Chinese examiners. This is problematic given the complexity of patent applications and the large number of applications handled to each examiner means that "a close look at the claims in the applications are not often followed".[6] The result of all this is that, despite IPO's critical stance on pharmaceutical patents, a large number of these are granted because patent examiners do not have the time to carefully review them. This creates a vicious circle in which lax patent standards induce more applications because it is easier to get a patent granted, further overloading patent examiners.[7]

The parliamentary standing committee mentioned in this line that in 2010 there were only 137 patent examiners in the four locations of the IPO. The report suggested adding a further 617 examiners by 2012.[8] However, a more recent report shows that it was only in 2016 that the Department of Industrial Policy and Promotion (DIPP) recruited 458 patent examiners, with an additional 263 being appointed on a contract basis.[9] Pharmaceutical patent examiners (categorized in the area of chemistry) took a large share (73) of these new recruitments as Figure 1 (below) shows.[10]

The government's aim has been to reduce the examination period from over five years to as little as 18 months by 2018. As part of these efforts, in 2016, the Ministry of Commerce and Industry introduced a new provision to fast-track the process of granting patents, which resulted in more than a dozen companies being granted patents within 113–300 days.[11] It must be noted that a lack of manpower pervades the whole Indian bureaucracy (a legacy from its thin colonial administration), which, despite its professionalization, is overburdened due to its limited size. We were often struck by this during our interviews with public officials in the country. In this context, it may well be that the recent overuse of Section 3(d) against primary pharmaceutical patents (Sampat & Shadlen 2018), and its reliance on private actors, such as legal firms (both detailed below), is a means to compensate for this regulatory weakness.

In addition to its patent office, India has developed trade-related legal capacities through private legal firms, which are particularly relevant in its more critical stance on pharmaceutical patents. Remarkably, the Indian state has sought the backing of private actors and transnational networks. A main initiative in this sense has been the creation of the Centre for WTO Studies, a government-sponsored think-tank also supported by the United Nations Conference on Trade and Development (UNCTAD). Through the center, and sometimes directly, the Ministry of Commerce has worked closely with Indian private lawyers, who as consultants have increased the legal capacities of the state in trade negotiations, as well as promoted legal innovation (Shaffer *et al.* 2015). These



Source: Author's elaboration on the basis of data from the Office of the Controller General of Patents (data from Annual Reports 2010 to 2017)

Figure 1 Examiners of patents by area (Chemistry). *Source*: Author's elaboration on the basis of data from the Office of the Controller General of Patents (data from Annual Reports 2010–2017).

legal scholars are mostly concentrated within five major law firms: Luthra & Luthra, Lakshmikumaran & Sridharan, Economic Laws Practice, Law Offices of Krishnan Venugopal, and Clarus Law Associates. They are often trained in the US and Europe, and closely connected with scholars and other trade lawyers abroad (Shaffer *et al.* 2015). Interviews that were conducted for this article with Indian lawyers and with one of the founding partners of one of these five law firms give a picture of a vibrant and active community that has strong links to other legal practitioners and academics in leading institutions in the US and Europe. It is in this ecosystem that the bolder implementation choices related to Section 3(d) and its diffusion to other jurisdictions, such as Brazil and South Africa, have taken place, as explicitly revealed by the interviewees involved in this process.[12]

Despite all of the above, the implementation of TRIPs in India did not happen overnight but was a complex and much contested process; in particular, in the field of pharmaceutical patents, it involved multiple state and non-state actors (Shaffer *et al.* 2015). The patent law in India went through several phases (by amendments in 1995, 1999, and 2002) to ultimately comply with India's obligations under the TRIPS by enacting the 2005 Indian Patent Act. India managed, in this transition, to resist the substantial pressure coming from multinational pharmaceutical companies and from the great powers, who also used the WTO dispute mechanism to push for a timely and full TRIPS implementation.[13] Responding to different local demands – coming, in particular, from the generic drug industry, but also from other communities, such as those striving to protect traditional knowledge – the Indian government tailored the Indian patent law and made good use of the available TRIPS flexibilities (Unni 2012; Oke 2015).

While this article puts emphasis on one particular such use – namely limiting the scope of patentability under Section 3(d) of the 2005 Indian Patent Act – there are other norms that showcase India's TRIPS implementation, so as to reflect the country's own economic and broader societal preferences (Unni 2012; Oke 2015). Overall, India has created a model of patent law and practice in the shadow of TRIPS that can be used by other developing countries, which often face similar conditions, as well as the constant struggle of reconciling innovation and development rationales. The IPO often tailors patent protection to suit policy needs (an indication of regulatory capability and not only of capacity), acting as a policy guardian of sorts through a conservative approach to the issue of patentability (Basheer 2005). The most publicized practice by the IPO, and the focus of the last section of this article, has been its application of Section 3(d) of the 2005 Indian Patent Act. This case involved the IPO's refusal to grant a patent to Novartis on its drug Gleevec arguing that it failed to pass the patentability test. Section 3(d) bans patents on both new uses of known substances and on new forms of known substances that do not enhance *efficacy*.

The role of the generics industry is not to be underestimated in determining India's approach to the health-IP regime. In fact, the industry pushed strongly against regulatory convergence with Western practices, which, during the mid-2000s, were being driven by domestic actors favoring stronger patent protection, especially by the Council of Scientific and Industrial Research (CSIR). CSIR has had some influence on shaping IP policies, in particular, encouraging the creation of a National Knowledge Commission in 2005 during the government of Manmohan Singh. Two of the five key objectives of the National Knowledge Commission were related to IP, namely to "improve the management of institutions generating Intellectual Property; [and] improve protection of IPRs and promote knowledge."[14] Opposition to these measures was led by the powerful interests of the generics pharmaceutical industry organized under the Indian Pharmaceutical Alliance and the Indian Drug Manufacturers Association.[15] The Commission's failure to strengthen patent protection may also have to do with the role of domestic and international NGOs, such as Doctors Without Borders (MSF). The Commission was thus never able to substantially shift policies toward stronger IP protection and, as of 2014, has been discontinued.[16]

The generics industry is evidently highly relevant in the Indian case as a crucial producer of cheap medicines domestically and, additionally, to most developing (and even developed) countries. This makes India, often called "the pharmacy of the developing world," a strategic actor and explains why it has been at the center of campaigns of NGOs, such as MSF and the Third World Network.[17] Overall, India's approach to access to health policies has been (in contrast to Brazil) market-driven (Eimer & Lütz 2010). TRIPS posed a challenge to the survival of this thriving generic industry[18], which triggered a strong mobilization and opposition to maximalist health-IP policies from domestic and international actors supporting the Indian state into recognizing how to defend its interests. India has henceforth become a major player in international IP disputes. Notable examples of domestic legal innovations are the Section 3(d) of the 2005 Patent Act, but also the Right to Information Act passed in October

2005, and the use of Public Interest Litigation, by which NGOs, individuals, and other institutions have gained the right to file public concern lawsuits. These changes have been motivated by local NGOs linking with transnational activists and epistemic communities. Legal scholars have also played an important role in developing regulatory capability and pushing courts to the forefront of domestic political battles in fields such as trade policy, which naturally includes IP.

In sum, despite some incoherence in its overall IP strategy, such as the mentioned creation of the National Knowledge Commission, and a lack of coordination between different parts of the bureaucracy that is often highlighted in the literature (Eimer & Lütz 2010), India is one of the few developing countries with "access to national or regional experts capable of tailoring the implementation of international IP obligations to foster national development objectives" (Deere Birkbeck 2008, p. 310). This has also been emphasized by Shaffer *et al.* (2015), who demonstrate that the Indian state could transform itself by establishing a public–private coordination mechanism (with Indian private lawyers), allowing it to enhance its legal capacity. Ultimately, India has substantially strengthened its institutions in this regulatory field to be able in turn to shape the health-IP regime.

3.2. Brazil

Brazil's patent office, INPI, much as the IPO in India, existed well before TRIPS and was created in 1970. The INPI transformed into a more powerful regulator in the context of pro-market reforms brought by the Collor and Cardoso administrations in the 1990s and pressure from the United States. It has since become closely aligned with the patent practices of the US, EU, and Japan (often known as the Trilateral offices). INPI thus plays a similar role to that of the CSIR in India, by promoting an expansive patent culture. However, if one compares the number of patents granted in the United States[19] that originated in India and Brazil since 2002 (a useful proxy for patenting activity), it rapidly becomes clear that Brazilian inventors have experienced less growth (with only 2,856 patents granted); as a comparison, Indian inventors were granted 16,941 patents in the same period (with the caveat that India has a much larger population).

Brazil increased its regulatory capacity both to fulfill the requirements of TRIPS and through economic coercion by the United States with the result that INPI was granted ISA status as early as 2009, only the second developing country to obtain such status after China. However, as explained by several of our interviewees, improvements in regulatory capacity lost steam over time, partly as a result of declining pressure from outside and partly as a result of domestic conflicts:

> *Brazil is much more active internationally compared with the lack of domestic advances on this field. Add to this the fact that the INPI has little institutional capacity. So overall, the capacity to do intellectual-property policies is currently very low. There is no big interest to do so,* ***interest existed when there was pressure from the outside****. The private sector (i.e. the pharmaceutical industry) does not feel threatened. There are enormous internal distortions,* ***particularly sectors that benefit from inefficiencies in the system, for example the slow pace of giving patents****…*

This last point is important since it explains at least partially why INPI had amassed an enormous backlog of patents, with applications taking over a decade to be decided. The backlog is, on the one hand, the result of a lack of patent examiners (raising the number of patent examiners has been challenging given that they are considered public officials and as such enjoy substantial privileges such as being employed for life, which makes these positions costly), but it also has a strategic component. The latter reflects a pushback by INPI against ANVISA (an agency of the Health Ministry), which was given, in 2001, the capacity to block the granting of pharmaceutical patents through a mechanism known as prior consent (discussed in more detail below). While it may appear contradictory (given that the backlog can be seen as a lack of capacity), it also worked in favor of INPI's objectives at the time, as explained by an interviewee:

> *Under Brazilian law if a decision on a patent takes too long, the company can extend the patent for as long as the decision took… this was a mechanism used by the INPI under the direction Jorge Avila to* de facto *extend patents. The new head of INPI Octavio Brandelli has focused on combating backlog in patent decisions.*[20]

Despite these challenges, one can observe an improvement in capacity over time, especially in the past decade. In 2012, INPI hired 70 new patent examiners and was awaiting approval of a new law in Congress that would authorize hiring 475 more patent and trademark examiners.[21] Between 2015 and 2017, INPI further increased the number of its patent examiners by 25% (or 210 new patent examiners),[22] the Federal Government also authorized hiring a further 50 new examiners in 2017, which reduced the substantial patent backlog that existed from 15,906 in 2015 to 9,288 in 2017.[23] While we did not find data, over time, of the proportion of pharmaceutical patent examiners from these overall figures, a 2017 government report by the Directorate for Patents, Computer Programs and Topographies of Integrated Circuits (DIRPA) stating the current capacities and needs of the Brazilian patent office by sectors (DIRPA 2017), shows that pharmaceutical patent examiners take the highest share (i.e. 27) amongst patent examiners. They are almost a third higher than the next category (mechanical engineering, which has 20) and are among those whose numbers are expected to rise the most (the report suggests adding 30 additional examiners by 2025). It must be said that if we normalize the 2017 figures (by the number of filings of pharmaceutical patents) and compare them to those of India for the same year (by the number of filings in the chemistry area), Brazil has a higher number of pharmaceutical patent examiners per filing than India (56.96 filings per examiner compared to 94.15 filings per examiner in India).

Later and in view of the results of the Pre-Exam Office Action, the impossibility of hiring new patent examiners, and the contingency of the budget imposed to INPI, in 2019, the DIRPA presented a Backlog Combat Plan, designed to reduce by 80% the number of pending patent applications (total of 160,000) within 2 years. The plan received support from the Ministry of Economy and, on 3 July 2019, was officially presented by Minister Paulo Guedes at a ceremony held in Brasilia.[24]

Regulatory capacity has not only been improved through hiring more patent examiners. More recently and in light of the budgetary crisis that has affected Brazil, INPI has sought to improve capacity through partnerships with leading patent offices. For example, as of January 2016, it began a pilot project with USPTO on a Patent Prosecution Highway. The pilot focuses on innovation patents and covers only patents in the oil sector. It reduces the length of the evaluation, the administrative costs, and leads to a faster granting of patents. The backlog has been reduced from a decade to 8.5 years. Similar pilot projects have been established with the EU's EPO (medical technology, and chemistry – except pharma), Korea's DKPTO (mechanical engineering, lighting, heating, weapons, and blasting), Japan's JPO (information technology, energy, machinery, audiovisual technology, telecommunications, digital communication, computing, semiconductors, polymers, metallurgy and materials, agrochemicals, microorganisms, and enzymes – except pharma), the UK's UKIPO (IT, telecommunications, semiconductors, machines, electric apparatus, energy, and biotechnology) and China's SIPO (information technology, package, measurement technologies, and chemistry).[25]

Increased regulatory capacity originating from the post-TRIPS modernization of INPI translated into bureaucratic strife with the Health Ministry's agency ANVISA given that their objectives collided. While INPI was expected to increase the number of pharmaceutical patents, ANVISA and the Health Ministry were concerned that the country would not be able to afford the drugs needed to fulfill the constitutional mandate of providing free healthcare.[26] This contestation is in line with the expectations of Dubash and Morgan (2012, 2013), regarding distributional effects of the regulatory state in the South. In this case, the social implications for health policy of strengthening the patents' regulator have translated into rivalry and a contested/split regulatory state. Inter-bureaucratic cleavages hampered for a long time a coherent domestic approach to health-IP issues. As we will show later, the outcome of these cleavages ultimately limited the use of prior consent by ANVISA and thus implied the loss of an important flexibility, within the limits set by TRIPS. On the basis of the framework proposed by Lavenex, Serrano and Büthe (2021), this can be seen as a reversal in a previous development of regulatory capability.

Through the mechanism of prior consent, ANVISA was, in practice, given a veto right over pharmaceutical patents granted by INPI.[27] This meant the existence of "a double tier examination procedure, in which both authorities analyzed the patentability requirements of the same patent application" (Souza *et al.* 2017, p. 2). Because of this, the two federal authorities were in a dispute for the role of examining pharmaceutical patents. If INPI considered a case patentable but ANVISA disagreed this meant that the application was rejected by ANVISA but remained pending at INPI, often leading to lawsuits against ANVISA. One such lawsuit in 2015 was particularly relevant because INPI decided to become a third party. The lawsuit was launched by the

pharmaceutical company, AbbVie, which challenged ANVISA's decision on its drug, Kaletra (Souza *et al.* 2017, p. 4). A Federal Judge rejected the arguments to annul ANVISA's decision and thus reinforced ANVISA's role in considering cases in light of public interest. This said, when considering the overall number of cases brought against ANVISA, it can be maintained that "the judges who are favorable to ANVISA's interference in the double tier examination of patentability requirements are a minority" (Souza *et al.* 2017, p. 5).

In this context, it is not surprising that the Health Ministry has been the lead promoter of access to medicines initiatives in Brazil, together with civil society organizations, such as MSF and the Third World Network. Brazil, in addition, tested the limits of TRIPS in its use of the so-called *local working requirements*.[28] While we cannot discuss local working requirements given the limits of this article, it is relevant to note that, in May 2000, the United States filed a complaint with the WTO challenging the legality of local working requirements under the TRIPS. The case was settled and should be interpreted as a victory for Brazil that revealed the possibilities of using the grey legal zone of the local working requirements as a balancing mechanism (Mercurio & Tyagi 2010). As Okediji (2004) argues, the interpretation of IP norms through domestic practice in cases when such practice leads to disputes at the WTO, and to favorable appellate body decisions, thicken the agreement by filling in the gaps that existed from the negotiation. In doing so, it compels industrialized countries to accept specific flexibilities (i.e. policy-space) within the TRIPS and it opens the door for other developing countries to use similar provisions, without fearing being challenged at the WTO.

Domestic bureaucratic battles motivated the Brazilian government to attempt to increase its policy coherence in this domain. To do so, it created a ministerial group on IP (GIPI for its initials in Portuguese).[29] The group is coordinated by the Ministry of Development, Industry and Foreign Trade (MDIC). Next to the MDIC, it is composed of representatives of the Ministry of Agriculture, Ministry of Science and Technology, Ministry of Culture, Ministry of Foreign Relations, and Ministry of Health. Despite these efforts to improve domestic coordination, and hence regulatory capacity and capability, the main domestic conflict between the Health Ministry's agency, ANVISA, and INPI remained unresolved until 2017. In April 2017, through a Joint Ordinance 01/2017, ANVISA, after 16 years of conflict, was forced to forgo its role under prior consent (Souza *et al.* 2017, p. 6). In effect, ANVISA would henceforth only be able to block pharmaceutical patents if they include a substance whose use was prohibited in Brazil, and its opinions on matters pertaining access to health would no longer be able to block INPI from granting pharmaceutical patents and would be considered as a third party-observation for INPI's examination (Souza *et al.* 2017, p. 7).[30]

The political context in which these changes occurred is relevant and shows that contextual factors matter for regulatory state formation. The change to ANVISA's role on prior consent occurred during the interim administration of Michael Temer, following major political turmoil which saw the Workers' Party (PT) lose power ensuing the impeachment of then President Dilma Rousseff and the prosecution and imprisoning of former President, Lula da Silva. The PT had provided a favorable environment for activist networks and epistemic communities who played an important role in promoting access to health policies, similar to that in India.[31] Under the PT, the executive and its powerful advisory board (Casa Civil) were generally sympathetic to these demands. Health policies played a central part in Brazilian politics for quite some time. This helps explain why parts of the bureaucracy, including the powerful and professional Foreign Affairs Ministry (Itamaraty), had been supportive of access to health policies and explains Brazil's strong multilateral activism. The fact that health had become a constitutional right also made the Health Ministry particularly powerful, as already stressed above.

During the time the PT was in power, an important informal network, consisting of exchanges between policymakers, activist networks, and epistemic communities, came into being. These exchanges included present and former diplomats, policy makers espousing developmentalist ideas, academics, think-tank, and NGO representatives.[32] The tapping of this expertise by the Brazilian state is similar to that found by Shaffer *et al.* (2015) in India and has allowed developmental states to respond to globalization in novel ways. Perhaps, the best example of the role of expert networks in promoting access to health policies in Brazil was a much-discussed patent reform proposal (*Innovation towards National Competitiveness*)[33] suggested by PT house representative, Newton Lima, and supported by a network of experts and legal scholars, including the governmental think-tank IPEA and the Getulio Vargas Foundation (FGV). The proposal was borrowed from, and specifically referred to, India's Section 3(d). It failed to become law and has been left out of the legislative agenda, but it is nevertheless a good

example of the actors involved and the type of south–south interactions, which lead to the diffusion of policies as is shown in more detail in the last section of this article.

It is important to note that there are also networks of market-oriented technocrats and academics that tend to support expanding Brazil's patent regime, including on pharmaceuticals. Often referred in Brazil as *técnicos*, these played a role in strengthening patent protection throughout the pro-market reforms enacted in the 1990s. *Técnicos* favor extensive patenting policies as they are seen as crucial in promoting innovation, and thus as drivers of long-term economic development and growth. They are well represented in INPI but also in other sectors related to economic planning (such as the Ministry of Development, Industry and Foreign Trade, which now has become part of a newly created Economics Ministry).[34]

Over the past years, there has been a significant debate among policy-making circles on whether the overall interests of Brazil would not be better suited by limiting policies, such as compulsory licensing and limited patentability, and instead furthering technology transfer through, among others, public–private partnerships (PPPs). This shift began with interim-President, Michel Temer, and has been further pushed by a major reorganization under current President, Jair Bolsonaro. Bolsonaro has in effect created a super-economics ministry (through the fusion of the previous finance, planning, industry, and trade and labor ministries) under the lead of University of Chicago-educated economist, Paulo Guedes. It is not surprising that, in this context, the "developmentalist agenda" that existed in Brazilian policymaking is now absent. These developments show the challenges of emerging economies rising to become regulatory powers, given the significant internal contradictions that they still face and the potential for policy reversals, which may weaken their institutional strength, particularly regulatory issues. One interviewee argued in this sense:

> *Brazil is a very complex country. As with other emerging countries, we are halfway between a developed economy and society that is still developing. We are aiming at many things at the same time. On the one hand, there is a very strong activism on health issues. We need to offer free drugs. At the same time, there is a strong interest on innovation, to increase the number of patent's and efficiency at the INPI (backlogs). The generics industry in Brazil has lost strength. The industry was bought by the big pharmaceuticals. This limits the options and capacity in real terms of creating a new system. Domestically the debate is quite mainstream, there are limits to what is possible, compared to what would be desirable. Particularly with regards to the substantive legal framework, which is the work of the Brazilian Congress… Overall then, there is a lack of coherence because the products of the Brazilian external discourse do not reflect internal debates. To give you an example, there have been attempts to modify copyright law since 1997, which have not been possible because of the opposition of domestic interest groups.*

4. From policy innovation to international rule-making: Prospects and challenges

After sketching the developments and contestations inherent to both the Indian and the Brazilian regulatory states, we now link to the analytical framework's hypotheses regarding how new economic great powers position themselves vis-à-vis international regimes for the governance of global markets. The analysis, presented above, shows that policy preferences in India and Brazil conflict substantially with the regulatory status quo in the area of pharmaceutical patents. This preference divergence was already present before the power-transition took place, as both India and Brazil had opposed to the strengthening of the IP regime on the grounds that it could hinder economic development and keep states in the South as consumers rather than producers of IP. Divergence has, however, become less clear-cut, particularly in Brazil, and even in India where, as economic growth picked up, high-productivity sectors have lobbied for stronger patent protection. In the case of India, preferences remain conflictive in the area of pharmaceutical patents, while in Brazil an important shift has taken. This shift has to do with the weakening of the developmentalist agenda that existed in many parts of Brazil's public administration. This, in turn, made Brazil's preferences less conflictual with the international status quo. At the same time, the reversal of the policy of prior consent implies a weakening of regulatory capability (since the policy made use of flexibilities under TRIPS to address public health concerns). We expect less conflictual preferences and a weakening of capacity to have limited Brazil's ability to become a rule-maker in the health-IP regime.

In contrast to India, we have not found evidence of other countries considering adopting Brazil's prior consent legislation.[35] Given that the policy widened Brazil's policy-space with regards to pharmaceutical patents (by limiting them), it could potentially have been a good candidate for horizontal diffusion to other developing countries. Beyond the fact that prior consent was domestically very conflictual (which ultimately led to lower preference divergence with the status quo, and weakened regulatory capability), a further reason for the policy's lack of diffusion might be salience. India's policies are more visible. As was already mentioned, many developing countries rely on India's low-cost generic drugs. NGO's such as MSF also depend on India's generics for, among others, their large access to medicines campaign. This may put Indian domestic health-IP initiatives more on the spotlight. Another relevant reason may be the domestic conflict that prior consent was created in Brazil. These aspects are relevant for our argument given that they show the challenges that domestic initiatives have in becoming larger examples of rule-making. Let us turn our attention now to the case of India, where we do observe such rule-making through the horizontal diffusion of its Section 3(d) legislation.

Taking the SI framework (Lavenex, Serrano & Büthe 2021) and given India's relatively stable preferences and divergence from the status quo, we expect the country to be either a resenting rule-faker, a regime-disruptive/undermining spoiler, or a regime-transforming rule maker. In the first case, India would not possess strong regulatory capacity and capability; in the second, India would possess strong capacity and capability (but the established powers would reject its demands for substantive changes); and in the third scenario, India's regulatory capacity and capability would be strong, and it would succeed in getting the other members of the global regulatory regime to accept and accommodate its diverging preferences.

We have already seen that India developed a certain degree of regulatory capacity and capability. This eliminates the case of remaining a resentful rule-faker. However, for India to become a rule maker (and not a spoiler), existing powers would need to accommodate its interests. Then, the question that needs to be addressed is whether and how established powers have responded to the challenging initiatives brought by this new regulatory state.

In the case of India's implementation and diffusion of Section 3(d), we can affirm international repercussions – more hesitant at the multilateral level and more forcefully in horizontal rule-diffusion to other developing countries. At the multilateral level, India was able to shift US/EU preferences by mobilizing support to this rule, not only through transnational networks, but also, and crucially, within the domestic political spheres of the existing powers. A member of the TRIPS Council suggested during one of our interviews that domestic pressure by local and international NGOs prevented the US and the EU from challenging Section 3(d) at the WTO, even if according to the interviewee the rule's expansive exclusion of patents would probably be found in non-compliance with TRIPS. Whether this is the case will only be known if (and when) such a challenge occurs (at the time of writing the appellate body is suspended due to the veto of the United States). The sensitivity of Section 3(d) is also reflected in the fact that it has been targeted in draft clauses of now-defunct draft trade agreements including the Transpacific Partnership Agreement (TPP), Transatlantic Free Trade Area (TAFTA), and the Transatlantic Trade and Investment Partnership Agreement (TTIP) (Cardoso *et al.* 2014; Correa 2015). Given that Section 3(d) is potentially challenging to the health-IP regime, and that the existing powers have, for the time being, tolerated this new rule, while attempting to limit it in the future, we can consider any propagation of the rule beyond India itself as a case of international rule-making. In the following, we retrace how an innovative domestic practice – in this case, Section 3(d) can evolve into international rule-making without directly challenging the multilateral level, namely through horizontal channels of (south–south) diffusion to other jurisdictions.

Section 3(d) of the Indian Patents Act bans patents on both new uses of known substances and on new forms of known substances that do not enhance "efficacy." Although many countries know limits to the subject matter of patents, the scope of Section 3(d) and its expansive exclusion of patents on new forms of known substances is novel to patent law (Mueller 2007, p. 550; Kapczynski 2009, p. 1590). The potentially far-reaching effect of this norm must be seen against the backdrop of contemporary pharmaceutical patent practice, whereby pharmaceutical compounds are rarely protected only with a patent on the active ingredient (Kapczynski 2009). Typically, there is a primary patent on the active ingredient itself and a set of secondary pharmaceutical patents – for example, on a salt or isomeric form, on a chemical intermediary or a particular formulation. This practice of creating a thicket of pharmaceutical patents aims at extending patent life and is referred to as "evergreening" or "life-cycle management." It is also often related to litigation strategies, so that control over a drug is retained for a longer

period (Kapczynski 2009, 2013; Kapczynski *et al.* 2012). Section 3(d) imposes substantial limits on these kinds of claims. This has caused significant unease at major pharmaceutical companies, especially after the rather narrow interpretation of "efficacy," as a criterion for patentability set out in Section 3(d), was tested in court in a well-advertised case concerning the multinational Novartis.

Novartis sought a patent on the beta crystalline form of imatinib mesylate, covering its blockbuster anti-cancer drug, Gleevec. Novartis said that the beta crystalline form was more "efficacious" than the base compound, imatinib (which was invented before 1995 and, therefore, could not be patented in India), because it was easier to store and process, and was also 30% more bioavailable (i.e. the proportion of a drug that is absorbed by the body and is thus able to have an active effect). The Indian authorities insisted, however, that efficacy should be interpreted as a "therapeutic" standard that requires the new form to show improved healing effect in the body. The Indian Supreme Court upheld this view. While the Court acknowledged the physical efficacy of imatinib mesylate in beta crystalline form, it said that no material had been offered to indicate that this form would produce an enhanced or superior therapeutic efficacy on a molecular basis than what could be achieved with imatinib-free base. The Court, therefore, held that the test of Section 3(d) is not satisfied.

This development is novel in patent law and practice, and reflects also some of the controversies related to the rationales underlying the global patent system, as to its benefits and potential drawbacks for sustainable innovation and the provision of global public goods (Maskus & Reichman 2005). In this sense, "…the decision in *Novartis v. Union of India & Others* provides an important model for other countries around the world – a step toward a 'patent law 2.0' that not only helps to ensure access to medicines but might also help better align pharmaceutical innovation with public health needs." (Kapczynski 2013, p. 1). Since then, Section 3(d) has been used as a reason for rejection in 45% of all pharmaceutical patent applications.[36] Furthermore, in a recent empirical study on the application of Section 3(d), Sampat and Shadlen (2018) show the provision is not only being used against secondary pharmaceutical patents, but increasingly of primary pharmaceutical patents as well.

We argued that it is possible for a country to become a rule-maker if parts of its domestic legislation diffuse to other jurisdictions (as long as they are applied consistently). In this context, it is notable that Brazil and South Africa discussed the adoption of similar legislation to Section 3(d), even if in the end it was not adopted. Even more relevant is that the Philippines and Thailand did incorporate similar rules into their patent laws (Correa 2015). China has adopted, and recently made use of another type of legislation to invalidate the same anticancer drug (Gleevec) as India did.[37] In addition, Section 3(d) is still being discussed in media reports of developing countries, such as Kenya.[38] As already mentioned, in Brazil, Section 3(d) came to be included in a legislative proposal. The proposal was never adopted but the case is still illustrative of the mechanisms behind this interesting form of south–south diffusion, therefore we discuss this case in more detail.

Political discussions in Brazil with regard to Section 3(d) were linked to the patent reform proposal: "*Innovation towards National Competitiveness*," launched in 2013. The initiative was brought forward thanks to efforts by transnational activist networks and scholars based at the Getulio Vargas Foundation (FGV) and IPEA, together with PT congressmen. The background of this initiative were discussions by the Grupo de Trabalho sobre Propriedade Intelectual (GTPI), a transnational network consisting of Brazilian domestic anti-AIDS NGOs, as well as international ones (particularly MSF), domestic generics producers (Fenafar), and consumer and human rights groups.

Brazil's HIV/AIDS crisis had encouraged linkages between Brazilian and Indian NGOs as early as in 2008. In fact, among the most important Brazilian anti-AIDS advocacy groups and one of the key actors driving the GTPI as its coordinator is the Brazilian Interdisciplinary AIDS Association (Associação Brasileira Interdisciplinar de AIDS – ABIA). The latter not only disputed the patenting of the antiretroviral drug, tenofovir, by INPI in 2008, but filed an opposition against the grant of a patent for that same drug in India, along with an Indian NGO (the Centre for Residential Care and Rehabilitation) on the grounds that granting a patent for tenofovir in India would undermine the ability of Brazil to import, produce, or distribute such an antiretroviral drug (de Souza 2017).

Some of the 14 organizations that currently form the GTPI,[39] in particular, ABIA, work closely with academics and civil society groups in India. The GTPI has organized various events related to pharmaceutical patents over the past decade, including on oppositions to patent grants, judicial processes, and monitoring the Brazilian Congress. The GTPI has also been able to set agendas on these issues through links to elected officials.

For example, in 2010–2011, PT members of Congress, interested in patent issues, organized seven seminars with academics and civil society organizations to which GTPI representatives were invited. One of the participants in these discussions explained us during an interview that these seminars were part of the process leading to the reform proposal by representative Newton Lima, and how Section 3(d) became explicitly included in the Brazilian patent reform proposal (*Innovation towards National Competitiveness*). This concrete case of diffusion thus shows well the significant links that exist between Brazilian and Indian activist and of the relevance of India's generic industry.

5. Conclusion

The power transitions theory of global economic governance proposed in the introduction to this Special Issue (Lavenex, Serrano & Büthe 2021) suggests that it is only through developing issue-specific institutional strength in their regulatory states (regulatory capacity and capability) that the new major powers in the world economy can become rule-makers (or spoilers). The result underscores the difficulty emerging countries have of developing stable regulatory capabilities and capacities in the face of contestation and political cleavages in their domestic bureaucracies, particularly in the light of changes of government, as has happened recently in Brazil where the left-wing government that oversaw these international and domestic efforts has been ousted from power. The Brazilian case shows that party preferences may be relevant in shaping the position an emerging power takes vis-à-vis an existing regime. Yet, as the article also shows, it is exactly this regulatory devolution and stability that is required if countries want to establish themselves as rule-makers in international governance.

We showed that regulatory capacity (mainly but not exclusively at the patent offices of India and Brazil) was developed largely as a result of the requirements of the TRIPS and often through pressure and training from the US and the EU. Preference divergence with the existing hegemons, however, also encouraged developing regulatory capability in various parts of their public administrations, such as Health and Foreign Ministries, with the support of NGOs, academics, and activists.

The strengthening of their regulatory states allowed India and Brazil to develop domestic legislation, which increased their policy-space. In the case of India, this has spread to other (developing) countries via south–south policy-diffusion. India's Section 3(d) has become internationalized and until now has not been directly challenged by the EU or the US at the WTO. It has thus created a novel interpretation of inventive step in patent law, which in the long-run may have important transformative effects to the IP-health regime.

Beyond offering support to the theoretical expectations advanced in the introduction to the Special Issue, our case studies provide a novel and unexpected result. Namely that the promotion, or supply of new rules on the part of emerging countries takes sometimes a different, less institutionalized form to that of north–north or north–south supply of rules, which regularly unfold bilaterally within intergovernmental channels or through multilateral institutions. While rule-making through intergovernmental channels tends to be dominated by industrialized countries, other, non-governmental channels seem more open to innovation from developing or emerging countries. Our analysis shows that, in the case of India and Brazil, experts and activists filled the void left, using their own transnational venues to strengthen regulatory capabilities and capacity by spreading ideas and knowledge. Epistemic communities of Southern intellectuals and legal scholars, based in trade policy centers in both emerging and industrialized countries, challenge the narratives brought forward by the existing trade hegemons (Scott 2015; Shaffer *et al.* 2015) and are central actors in the promotion of alternative health-IP policies. This is an interesting finding, which may provide further clues as to the actors, means, and arenas by which the ongoing economic power transition will play out. However, an important caveat for this type of rule-making is its endurance. As the case of Brazil revealed, crucial domestic cleavages persist, which may lead to dramatic turns in policy once a new government is in power.

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Endnotes

[1] The article excludes China given that, in the field of public health, until very recently the country has not challenged the status quo (Serrano 2016). This is, in part, due to the fact that China had been subjected to a significant amount of external pressure related to its membership in the World Trade Organization (WTO). Before excluding this case, we conducted more than a dozen interviews in Beijing with academics, government officials, and representatives from industry. From these interviews, it became apparent that Chinese policymakers considered making use of flexibilities under TRIPS as being "too aggressive". China also perceived foreign pharmaceutical companies as important actors in developing its own industry. As an interviewee noted: "China is interested in developing new medicines and wants to attract big foreign pharmaceutical firms for this. In the long-run using flexibilities is likely to be counterproductive. In my view, the focus is on future growth prospects and hence it is very unlikely that China will follow other emerging countries such as Thailand, Brazil, or India in this."

[2] We conducted 36 semi-structured interviews with diplomats, policy-makers, judges, activists, private sector representatives, and academics in Brasilia, São Paulo, Rio de Janeiro, New Delhi, and Geneva between September 2012 and August 2014. The interviews lasted between one and two hours. Follow-up interviews were made in May 2016 (for India) and October 2016 (for Brazil).

[3] In the case of India, recognizing the importance of pharmaceutical patent examiners, efforts have been made by both the Indian generics industry and by the United States India Business Council (in part funded by US pharmaceutical companies) to train these examiners. However, the more longstanding and consequential efforts have been bilateral (by USPTO and EPO) and multilateral (by WIPO).

[4] As Drahos suggests, "Doha is a concrete success to which developing countries and NGOs can point" (Drahos 2002, p. 26).

[5] See: Mint "Indian IP examiners have world´s highest workload, lowest pay," 28th September, 2010. [Last accessed 29 Feb 2020.] Available from URL: https://www.livemint.com/Politics/BV5jXcxAd1fU1ZuYNqVF2M/Indian-IP-examiners-have-world8217s-highest-workload-low.html.

[6] Ibid, p. 2.

[7] Ibid, p. 4.

[8] Ibid.

[9] India: Patent Office Welcomes Hundreds of New Examiners, Hoping to put Major Dent in Backlog. Chadha & Chadha Intellectual Property Law Firm. January 4th, 2017. [Last accessed 29 Feb 2020.] Available from URL: https://www.lexology.com/library/detail.aspx?g=adef0e21-d394-4684-bd4b-d6f360728832.

[10] See for example Annual Report 2017–2018 from the Office of the Controller General of Patents. [Last accessed: 16 Jun 2020.] Available from URL: http://www.ipindia.nic.in/writereaddata/Portal/IPOAnnualReport/1_110_1_Annual_Report_2017-18_English.pdf.

[11] See: Chatterhee P (2017) "Is India´s Expedited Examination of Patents A Big Deal?" [Last accessed 29Feb 2020.] Available at: https://www.ip-watch.org/2017/09/04/indias-expedited-examination-patents-big-deal/.

[12] Interviews, three legal practitioners and a partner of a major legal firm, New Delhi, 31 January 2014.

[13] In very first year after the WTO was established, the US and EU successfully challenged India's implementation of its commitment under the TRIPS to create a transitional "mailbox system" where patent applications could be filed to establish priority and obtain exclusive marketing rights (India-Patents, AB 1997).

[14] See press release of government of India: http://pib.nic.in/newsite/erelease.aspx?relid=9576 (Last accessed 27 Aug 2018).

[15] Interview, representative of the Indian Drug Manufacturers Association, New Delhi, 20 February 2014.

[16] Interview, think-tank representative and government advisor, New Delhi, 16 January 2014.

[17] Interestingly, it was NGOs that helped develop the industry, by encouraging generics producers to export to developing countries, and thus reshape the generics market. The Clinton HIV/AIDS Initiative (CHAI), for example, negotiated with Indian generics producers, convincing them to lower prices by re-organizing and pooling demand. By changing the incentive-structure for India's main generics producers (Cipla, Ranbaxy, and Matrix) by turning the market from a scattered one into a low-prices high-volume one, CHAI created an enduring interest for Indian generic producers to promote flexible IP policies at the domestic and global levels (Kapstein & Busby 2013, pp. 157–158).

[18] This is a slight generalization. The generics industry is not a unitary actor, particularly so after consolidation of the past decade that saw big pharmaceutical multinationals buying Indian generics producers. Some of these acquisitions seem to have led to a less vocal position from previously vocal generic actors, such as Ranbaxy, which was acquired by the Japanese Daichi. Besides, some generics producers have also started investing significant funds in R&D and joined strategic alliances with big pharmaceutical corporations. Despite this, from our interviews with industry representatives and government officials throughout January and February 2014, it was made clear that the generics industry is still an important and influential voice resisting pharmaceutical patents. This is particularly the case for drugs that are likely to reap them significant economic benefits, such as those related to cancer treatment.

[19] US Patent and Trademark Office (2015) Patent Counts By Country, State, and Year - All Patent Types. [Last accessed 12 Nov 2018.] Available from URL: https://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.htm.

[20] In September 2013, INPI's federal attorneys submitted a letter to Jorge Avila requesting to invalidate all of these extensions (for patents in the Mailbox under Art. 40). The brief was signed by Avila, and subsequently he was removed as president (Müller 2013).

[21] See: https://www.managingip.com/Article/3195518/Interview-Jorge-Avila-INPI-president.html. Last accessed 28 Jan 2020.

[22] MDIC (2017) Acordo entre INPI e Anvisa acelera exame de patentes na área de fármacos. [Last accessed: 28Jan 2020.] Available from URL: http://www.mdic.gov.br/index.php/ultimas-noticias/2435-acordo-entre-inpi-e-anvisa-acelera-exame-de-patentes-na-area-de-farmacos.

[23] See INPI (2017) Activity report. [Last Accessed: 28 Jan 2020.] Available from URL: http://www.inpi.gov.br/sobre/arquivos/relatorio-de-atividades-inpi-2017-english-version.pdf.

[24] See INPI (2019): Note C. 8,893: Quality of Patents, including Opposition Systems; Use of foreign search as a tool for the efficiency improvement of the Brazilian INPI: The Patent Backlog Combat Plan.

[25] Phillips, Leigh (2019) Brazil: Accelerating Patent Examination In Brazil, 26 September 2019. [Last accessed 28 Jan 2020.] Available from URL: http://www.mondaq.com/brazil/x/848804/Patent/AI+Artificial+Infringer+or+Annihilator+of+Inventiveness.

[26] The Sanitary Movement (Movimento Sanitário) has been a powerful internal actor advocating for public health in Brazil. The movement became an important element pushing for democratization in Brazil, in effect criticizing the "highly centralized, hierarchical, and fragmented health system established by the authoritarian military regime" (Souza 2007, p. 38). Its relevance in the democratization process explains why it played a central role in codifying a provision in the 1988 Constitution anchoring the right to health as a fundamental right and establishing an integrated health system (Sistema Único de Saúde), publicly funded, decentralized, and open to community participation (Souza 2007; Escorel 2008).

[27] In February of 2001, the Brazilian Congress through law 10.196 gave a central role to the Health Ministry and the health surveillance agency ANVISA in decisions involving pharmaceutical patents.

[28] Article 68 of the 1996 Brazilian Industrial Property Law determines that compulsory licenses may be issued for patented goods which are not produced locally after 3 years of the granting of their patents.

[29] Interview, representative of GIPI, Ministry of Development, Industry and Foreign Trade (MDIC), Brasilia, 6 August 2014.

[30] MDIC (2017). Acordo entre INPI e Anvisa acelera exame de patentes na área de fármacos. [Last accessed: 28 Jan 2020.] Available from URL: http://www.mdic.gov.br/index.php/ultimas-noticias/2435-acordo-entre-inpi-e-anvisa-acelera-exame-de-patentes-na-area-de-farmacos.

[31] Interview, Brazilian trade negotiator, Geneva, 18 September 2012.

[32] Fifteen interviews with diplomats, policymakers, academics, and NGO representatives in Brasilia and Rio de Janeiro. July/August 2014.

[33] See: http://www2.camara.leg.br/a-camara/estruturaadm/altosestudos/pdf/brazils_patent_reform_eng.pdf. Last accessed 28 August 2018.

[34] Twelve interviews with policymakers in Brasilia, Rio de Janeiro and São Paulo, July, August 2014.

[35] Please note that a number of jurisdictions (both developed and developing) have adopted prior consent with regards to Traditional Knowledge and Access and Benefit Sharing. This policy is part of a different regime (governed by the

Convention of Biological Diversity) and thus should not be confused, despite having the same name, with Brazil´s prior consent which falls under the IP-Health regime.

[36] The Hindu (2017) How India Rejects Bad Patents, December 27, 2017. [Last accessed 13 Sep 2018.] Available from URL: https://www.thehindu.com/opinion/op-ed/how-india-rejects-bad-patents/article22282403.ece.

[37] Third World Network, January 27, 2016: 'Patent Reexamination Board of China's Patent Office Invalidated Novartis' Patent on Gleevec', available at: http://www.twn.my/title2/health.info/2016/hi160101.htm.

[38] Business Daily Africa (2018) "India proved patent laws not cast in stone". September 12, 2018. [Last accessed 13 Sep 2018.] Available from URL: https://www.businessdailyafrica.com/analysis/columnists/4259356-4756610-uy3rmr/index.html.

[39] Coordinated by ABIA it includes various international, national, local, and regional NGOs as well as business associations and universities. These are: Grupo Pela Vidda (Rio de Janeiro & Sao Paulo), GAPA (Rio Grande do Sul), GRAB (Ceará), Gestos (Pernambuco), the consumer defense institute (idec), the national pharmaceutical federation (Fenafar), Conectas, Doctors Without Borders (MSF), Allied Universities for Essential Medicines (UAEM), RNP +, GAPA (Bahia), Forum das ONG-AIDS (Sao Paulo & Rio Grande do Sul), and GIV.

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