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Two TRIPs to Innovation

Pharmaceutical Innovation Systems in India and Brazil

Verena Schüren

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Two TRIPs to Innovation. Pharmaceutical Innovation Systems in India and Brazil

Verena Schüren

Abstract

So far, the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the dynamics of innovation systems have been discussed fairly separately from each other. Research on TRIPs implementation has tended to focus on the (non-) adoption of certain TRIPs flexibilities while the literature on National Systems of Innovation (NSI) widely neglects the impact of global norms on innovation systems. This paper aims to reconcile these two approaches. My analysis of the post-TRIPs pharmaceutical innovation systems (PIS) in India and Brazil reveals major differences in the regulatory outcomes that go far beyond the mere (non-)adoption of certain flexibilities. Driven by unequal state roles, India and Brazil have evolved into having two different types of innovation systems in the post-TRIPs era. The paper asks how innovation systems are developing under the conditions of globalization and, through this, it contributes to the discussion on innovation systems in emerging economies.

Zusammenfassung

Bislang wurden die Implementierung des Übereinkommens über handelsbezogene Aspekte der Rechte des geistigen Eigentums (TRIPs) und die Anpassungsprozesse von Innovationssystemen weitgehend getrennt voneinander diskutiert. Arbeiten zur TRIPs Implementierung konzentrieren sich auf die (Nicht-)Anwendung bestimmter Flexibilitäten zum Schutz von öffentlicher Gesundheit, während die Forschung zu nationalen Innovationssystemen den Einfluss von globalen Normen nur schemenhaft in den Blick nimmt. Das Arbeitspapier bringt diese beiden Ansätze in Einklang. Eine Analyse der pharmazeutischen Innovationssysteme (PIS) in Indien und Brasilien deckt regulative Unterschiede auf, die weit über die Nicht-(Anwendung) einzelner Flexibilitäten hinausgeht. Es wird argumentiert, dass sich in den beiden Ländern – ausgehend von zwei unterschiedlichen Staatsrollen – zwei verschiedenartige Typen von Innovationssystemen herausgebildet haben, die sich in ihrer Ausrichtung voneinander unterscheiden. Das Papier stellt die Frage, wie sich Innovationssysteme unter den Bedingungen von Globalisierung entwickeln und leistet damit einen Beitrag zur Diskussion über Innovationssysteme in aufstrebenden Ländern.

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1. Introduction[1]

Emerging countries' innovation policies are increasingly the subject of government attention as well as academic debate. Although most of the BRIC countries have put innovation at the center of their development strategies, we still know little about their efforts to establish innovation systems (Arroio/Scerri 2010). According to the National Systems of Innovation theory (NSI),[2] innovation and technology development are rooted in a country-specific set of institutions whose configurations and interactions determine the performance of an economy (Hollingsworth 2000; Niosi 2011: 1638). Through their impact on investment, patent systems constitute a core feature of NSI (Basant 2006; Mani 2006; Chaturvedi/Chataway 2006). The adoption of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), hence, put emerging countries' innovation systems under tremendous pressure (Hasenclever/Paranhos 2009: 11). The agreement obliges all WTO member countries to comply with a set of global patent standards, which, in turn, forces them to abandon their hitherto developmental patent regimes. Conflicts between TRIPs exigencies and developmental patent regimes have become most prevalent in the pharmaceutical sector, where the trade-off between access to and protection of knowledge is most pronounced (Laforgia et al. 2009; Shadlen 2011).

So far, the implementation of TRIPs and the dynamics of innovation systems have been discussed fairly separately from each other. The research on TRIPs implementation has tended to focus on the (non-)adoption of the TRIPs flexibilities, which provide emerging and developing countries with a certain leeway in the field of pharmaceuticals for the protection of public health (Cullet 2001; Milistien et al. 2007; M. D. Nair 2008; George et al. 2009), and their (non-)effective utilization (Drahos 2007; Shadlen 2007; Costa Chaves et al. 2008; Kapczynski 2009; Gopakumar 2010). However, little attention has been paid to how innovation systems in emerging countries have adapted in the post-TRIPs era. People writing on NSI, similarly, tend to overlook the importance of developing and emerging countries' innovation systems in general, as well as their underlying global influences (Intarakamnerd 2002; Baskaran/Boden 2006).

Drawing on the NSI framework, this paper asks how innovation systems are developing under the conditions of globalization. Comparing the post-TRIPs pharmaceutical innovation sys-

1 This paper summarizes findings from a political science research project funded by the German Research Foundation (DFG). Empirical evidence has been obtained by document-based process tracing and semi-structured interviews in Europe (Geneva, Brussels), India (Delhi, Mumbai), and Brazil (Rio de Janeiro, Brasília, São Paulo) between 2010 and 2012. All interview partners are assured their confidentiality as their individual names and other information that might endanger their anonymity are not revealed here. I would like to thank Susanne Lütz, Thomas Eimer and Željko Branovic (SFB 700) for helpful discussions on the concept of innovation systems. Furthermore, I am indebted to Ken Shadlen (LSE London) and Pranav N. Desai (JNU New Delhi) for their most valuable suggestions. I would also like to thank Charlotte Schöne for her editorial support. A first version of this paper was presented at the BISA/DVPW Conference in St. Andrews, Scotland, 19-21 December, 2011.

2 Throughout this paper, I will use the term "(pharmaceutical) innovation system" when talking about the *de facto* developments in India and Brazil. With the term "National Systems of Innovation" (NSI), in turn, I solely refer to the theoretical and analytical concept as Christopher Freeman and Bengt-Åke Lundval introduced it in the 1980s.

tems (PIS) in India and Brazil, I reveal major differences in the regulatory outcomes that go far beyond the mere (non-)adoption of certain flexibilities. While the Indian PIS has become strongly oriented to and integrated in the global market, the Brazilian PIS largely centers on domestic demand, thus remaining rather unrelated to the global market. I suggest a threefold argument to address the different outcomes produced in these two situations:

- First, the Indian and Brazilian governments assume different state roles in the realm of pharmaceutical innovation that impact the demand in the PIS.
- Second, these different state roles are linked to varying patterns of government intervention that, in turn, impact linkages in the PIS.
- Third, trajectories are consolidated through the way learning is taking place.

By placing state roles at the center of its analysis, this paper complements former studies that largely hold the private sector responsible for separated different PIS outcomes (Thorsteinsdóttir et al. 2004).

The rest of the paper is organized as follows: The next part introduces the NSI approach and places it in the context of TRIPs. Part 3 addresses the PIS developments in India and Brazil. In part 4, 5, and 6, I analyse the sources of the varying developments by assessing demand, linkages, and learning. In part 7, I provide an overview of the empirical results and interpret them against the background of the NSI framework. Finally, the conclusion points to some topics for future research.

2. Bridging the gap: Implementation of TRIPs from an NSI perspective

The NSI approach emerged in the 1980s as a conceptual framework for analyzing patterns of technological change and has achieved a lot of recognition from scholars as well as policymakers since then (Freeman 1982; Lundvall 1992; Nelson/Rosenberg 1992; Edquist/Hommen 2006). Departing from the orthodox perspective on growth, the NSI approach explains differing economic outcomes from a microeconomic perspective – placing linkages in the production and innovation system at the center of its analyses. In this sense, innovation is described as an interactive process between actors and institutions (Malerba 2005: 385; Parto et al. 2006).

Countries are assumed to follow specific trajectories when adjusting their innovation systems. The NSI concept still suffers from definitional fuzziness and conceptual fragmentation (Scerri/Lastres 2010: 7). In fact, authors have identified several factors that determine the output of these "'national' models" (Amable 2000: 657). These include market orientation, institutional settings, and socioeconomic context (Niosi 2011: 1638; Guennif/Ramani 2012: 430). However, in the case of economies that are "catching up," three key determinants prevail: the nature of *demand*, *linkages*, and *learning* (Malerba/Nelson 2011: 1650ff). Here, *demand* is not being seen as an aggregate set of equally oriented end users, but rather as a specific pattern of public and private actors that forms innovators and producers' preferences. It can arrive from end users, firms, as well as government entities (Edquist/Hommen 2006: 10; Malerba 2006: 9; Malerba/Nelson

2011: 1650). *Linkages* among actors involved in innovation processes determine the range of interaction between public and private sector entities. The NSI concept rests on the premise that the scope and character of these linkages are crucial for technological improvements (Edquist 2005; Edquist/Hommen 2006; Chaturvedy/Chataway 2006; Nassif 2007). Key innovation actors are the government, universities, public production and research facilities, as well as private firms (Feinson 2003: 25f; Guennif/Ramani 2012: 430). The term *learning*, meanwhile, places emphasis on knowledge acquisition and human resource development. This includes formal training as well as the outcome of interaction between actors. In this regard, the NSI approach attaches value to linkages and the education system as it strengthens the future orientation of actors and knowledge creation within the innovation system (Amable 2000: 651; Lundvall 2007: 107; Parto et al. 2006: 13).

Although market actors have an important role in the innovation system, NSI authors recognize the fact that it is the government that assigns their place. Demand, linkages, and learning can differ according to the scope and coherence of government actions. State roles and government interventions, thus, can be strong factors that influence innovation systems (Edquist 2005: 197ff; Parto et al. 2006: 18; Bakovic 2010: 4; 4f; Niosi 2011: 1639). This is especially true for developing economies where the adaptation of innovation systems can be most exigent (Scerri/Lastres 2010: 9).

Building on the assumptions of NSI literature, Bruno Amable (2000: 670ff) suggests four types of social systems of innovation and production (SSIP) that can be distinguished by their differing economic performances, including specific patterns of industrial specialization and innovation (table 1, page 8). In the *market-based SSIP*, economic activities are mainly governed through competition. Government interventions are on the decline and serve at most as a complement to the private sector. Strong IP protection is the key incentive for innovation, while collective goods suffer from structural underinvestment. The market-based SSIP is strongly linked to the global market economy, where niche products and radical innovation is a key factor for industrial and technological advancement. Another category suggested by Amable is the *social-democratic SSIP*, where bargaining between social partners forms the general principle of interaction. Government interventions are extensive and do not only complement but also replace activities in the private sector. IP protection exists but can become subordinated to health concerns in case of doubt. Technological advancement is rooted in gradual evolution rather than radical change. The social-democratic SSIP is firmly linked to attempting to solve social problems, and here the state takes the most active stance. Lying in between these two SSIP categories are the *meso-corporatist* and the *public SSIP*. In the *meso-corporatist SSIP*, government regulations are driven by the aim to moderate between interest groups. Government intervention is taken to furnish and coordinate rather than to steer the private sector. Technological adaptation is seen as interim step toward product innovation, while the catching up process heavily relies on in-house research. In the *public SSIP*, finally, conciliation between public interests is reached under the control of the state. Large public programs encourage the private sector. Production and innovation are mainly linked to the public infrastructure, while new product development remains out of reach.

Table 1 – Social Systems of Innovation and Production (SSIP)

	Social-democratic	Public	Meso-corporatist	Market-based
General principle	Bargaining between social partners	Conciliation between public interests under state control	Moderation between interest groups	Market-based competition
Development priority	Solution of social problems	Regional (European) integration	Economic development	Economic development and global integration
Government intervention	Extensive and coherent Replacement of private sector	Large programs Important encouragement of private sector	Partial Furnishing and coordination of private sector	Declining and fragmented Complement to private sector Underinvestment in collective goods
IP regime	Subordinated to health in case of doubt	-	-	Key incentive for innovation
Innovation	Gradual evolution toward advanced technologies	Research disconnected from development of new products	Adaptation in catching-up phase, product innovation after Importance of in-house research	Importance of niche products and radical innovations
Industrial specification	Linked to social demand	Linked to public infrastructure	Linked to local skills	Linked to global market

Source: Own compilation; based on Amable (2000: 671ff).

While the aforementioned NSI determinants (demand, linkages, and learning) are useful parameters to assess variations in the output of an innovation system in terms of technological development and interactions, the SSIP framework goes one step further by referring to different system principles and priorities. However, neither the NSI framework nor Amable's typology fully reflect on how SSIP respond to global influences.

TRIPs, in fact, is a prime example of a global influence. It is the biggest challenge related to innovation in emerging countries, especially in the pharmaceutical sector (Hasenclever/Paranhos 2009: 11). The agreement requires the provision of patent protection for pharmaceutical processes and products – which strongly impacts the patent systems of these countries as most of them didn't provide for product patents in this field before (Shadlen 2007: 559f; Li 2008: 1368). Patents, in turn, represent an essential part of an NSI (Amable 2000: 650; Edquist 2005: 190f; Basant 2006: 1; Parto et al. 2006: 2ff). This is especially true for the pharmaceutical sector where "patents are unambiguously recognized as being key instruments for privately appropriating the economic benefits of innovation and, therefore, serving as an important incentive for further innovation" (Laforgia et al. 2009: 293).

I expect a change in global patent standards to impact PIS in emerging countries for at least three more reasons. First, TRIPs changes the perceptions and preferences of local firms. To the extent that the copying of technologies that already exist becomes an obsolescent business model, local firms have to adapt their strategies to ensure sales markets. Here again, government interventions can have an important catalyzing effect (Guennif/Ramani 2012: 431). Second, the adoption of TRIPs and its subsequent implementation lure global firms, who, for their part, are in search for profitable business models, e.g., in the field of contract research and licensing (Baskaran/Boden 2006). The entry of foreign market actors, in turn, can result in new linkages in the PIS. And finally third, local governments, anticipating these trends, will take measures in order to optimize national development priorities against the backdrop of global regulatory pressure (Niosi/Bellon 1994: 189ff). Overall, TRIPs urges developing and emerging countries to adopt an innovation system in which technological advancement is patent driven. In doing so, the treaty exerts a considerable "harmonizing power" on these countries (Kapczynski 2009: 1571). However, as a closer analysis of post-TRIPs pharmaceutical innovation systems in India and Brazil will show, countries can still opt for different trajectories when adapting their PIS.

In order to assess how PIS in India and Brazil have developed under the conditions of globalization, I refer both to the NSI and the SSIP framework. The following analysis is split into three steps. First, I identify differences in the regulatory and innovative capabilities of post-TRIPs PIS in India and Brazil. Second, I trace these differences back to the aforementioned NSI determinants. Third, inspired by Amable's work, I assess the existence of two different types of SSIP. In this sense, this paper does not strive for a causal explanation of the differing developments. Rather, it begins from a description and analytical classification of these differing developments.

3. The development of PIS in India and Brazil

India and Brazil are interesting cases to compare as they share important features in the pharmaceutical sector. First, both countries have a single, large market and a relatively large amount of qualified scientific personnel. Second, governments in both states pursued strong industrial development as a priority since the mid 1950s. As a result, PIS in both countries have been designed to foster domestic production, promote import substitution, and reduce prices. Third and related to this, both countries share a history of having had a considerable period of lax patent protection (excluding product patents in the pharmaceutical sector). Reverse engineering – the copying of already existing technologies – has been the dominant strategy of "catching up" in both these countries for decades (George et al. 2009: 117f; Thach/Marsnik 2009: 250; Guennif/Ramani 2010: 5f; Peterson 2010: 10). With the establishment of the TRIPs agreement, however, India and Brazil had to abandon their developmental strategies (Shadlen 2007). Since the beginning of the 2000s, governments in both countries have launched policy initiatives that acknowledge innovation as a fundamental tool for development in general (MST 2003; Presidente da República 2004) and for the pharmaceutical sector in particular (Governo Federal 2003; MoCF 2005).

Despite these common grounds, India and Brazil's post-TRIPs PIS have evolved in quite different ways. A first noticeable difference lies in the accumulation of innovative capabilities in the private sector. After TRIPs was agreed upon in 1995, leading Indian generic firms started to invest heavily in research and development (R&D). They established innovative branches to complement their generic business model and, by today, widely prove their success in the field of incremental innovations. Some firms, however, are also reaching out to acquire new drug discovery and development capabilities. High rates of in-house R&D have been the main driver for these advancements (Basant 2006: 3; Guennif/Ramani 2012: 437f). A common indicator to measure innovative capabilities in the private sector is the number of foreign patent applications (Bakovic 2010: 5). Two differences attract attention here. First, the amount of Indian patent applications far outstrips Brazilian applications. Second, while in India research activities are concentrated in the private sector, Brazilian private sector firms have largely remained focused on the imitation of foreign technologies; the more innovative efforts are in Brazil taking place in public sector entities (Rezaie et al. 2008: 627ff; Guennif/Ramani 2012: 438).[3] It is safe to say that hardly any private firm is at present taking serious steps toward drug discovery, let alone development. An exception to this rule is the company Cristália, which has nine patents according to the statistics of the United States Patent and Trademark Office (USPTO 2012).

3 In 2010, India filed 1,285 patents under the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO). Nine of the top ten applicants are involved in pharmaceutical research (WIPO 2011a). Almost thirty Indian pharmaceutical firms received five or more patents at the US Patent and Trademark Office (USPTO) between 2007 and 2011. Brazil, in comparison, submitted only 488 patent applications to the PCT in 2010. In the top ten applicants, only two are engaged in pharmaceutical research. Significantly, these two parties are state universities (WIPO 2011b). A second important indicator for innovation is the number of scientific publications. In this area, Brazil is one of the world leaders. However, it is again the public entities that account for this achievement (Ferrer et al. 2004: 8f).

A second difference lies in the portfolio of research activities. In India, research focuses on lifestyle and chronic diseases, like diabetes and cardiovascular diseases, as well as on niche sectors like biogenetics and stem-cell research (Interview 284; 278; 324). Even publicly funded research entities have been involved in this trend (Eimer/Lütz 2010: 138; Interview 322). This development has caused much controversy, as it centers national research capacities on foreign rather than domestic disease patterns (Mani 2006: 20; Abrol 2006: 25ff; Hassan et al. 2010: 30ff). In Brazil, in contrast, current research activities to a large extent remain focused on fields relevant to the health problems within the country. Immunization and tropical as well as sexually transmitted diseases are at present the predominant areas of scientific research (Thorsteinsdóttir et al. 2004a: DC48; Ferrer et al. 2004: 8f; OSEC 2010: 41).

A third difference lies in the degree of internationalization. The Indian PIS is recording rising export rates and a high connection with international regulatory authorities, making India's pharmaceutical industry the "single largest pharma player in the world 'post-TRIPs'" (G. G. Nair 2008: 441). Indian pharmaceutical exports have been increasing at an annual compound rate of approximately 22% since the mid 1990s and reached a volume of 12 billion US dollars by 2011 (Chaudhuri 2008: 278; Neeraj 2011). As imports have remained relatively stable, India has achieved a positive trade balance in which exports increasingly outstrip imports (Joshi 2003; Hasenclever/Paranhos 2009: 4; Neeraj 2011; Guennif/Ramani 2012: 438). The boost in exports goes hand in hand with a high degree of international regulatory compliance. Firms and research institutes increasingly comply with the Good Manufacturing Practices (GMP), the Good Clinical Practices (GCPs), and the Good Laboratory Practices (GLPs). These three practices harmonize the quality controls in formulation manufacturing and research (ICMR 2008: 2; Interview 299). Today, more than 100 Indian firms are already engaged in clinical research. While most of them are acting on a low-threshold level, leading enterprises like Dr. Reddys and Glenmark are also conducting high-end tests up to phase four (Interview 299). Companies are also firmly integrated into international aid programs where they act as major suppliers of generic HIV/AIDS drugs for sub-Saharan Africa (Van Dyk 2007: 143). All in all, Indian firms have established strong links to foreign actors and nowadays function as "an integral part of the strategies of western firms" (Abrol 2006: 43).

The Brazilian PIS, in comparison, has remained rather centered around the domestic market. Stagnating exports and increasing imports of pharmaceuticals in the post-TRIPs period have resulted in a trade deficit of nearly 3 billion US dollars (Hasenclever/Paranhos 2009: 4). The vast majority of Brazilian producers focus their firms' strategies on domestic supply and refrain from export-oriented activities (Interview 235). Brazilian firms hold only a small share of the global pharmaceutical market and, in contrast to their Indian counterpart, remain virtually unconnected to foreign regulatory authorities and international programs. Brazilian Good Practices Standards do not match OECD standards and several airports still do not comply with the applicable requirements for export (Hasenclever/Paranhos 2009: 14). To date, practically no local producer has applied for a WHO prequalification (OSEC 2010: 41; Interview 226). Instead, Brazilian firms serve as supplier to the government's health programs, which strongly link them to the national procurement and production system (Cohen/Lybecker 2005: 214f; Rezaie

et al. 2008: 630ff). Table 2 gives a summary of the post-TRIPs PIS characteristics in India and Brazil.

Table 2 – Post-TRIPs PIS characteristics in India and Brazil

	Brazil	India
Innovative capabilities	Concentration in the public sector	Concentration in the private sector
Research portfolio	Oriented toward the domestic market	Oriented toward foreign markets
Internationalization	Low	High

The following section tries to assess the different PIS developments. Referring to demand, linkages, and learning, I will argue that the states, by assuming different roles, have triggered two different systems of innovation and production.

4. Demand matters: Benevolent shopaholic vs. withdrawn miser

According to NSI theory, demand forms an integral part of an innovation system. It determines the size of the sales market and provides incentives for entrepreneurial thinking and action (Edquist/Hommen 2006: 10; Malerba 2006: 9).

With 1.2 billion inhabitants, India is more than six times bigger than Brazil. However, due to a significantly higher per capita expenditure on health, total Brazilian health spending is 16% higher than in India. This mismatch becomes even more evident when looking at the spending on pharmaceuticals. In 2000, the annual average per capita expenditure on pharmaceuticals in India was only 3 US dollars as compared to 61 US dollars in Brazil (WHO 2004). This relatively high spending makes Brazil one of the most attractive emerging sales markets for local as well as global pharmaceutical producers (TransWorldNews 01/06/2011).

One major cause for the huge differences in pharmaceutical sales lies in the different state roles in the articulation of demand. Brazil is considered an "activist state" in the field of health that sees the provision of drugs as an important part of its responsibilities (Biehl 2004: 115). The government not only acts as a regulator but also as a supplier and – most notably – as a buyer in the PIS, thereby assuming the role of a leading "health entrepreneur" (Cassier/Correa 2007: 84). It sustains a sizeable procurement system and is responsible for almost half of the total national health spending. Furthermore, the government counts as single largest purchaser of pharmaceuticals within Brazil and as one of the biggest buyers worldwide (Interview 166; 255). In 2009, the total amount for acquisition of medicine for its national health system, the Sistema Único de Saúde (SUS), was approximately 4.9 billion US dollars. And as the government is

expanding publicly paid health coverage to new areas like diabetes and hypertension, further increases are to be expected (Vieira 2009; Vieira/Zucchi 2011; Giugale 2011; MS 2011).

In sharp contrast to Brazil, the Indian state is hesitant to actively engage in the PIS. It acts foremost as legislative body and regulator and abstains from assuming the role of a buyer for health care generally and for pharmaceuticals in particular (Abrol 2006: 41). Public health expenditure has been decreasing over years.[4] Domestic demand for pharmaceuticals therefore mainly derives from private consumption. Yet, due to inefficiencies in the distribution systems and the prevalence of traditional healing methods such as ayurveda and homeopathy, "modern" drugs are not widespread among private households, especially in rural areas. According to estimations, only 30% of the Indian population has access to these drugs (Interview 279; 283; Kaplan/Laing 2005: 15; TransWorldNews 01/06/2011). As the government does not step in as buyer, the domestic purchasing power for pharmaceuticals remains relatively low, making an orientation toward foreign markets more profitable for Indian manufactures (Interview 156; Interview 283; MoCI 2008: 29).

Thus, by assuming different roles, India and Brazil's governments produce different demand patterns that spur global integration in the first PIS and domestic orientation in the second PIS. The next section will show that these state roles correspond with different types of government intervention that, in turn, contribute to the orientation of the PIS.

5. Made linkages: Cosmopolitan laissez-faire vs. monitored stay at home

Actor linkages and interactions are the second decisive feature for an NSI. Government interventions play an important role in shaping these bonds. They account in a major way for which public and private producers become linked to each other and, in doing so, influence the market orientation of manufacturers (Chaturvedi/Chataway 2006: 4). After TRIPs, the pharmaceutical sector was declared a priority area both in India and Brazil. R&D efforts were broadened and governments in both countries took action to foster innovative capabilities in this field including financial and fiscal incentives (Hasenclever/Paranhos 2009: 3). The scope and depth of public action, however, differ considerably and have resulted in varying patterns of government intervention.

The rather passive role of the Indian state corresponds with a strengthening of the private sector and an increasingly market-based governing mode within the PIS (Abrol 2006; Interview 275). Three features of government intervention are noticeable in this regard. First, even though Indian leaders recognize innovation as the "survival kit" in the post-TRIPs scenario, government involvement has been restricted to the coordination of the private sector while public sector entities have been continuously neglected since the 1990s. Publicly funded

4 Recently, the Indian government announced plans to expand its public drug procurement from around 0.1% to 0.5% of the gross domestic product (GDP). Concrete measures are, however, outstanding (ToI 2012).

research on health has been sinking or stagnating (Krishna 2001: 192). Meanwhile, Indian public sector undertakings (PSUs) – once the pioneers of pharmaceutical technology development – have fallen behind private competitors after liberalization in the pharmaceutical sector (Gopakumar 2010: 351).

Interestingly, the demise of PSUs is being less attributed to liberalization than it is to political mismanagement and lack of political will (Interview 276; 300; 320).[5] The two public institutes that remain that play a role in pharmaceutical R&D – the Council for Scientific and Industrial Research (CSIR) and the Indian Council for Medical Research (ICMR) – are suffering from two major shortcomings. First, financial support is insufficient to seriously enter into drug development. Research efforts consequently remain widely limited to pre-clinical endeavors (Interview 294). Second, neither the ICMR nor the CSIR possess appropriate manufacturing facilities. Accordingly, both entities rely on private sector firms in order to commercialize their R&D achievements, making them subject to market terms (Interview 280; 313). Final products partly end up in exports. It has also been reported that publicly acquired technology has gone missing after a foreign takeover of the technology receiver (Interview 320). In light of these developments, a former representative of the Indian Ministry of Commerce and Industry (MoCI) concedes: "The public sector has not been encouraged. It has been ignored by the government" (Interview 276).

The government's reluctant posture is also mirrored in the way that it deals with compulsory licenses (CL). Even though all legal and technical requirements for a government issuance are met (grounds, capacity, need), it is reluctant to independently initiate a CL although this could substantially improve domestic health care (Interview 146; 292). This does not imply that Indian authorities want to hinder compulsory licensing in general. However, they state quite clearly that this is not going to happen under their lead (Interview 146; 154; 156).[6] This even includes the Ministry of Health, where an estimated three million people living in India with HIV/AIDS counts as "insufficient" to pass for real urgency. The Ministry of Health moreover generally refrains from engaging in CL issues. As one ministry official indicates: "For me, patent is a private right where the government should step out" (Interview 283).

A second notable feature of government intervention is that the Indian government tools are largely restricted to the supply-driven furnishing of the private sector without setting domestic health priorities. Fiscal reliefs and tax-free bonds are the core instruments for innovation promotion. The government offers a weighted deduction on in-house R&D as well as subsidies for drug discovery and development projects up to 50% (Jeffrey/Santhosh 2009: 23; Interview 295; 300; 322). What the tools have in common is that they explicitly do not differentiate bet-

5 One interviewee puts it drastically: "The PSUs have politically been allowed to become sick"(Interview 284).

6 Recently, the issuance of a CL for Bayer's cancer drug Nexavar in favor of an Indian company caused a stir in the public health community. Yet, it is fair to say that the CL stems from the Indian private sector without any major ministerial involvement. Quite to contrary, the Indian Ministry of Health explicitly refused the Indian applicant any support in this matter (Interview 283).

ween pathology, purpose, or applicability of the future invention. Instead, assistance is made available to every applicant whose project promises to comply with the patentability criteria "inventive step" (Interview 276; 294; 313).

A third notable feature is that Indian authorities promote conformity with international standards in order to foster export-led growth (Chaturvedi/Chataway 2006: 8). Indian pharmaceutical companies receive extra funding if they have internationally approved production facilities (Damodaran 2008: 418f). Besides, in order to expediting marketing and commercialization measures abroad, the government has intensively pushed forward the compliance with the above-mentioned standards for pharmaceutical research and manufacturing which are in line with the rules of the OECD, the US Food and Drug Administration, and the WHO (Interview 299; Mani 2006a: 22; Neeraj 2011: 3).[7] India's proposed National Pharmaceuticals Policy explicitly formulates the aim to "enable domestic pharma companies to become internationally competitive by implementing...established international guidelines" as well as to "facilitate higher growth in exports...by reducing the barriers to internationally trade" (MoCF 2005).

In sum, government activities in India are characterized by a neglect of the public sector, broad and supply-driven innovation schemes, and an explicit promotion of export-led growth. This partial type of government intervention not only has shifted pharmaceutical innovation efforts from the public sphere to the private sector, but it has also linked it to the global market. Today, export-oriented private firms account for two thirds of total R&D expenditure and have become the undisputed center of the Indian PIS (Chaturvedy/Chataway 2006; Mani 2006: 27f).

Government intervention in Brazil differs considerably. The already mentioned "active state" directs all innovation activities toward sustaining the SUS. In this spirit, innovation is not primarily seen as a bridge to global integration but, on the contrary, as a means to become less vulnerable to global economic cycles and as a means to solve social problems (Interview 227; 245; 253; 255). In order to guarantee sustainability in national health care, the Brazilian state adopts a "tight political management" (Doctor 2009: 14) and puts itself at the center of the PIS. Again, three features of government intervention are noticeable in this regard.

First and in contrast to India, state activity in the Brazilian pharmaceutical sector was not cut back after TRIPs. Indeed, the opposite is true. When state-owned laboratories were suffering from rising competition and inefficiencies in the late 1990s, Brazil's National Health Congress decided against privatization and reaffirmed the role of government companies in supplying medicines to the national health system (Flynn 2008: 517). Since then, the expansion of public production and innovation capabilities depicts one central pillar in the government's effort to guaranteeing sustainable and affordable health products (Chamas 2005: 83f). Unlike Indian

7 Significantly, while these standards assure a high quality for exports, regulatory marketing approvals sought for the Indian market suffer from corruption and lax enforcement (Reddy 2012).

authorities, the Brazilian government has effectively and aggressively enacted its CL system as a means of guaranteeing access to treatment and enhancing national industrial production capabilities for greater autonomy from multinationals (Cassier/Correa 2007: 84).[8] Although Brazilian authorities recognize CL as a last resort instrument, they leave no doubt that they would enact it again if domestic health care came into risk (Interview 227; 246; 253; 255).

Second, in Brazil, government intervention is not limited to the furnishing of the private sector but includes its replacement. Brazil has a total of eighteen public pharmaceutical laboratories. One of these, Far-Manguinhos, is directly subordinated to the federal government's Ministry of Health (Flynn 2008: 515). Unlike CSIR and ICMR, Far-Manguinhos encompasses research and manufacturing capabilities and can hence formulate without private sector participation. The public laboratories function as main supplier for the Ministry of Health's procurement policy and strictly follow the demand of the SUS (Rezaie et al. 2008: 627). To ensure the supplies of SUS relevant technology, Brazil's Ministry of Health has established a complex of industry and innovation for health (*Complexo industrial da Saúde* or CIS) that fosters public-private partnerships for the development and production of pharmaceuticals needed for the SUS. The program is a direct reaction to the increased vulnerability of the SUS through TRIPs and places a strong emphasis on politically monitored technology transfer and on domestic technological development where private partners generally supply the active pharmaceutical ingredients (APIs) while public laboratories formulate the drug. The end product, again, is exclusively delivered to the Ministry of Health (Interview 226; 245). So far, the majority of the API suppliers are domestic companies. However, multinationals are also incorporated provided that they are disposed to transfer technology to domestic laboratories. As an official in the Ministry of Health states: "It is not about a cut between the national and the international, but about an utmost security for the SUS" (Interview 227).

Third, government funding and fiscal reliefs for in-house R&D are earmarked and closely monitored (De Brito/De Mello 2006: 19ff). Research funds are managed by public agencies – most prominently by the Brazilian Development Bank (BNDES) and the Financing Agency for Studies and Projects (FINEP), who work on a tendering basis. Their distributions are bound to certain conditions that largely hamper the export orientation of private firms. FINEP funds have to be spent inside Brazil exclusively, even if the required capabilities are not available in the country. If a firm intends to license a technology where public funds have been used, it must obtain permission from FINEP (Rezaie et al. 2008: 634). Similar rules apply to the public laboratories (Interview 226; 236). In addition to this, money is distributed on a topical basis. The Health Sector Fund, created in 2001 to encourage the increase of private investment in R&D, provides money exclusively for health research in areas that are of interest to the SUS (Chamas 2005: 101; Doctor 2009: 13f). Equally, in the case of the Technology Fund (Funtec),

8 Brazil has used the threat of issuing a CL as a bargaining chip several times. Between 2001 and 2005, Brazil reached price discounts with Merck, Roche, Abbott, and Gilead of up to 65% for Antiretrovirals (ARVs) and anti-cancer drugs in return for not issuing CLs. What caused the most stir was the discussion about Merck's ARV drug Efavirenz, which was declared as being "public interest" by the Ministry of Health in 2007. After talks over price reductions failed, Brazil kept its threat and issued a compulsory license for Efavirenz in May 2007 (Love 2007: 14ff).

which declares drug development a key objective, research activities have to be "in conformity with the strategic interests of the country as well as the federal public programs and policies"[9] in order to be entitled to receive funding. The schemes restrict government support to research that is considered relevant for domestic health. What comes out of this is a chain of (domestic and foreign) private and public sector health product developers and manufacturers that, held together by the government's overall "promise of markets," orients its actions almost exclusively to the health needs of the Brazilian domestic market (Cassier/Correa 2007: 85; Interview 227).

6. Learning shapes: Technical steeling vs. social compatibility

In the previous two sections, I have argued that different state roles and types of government intervention have promoted global integration in India and a continuing domestic orientation in Brazil. In this section, I suggest that state roles and government interventions spur different learning strategies that, in turn, consolidate the varying PIS orientations. Learning takes place both through interaction and formal education (Lundvall 2007: 107; Parto et al. 2006).

First, due to the relatively weak domestic demand in India and strong competitive structures, private firms successively entered into cooperation with foreign actors. Left without any major government protection, they are trying to use their cost advantage to access large Northern markets. Strong compliance with global standards and elaborate in-house R&D capabilities, both of which have been encouraged by public policies, make them a preferred global destination for contract research and licensing agreements with foreign multinationals (Chaturvedy/Chataway 2006: 15f; Chaudhuri 2008: 269; Neeraj 2011: 2). Maintaining ever more links with global players, Indian firms and institutes are creating a high profile for outsourcing R&D and manufacturing for the global market. And as developed country markets are more lucrative than the Indian market, Indian companies have an incentive to enhance their knowledge base in fields that are needed abroad rather than to respond to the domestic market. A former chief official at CSIR states that, "Indian companies work more and more in direction of multinational companies" (Interview 322). Today, they are hardly involved in drug development in the field of neglected diseases and local production and research efforts are becoming increasingly detached from domestic health care needs (Abrol 2006: 26; Chaudhuri 2008: 269ff).

For Brazilian private firms, in contrast, international links play practically no role (Interview 227; 235). Entrepreneurial cooperation with foreign entities is mostly restricted to marketing or service provision relationships. Foreign R&D partnerships that could impact the learning within the PIS take place very rarely.[10] This is not surprising considering the relatively low

9 http://www.bndes.gov.br/SiteBNDES/bndes/bndes_pt/Areas_de_Atuacao/Inovacao/Funtec/, last viewed on 10/26/2011.

10 The very few co-development of R&D efforts with foreign entities in Brazil are generally done together with universities or public entities. One exception is Eurofarma, which formed a joint venture with the Portuguese firm Edol Laboratory (Rezaie et al. 2008: 634).

degree of both international conformity in terms of production standards and R&D capabilities in most Brazilian private firms, which make them far less attractive for multinationals than their Indian counterparts (Paranhos 2010). Apart from this, it doesn't seem attractive for Brazilian firms to enter into international partnerships outside the governmental framework as this would restrain both access to funds and market sales. Against this backdrop, the most rational way for Brazilian firms to allocate their resources is to focus on the demand of the national health system as formulated by the government thereby consolidating their knowledge base in domestically relevant areas.

Second, human resource development shapes actors' orientations. Formal education and training are crucial sources for the orientation of future personnel within the PIS. India and Brazil are adopting different approaches in this regard. In Brazil, emphasis has been placed on human resources development in health innovation that keeps with the priorities of the SUS. Brazil is one of the few countries that sustain decided governance instruments in the field of health science. The government has established a specific learning strategy for the education, training, and incorporation of human resources as part of its PIS. A key principle within this system is that research priorities should be defined domestically and not by external entities (Alger et al. 2009: 7f; Chamas 2005: 89). Brazil's PIS comprises of a network of universities, national schools, and research institutes that encourages scientific and technological production in health research. Formal education of health personnel is basically accomplished within the country. In addition to the regular pharmaceutical formation system, a broad range of public health degrees can be completed throughout the country. The government also provides support for post-graduates in the fields of health science. In addition to this, the Ministry of Health maintains a National School for Public Health (Escola Nacional de Saúde Pública or ENSP) which has the stated objective to train and form human resources for the SUS and which has one of the largest and best equipped faculties within the country.[11] More than one quarter of the active research groups in Brazil are linked to the field of public health, including more than 18,000 researchers. And government authorities endeavor to further match their research priorities with the emphases of its public health priorities, e.g., by giving out awards for outstanding scientific achievement for the SUS (Chamas 2005: 89f, 104).

By improving its formation system, the Indian state in contrast has placed its emphasis on technology management and the establishment of business schools, thereby hoping to build on global competitiveness (Wright 2008: 10f). There has been a steady rise in education in pharmaceutical innovation during the last few years with an extension of courses and teaching capacities. Currently, pharmaceutical teaching takes place at 500 colleges encompassing around 61,000 places for students. The Indian pharmaceutical education is inspired by the US system and meets international standards. It is comprised of a professional pharmacy doctoral program, which lasts six years, including one year of practical study, and five additional years for a PhD (Neeraj 2011: 5).[12] However, unlike in Brazil, pharmaceutical education is not

11 http://www.ensp.fiocruz.br/portal-ensp/apresentacao/, last viewed on 12/17/2011.

12 http://www.pharmainfo.net/abhi271183/pharmd-program-india, last viewed on 06/25/2012.

linked to national health policies. Education in this field is lead by the Pharmacy Council of India (PCI), a statutory body under the Ministry of Health, and the All India Council of Technical Education (AICTE), which is linked to the Ministry of Human Resource Development. Both institutions pursue a strongly technical and market-oriented approach in fulfilling their mandate (Interview 295; Interview 324). The PCI focuses on the need for "clinically and technologically trained pharmacy professionals who can face global challenges and compete with the multinationals."[13] At the PCI-organized National Seminar on Recent Trends in Pharmacy Education and Practice in 2010, a clear emphasis was put on technical skills. Of the 21 scientific programs, only one addressed public health – and significantly it was global not national health issues (PCI 2010). In the same vein, the AICTE highlights "technological development and economic progress" without pointing to aspects of health care.[14]

7. India and Brazil: On the road to different SSIP?

The previous sections have revealed that PIS in India and Brazil differ considerably in terms of demand, linkages, and learning. In all three cases, the state plays a decisive role. Motivated by the aim to guarantee sustainable and affordable health products, Brazil has articulated a PIS in which demand, linkages, and learning remain focused on the domestic market in order to sustain the SUS. India, in contrast, neglects the integration of innovation forces with domestic health care and instead orients its innovation capabilities to export-led growth. This approach is expressed in a globalized demand structure, strong linkages with foreign market actors, and a technical- as well as global-oriented learning system (table 3).

Table 3 – Post-TRIPs NSI characteristics in the Indian and Brazilian PIS

	Brazil	**India**
Demand	Predominantly domestic Concentrated in public sector	To large extent international Concentrated in private sector
Linkages	Oriented toward the government and the national health system	Oriented toward the foreign market and global partnerships
Learning	Oriented toward technical skills and public health	Oriented toward technical skills and global standards

The differences presented in this paper between India and Brazil point to two distinct social systems of innovation and production (SSIP) as introduced in the first section of this paper. The Brazilian case meets the specifications of the social democratic and public SSIP. In this model, the solution of social problems takes priority over the enforcement of intellectual property rights and radical innovation. The state takes an active stance in the conciliation bet-

13 http://www.pci.nic.in/, last viewed on 10/28/2011.

14 http://www.aicte-india.org/aboutus.htm, last viewed on 10/28/2011.

ween public interests, aligning innovation efforts with public health objectives. Government interventions are extensive and coherently directed to the national health system. Activities include encouragement as well as the replacement of the private sector. The public sector is the undisputed leader in innovative and manufacturing processes while private sector firms link their resources to public infrastructure and social demand. The Brazilian approach results in a strong representation of local resource-based activities and a pressure to adopt new techniques linked to societal health needs.

The Indian case, by contrast, fits into the model of the market-based and meso-corporatist SSIP. Driven by strongly competitive structures, the pharmaceutical sector operates "in the strict framework of market incentives" (Cassier/Correa 2007: 84). Government interventions are restricted to furnishing and complementing the private sector. They act as booster for economic development and global integration, linking private firms to the global market. Large amounts of in-house R&D and a pronounced IP regime are the important drivers for "catching up" and product innovations. The Indian model results in strong innovation capabilities and a structural underinvestment in collective goods (table 4).

Table 4 – Social Systems of Innovation and Production (SSIP) in India and Brazil

	Brazil	**India**
SSIP	**Social-democratic**/*public*	**Market-based**/*meso-corporatist*
General principle	*Conciliation between public interests under state control*	Market-based competition
Development priority	Solution of social problems	Economic development and global integration
Government intervention	Extensive and coherent *Encouragement* and replacement of private sector	Declining and fragmented *Furnishing* and complementing the private sector Underinvestment in collective goods
IP regime	Subordinated to health in case of doubt	Key incentive for innovation
Innovation	Gradual evolution toward advanced technologies *Public research disconnected from new products development*	*Adaptation in "catching-up phase" and product innovation after* *Importance of in-house research* Importance of niche products and radical innovations
Industrial specification	*Linked to public infrastructure* and social demand	Linked to global market

Source: Own compilation; based on Amable (2000: 671ff).

8. Conclusion

Departing from the observation that TRIPs is impacting emerging countries' innovation systems, this paper has analyzed the post-TRIPs pharmaceutical innovation developments in India and Brazil. The empirical findings reveal major differences in the regulatory outcomes that go far beyond the (non-)adoption of certain legal flexibilities that have been put at the center of analysis by scholars so far. While India has oriented its PIS strongly toward export-led growth, the Brazilian PIS functions almost exclusively for the satisfaction of domestic demand as determined by its national health system. As the case of compulsory licensing reveals, distinct implementation of certain flexibilities can be assessed more appropriately if interpreted against the backdrop of the overall innovation system. The Indian government denies actively supporting the enactment of CL in order to not deter economic growth and global integration. The Brazilian authorities, in contrast, take a robust stance against multinational companies in order to ensure the sustainability of their health program. The differences are rooted in varying development priorities that, in turn, point to different social systems of innovation and production. Brazil has developed a social-democratic and public SSIP, whereas in India, characteristics of a market-based and meso-corporatist SSIP prevail.

The analytical classification of the varying regulatory outcomes adds to comparative analysis of NSI. This study confirms that the NSI framework is not restricted to OECD countries. Rather, its assumptions can be transferred to emerging countries like India and Brazil. The findings discussed here also indicate that emerging countries can choose between different trajectories when adapting their innovation systems. However, this recognition is quite recent and much more research is required with special attention to the underlying conditions in these adaptation processes. This paper, therefore, presents a first step within a larger research context in which I aim to investigate the ways in which TRIPs impact national innovation systems of developing countries. This paper already suggests that the emerging countries' adaptation efforts are taking place under the pressure of globalization. The NSI concept must therefore be expanded to include the international dimensions of innovation systems and to properly assess linkages between national and international innovation systems.

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