Norm diffusion through Advocacy Coalitions:
Implementing international intellectual property norms in India and Brazil

Thomas Eimer, Susanne Lütz and Verena Schüren

Free University Berlin, Radbout University Nijmwegen and
Collaborative Research Centre „Governance in Areas of limited Statehood“

Paper to be presented at the ISA 54th Annual Convention 2013 in San Francisco

Contact:

Dr. Thomas Eimer
Radboud University
NL-6500 HK Nijmegen

Phone: Tel.: +31(0) 24 36115870
t.eimer@fm.ru.nl

Prof. Dr. Susanne Lütz
Verena Schüren

Chair for International Political Economy
Otto-Suhr Institute for Political Science
Free University Berlin
Ihnestr. 22
D-14195 Berlin

Phone: +49 (0) 30-838-56444/56470
luetz@zedat.fu-berlin.de
vschueren@zedat.fu-berlin.de

1. Introduction[1]

Usually, the literature on policy diffusion starts from a sender / receiver model. From this perspective, scholars ask under which conditions international norms are institutionalized on a domestic level. Even if they expect a certain degree of "localization", they still assume that the international wording remains the major blueprint for reform (Acharya 2004). In our paper, however, we argue that the diffusion of international norms may give momentum to an original process of reframing, by which the initial intentions of international norms are substantially reinterpreted on a domestic level. Research on regime implementation and on transnational activism has already exemplified how public-private interaction across borders and particularly, "transnational advocacy networks" (Keck/Sikkink 1998) impact on norm implementation and on monitoring of compliance with regional and international standards. Advocacy networks are seen to promote causes, principled ideas and norms, and often involve individuals advocating policy changes that cannot be easily linked to their interests. Not surprisingly, advocacy networks have been particularly important in value-laden debates over human rights, the environment or indigenous peoples (Keck/Sikkink 1999: 91).

In our paper, we share the notion that value priorities and shared norms of actor coalitions help us to understand why international agreements are sometimes implemented in an unprecedented and unforeseen way. We draw on the Advocacy Coalition Framework (ACF), created by Sabatier and Jenkins-Smith (Sabatier 1988; Sabatier/Jenkins-Smith 1988), to conceptualize the process and outcomes that are associated with the implementation of international norms on a domestic level. The ACF allows us to examine whether or not the value priorities, and assumptions concerning the efficacy of specific policy instruments of domestic advocacy coalitions deviate from those enshrined in international agreements, thus paving the way for substantial norm revisions on the domestic level. We argue that the domestic outcomes of international norm implementation seem to depend upon two factors respectively: the existence (or absence) of one *dominant advocacy coalition* in the policy subsystem on the one hand, and on the existence (or absence) of a *policy broker* on the other.

[1] The paper summarizes findings from a research project funded by the German Research Foundation (Project SFB 700-TP D7). Empirical evidence has been obtained by document-based process tracing and by 110 interviews with government officials, representatives of interest groups, companies and academic experts in India and Brazil from 2009 to 2012. All interview partners were ensured confidentiality by not revealing individual names or other information that might endanger their anonymity.

We substantiate our claims by a comparison between the Indian and the Brazilian implementation of two international accords related to the regulation of pharmaceutical patents and traditional knowledge – the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the Convention on Biodiversity (CBD). In general, both accords incorporate the norm of private ownership of intellectual knowledge and the idea that a commodification of intellectual knowledge may trigger collective welfare effects.

The CBD is inspired by the sustainability paradigm of the Brundtland report, by which ecological, developmental and economical goals shall be reconciled (Bastos 2009: 33ff.). It stipulates that biological resources and associated traditional knowledge must be regarded as property that is owned by the nation-state of its origin (Götting 2004). At the same time, however, indigenous groups and local communities are perceived as "knowledge holders", which means that the commercial exploitation of their resources shall only be allowed in the case of a "fair and equitable access and benefit sharing" (ABS) agreement between local communities and bio-prospecting institutions.

The TRIPs agreement introduced intellectual property law into the international trading system which includes consistent patent protection for inventions in all technology fields as well as rules on its enforcement. Most notably, it requires WTO members to bring their national IP laws into compliance with the global standards as set out in TRIPs. TRIPs shares the blueprint of orthodox economic perspectives that IPR is a crucial driver for trade, foreign direct investment and global innovation, thereby creating welfare gains even for developing countries when reinforcing their IPRs. While strengthening the rights of technology holders vis-à-vis technology consumers, TRIPs also contains a number of exemptions and flexibilities to protect public health, for example compulsory licensing, temporary restrictions of patent protection or parallel imports. Thus, national governments are provided with some leeway to face political distress when amending their laws.

While both accords incorporate the general norm of commodification and private ownership of intellectual knowledge, they leave room for implementing countries to shape a range of important aspects since both TRIPs and the CBD are finally being implemented through the enactment of domestic legislation. We find that India and Brazil have used this leeway to reinterpret the international norms when implementing legislation on pharmaceutical patent protection and on traditional knowledge. Depending on the existence (or absence) of a dominant advocacy coalition and a policy broker in the respective policy subsystem, we

differentiate between four types of norm implementation, representing different degrees of deviation from the international blueprints:

A case of a relatively smooth *adoption* of the international norm of commodification of traditional knowledge can be seen in India. Here we find a dominant advocacy coalition which assumes that the commodification of scarce resources (traditional knowledge, biological resources) shall advance developmental, economic, and environmental goals at the same time. A policy broker is not present (3.1.).

Brazil generally complies with the general norm of commodification in the field of traditional knowledge while adding the requirement of a mandatory prior informed consent of the affected indigenous communities *(adjustment)*. While the liberal environmentalist advocacy coalition is equally dominant as in India, the Brazilian government acts as policy broker (3.2).

In the field of patent law, India assumes the general paradigm of commodification enshrined in TRIPs, yet steers the wording in favor of its national interest (*modification*). The implementation course is accompanied by two opposing advocacy coalitions of which one conforms with the paradigm of commodification whereas the other places human rights prior to economic considerations. The Indian government does not assume the role of a policy broker (4.1.).

A rather substantial *replacement* of the international paradigm happens in the case of Brazilian patent law. Here, the ideological contestation between the two opposing advocacy coalitions "innovation" and "human rights" is mediated by the government which actively assumes the role of a policy broker. Under these circumstances, Brazil has initiated institutional reforms that are not necessarily against, but at least not foreseen by the international norms. (4.2.)

The following section 2 sketches out the pillars of the Advocacy-Coalition Framework, followed by four case studies (sections 3 and 4). We conclude (section 5) by discussing our findings and particularly the usefulness of Sabatier's advocacy coalition approach in the context of international norm diffusion.

2. The Pillars of the Advocacy Coalition Framework (ACF)

The Advocacy Coalition Framework (ACF) was created by Sabatier and Jenkins-Smith (Sabatier 1988; Sabatier/Jenkins-Smith 1988) in the late 1980s to help explain coalition structure, belief and policy change in contentious policy subsystems. Within a policy subsystem, actors are aggregated into a number of (usually one to four) "advocacy coalitions", composed of public and private actors, such as agency officials, legislators from multiple levels of government, international organizations, interest groups, applied researchers, and members of the media. Thus, a subsystem includes more than the traditional iron triangles' members, but a broader number of actors, some of which may at first be unassociated with any coalition and only later be incorporated into one of the coalitions. The ACF assumes that advocacy coalitions share value priorities, perceptions of world states, and assumptions concerning the efficacy of various policy instruments (Sabatier 1998: 99), thus certain *belief systems*.

The belief systems of each coalition are organized into a hierarchical, tripartite structure, with higher levels constraining more specific beliefs. At the highest level, the *deep core* of the belief system includes basic normative beliefs such as the relative valuation of individual freedom versus social equality. In our case, both the TRIPs agreement and the CBD are based on the idea that individual profit seeking enhances the public welfare. This paradigm may be disputed by opposing groups who insist on the supremacy of human rights with respect to intellectual property protection**.** At the second level are *policy core beliefs* representing a coalition's "basic normative commitments and causal perceptions across an entire policy domain or subsystem" (Sabatier 1998: 103). They cover value priorities such as the relative importance of economic development and innovation versus indigenous identity and public health. The ACF considers policy core beliefs as the fundamental glue of coalitions because they represent basic normative commitments within the respective policy domain. Finally, the *secondary beliefs* comprise a narrower, less than subsystem-wide, set of beliefs concerning for instance, preferences regarding desirable regulations, policy instruments or policy institutions. In the case of the TRIPs implementation, quarrels between the two ACs basically revolve around the scope of patentability for pharmaceuticals. Advocates of "innovation" plead for broad possibilities for patenting in order to foster investments in research and development whereas public health opponents demand major restrictions in this field of technology in order to not threaten the drug accessibility by high prices. In the case of the

CBD, conflict arises around whether or not traditional knowledge should be documented in order to enable its commodification. Sabatier assumes that deep core beliefs are resistant to change while a coalition's policy core beliefs are more likely to change. Secondary beliefs are assumed to be more readily adjusted in the light of new data, experience or changing strategic considerations (Sabatier 1998: 104).

Conflicting strategies from competing coalitions are normally mediated by a third group of actors, termed "*policy brokers"*, whose concern is to find a reasonable compromise that will reduce intense conflict (Sabatier 1988: 133, 135). The role of brokers is to search for stability in the specific political subsystem and to mediate between the opponents in order to make compromise solutions feasible. Weible et al. (2009: 129, 132, 134-5) explicitly admitted that most ACF applications have largely overlooked the role of policy brokers as components of the ACF. ACF research has revealed so far that traditionally elected officials (particularly chief executives of governments), courts, internally fragmented parties or high civil servants very often play the role of policy brokers (Sabatier 1987: 662). While the administration seeks widened political influence by acting as mediator, political parties, internally divided on the issue at stake, strive for political cohesion, particularly in light of upcoming elections (Ingold/Varone 2012).

The ACF approach takes issue with the emergence of policy change in contentious policy subsystems. In our case, policy change refers to the degree of deviance from the dominant norm of introducing private property rights for intellectual knowledge to the domestic legal system. According to the ACF framework several paths to policy change are possible**:** the first path is *external subsystem events or shocks* which include broad changes in socioeconomic conditions, public opinions, governing coalitions, and other subsystems. External events can spur change in a subsystem by shifting resources or tipping the power of coalitions. A second possible path to policy change – *policy learning* – is particularly important in our cases. Policy learning is defined as "relatively enduring alternations of thought or behavioral intentions that result from experience and/or new information and that are concerned with the attainment or revision of policy objectives" (Sabatier/Jenkins-Smith 1999: 123). Policy-oriented learning usually affects secondary beliefs or secondary aspects of the policy subsystem over extended periods of time as can be seen in the case of Indian traditional knowledge regulation. Furthermore, policy learning can build on processes of cross-coalition learning and occurs through *negotiated agreements involving two or more coalitions* like in our case of patent regulation in Brazil**.** The ACF hypothesizes that cross-coalition learning is

more likely to evolve when discussions focus on secondary beliefs, when the issues are more technical, when conflict is at intermediate levels, and when there is a professional forum (Weible et al. 2009: 130). Moreover, existing studies point to the political role played by scientists as coalition members (Weible/Sabatier 2005).

3. The implementation of the Convention on Biodiversity (CBD)

The Convention on Biodiversity (1992) can be described as a compromise between developing and industrialized countries with regard to the extraction of biological resources and associated indigenous knowledge in the Global South. Since the late 1980s, the secretariat of the United Nations Environment Program (UNEP) and other U.N. organizations, environmental NGO, scientists, and business actors had been involved with intensive discussions how to facilitate the access to the genetic diversity of developing countries while at the same time preventing an unremunerated exploitation of these resources. Inspired by the Brundtlandt-Report (1987), the participants of these discussions attempted to reconcile ecological, developmental, and economical goals at the same time (Bastos 2009: 33f; Bernstein 2000).

During the course of the CBD negotiations, the conventional perception of biological resources as "common heritage of mankind" was abandoned. Instead, government negotiators and private actors agreed on the wording that both genetic resources and the associated indigenous knowledge fall under the ownership of the nation-state of its origin. The convention frames indigenous groups and local communities as "knowledge holders", because they know best how to make use of the local flora and fauna for their daily needs. In an exchange for their contribution to the economic and ecological utilization of their knowledge, any commercial exploitation shall be subjected to an agreement of "fair and equitable access and benefit sharing". Moreover, the CBD stipulates that national regulations may optionally include safeguards to ensure the consent of the affected groups (Götting 2004). While these provisions clearly express the historical compromise of "liberal internationalist environmentalism" (Brand 2010: 143), the CBD lacks any indication of how to resolve the complex technical and distributional questions which arise during its implementation on a domestic level (Raustiala / Victor 2004).

Both in India and Brazil, the implementation of the CBD is strongly influenced by a dominant transnational advocacy coalition that subscribes to the values of the international convention.

Scientists, environmentalists from civil society organizations, and business representatives agree on the *deep core belief* that that individual benefits may act as an incentive for behaviors that are likely to further public welfare. With regard to their *policy core beliefs*, they have adopted the perspective that is enshrined in the CBD. They are convinced that biological resources and the associated traditional knowledge can be used for environmental, economic, and developmental goals at the same time. On a practical level (*secondary beliefs*), they usually subscribe to the recommendations that are discussed in the context of CBD follow-up conferences and meetings (Conferences of Parties, Rio+20 etc.). They usually claim that biological resources shall be assessed and the associated traditional knowledge shall be documented in order to use it in a commodified form for different (environmental and economic) purposes. While most members of the coalition at least rhetorically agree on a financial reward for indigenous groups'contributions, the hereto-related regulations and mechanisms remain highly contested.

3.1 *Adoption* of the CBD in India

Most Indian opinion leaders on biodiversity politics share the basic ideas of the CBD, although the various actors lay the focus on different aspects. Scientists usually hint to the importance of India's aboriginal peoples' (adivasis) traditional knowledge for research and development. From their perspective, indigenous knowledge on biodiversity contains a wealth of information about potential active ingredients for pharmaceuticals and agronomic improvements. Indian business actors agree with scientists on the practical usefulness of indigenous communities' knowledge, but they emphasize that any uncontrolled exploitation by foreign corporations should be prevented in order to defend the long-term interests of the Indian industry. Their criticism of "biopiracy" is widely shared by civil society actors (Shiva 2001). While a handful of rather leftist NGO argue that local communities' traditional knowledge shall be used for developmental purposes, most environmental civil society groups argue that indigenous groups should be financially encouraged to employ their knowledge on the local environment in the context of CDM (Clean Development Mechanism) or REDD (Reducing Emissions from Deforestation and Degradation) projects. This view is supported by international organizations like the Global Environmental Facility (GEF) or the U.N. Development Program, whose local representatives participate at the Indian debate on biodiversity and traditional knowledge.

The most striking characteristic of the Indian debate on traditional knowledge is the complete absence of adivasis themselves, at least at the federal level. This can be explained by the fact that adivasis usually face serious obstacles to organize collectively (Sundar 2012; Spivak 2005). Due to local repression from governmental authorities, paramilitary forces, and private landlord attacks, they do not have the capacities to get involved with biodiversity policies on the federal level (Interview 297; 303). This applies all the more since discriminatory practices towards indigenous interest articulations are not limited to the local level, but are continued (albeit more subtly) by the federal bureaucracy (Interview 314). Indian public officials usually share the perspective that traditional knowledge shall be used for economic and environmental goals. They argue that "the application of biotechnology on a sustainable basis (…) can convert the biodiversity into economic wealth for the country" (quoted in Dutfield 2004: 175). Under these conditions, public officials do not act as a policy broker, but take part in the dominant advocacy coalition on biodiversity. This holds especially true since the lines between public and private actors are constantly blurring, as there are many revolving doors between Indian ministries, international organizations, business, and civil society groups (Interview 112; 135, 140).

Due to the lack of alternative voices, the Indian implementation of the CBD completely adopts the internationally prevailing perspective that traditional knowledge should be catalogued in order to prepare a commercial exchange. In order to reach these goals, India has established the National Biodiversity Authority (NBA) which is responsible for the authorization of bioprospection in India. The approval procedure, as it is described by the Indian Biodiversity Act (2002), recommends that the position of indigenous and local communities is taken into account, but the NBA is under no obligation to obtain their consent (Cullet/ Raja 2004). While Indian regulations generally prescribe an access and benefit sharing (ABS) agreement, the distribution of financial remunerations among the affected local communities depends on the discretionary power of the authority (Damodaran 2003).

At the same time, there is a vast multiplicity of initiatives to document and to catalogue biological resources and associated traditional knowledge all over the Indian subcontinent (Venkataraman/ Latha 2008). Public research institutes often cooperate with Indian firms in order to document indigenous knowledge that might be useful for the further research in public research institutions or private firms. These public-private-partnerships often imply the cooperation with multinational companies, as they are financially connected with Indian firms (Interview 335; Mukherjee 2004). In many cases, documentation projects are financially supported by international organizations like the UNDP or (in the case of ecologically

relevant projects) the GEF (Griffiths 2006). Many civil society organizations are involved with local documentation projects of adivasis' knowledge. While a handful of groups aim at individual empowerment and development of adivasi groups, the majority of environmental NGO focus on preservationist goals. Multinational firms often finance the projects of the latter, which in turn agree to sell the documentations of the adivasis' traditional knowledge to researchers abroad (Sharma 2006; Interview 138; 141; 329). In most of the Indian documentation projects, however, the consent and interests of the affected indigenous groups remain largely neglected. Although their knowledge is increasingly registered and used for environmentalist and economic purposes, the access and benefit sharing often remains limited to a lump-sum or even a non-monetary compensation, which mainly consists of tools that are of no use for the traditional subsistence of the communities (Sharma 2006).

All in all, it seems that the dominant advocacy coalition, which also includes parts of the Indian ministerial bureaucracy, has furthered the implementation of the CBD in a way that prioritizes the documentation and commodification of traditional knowledge. Due to the prevailing political repression, adivasis are not able to form an alternative advocacy coalition which could bring in their perceptions and preferences. As their voices are not heard, the Indian implementation of the CBD can be characterized as a mere adoption of the international convention. That means that Indian regulations also copy the legal ambivalences with regard to distributional questions and indigenous rights, which implies that they are unable to solve those questions that remain unanswered by the international blueprint itself.

3.2 *Adjustment* of the CBD in Brazil

As in India, the Brazilian public discourse on the implementation of the CBD is dominated by an advocacy coalition that favors a documentation of biological resources and associated traditional knowledge. The coalition is deeply rooted in the networks of transnational environmental groups (e.g., The Nature Conservancy, Greenpeace) and local civil society organisations in the field of environmental policies. Whereas transnational organisations usually bring in an international reputation as well as technical infrastructure facilities, local groups have better contacts with Brazilian decision-makers (Interview 196). In some cases, they are also linked to Brazilian public research institutions, whose scientists support an unhindered access to indigenous groups' resources in order to use it for scientific research that might stimulate the export of nature-based products (Interview 190; 192). Many business actors, most notably from multinational companies, share this perspective. They have

organized themselves within the Corporate Biodiversity Movement (*Movimento Empresarial pela Biodiversidade*, MEB), which in turn closely cooperates with transnational environmental organisations like WWF.

Although the advocacy coalition disposes of considerable financial and reputational means, Brazilian índios and other local communities (e.g., rubber-tappers) benefit from the protective approach of Brazilian public decision-makers (Pinton 2003; Bastos 2009: 102). Most notably, the Ministry of Environment (*Ministério do Meio Ambiente*, MMA) insists on the inclusion of the minorities in all relevant decision-making processes. Throughout the years, the ministry has organized several outreach programs throughout the Brazilian countryside in order to ensure their participation. Within the competent authorities of the MMA, indigenous groups enjoy equal observer rights as other stakeholders from industry, civil society, or academia (Azevedo 2005). While some other ministries tend to favour the interests of dominant advocacy coalition, indigenous groups benefit from the assistance of powerful Brazilian public prosecution department (*Ministério Público*), whose officials take a pride of their "judicial activism" for indigenous and other minorities (Arantes 2007: 108; Interview 202; 221).

All in all, it seems fair to say that the Brazilian government acts as a policy broker which anticipates that the interests of less privileged groups might deviate from the positions of the dominant advocacy coalition. And indeed, when asked by governmental authorities, indigenous groups usually indicate that they do not wholeheartedly agree with the Brazilian mainstream debate on the utilization of their knowledge for environmental and economic goals. Although they are not necessarily fundamentally against a commercial exchange, indigenous representative emphasize the need to preserve their communities' cultural identity with regard to religious convictions, customary laws, and rituals. Given that their social identity is intrinsically linked to their natural environment and the hereto-related knowledge, indigenous groups claim the right to decide by their own rules, whether or not they agree to a documentation and commodification of their knowledge (Interview 185).

While inter-ministerial controversies have so far impeded a technically and legally waterproof solution, the provisionally applied presidential decree (MP 2.186/2001) tries to balance the claims of the powerful advocacy coalition with the needs that are expressed by indigenous groups. It refers to the CBD's optional clause in order to make the indigenous "prior informed consent" (PIC) mandatory for the documentation of traditional knowledge. In a two-tiered application process, bio-prospectors must prove that they have obtained the consent of indigenous groups to access their knowledge and to a mutually agreed benefit-sharing

mechanism (Azevedo 2005: 23; Bucher 2007: 223ff). Within the competent authorities (Council for the Management of Genetic Heritage, CGEN, and Institute for the Historical and Artistic heritage, IPHAN), representatives from indigenous communities have to agree on the approval of an application. The participatory procedure is enforced by a mixture of sticks and carrots. On the one hand, illicit bio-prospecting activities are regarded as an offense and are subject to considerably high administrative penalties (Pereira et al. 2010). Most notably during the last years the governmental Environmental Protection Agency (IBAMA) has cracked down on a significant number of allegedly illegal projects (Novos Rumos 2012). On the other hand, Brazilian law rewards bio-prospectors who abide by the rules. In case they prove that they obtained permission from the competent authorities, they can apply for a patent on inventions that are based on traditional knowledge (Bucher 2007: 227f). Recently, the Brazilian patent office proactively supports civil society initiatives that use traditional knowledge for the commercialization of artisanal products by the promotion of geographical indications (GI) as an alternative intellectual property right. However, the support is conditional upon indigenous groups' consent and participation (Interview 180).

All in all, it seems that the Brazilian government does not fundamentally challenge the dominant advocacy coalition's interpretation of the CBD. However, its proactive role as a policy broker ensures that the consent of indigenous communities is added as a constitutive part of its implementation. Thus, while the international blueprint's principal goals remain unquestioned, the Brazilian adjustment of the convention tries to prevent the negative distributional side-effects of an uncontrolled commodification of traditional knowledge.

4. The implementation of the TRIPs agreement

The TRIPs agreement (1995) forms one of three pillars of the WTO framework. TRIPs sets out minimum standards for global patent protection. It demands patents for inventions in all fields of technology provided that they conform with three central patent criteria, namely novelty, non-obviousness and industrial application (Art. 27). The agreement is a manifestation of the "Western paradigm" of science where patent systems are designed to recognize and compensate for individual profit seeking (Sell 1995: 318; Drahos/Braithwaite 2002: 10; Oguamanam 2004: 145). It embodies the orthodox view that sustainable economic and social welfare can only be reached through innovation (Lanoszka 2003: 182). Patents count as key incentive in this regard. They award the "individual merits" (Art. 31) of right

holders by conceding monopoly prices for their inventions (Eren-Vural 2007: 111; WIPO 2011). The agreement is hence based on the "utilitarian justification" that societal benefits from innovation will outweigh the negative effects of higher consumer prices in the medium to long term (Abbott et al. 2005).

The orthodox paradigm has been pushed by a coalition of big companies from industrialized countries and their respective governments. Recent research has revealed excessive influence of big business (especially the U.S. software and pharmaceutical industry) on the substance of the treaty on the one hand (Drahos 2004; May 2000; Sell 2000; Tyfield 2008: 535f) and harmonizing effects on the administrative level through the work of the three leading patent offices ("trilaterals") on the other hand (Davies 2002; Drahos 2007).

This coalition, however, has not remained undisputed. Fueled by the "South Africa Case" (1998) when multinational pharmaceutical manufacturers had accused the South African government of violating TRIPs, a second coalition has entered the stage which insists on the supremacy of human rights over economic considerations (*deep core belief*). The coalition highlights the detrimental effects of patent protection on access to essential medicines (*policy core belief*) and therefore stipulates restrictions to their patentability (*secondary belief*) (t' Hoen 2003). Claims have especially centred around the adoption of the TRIPs flexibilities, a catalogue of exceptions to the exclusive rights which provides developing countries with a certain leeway for the protection of public health (Chaves et al. 2008; George et al. 2009; Shadlen 2007). The impact of this vociferous coalition is being revealed in the Doha Declaration on Public Health (2001). The declaration reaffirms that the TRIPs agreement should not obstruct „WTO Members' right to protect public health" (WT/MIN(01)/DEC/2 2001). In this regard it provides governments with room for maneuver to make exceptions in the field of pharmaceuticals (Roemer-Mahler 2013: 131). Yet, the declaration does not provide for concrete guidelines as regards the implementation of TRIPs (Cohen/ Lybecker 2005: 224f).

India as well as Brazil have gained certain prominence as regards their dealing with TRIPs flexibilities (Cullet 2001; Eren-Vural 2007; Milstien et al. 2007; Shadlen 2009a). Yet, their implementation courses embody two different positions vis-à-vis the paradigm of innovation enshrined in TRIPs.

4.1. *Modification* of TRIPs in India

The Indian public discourse on the implementation of the TRIPs agreement is characterized by a continuous confrontation of the two above mentioned advocacy coalitions.

One the one side, there are research and innovation driven pharmaceutical companies, governments from industrialized countries, and Indian business associations. They all share the basic orthodox idea of individual profit-seeking (*deep core belief*) which is enshrined in TRIPs, though for different reasons. The innovative pharmaceutical industry (mainly represented by multinational companies with headquarters abroad) considers a "[p]roper implementation of world class Patent Law" a basic condition for foreign direct investment, technology transfer and innovative local research. Any deviation from global patent standards would lead to a drive out of the market threatening the availability of newer and better medicines (*policy core belief*). As regards the scope of patentability, these companies consequently demand that all forms of inventions should be patentable as long as they conform with the three criteria novelty, non-obviousness and industrial use (*secondary belief*) (OPPI 1999, 2008). Indian business associations equally stress the importance of "Western-style" patent standards, yet they emphasize the prospects of the Indian pharmaceutical industry. Globally conform patent standards are seen as necessary incentive to accelerate the transformation of the generic based manufacturing facilities into a globally competitive and innovative sector (FICCI 2011; CII 2012). Furthermore, these actors stress the damaging economic consequences of counterfeiting for the local industry due to the absence of effective intellectual property enforcement (FICCI 2013).

This latter view is broadly shared by government officials. By aligning with the orthodox advocacy coalition, Indian public officials refrain from assuming the role of a policy broker. In India, patent regulation falls under the realm of the Department of Industrial Policy Promotion (DIPP) which belongs to the Ministry of Commerce and Industry (MoCI). As a consequence, patent regulation has been assessed first and foremost under the angle of local industry promotion (MoC&I 2004). This is even true for health personnel. Asked about the government's stance towards patentability of pharmaceuticals, a leading official in the Ministry of Health counters: "for me, patent is a private right where the government should step out" (Interview 283).

On the other side, transnational NGO and local public health activists insist that human rights protection has to take precedence over economic considerations (*deep core belief*). Backed by non-orthodox scholars, these groups have pointed to India's pivotal role as supplier of life-

saving drugs to much of the developing world (Abbott et al. 2005; INP+ 2009; MSF 2007; MSF 2013). India is the biggest producer of low-cost generic medicines and a major drug provider for Sub-Sahara Africa (Van Dyck 2007). A strengthening of patent standards would therefore endanger health provision not only in India, but on a global level (*policy core belief*). These concerns coincide with the claims of Indian generic producers. They have stressed their need for a patent system which allows them to at least partly continue generic production while according protection to their innovations which are incremental in nature (IDMA 1999; IPA 2002). These actors are united by their demand to restrict the scope of patentability in the field of pharmaceuticals (*secondary belief*).

The presence of two conflicting advocacy coalitions is reflected in India's implementation of the TRIPs agreement. The Indian patent regulation accepts the overall idea of welfare enhancing individual profit-seeking (Gopakumar 2010). However, it deviates from the specification of the TRIPs agreement as regards the codification of patentability standards. While assuming the three patent criteria as set out in TRIPs, India's Patent Amendment Act (2005) redirects their spirit by specifying the wording. The Act contains a special clause – Section 3(d) – which is designed to restrict the number and type of pharmaceutical patents granted. The section restricts patentability by providing that only those pharmaceutical derivatives are patentable that demonstrate significantly enhanced "efficacy" as well as "economic significance" (as opposed to "technical significance") which has the potential to considerably diminish the number of patents granted (George et al. 2009: 120f; Kapczinsky 2009: 1592f).[2] The section depicts a deviation of the global norm of novelty and has therefore been characterized as „institutional innovation" (Sampat 2010: 11ff).

Yet, the section has only been introduced after heavy controversies. The Patents Ordinance which was first passed by the Indian government in December 2004 has provoked a public outcry because it clearly "bore the stamp of multinational pharmaceutical companies" (Bhattacharya 2008: 398). Non-orthodox academics of the Delhi Science Forum (DSF) that had been seeking to influence the government's stance toward intellectual property protection

[2] Section 3 (d) reads as follows: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant". The section has been legally challenged by Novartis after they had been denied a patent on the mesylate salt of the cancer drug imatinib. So far, Indian courts have upheld the Section. The case is currently pending before India's Supreme Court (Business Line 2012).

since the late 1980s, and whose efforts later resulted in the creation of the National Working Group on Patents, heavily attacked the far-reaching extension of patent protection in the government's ordinance (Abrol 2005; DSF oJ; Keayla 2005; Interview 155; 300). They were joined by transnational public health groups, first of all *Médecins Sans Frontières* (MSF), who mobilized local patient groups and criticized the ordinance for not implementing sufficient TRIPs flexibilities to prevent increases in drug prices. In this regard, they also argued for arrangements to prevent ever-greening (Interview 149; MSF 2005). Their claim was backed by local generic companies who insisted on the inclusion of a clause that would prevent the patenting of new uses of known substances, as well as the patenting of many new forms of known substances (Kapczinsky 2009: 1586). The alliance with generics producers was important. It gave the movement an economic spin which was necessary „to transform a vision of improving access to treatment in developing countries into a viable policy alternative" (Roemer-Mahler 2013: 132). As the Indian government appeared rather inaccessible to these claims, the coalition carried their demands to the Indian Parliament which responded favourably to the limitation of patentability and even reverted to the exact wording of the generic industries' propositions when drafting Section 3(d) (Interview 161). As a consequence, India´s Patent Act limits the scope of pharmaceutical patenting much more than TRIPs suggests.

All in all, it seems that the interaction between two equally strong advocacy coalitions led to a *modification* of the international blueprint. While imitating the international wording, Section 3(d) of the Indian Patent Act partly perverts its meaning by designing the criteria for patentability according to India's businness and public interests alike.

4.2 *Replacement* of TRIPs in Brazil

In Brazil, the implementation of the TRIPs agreement has also been accompanied by two opposing advocacy coalitions. However, unlike in India, the process has been actively shaped by the government who has been acting as policy broker.

Brazil's implementation course was first marked by multinational companies and the U.S. administration who lobbied the Brazilian government to codify a broad scope of patentability

when amending the patent legislation (Bastos 1994; Tachinardi 1993).[3] Yet, these changes have not remained unchallenged. The Industrial Property Law (1996) has provoked vociferous opposition and the public discourse on TRIPs has become characterized by two equally strong coalitions hereafter.

The first coalition involves research-based pharmaceutical manufacturers, leading Brazilian patent attorneys (the Brazilian Association of Intellectual Property –ABPI), and the Brazilian patent office INPI (*Instituto Nacional da Propriedade Industrial*). Backed by WIPO and the "trilateral" global patent offices, this „transnational IP community" (Shadlen 2009a) advocates for a broad interpretation of patentability, including patents for pharmaceutical derivatives like esthers and polymorphs (*secondary belief*). While multinational pharmaceutical companies aim to control their downturn in earnings resulting from imitation,[4] patent attorneys and the INPI justify extensive patent protection with the natural right to property and its expected benefits for the Brazilian industry development (Interview 244; Momsen Leonardos & CIA 2003).

The second coalition, in contrast, argues with the „supremacy of society's interest" over intellectual property protection (*deep core belief*) demanding strict rules for the patentability of pharmaceutical products and processes (*secondary belief*) (Rosina et al. 2010: 118). It is driven by the local HIV/Aids movement who began to stand up against the Industrial Property Law in the late 1990s claiming that the universal access to anti-retroviral medicines (ARVs) should not be endangered for economic considerations (*policy core belief*) (Chaves et al. 2008: 164ff; Chaves 2006). The movement is backed by humanitarian and development-oriented international organizations (ICTSD/ WHO/ UNCTAD 2007; WHO 2006) and receives financial as well as technical support of transnational NGOs. MSF and Oxfam laid the foundations for the Working Group on Intellectual Property (*Grupo de Trabalho sobre Propriedade Intelectual*, GTPI) which was established in 2003 (Interview 170). The GTPI is composed of around 20 non-profit organizations and counts as one of the most active and influential actors in the field of pharmaceutical patents today (Reis et al. 2009: 33). Apart from campaigning and lobbying, their activities include legal actions which aim to subsequently restrict the patentability of pharmaceuticals (Interview 256). At this point, the public health movement is joined by Brazilian generic companies whose primary goal is to

[3] The legislation left out several TRIPs flexibilities and, most notably, enabled a *pipeline mechanism* that grants patents retroactively provided that they have been granted abroad before (Rosina et al. 2010: 116; Reis et al. 2009: 21).

[4] When Brazil strated to implement TRIPs in 1996, the Pharmaceutical Research and Manufacturers of America (PhRMA) estimated that their members have losses around 600 million USD a year due to the absence of effective patent protection (ThePharmaLetter 1996).

expand the proportion of generic medicines in the national health program (PróGenéricos 2011). In 2007, the National Federation of Pharmacists (*Federação Nacional de Farmacêuticos*, FENAFAR) issued a formal complaint to the General Attorney claiming the unconstitutionality of the pipeline mechanism (Guise/ Novaes 2011: 18). Generic associations also maintain contacts with transnational NGOs as well as representatives from the Indian Pharmaceutical Alliance (IPA) in order to exchange information and strengthen their position internationally (Interview 178; Interview 241).

Unlike in India, the Brazilian government does not unilaterally consent with the proponents of broad patentability but assumed the role of a policy broker. While patent regulation as such falls under the realm of the Ministry of Development, Industry and Foreign Trade (*Ministério do Desenvolvimento, Indústria e Comércio Exterior*, MDIC) the patentability of pharmaceuticals is chiefly handled by the Ministry of Health (*Ministério da Saúde*, MS). The MS coordinates the public health care system for which it sustains a large procurement system for essential medicines. The issue of drug patents is hence primarily dealt from the perspective of affordability and accessibility (Interview 247). Ministerial officials responded to the citizens' demand for access to generic medicines and actively engaged in balancing the conflicting pressures from the two coalitions.

The government involvement has led to major changes during the implementation of the TRIPs agreement. Since the end of the 1990s, the scope of patentability has been progressively restricted through the abolition of the pipeline mechanism on the one hand and the incorporation of additional TRIPs flexibilities on the other hand.[5] Yet, the most far-reaching amendment was the establishment of the National Health Regulatory Authority (*Agência Nacional de Vigilância Sanitária*, ANVISA) and its incorporation to the process of patent examination. ANVISA is an autonomous body affiliated to the MS with the ultimate mandate to protect human health within the country (Bermudez et al. 2006: 146f). In 2001, an addendum was made (Law 10196/01) which added Article 229 C to Brazil's patent legislation. The article binds the granting of pharmaceutical patents to ANVISA's prior consent (*anuência prévia*). Consequently, patent applications which have been examined by the INPI have to be sent to ANVISA for an additional review. ANVISA formally holds a veto position over the INPI which means that in the event of disagreement the patent will not be granted (ANVISA 2004; Rosina et al. 2010: 122).

[5] Brazil included the *Bolar Exception* (Art. 43) which allows third parties to manufacture limited quantities of patented drugs without seeking a license, specifically for drug approval purposes. Furthermore, it facilitated the import of non-patented drugs from abroad (Art. 10), and substantially expanded the grounds for compulsory licensing (Decree No. 3.201/99) (Bermudez et al. 2006: 171f; Rosina et al. 2010: 123).

The establishment of the *prior consent* would not have been possible without the engagement of José Serra, influential member of the Brazilian Social Democracy Party (*Partido da Social Democracia Brasileira*, PSDB) and health minister at that time. In anticipation of his presidential campaign in 2002, he made the national drug supply a key issue of his ministerial term (Interview 252). He enforced a strategy paper of the MS and the MDIC which proposed the establishment of a separate inspection authority in order to improve the overall quality of the patent examination process. The proposition which was sanctioned by a provisionally applied presidential decree (*Médida Provisória*) through President Lula finally led to the establishment of COOPI (*Coordenação de Propriedade Intelectual*), a subdivision of ANVISA (Interview 176). Though being hampered by administrative procedures and legal counter-attacks,[6] the existence of COOPI has had a considerably diminishing effect of the number of drug patents granted. Between 2001 and 2008, COOPI has rejected 53 approvals of INPI. In 40% of the applications, COOPI gave its consent only after further restrictions to the patent width on part of the applicant (Shadlen 2009b: 10). What weighs more is its replacing character vis-à-vis the TRIPs agreement. ANVISA/COOPI considers itself as "guardian of public health" which puts humanitarian concerns at first place (Interview 239). Unlike in India, where patent regulation is seen as a tool for industry and innovation promotion, the Brazilian approach treats drug patents as a "key tool of public health policy" (Orsi et al. 2003: 116). COOPI's participation in the process of patent examination hence poses a clear replacement of the paradigm of commodification (Nair 2008: 459; Reis et al. 2009: 30ff).

All in all, it seems that the interaction of two equally strong advocacy coalitions and their mediation through the government has led to a *replacement* of the international blueprint. While not negating the idea of pharmaceutical patenting in principle, Brazil's approach replaces its uppermost objective by treating human rights prior to individual profit-seeking.

[6] Ken Shadlen (2011: 153) and Mónica Guise Rosina, Daniel Wei Liang Wang and Thana Cristina de Campos (2009: 122) have pointed to the fact that ANVISA's denial of a patent request has to be published by INPI in order to be officially denied which INPI frequently refrains to do. The prior consent mechanism has also been legally questioned by research-based pharmaceutical companies and the INPI. The final resolution of the conflict remains pending (Reis et al. 2009: 42).

5. Conclusion

In this paper, we have drawn on the advocacy coalition framework to examine how and to what extent international norms are being reshaped in the process of domestic implementation, thereby leading to policy change. At least in our four case studies, the empirical evidence clearly illustrates that the implementation of an international norm has contingent outcomes. Our comparison of the implementation of the TRIPs agreement and the Convention on Biodiversity (CBD) in India and Brazil reveals different degrees of deviation from the general blueprints of private ownership of intellectual knowledge. While the adoption of the CBD in India and the partial replacement of TRIPS in Brazil can be considered as extreme points of replication and change, the adjustment of the CBD in Brazil and the modification seem to form some middle ground. Our four variations are summarized in the following table. Far more research is needed to assess whether our proposed categorization can be upheld in other cases.

		Government acts as „policy broker“	
		No	**Yes**
Dominant transnational „advocacy coalition“	**Yes**	Traditional knowledge regulation in India **=> adoption**	Traditional knowledge regulation in Brazil **=> adjustment**
	No	Patent regulation India **=> modification**	Patent regulation Brazil **=> replacement**

Based on our empirical evidence, we argue that neither policy-specific nor country-specific factors determine the degree of norm deviation. Rather, the dominance or (relative) absence of a transnational advocacy coalition seems to be decisive factor in the implementation phase of international norms. While a strong transnational coalition is likely to stipulate a rather imitative implementation style, a larger degree of deviation can expected if its beliefs are contested by a rival group on the domestic level. At the same time, our case studies highlight the role of public actors, which are usually (though not prominently) discussed as potential policy brokers in the literature on advocacy coalitions (Sabatier 1988). If public actors assume this role, they can trigger or even enforce a process of cross-coalition learning, as it can be seen in the Brazilian implementation of the CBD. The Indian TRIPS implementation, however, seems to indicate that the relative power of the prevailing advocacy coalitions determines the outcome of an implementation process if public actors abstain from policy brokerage.

In our view, the AC framework seems to create added value to the study of regime implementation and norm diffusion, particularly compared with Keck and Sikkink's advocacy network approach. The ACF allows to conceptualize different and even antagonistic coalitions that are associated with the implementation of international norms, provides increased attention to the government as an actor sui generis (due to its authoritative power), and shares a general openness towards deviations of the implementation results from the original blueprint. However, like all models and concepts, the AC framework can at best offer a retrospective explanation of previous implementation activities, whereas it seems unable to allow a prognosis of the future development in the policy field. This holds especially true in the volatile environment of decision-making processes in developing countries and emerging economies. That having said, it seems that the identification of advocacy coalitions and a closer look on the broker role of governmental actors could give us a clue to understand the dynamics of both norm implementation and transformation in the Southern hemisphere.

References

't Hoen, Ellen F. M. 2003. "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond." In *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries: Issues and Challenges*, ed. J.-P. Moatti, B. Coriat, Y. Souteyrand, T. Barnett, J. Dumoulin and Y.-A. Flori. Paris: Le Publieur.

Abbott, Frederick M., Amy Kapczinski, and T.N. Srinivasan. 2005. "The draft patent law." In *the hindu*.

Abrol, Dinesh. 2005. "Big players and our national interests." *Combat Law: The Human Rights magazine* 4 (2): 37-42.

Acharya, Amitav. 2004. "How Ideas Spread: Whose Norms Matter? Norm Localization and Institutional Change in Asian Regionalism." *International Organization* 58 (2): 239-75.

ANVISA. 2004. "Patentes farmacêuticas: em busca do equilíbrio." In *Boletim Informativo*. Brasília: Agência Nacional de Vigilância Sanitária.

Arantes, Rogério B. 2007. "Judiciário: entre a justiça e a política." In *Sistema Político Brasileiro: uma introdução*, ed. L. Avelar and A. O. Cintra. Rio de Janeiro: Fundação Konrad Adenauer / Fundação Editora da UNESP.

Azevedo, Cristina Maria do Amaral. 2005. "Regulation to access to genetic resources and associated traditional knowledge in Brazil." *Biota Neotropica* 5 (1): 1-9.

Bastos, Maria Ines. 1994. "How international sanctions worked: Domestic and foreign political constraints on the Brazilian informatics policy." *Journal of Development Studies* 30 (2): 380-404.

Bastos, Rodolpho Zahluth. 2009. *Rivalités géopolitiques sur la biodiversité, l'enjeu de régulation de l'accès aux ressources génétiques au Brésil*. Paris: Thèse doctorale. Download: http://www.bibliotheque-numerique-paris8.fr/eng/notices/103798-Rivalit%C3%A9-s-g%C3%A9-opolitiques-sur-la-biodiversit%C3%A9-l-enjeu-de-r%C3%A9-gulation-de-l-acc%C3%A8-s-aux-ressources-g%C3%A9-n%C3%A9-tiq....html (accessed on May 13, 2012).

Bermudez, Jorge A., Maria Auxiliadora Oliveira, and Egleubia Andrade de Oliveira. 2006. "Ampliando el Acceso a los Medicamentos Esenciales en Brasil: Recientes Regulaciones y Políticas Públicas." In *La Propriedad Intelectual en el Contexto del Acuerdo de la OMC sobre los ADPIC: Desafíos Para la Salud Pública*, ed. J. A. Bermudez and M. A. Oliveira. Rio de Janeiro: Centro Colborado de OPS/OMS en Políticas Farmacéuticas, Escuela National de Salud Pública Sergio Arouca, Fundación Oswaldo Cruz, 139-172.

Bernstein, Steven. 2000. "Ideas, Social Structure and the Compromise of Liberal Environmentalism." *European Journal of International Relations* 6 (4): 464-612.

Bhattacharya, Radhika. 2008. "Are Developing Countries Going Too Far on Trips? A Closer Look at The new Laws in India." *American Journal of Law and Medicine* 34 (2-3): 395-421.

Brand, Ulrich. 2010. "Sustainable development and ecological modernization - the limits to a hegemonic policy knowledge." *Innovation: The European Journal of Social Science Research* 23 (2): 135-52.

Bucher, Stephanie. 2007. *Der Schutz von genetischen Ressourcen und indigenem Wissen in Lateinamerika*. Baden Baden: Nomos.

Business Line. 2012. "Novartis' Glivec case: Stage set for a verdict." Chennai: The Hindu Business Line. http://www.thehindubusinessline.com/companies/novartis-glivec-case-stage-set-for-a-verdict/article4167349.ece (accessed on March 20, 2013)

Chaves, Gabriela Costa. 2006. *Patentes Farmacéuticas: ¿Por qué dificultan el acceso a los medicamentos?* Rio de Janeiro: Associação Brasileira Interdisciplinar de AIDS (ABIA).

Chaves, Gabriela Costa , Marcela Fogaça Vieira, and Renata Reis. 2008. "Access to medicines and intellectual property in Brazil: reflections and strategies of civil society." *Sur: Revista Internacional de Direitos Humanos* 5 (8): 163-89.

CII - Confederation of Indian Industry. 2012. "Intellectual Property Rights (IPR)." *CII Media Releases*. http://www.cii.in/PressreleasesDetail.aspx?enc=4l9ZqQZ6mp65/6EBuEe9zuy3OELk+a5L506DRG++qmPI/kFNEemvt+eeaB2I9iQBHsUzLkSZ4AKeiLo1RvsAmL2lwUV61qbbYOcvDgxa1GZvjydxlg7g9eMuQCMjSBMNbnRIJ0EabGm2CZ4NMTNdM77pDOHTi6AAiLtiV5HH8Z15fPU3ZpOn06bqXajT/BvR (accessed on March 20, 2013)

Cohen, Jillian Clare, and Kristina M. Lybecker. 2005. "Aids Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health." *The World Economy* 28 (2): 211-30.

Cullet, Philippe. 2001. "Patents Bill, TRIPs and Right to Health." *Economic and Political Weekly* 36 (43):4049-51.

Cullet, Philippe, and Jawahar Raja. 2004. "Intellectual Property Rights and Biodiversity Management - The Case of India." *Global Environmental Politics* 4 (1).

Damodaran, A. 2003. "Economics and Policy Implications of National Biodiversity Legislation." *Economic and Political Weekly* 38 (49): 5201-9.

Davies, Louise. 2002. "Technical Cooperation and the International Coordination of Patentability of Biotechnological Inventions." *Journal of Law and Society* 29 (1): 137-62.

Drahos, Peter. 2004. "The Regulation of Public Goods." *Journal of International Economic Law* 7 (2): 321-39.

———. 2007. "Trust me: Patent offices in developing countries." *Australian National University Working Paper* 11.

Drahos, Peter, and John Braithwaite. 2002. *Information Feudalism*. London: Earthscan Publications Ltd.

DSF - Delhi Science Forum. "TRIPS Agreement under Attack By Amit Sen Gupta." Delhi Science Forum. http://www.delhiscienceforum.net/pharmaceuticals/241-trips-agreement-under-attack-by-amit-sen-gupta-.html (accessed on March 20, 2013)

Dutfield, Graham. 2004. *Intellectual Property, Biogenetic Resources and Traditional Knowledge*. London: Earthscan.

Eren-Vural, Ipek. 2007. "Domestic contours of global regulation, Understanding the policy changes on pharmaceutical patents in India and Turkey." *Review of International Political Economy* 14 (1): 105-42.

FICCI. 2011. "FICCI's Suggestions on Proposed National Intellectual Property Policy." New Delhi: Federation of Indian Chamber of Commerce and Industry. http://www.ficci.com/SEdocument/20170/ip-policy.pdf (accessed on March 20, 2013)

———. 2013. "Suggestions in reaction to the September 26, 2012 Invitation of Views on the Draft National IPR Strategy issued by the Sectoral Innovation Council on IPR." New Delhi: Federation of Indian Chamber of Commerce and Industry. http://www.ficci.com/SEDocument/20224/ficci-policy-anti-smuglling.pdf (accessed on March 20, 2013)

George, Julie , Ramaya Sheshadri, and Anand Grover. 2009. "Intellectual Property and Access to Medicines: Developments and Civil Society Initiatives in India." In *Civil Society Resistance in the Global South*, ed. ABIA and Ford Foundation. Rio de Janeiro: ABIA, 110-127.

Gopakumar, K.M. 2010. "India: A Critical Review of the Implementation of TRIPS Patent Regime." *The Law and Development Review* 3 (2): 324-68.
Götting, Horst-Peter. 2004. "Biodiversität und Patentrecht." *GRURInt* 9: 731-36.
Griffiths, Tom. 2006. *The Global Environment Facility and its Local Benefits Study. A critique*. Edited by Third GEF Assembly. Cape Town: Forest Peoples Programme,
Guise, Mônica Steffen, and Adelina de Oliveira Novaes. 2011. "Balancing Health and Wealth - the Case of Patents and Access to Medicines in Brazil."
ICTSD, WHO, and UNCTAD. 2007. "Guidelines for the examination of pharmaceutical patents: developing a public health perspective - A Working Paper." Geneva: ICTSD, WHO, UNCTAD.
IDMA - Indian Drug Manufacturers' Association. 1999. "Letter to the Minister for Commerce & Industry, Government of India." Mumbai: Indian Drug Manufacturers' Association, 22 November 1999.
Ingold, Karin, and Frédéric Varone. 2012. "Treating Policy Brokers Seriously: Evidence from the Climate Policy." *Journal of Public Administration Research and Theory* 22 (2): 319-46.
INP+. 2009. *Seedee 4*, 01/2009. Chennai: Indian Network for People living with HIV/AIDS.
IPA - Indian Pharmaceutical Alliance. 2002. "Letter to the Department of Industrial Development, New Delhi - Subject: Patent (Second Amendment) Bill, 1999." Mumbai: Indian Pharmaceutical Alliance, 7 March 2002.
Kapczynski, Amy. 2009. "Harmonization and Its Discontents: A case Study of TRIPS Implementation in India´s Pharmaceutical Sector." *California Law Review* 97: 1571-650.
Keayla, B. K. 2005. "Amended Patents Act: A critique " *Combat Law: The Human Rights magazine* 4 (2). http://www.indiatogether.org/combatlaw/vol4/issue2/patents.htm (accessed on March 20, 2013)
Keck, Margaret E., and Kathryn Sikkink. 1998. *Activists beyond Borders. Advocacy Networks in International Politics*. Ithaca: Cornell University Press.
———. 1999. "Transnational advocacy networks in international and regional politics." *International Social Science Journal* 51 (159): 89-101.
Lanoszka, Anna. 2003. "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries." *International Political Science Review* 24 (2): 181-97.
May, Christopher. 2000. *A Global Political Economy of Intellectual Property Rights. The new enclosures?* London: Routledge.
Milstien, Julie B., Patrick Gaulé, and Miloud Kaddar. 2007. "Access to Vaccine Technologies in Developing Countries: Brazil and India." *Vaccine* 25 (44): 7610-9.
MoC&I. 2004. "Kamal Nath's Statement on the Ordinance Relating to Patents (Third) Amendment." *PRESS INFO. BUREAU (India) 27. 12*.
Momsen Leonardos, and CIA. 2003. "RE: Parecer sobre Projeto de Lei no. 139/99 (N/ref: PGI Luiz Leonardos)." Rio de Janeiro: Momsen Leonardos & CIA, 23 October 2003. http://www.abpi.org.br/materiais/textospublicos/parecerlleonardos.pdf (accessed on March 20, 2013)
MP 2.186/2001: Medida Provisória No 2.186-16, de 23 de Agosto de 2001. http://www.planalto.gov.br/ccivil_03/mpv/2186-16.htm (accessed on March 26, 2013)
MSF - Médecins Sans Frontières. 2005. "Will the lifeline of affordable medicines for poor countries be cut? Consequences of medicines patenting in India." *Médecins Sans Frontières External briefing document*. Geneva, February 2005. http://www.who.int/hiv/amds/MSFopinion.pdf (accessed on March 20, 2013)
———. 2007. "Indian Court Ruling in Novartis Case Protects India as the 'Pharmacy of the Developing World'." New Delhi & Geneva, August 2007.

http://www.doctorswithoutborders.org/press/release.cfm?id=2096 (accessed on March 20, 2013)
———. 2013. "Letter from MSF to the Indian Prime Minister regarding access to medicines and the EU-India FTA." Geneva, March 2013. http://www.msfaccess.org/content/letter-msf-indian-prime-minister-regarding-access-medicines-and-eu-india-fta (accessed on March 20, 2013)
Mukherjee, Santanu. 2004. "The Journey of Indian Patent Law Towards TRIPS Compliance." *IIC* 2: 125-50.
Nair, MD 2008. "Compromizing TRIPS: Brazil´s Approach to Tackle the HIV/AIDS Imbroglio." *Journal of Intellectual Property Rights* 13: 456-63.
Novos Rumos. 2012. "Ibama divulga lista com 35 empresas autuadas por biopirataria." In *Vermelho*, 13 de Julho de 2012. http://www.vermelho.org.br/tvvermelho/noticia.php?id_noticia=188479&id_secao=29 (accessed on September 1, 2012)
Oguamanam, Chidi. 2004. "Localizing Intellectual Property in the Globalization Epoch: The Integration of Indigenous Knowledge." *Indiana Journal of Global Legal Studies* 11 (2): 135-69.
OPPI - Organisation of Pharmaceutical Producers of India. 1999. "Letter to the Government of India, Ministry of Chemicals and Fertilizers - Subject: Issues relating to the Patents Act, 1970." Mumbai: Organisation of Pharmaceutical Producers of India, 28 April 1999. http://www.indiaoppi.com/OPPIPositiononIPR.pdf (accessed on March 20, 2012)
———. 2008. "OPPI Position on IPR & Indian Patent Act, 2005." Mumbai: Organisation of Pharmaceutical Producers of India. http://www.indiaoppi.com/OPPIPositiononIPR.pdf (accessed on March 20, 2012)
Orsi, Fabienne, Lia Hasenclever, Beatriz Fialho, Paulo Tigre, and Benjamin Coriat. 2003. "Intellectual property rights, anti-AIDS policy and generic drugs: lessons from the Brazilian public health program." In *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Challenges*, ed. J.-P. Moatti, B. Coriat, Y. Souteyrand, T. Barnett, J. Dumoulin and Y.-A. Flori. Paris: Agence Nationale de Recherches sur le Sida, 109-135.
Pereira, Andréia M., Bastian P. Reydon, and Divina A.L.L. Lima. 2010. *Análise institutional da bioprospecção e conhecimento tradicional para o desenvolvimento econômico, social e cientifico*. Ponencia presentada al VIII Congreso Latinoamericano de Sociología Rural. Porto de Galinhas.
Pinton, Florence. 2003. "Traditional knowledge and areas of biodiversity in Brazilian Amazonia." *International Social Science Journal* 55 (4): 607-18.
Pró Genéricos. 2011. "Medicamentos Genéricos No Brasil: Avanços e Desafios." São Paulo: Associação Brasileira das Indústrias de Medicamentos Genéricos – Pró Genéricos.
Raustiala, Kal, and David G. Victor. 2004. "The Regime Complex for Plant Genetic Resources." *International Organization* 58 (2): 277-309.
Reis, Renata, Marcela Foçaça Vieira, and Gabriela Costa Chaves. 2009. "Access to medicines and intellectual property in Brazil: A civil society perspective." In *Intellectual Property Right and Access to ARV Medicines - Civil Society Resistance in the Global South*, ed. R. Reis, V. Terto Jr. and M. C. Pimenta. Rio de Janeiro: ABIA, 12-54.
Roemer-Mahler, Anne. 2013. "Business conflict and global politics: The pharmaceutical industry and the global protection of intellectual property rights." *Review of International Political Economy* 20 (1): 121-52.
Rosina, Monica Steffen Guise, Daniel Wei Liang Wang, and Thana Cristina de Campos. 2010. "Access to Medicines: Pharmaceutical Patents and the Right to Health " In

Access to Knowledge in Brazil: New Research on Intellectual Property, Innovation and Development, ed. L. Shaver. London & New York: Bloomsbury, 103-134.
Sabatier, Paul A. 1987. "Knowledge, Policy-oriented Learning and Policy Change: An Advocacy Coalition Framework." *Science Communication* 8 (4): 649-92.
———. 1988. "An advocacy coalition framework of policy change and the role of policy-oriented learning therein." *Policy Sciences* 21 (2-3): 129-68.
———. 1998. "The advocacy coalition framework: revisions and relevance for Europe." *Journal of European Public Policy* 5 (1): 98-130.
Sabatier, Paul A., and Hank Jenkins-Smith. 1988. "Symposium on policy change and learning." *Policy Sciences* 21 (2-3): 123-278.
———. 1999. "The Advocacy Coalition Framework: An Assessment." In *Theories of the Policy Process*, ed. P. A. Sabatier. Boulder, CO: Westview Press, 117-68.
Sampat, Bhaven. 2010. "Institutional Innovation or Institutional Imitation? The Impact of TRIPS on India´s Patent Law and Practice." Columbia University.
Sell, Susan. 1995. "Intellectual Property Protection and Antitrust in the Developing World." *International Organization* 49: 315-49.
———. 2000. "Structures, agents and institutions." In *Non-State Actors and Authority in the Global System*, ed. R. A. Higgott, G. R. D. Underhill and A. Bieler. London/New York: Routledge, 74-90.
Shadlen, Kenneth C. 2007. "The Political Economy of AIDS Treatment: Intellectual Property and the Transformation of Generic Supply." *International Studies Quarterly* 51 (3): 559-81.
———. 2009a. "Politics of Patents and Drugs in Brazil and Mexico - the Industrial Bases of Health Policies." *Comparative Politics* 42 (1): 41-58.
———. 2009b. "The Political Contradictions of Incremental Innovation in Late Development: Lessons from Pharmaceutical Patent Examination in Brazil." APSA 2009 Toronto Meeting Paper.
———. 2011. "The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil." *Politics & Society* 39 (2): 143-74.
Sharma, Devinder. 2006. "Selling Biodiversity: Benefit sharing is a dead concept " In *Understanding the Biological Diversity Act 2002. A Dossier*, ed. K. Kohli: GRAIN, IIED, 65-68.
Shiva, Vandana. 2001. *Protect or Plunder? Understanding Intellectual Property Rights*. London: Zed Books.
Spivak, Gayatri Chakravorty. 2005. "Scattered speculations on the subaltern and the popular." *Postcolonial Studies* 8 (4): 475-86.
Sundar, Nandini (2012): "Winning Hearts and Minds': emotional wars and the construction of difference." *Third World Quaterly* 33(4): 705-720.
Tachinardi, Maria Helena. 1993. *A Guerra Das Patentes: O conflito Brasil x EUA sobre propriedade intelectual*. Sao Paulo: Paz e Terra.
ThePharmaLetter. 1996. "PhRMA Welcomes Brazilian Patent Law." In *The Pharma Letter*. London: The Pharma Letter, 6 May 1996. http://www.thepharmaletter.com/file/84580/phrma-welcomes-brazilian-patent-law.html (accessed on March 20, 2013)
Tyfield, David. 2008. "Enabling TRIPs: The pharma-biotech-university patent coalition." *Review of International Political Economy* 15 (4): 535-66.
Van Dyck, Pooja. 2007. "Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa." *North Western Journal of Technology and Intellectual Property* 6 (1): 138-51.

Venkataraman, K. and Swana S. Latha. 2008. "Intellectual Property Rights, Traditional Knowledge and Biodiversity of India." *Journal of Intellectual Property Rights* 13 (7): 326-35.
Weible, Christopher M. and Paul A. Sabatier. 2005. "Comparing Policy Networks: Marine Protected Areas in California." *Policy Studies Journal* 32 (2): 187-207.
Weible, Christopher M., Paul A. Sabatier, and Kelly McQueen. 2009. "Themes and Variations: Taking Stock of the Advocacy Coalition Framework." *The Policy Studies Journal* 37 (1): 121-40.
WHO. 2006. "Public Health: Innovation and Intellectual Property Rights." *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*. Geneva: World Health Organization.
WIPO. 2011. "World Intellectual Property Report - The Changing Face of Innovation." Geneva: WIPO.

Interviews

Interview 112: Representative of an Indian NGO, 14 September 2010, Geneva

Interview 135: Indian Lok Raja member, 21 February 2011, New Delhi

Interview 138: Representative of an Indian research institute, 25 February 2011, Ahmedabad

Interview 140: Representative of a transnational NGO, 28 February 2011, New Delhi

Interview 141: Indian Raja Sabha member, 28 February 2011, New Delhi

Interview 149: Representative of an Indian NGO, 21 February 2011, New Delhi

Interview 155: Representative of the Delhi Science Forum, 24 February 2011, New Delhi

Interview 161: Representative of an Indian pharmaceutical association, 3 March 2011, New Delhi

Interview 170: Representative of a Brazilian NGO, 27 July 2011, Rio de Janeiro

Interview 176: Former representative of ANVISA, 29 July 2011, Rio de Janeiro

Interview 178: Representative of a Brazilian pharmaceutical association, 29 July 2011, Rio de Janeiro

Interview 180: Representative of the Brazilian patent office, 1 August 2011, Rio de Janeiro

Interview 185: Representative of a traditional community, 3 August 2011, Brasília

Interview 190: Representative of a Brazilian research institute, 5 August 2011, Brasília

Interview 192: Representative of a Brazilian ministry, 8 August 2011, Brasília

Interview 196: Representative of a Brazilian NGO, 11 August 2011, Brasília

Interview 202: Representative of an indigenous community, 18 August 2011, Brasília

Interview 221: Representative of the Brazilian public prosecution department; 30 August 2011, Sao Paulo

Interview 239: Representative of ANVISA, 5 August 2011, Brasília

Interview 241: Representative of a Brazilian pharmaceutical association, 22 August 2011, São Paulo

Interview 244: Representative of the Brazilian patent office, 1 September 2011, Rio de Janeiro

Interview 247: Representative of a Brazilian research institute, 1 August 2011, Brasília

Interview 252: Member of Brazilian Chamber of Deputies, 11 August 2011, Brasília

Interview 256: Representative of a Brazilian NGO, 25 August 2011, São Paulo

Interview 283: Representative of the Indian Ministry of Health, 13 February 2012, New Delhi

Interview 297: Catholic nun, 17 February 2012, Jharkhand

Interview 300: Representative of a Indian research institute, 21 February 2012, New Delhi

Interview 303: Adivasi activist, 23 February 2012, Jharkhand

Interview 314: Civil society activist, 25 February 2012, New Delhi

Interview 329: Representative of an Indian NGO, 2 March 2012, New Delhi

Interview 335: Representative of an Indian pharmaceutical company, 6 March 2012, New Delhi