# **IDEAS IN DISCOURSE**

## HOW NON-MATERIAL MEANS OF POWER EXERTION SHAPE POLICY

The case of the discourse on access to medicines versus intellectual property protection

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### ABSTRACT

The role of the state as the most powerful entity within the political system has doubtlessly waned. This is due to several larger transformations that have impacted and altered global politics - transformations such as the end of the cold war, rapid technological progress and economic globalization. Along came a decentralization of power outlets that determine political decision-making. Traditional means of power exertion that were usually executed by a state authority, such as military force or financial capacity, no longer enjoy an exclusive status. Rather, non-traditional discursive means have gained influence. Discursive power entails the ability to dominate the political debate with certain ideas and thus control public opinion. Holzscheiter (2005) argues that the less formalized the policy venue the higher is the likability of discursive power to prevail. International politics lacking a central authority exactly fit this case.

Ideas help individuals make sense of complex situations and guide action. This is particularly the case, when ideas are taken as given conventions and manifest in institutions. Once they are institutionalised, there is higher probability of an idea being realized in policy practice. Ideas are exchanged through discourses, whose partakers are confronted with different sets of ideas that constitute frames. Discourses serve as forums for the formulation of policy problems and proposals for their solution. Discourse partakers can influence the dynamics responsible for the emergence of a dominant idea through different means and strategies, such as employing frames for argumentation. Actors who lack the means to exert coercive power can instead generate larger networks of like-minded adherents. These networks can be referred to as Transnational Advocacy Networks (TAN) (Keck and Sikkink 1998) and extensions can entail an expansion of the geographical scope or to actors from different societal domains.

By applying discourse-historical critical discourse analysis (Wodak 2011b), I examine the strategies TANs employ within a discourse. The case discourse deals with the conflict between rigid enforcement of intellectual property protection and access to medicines. In order to isolate reasons for why certain ideas gain more attention than others, I will apply frame analysis (Benford and Snow 2000) and compare two policy proposals discussed within the discourse.

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### LIST OF AKRONYMS

(In alphabetical order)

CDA	Critical Discourse Analysis	NGO	Non-Governmental Organization
CL	Compulsory License	PI	Parallel Import
CSO	Civil Society Organization	PT	Parallel Trade
IP	Intellectual Property	TAN	Transnational Advocacy Network
IGO	Intergovernmental Organization	TNC	Transnational Corporation
ΙΟ	International Organization	TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
LDC	Least Developed Country	WHA	World Health Assembly
MIC	Mid-Income Country	WHO	World Health Organization
MSF	Medicines Sans Frontières / Doctors without Borders	WTO	World Trade Organization

### INTRODUCTION

During the World Trade Organization's (WTO) 2001 Ministerial Conference in Doha, the trade ministers from industrialized countries encountered fierce criticism from their fellow colleagues from the developing world. Unprecedented in the then brief history of the WTO, developing countries joined forces to tackle a cornerstone of the institution: rigid enforcement of intellectual property (IP) rights. In a joint statement and backed by public health experts and activists, the trade ministers from the developing world argued that the implementation of a strict patent enforcement required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would jeopardize access to needed medicines in poorer regions. The Doha Ministerial Conference concluded with the Doha Declaration on TRIPS and Public Health, which posited a primacy of public health over commercial interests and extended the applicability of several so-called safeguard mechanisms. These mechanisms included compulsory licensing, which entails the right of governments to issue temporary licenses for domestic manufacturers to produce generic versions of patented drugs in case of a health emergency. Another Doha safeguard is the legalization of parallel import, which is the right to import drugs from countries with lower medicine prices; this practice enables countries to buy medical stocks at a discount ('t Hoen 2009; Schüklenk and Ashcroft 2002).

The Doha Declaration illustrates a turning point in the international trade and intellectual property (IP) regime (Sell and Prakash 2004: p. 167). This is due to the fact that prior to 2001, WTO policies ran counter to what was said in the Doha Declaration. Until then, industry interests dominated the discourse, which largely followed their position that the protection of patents is a necessary precondition for economic growth and provides important incentives for corporate innovation. Industry representatives started to exert their influence on government agencies in the US from the beginning of the 1980s and continued to do so through the negotiations leading up to the formation of the WTO. The aggravating HIV/AIDS crisis however was one pivotal requisite for the emergence of a critical movement consisting of activists and health experts working for intergovernmental and international organizations. These individuals raised concerns about how TRIPS regulations impacted the economic and social development of developing countries and

were able to mobilize parts of the public for their cause. The credibility of the liberal democracies of Europe and North America started to wane when they continued to reject relaxations to TRIPS in the face of their publics demanding action. Due to the activists' intervention, the public opinion in terms of IP protection was effectively altered (Sell and Prakash 2004; Sell 2001; 't Hoen 2009).

This shift from one dominant idea – IP as institutional requirement for growth – to another – IP as a danger to people's lives – was accompanied by a concerted change in the public discourse about TRIPS. Sell (2001) talks of a network of individuals and organizations that represent a wide spectrum of the society. While international NGOs such as Doctors without Borders (MSF) have been the architects of a campaign intended to modify a prevailing policy, they were also able to reach out to domestic groups and to win actors such as the WHO and other experts. This network of advocates of TRIPS reform, which I will henceforth refer to as the access network, thus qualifies as a Transnational Advocacy Network (TAN). According to Keck and Sikkink (1998), TANs share ideas and trust in the ability of individuals' actions to bring about change. They consist of a wide array of actors, including domestic and international groups, media outlets and governmental agencies. They generate and extend access to international policy-making by seeking to enlarge their own network, both thematically and geographically, and strengthening ties among its members.

Ideas are what TANs employ to exert their influence on policy makers and they can be powerful tools in politics. Ideas are exchanged and diffused through discourses. Within policy discourses, different actors compete for whose ideas get implemented and turned into actual policy practice. These ideas need to be communicated among the target audiences and thus need some sort of moderation medium, which often times are texts, either written or spoken. By assessing *typical*, hence representative, textual documents from the discourse described above, I shed light on the process of how TANs determine which ideas dominate a public policy debate. My analysis follows Wodak's approach of a discourse-historical critical discourse analysis (CDA) (Wodak 2001a; Wodak 2001b). In addition to the discourse-historical CDA, I seek to compare the two safeguard mechanisms presented above – the production of generic drugs through compulsory licensing and parallel import – and assess why the former is featured more prominently in documents issued by the actors of the access network. In my analysis, I draw on Benford and Snow's concept of collective action frames (2000) to operationalize these ideas. Frames organize ideas in a way that actors can easily interpret difficult social situations. By reducing complexity, frames guide policy actors in their actions and behaviour. Policy positions rest on particular frames and frames can lead policy makers to support or reject certain policy solutions (Wodak 2001b). According to Benford and Snow (2000), the effectiveness of a frame depends on its resonance among the target audiences. Resonance depends on the relative salience and the credibility of a frame. In this thesis, I explore how the frames created by members of the access network differ and what determines this variation.

### Part I: THEORY

#### **1.1. INTRODUCTORY NOTE**

At first glance, international policy is confined to traditional sources of power. These include military force, financial capacity or the political authority of a sovereign. There are other means to influence policy that go beyond a traditional concept of power. Non-traditional means comprise shared ideas, principles, values and beliefs. Once humans regard particular ideas or explanations as true in the sense that they depict actual reality, they become manifest in institutions (Holzscheiter 2005). Institutionalized ideas can emerge into formal organizations or, on a more abstract level, be articulated in norms and shared values. These normative ideas are the constitutive elements of a discourse. Individuals and organizations partaking in a discourse are guided by the rules and conventions a discourse purports when defining policy problems and corresponding solutions. Definitions are influenced by how actors make sense of their environments. Institutions guide individuals' choices and simultaneously derive from their actions and behaviour (Berger and Luckman 1966). Discourse actors can thus actively facilitate and impede changes within or across institutions (Holzscheiter 2005). I am considering the

process of making meaning as a dynamic interplay of structural patterns and agency. Studying the creation and transformation of discourses thus helps considering both agency and structure when discussing how policy and societal practice take shape, without overemphasizing either of these concepts.

Holzscheiter (2005) posits that discursive means are particularly significant when there is little formal authority. Evidence for this is delivered by the international political system characterized through the absence of central sovereign authority and law making. Due to developments over the past few decades, many political decisions have been transferred from the national to the global level. Simultaneously, global decisions can have a greater impact on local and regional development. In this scenario, the authority of national governments has waned in significance and decisive power has been gradually delegated to inter- and supranational organizations (IOs) and non-state actors. The latter include private transnationally operating corporations (TNCs) and a number of globally active civil society organizations (CSOs). What CSOs lack in financial and authoritative force they can make up in expertise and their claim to moral integrity founded in their autonomy from the state and their non-profit orientation.

With the rising importance of transnational organizations, finding a consensual solution for policy problems has become a somewhat more complex process; it involves a much larger number of both domestic and transnational stakeholders. The literature focusing on these changing patterns of international political order can be summarized under the label *Global Governance* (Pattberg and Dingwerth 2006). One strategy to improve CSO's access to the international system has been to form networks that embody both state and non-state actors. The formation of these networks is motivated by shared ideas. By introducing new issues into a policy discourse or linking already existing discourses, advocacy networks can have significant impact on how a policy problem is defined. The power of such networks derives from the expertise and credibility attributed to their members by parts of the public. Advocacy groups exert their power within the setting of policy discourses by pursuing a set of strategies aimed at influencing political decision-making (Keck and Sikkink 1998).

In this chapter, I am going to discuss the theoretical foundations of my analysis. At the core of my argument lies the understanding that ideas and discourses materialize and manifest in institutions that guide people's perception of social reality (Berger and Luckman 1966). Since my analysis focuses on a transnational case, I will then map and characterize the international ecology of organizations involved in the relevant policy-making process identified as *Global Governance*. In this policy scheme, where state authority suffered a loss in significance and governing is weakly formalized, non-traditional discursive sources of power have gained significance (Pattberg and Dingwerth 2006; Holzscheiter 2005). Since the function of government gets disaggregated in this policy environment, actors tend to form networks in order to broaden their scope of influence. As a result, various transnational policy networks have emerged. I will discuss the role of advocacy networks, whose formation roots in their shared ideas (Keck and Sikkink 1998). Lastly, I will introduce framing theory as one promising explanation of how TANs succeed.

#### 1.2 DISCURSIVE SOURCES OF POWER: IDEAS, INSTITUTIONS, AND DISCOURSES

#### 1.1.1 IDEAS

There are competing conceptualizations of how ideas influence social action. Why certain ideas are being taken up and turned into the policies, programs, and philosophies that shape and determine political practice and others are not, is one of the essential questions for scholars working with ideas (Béland and Cox 2010). In political science, ideas have long been conceived as mere reflections of stable and objective economic interests. Steven Lukes (2005) challenged this notion with his conception of a third dimension of power stressing the influential character of social (or institutional) arrangements that pre-select topics, participants or entire worldviews for societal debate, thus basically the power to set the agenda and exert control over the decisions resulting formalized and centralized authority for law- and norm-creation through the central government because – unlike large corporations or state agencies – they often cannot resort to bloated war chests and therefore have to rely almost entirely on non-material and/or discursive sources to substantiate their influence, such as the establishment of networks, public sentiment, or knowledge (Holzscheiter 2005).

Béland and Cox (2010) hold that ideas are a "primary source of political behavior" that "shape how we understand political problems, give definition to our goals and strategies", and that they are the "currency we use to communicate about politics" (2010: p. 1). Ideas provide the interpretive frameworks through which individuals can decide what incidences and experiences are important for them. Ideas hence can constitute entire theories by ordering those and mapping the causal relations that guide the respective assessments. Ideas are constantly being reconsidered, reformulated and redefined as the actors communicate and debate with each other. They can be employed to shape and influence the political debate through the means of frames or discourses or stay implicit and subtle in paradigms.

Ideas can be classified into two types, namely cognitive and normative ideas (Schmidt 2008). Cognitive ideas give direction for political action and aim at justifying policies in a way as to deliver logical explanations. They explain the solutions policy ideas offer to problems defined through programs referring to scientific or technical practices outlined through a certain philosophy. On a more general level, they connect individual notions and cognitions to the material world through interpretations of what respective surroundings there are. Normative ideas, on the other hand, aspire to legitimate policy by referring to their appropriateness and acceptance through the ideals and values of the public. These values can be either newly emergent or traditional and long-standing.

Moreover, Schmidt (2008) presents ideas in political science and policy making as operating on three different levels that are ranked according to their level of abstraction. First, there are policy ideas and solutions. In this most narrow sense of ideas in policy, it is implicated that the problems and objectives are already pre-defined and given and the idea serves to provide the means to solve those problems and realize the objectives. Second, there are problem definitions or programmatic ideas underpinning these policy ideas that reflect the underlying assumptions and organizing principles of a possible policy paradigm. They help decision-makers to comprehend complex realities and define the problems in need of solution, what issues should be considered, the goals desirable, *"the norms, methods, and instruments to applied"* as well as *"the ideals that frame the* 

more immediate policy ideas proposed to solve any given problem" (2008: p. 306). The framing of a problem can be essential for which policy solutions are rendered appropriate, which is why the problem definition is where a lot of contestation happens in political debate. Finally philosophies or general worldviews represent a third level of generality of ideas. Metha (2010) refers to them as *Zeitgeist* (p. 27). *Zeitgeist* provides the policy ideas and programs with organizing ideas, values and principles and, based on very general assumptions about society and the societal institutions, they constitute a general understanding of what purpose government or public policy serve. Public philosophies can emerge to having a *zeitgeist* status, which entails that its notions are widely shared by the public and not to be criticised within a particular period or point in time. When uncontested, such philosophies can have a tremendous impact on politics and society.

### 1.1.2 INSTITUTIONS

Ideational studies analyse the relationships between ideas and institutions, interests, and change (Béland and Cox 2010). Ideas are the foundation of institutions, which are established through routinely performed human actions. In The Social Construction of Reality (1967), Berger and Luckman argue that "social order is (...) an ongoing human production" (p. 69). Repetition of human activity forms habits that delimit the selection of and give direction to action. When certain habits are reciprocally assigned (typified) to actors, they turn into institutions. Simultaneously, institutions typify actors and actions, which constitutes a certain social order. Every institution has a history, of which the institution itself is a product and enables it to set up pre-defined patterns of conduct that guide actors in their behaviour. In contrast to the fact that institutions are a human and social creation, actors experience institutions as historically grown and therefore as given (externalization) and real (objectivation). Institutions manifest through actors passing on institutional knowledge to future generations. The socialization of the actors' descendants reflects back on the former through which institutions manifest further (internalization). Once the actors internalize this order, institutionalization is complete. Owens (2010) sees ideas as causal for actions. They can not only trigger the entire institutionalization process but also get enshrined into institutions by the actions they prescribe to the respective actors. Thus, I attest there is a connection between ideas and institutions.

Berger and Luckman (1967) see humans as guided through institutions, which help individuals to make sense of their environment, and give meaning to social phenomena. The authors focus on how ideas get embedded into an existing institutional framework, which stabilizes already established norms and makes sudden policy shifts difficult. Ideas transfer power to actors through institutions and institutionalized beliefs (Béland and Cox 2010). They can legitimize distinctive hierarchies, rule systems, and power relations as well as differentials. They can constrain but also facilitate changes to an institutionalized order.

With the advent of new institutionalism, institutions experienced a heyday in the social sciences. This was seen as a response to a somewhat dominating preference for rational choice theories and methodology and their overemphasis of agency while disregarding the role of structures (Schmidt 2008). New institutionalism perceives institutions as given. They function as structure through continued repetition or as the context in which agents perform activities spurred by their interests or cultural norms. Hence, action always follows a rule-based logic, resting either on path dependency, appropriateness based on norms, or calculation based on interests. These examples capture the three most prominent schools within new institutionalism, namely historical, sociological and rational-choice institutionalism.

In the former two branches of new institutionalism, agents are mostly considered passive and controlled by values deriving from external structures and internalized norms. Blyth (1997) fears that limiting the analysis to structures only harbours the risk of disregarding actors' agency. At the same time, resorting to rationalist concepts of ideas as mere *interests* of actors purely driven by utilitarian considerations and not by shared institutional values however could easily lead to a reductionist view that neglects the role of structural forces and norms. In response to institutional theory's inability to explain sudden and rapid changes, Blyth argues for a treatment of ideas as "*object[s] of investigation in their own right*" (1997: p. 246) and not just as causes for institutional effects. He proposes discussing ideas' role as provider of the necessary conditions to build collective action among agents and their role in redefining existing and creating new interests. For Blyth, ideas can be considered both facilitators and preconditions for radical policy change.

Overcoming the seeming negligence of agency in the debate on the role ideas have on policy formulation and to establish an integrated framework that takes both structure and agency into account at attempting to analyse and explain social reality has surely been something social scientists have preoccupied themselves with. Schmidt (2008) argues that this can be accomplished by looking at discourses and their embeddedness into institutions, hence structures. In her view this is necessary to capture social science's turn to ideas and their relevance to influence policy decisions and thus practice. Similar to Blyth, she criticizes the fact that institutions are seen as static and constraining.

Just as much as Berger and Luckman, Schmidt's so-called *discursive institutionalism* (2008) considers institutions to be the result of human activity. Human's *ideational abilities* help them to make sense and give meaning to social phenomena in accordance to the rationality of the institution they are part of, which then helps them to maintain and secure those. *Discursive abilities* further enable them to question the respective institutional rationality, which allows them *"to think, speak, and act outside their institutions even as they are inside of them (…) and to persuade one another to change those institutions"* (p. 314). Discursive institutionalism accepts that interests can be real but doesn't consider them imperatively objective or material either. Norms are perceived as dynamic rather than static.

### 1.1.3 DISCOURSES

There are manifold uses and definitions of discourses in the social sciences. Jürgen Habermas for instance, who is considered an adherent of a deliberative and somewhat idealist conception of discourse theory, characterizes discourse as the argumentative element within a *communicative action*, as a kind of dialogue where the validity of particular claims is negotiated. The ideal outcomes are then regarded as intersubjective and therefore commonly accepted by the public (Habermas 1981 cf. Bohmann and Rehg 2014).

For Schmidt (2008 and 2010), discourses embody ideas in its multiple forms, types and on different levels, as well as how they are conveyed through a range of agents in various spheres. Analysing these discursive processes and the ways ideas are communicated to whom and where can help drawing conclusions on why ideas succeed or fail. Within a discourse it is further determined what ideas are represented in the arguments brought forward, for instance by combining arguments informed by technical expert knowledge with narratives more accessible to a broad audience. Schmidt further distinguishes between coordinative discourses in the policy sphere and communicative forms of discourse in a political sphere. Coordinative discourse includes those actors contributing to the policy construction and the design and justification of policy ideas and programs seeking for agreement on how to define and solve a myriad of policy issues. They can come together based on a common status as experts or shared ideas and beliefs. Communicative discourse is occupied with the communication of the outcomes of the coordinative discourses to the wider public. Their essential task is to persuade their audience groups. A wide range of actors takes part in the communicative processes, such as media, activists, interest groups, and the general public, by expressing and voicing their opinions and responses to the policy proposals circulated. Discursive interaction, especially in terms of policy coordination, remains to have a top-downstructure, facilitated and moderated mostly through elite groups in negotiations closed off from public audiences.

A strong or successful discourse normally fulfils measuring criteria such as "relevance to the issues at hand, adequacy, applicability, appropriateness, (...) resonance (...) [,] consistency and coherence" (Schmidt 2008: p. 311). A certain extent of vagueness can however ease the interpretation and re-interpretation of different actor groups to their likings. Apart from the expression of an actor group's strategic interests and values (bargaining) a discourse also functions as a tool of persuasion for the necessity of certain actions (arguing). The complexity of a discourse very much depends on the set and breadth of actor groups involved. On a domestic level, communication might be much more cumbersome than coordination, while it might be the opposite on a transnational level, which is signified through a much more diverse range of stakeholders involved. Moreover, institutional factors play a significant role for the success or failure of a

discourse. Speakers need to adjust the remarks expressed to the audiences addressed. Their messages need to be justifiable and appropriate, applying both to a cognitive and a normative dimension. As already mentioned above, discourses are embedded into a socially constructed institutional setting and thus follow the inherent rules and norms.

Michael Foucault represents a more linguistic branch. For him, discourses signify how language shapes society, and simultaneously incorporates power relations into language and how it is used. He further posits that the knowledge embodied in discourses can serve as tool of domination. The power of discourses is not just restricted to providing the ones controlling them with authority over interpretation but also that it can render certain groups as powerless (Foucault 1984 cf. Ebrahim 2003). They enable the linkage of language to social practice and determine what is and can be said within a particular locus of society and time. Different discourses are also linked to each other and thereby facilitate the growth of a discourse into additional topical and social realms. Jäger (2001) also stresses the function of discourse as potential bridge between structure and agency. Discourses produce reality through actors actively conveying them. Following Foucault in his linguistic tradition, Wodak (2001b) considers both written and spoken language as forms of social practice. Discourses are then the result of interrelated linguistic acts both within and across topical fields. This corresponds with the notion that control over what is on the agenda and held true and real by whatever constituents is an essential form of power.

A decision-making process in politics entails the construction of meanings that serve as mechanisms to exclude certain uses of language, particular issues and the participation of certain actors and entities. Discourses are particularly important for the dimension of the use of language seeing that they are mediating the reciprocal influence of social relations and language (Wodak 2011b). Meaning is constructed through the discursive confrontation of different sets of ideas. Apart from their role as mediators, discourses also serve as loci for the struggle over the meaning of social phenomena. According to Anna Holzscheiter (2005), discourses incorporate several dimensions of power, namely *"ideas and meaning-structures that constitute (and constrain) social society, the power inherent in the possibilities for transformation within those structures, and the power of the actors* 

*who*" (p. 724) both create these structures and serve as agents in this transformation. Power within discourses is then either exerted through processes such as persuasion or the diffusion of ideas and norms. When traditional mechanisms of decision-making through a central political authority are either not sufficiently institutionalized or entirely absent, discursive means can fill this void. This is very much the case for international politics, since there is no such thing as a world government.

#### 1.2 "GOVERNING WITHOUT GOVERNMENT": CONCEPTIONS OF GLOBAL GOVERNANCE

It is hard to imagine getting around reading the term *global governance*, which has emerged as a new and powerful concept in contemporary political science and international relations literature. Scholars presume a changing role of the state within the international system as the main underlying conceptual basis and have therefore been eager to investigate this (Sending and Neumann 2006; Rhodes 1996). Several larger transformations have altered the international system. They serve as potential triggers for the changing role of the state. Among these transformations are the end of the cold war and the resulting change from bi- to multi-polarity of the world's power hubs, technological progress, especially in terms of information and communications technology, and the process of economic globalization. Through analysing governance, scholars intend to assess the different strategies humans employ when managing their affairs aiming at achieving collective objectives in reaction to a modified environment (Pattberg 2006).

In addition to traditional modes of governing through market structures and hierarchical ruling systems, contemporary governance also rules through networks (Powell 1990). Networks span the boundaries of the public, private and voluntary sectors often operating independently and autonomously from state regulation. Rhodes (1996) finds interactions between interdependent members of networks that happen autonomously from any moderation through the state or state-like structures to be the key characteristic of governance. These interactions are meant to facilitate exchange of resources and negotiate shared goals. He locates this phenomenon within in a range of developments all aiming at the introduction of instruments traditionally only practiced in the private for-

profit sector. Rhodes refers to this as a *hollowing out* of the state: central government functions are transferred to agencies and supranational institutions that are increasingly de-coupled from the domestic political sphere (pp. 661f). Governance focuses on outcomes and strives to improve performance by focusing on the effectiveness of processes and by enhancing principles such as accountability. Governance networks may foster civic engagement and empowerment. This poses a challenge to democracy, for representation is not necessarily organized in a more democratic way than in traditional state systems and information remains to be largely filtered. Rosenau (1995) defines governance very broadly as ruling systems at all levels of human activity.

Despite its frequent usage through scholars and policy practitioners, global governance still lacks a clearly defined direction as research program, a framework as political idea, or even a definition as term (Dingwerth/Pattberg 2006). The frequent and at times arbitrary use of the term bears the danger of losing credibility in its use as a theoretical concept. Concepts posit generalizations about specific social phenomena. They enable individuals and researchers to decide what information is relevant for their analysis and thus help organizing observations and experiences to constitute whatever interpretation of social reality. Concepts can easily lose their analytical power, however, if multiple explanations that do not share essential features are grouped into the same conceptual framework.

Ambiguity in the use of the term *global governance* as a concept has certainly contributed to the vagueness associated with it among scholars and policy-makers. However, the term's wide range of application can also be seen as partial basis for its success and durability (Pattberg 2006). Several authors have attempted to clarify how the concept can be understood and delimit which meanings the literature points at. Finkelstein's definition of global governance appearing *"to be virtually anything"* (1995: p. 368) indeed admits to a somewhat ambiguous use of the term in academic literature. According to him, a process qualifies as governance, when some sort of activity is given and the realm of decision-making governed is transnational. He characterizes international politics as a locus where national states' interests potentially overlap and the authoritative power of a unitary sovereign is missing.

Dingwerth and Pattberg (2006) argue that the lack of definitory clarity of the term mainly stems from its careless use in the scholarly debate. Hence, they identify two directions of how global governance is commonly used in the literature. First, as an *"analytical concept that attempts to capture (...) the reality of contemporary world politics"*, and second as *"specific political program, expressing (...) a normative perspective on how political institutions should react to the reduced steering capacity of national political systems"* (pp. 188f). Pattberg (2006) adds a third possible understanding to this, which stresses *"the discursive nature of the (...) debate and analyses the concept (...) as a hegemonic discourse to conceal the negative implications of the neo-liberal (...) agenda"* (pp. 9f).

Sending and Neumann (2006) see the debate sparked by discussions on the sources and effects of globalization and locate regime theory as a proto-formulation of global governance, which has already put emphasis on the relevance of networks in global politics that usually form around salient issues. Moreover, they attest that the concept embarks on three key characteristics claims in the literature. First, that government should be assessed as dynamic process rather than a static institution. Second, that importance of non-state actors in global policy-making is growing. And third, that political authority is progressively shifting from sovereign states and passed towards decentralized transnational policy networks. According to this, the state's role has lost significance and waned into a solely strategic role. Holzscheiter (2005) points to the expression of a critical assessment of power that global governance seemingly carries out. This is conveyed by the central claim that international decision-making has been reordered by the growth of non-state actor participation. Their skill to take part and question the procedures and routines of international policy-, law-, and in effect norm making is described as a very effective mode of power exertion. Often cited is further the UN's official definition of global governance, which was devised by the UN Commission on Global Governance. They defined governance in their first report as the "sum of the many" ways individuals, and institutions (...) manage their common affairs" in a "continuing process through which conflicting or diverse interests may be accommodated and cooperative action may be taken" (UN 1995: p. 1).

Rosenau (1995) conceptualizes governance as ruling systems on all levels of human activity. Ruling is exerted through both vertical and horizontal flows of control. If the goals pursued through the exercise of that control have transnational repercussions, this governance qualifies as global. At the same time, transnational matters can also have impact on the local or the regional level. Rosenau describes this as interdependence that does not only affect flows of control within systems, but also across systems in a nonhierarchical manner. He uses processes of both globalization and localization simultaneously unfolding as an example of how there is a constant and on-going shift of where governance occurs and is located due to dynamic tensions in the interactions between actors and issues. Global entails an inclusion of a wider range of actors or actor networks - practically any sort of social system. Rosenau's notion of global is therefore less of a reference to transnational issues but rather signifies the relevance of various actors and institutions operating in rather diverse settings when it comes to influencing and determining human activity and behaviour. This manifests through recurrence and not necessarily through authoritative coercion. Due to the increase of organizations and an ever-growing number of specialized agencies within internally operating organizations, steerage and control have become more complex. In aspiring to gain legitimacy, any governance thus has to allow flexibility to a greater extent, which also includes bottom-up models. Rosenau refers to this as a growing "collective capacity to govern" (p. 18) amounting to a disaggregation of authority. This has catered to the empowerment of particular groups and led to the formation of new organizations and additional sites of authority. This group-formation has been spurred by the emergence of interdependent global issues that called for concerted forms of transnational cooperation, such as environmental concerns or HIV/AIDS.

Similar to this, Pattberg (2006) proposes to use the term to describe an array of related occurrences that make up the "sum of all institutions, processes and interaction[s] between various actors at all levels of the socio-political system that address (...) [a] global problem by describing (...) norms and rules of behaviour" (p. 15) that have transnational impact. The relationship between actors is described as non-hierarchical due to the absence of a central authority. His analysis captures how actors pursue policies and apply instruments through their activities in a certain governance

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arrangement – characterized through norms, rules, and networks – with various material and ideational outcomes. Arrangements of global governance vary in terms of who participates, how that participation is organized, and what role the participating actors play. Locating governance arrangements in a framework along three conceptual continua captures this best (pp. 16f). The first continuum is concerned with the *publicness* of governance, ranging from international to private governance. The second addresses the congruency of the governing ones and those ruled. The third assesses governance functions, thus the level of autonomy.

Sending and Neumann (2006) criticize the fact that earlier works on global governance merely explore the actors involved and their respective forms of authority in the process of governance. Yet, they fail to identify the substance of the governance processes stemming from this authority. They point out that the concept of governmentality, originally developed by Michel Foucault (1991) could help to bridge those gaps. Governmentality describes the growing importance of non-state and civil society actors as an expression of a changing logic of government, which signifies a re-definition of civil society from being an object that is passive and to be governed by the central authority to being both an object and a subject that also governs. Governmentality seeks to investigate techniques of governing and replace the institutional focus with an emphasis on what is practiced. In this, they stress the importance of agency and also apply this on the ones appearing to be governed, meaning the civil society. The transferral of responsibility and power to civil society actors illustrates the need for legitimacy governments encounter in modern society, which marks the changing government logics of governing being performed through autonomous subjects. They are often convened in networks comprising states, NGOs, International Organizations, and corporations.

While the role of the state as a locus of authority appears to be challenged by several actors in governance, the notion of states being essential facilitators of power exertion nevertheless prevails. Systems of rule are established through the sponsorship of states or non-state actors, or both of them jointly. Rosenau (1995) mentions NGOs and social movements – often through so-called issue regimes covering a wide array of diverse organizations with a shared cause as commonplace, both on a sub- and a trans-national

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level –, regions and local initiatives, institutionalized control mechanisms, such as credit rating agencies, and international institutions representing nation states, like the United Nations or the European Union as potentially alternative sources of their creation. Similar to this, Sending and Neumann (2006) assert that political will-formation in civil society groups does not run opposite to a state authority but is rather one facet of how power operates in modern society.

Diane Stone (2008) characterizes global policy as fluid, dynamic and with interlinked interactions between the political, economic, cultural and social realm. For this, she uses the analogy of an *Agora*, a commonplace where public discourse has commercial and public domains merge. The participants are contributing to global policy to varying extents. Stone identifies civil society groups and international organizations as the main drivers (*wholly active citizens*) of policy formulation. There are different types of global policy problems. This includes trans-boundary ones, such as international crime syndicates, those that affect common goods, such as pollution of the oceans and the atmosphere, and others that are simultaneous, entailing problems of a similar fashion that are being observed in a number of countries, such as urbanization. A way of tackling such issues is by facilitating policy transfer, which means that specific knowledge produced by the results of policy practice in one place is used to develop policy proposals elsewhere. Their venues are international conferences or commissions focused on a particular issue area. Forms of multilevel and polycentric rule systems have emerged as response to the lack of a formal authority of global governance.

Any attempt to deliver a clear-cut definition of global governance will continue to be easily contestable. Essentially, global governance marks the end of a state-cantered assessment of power and the inclusion of various actor groups. Their activities do not necessarily run opposite to state efforts, which depends on various factors such as the issue area or the location. The growing complexity of various policy issues that can no longer be solved isolated from a wide array of stakeholders and regions has also led to interdependence, which policy-making has to adapt to. All this corresponds with the argument that power rests on discursive means in addition to material sources. To me, the term global does not just refer to the geographical scope of an extended sphere of

influence that political decisions have but also to the changed composition of actors making these decisions as well as the political areas affected by them. Global in that sense foremost means interconnected. Actors such as the civil society organizations have enlarged the size of the group of participants. These organizations have also seen an increased globalization of their actions. In the next section, I want to discuss conceptions dealing with such a global civil society, which again very much exerts discursive power.

#### **1.3 GLOBAL CIVIL SOCIETY**

The emergence of a global civil society is an epiphenomenon of a development towards a global mode of governance. Civil society adheres to legal principles independent from stately legal conduct. This is grounded in the groups' *ethics*, which in turn constitute a collective identity that is often cosmopolitan and transnational (Price 2003). Civil society groups benefit from the transition of power relations inherent in global governance, which is drifting away from the state both upwards, to supranational institutions, and downwards, to civil society groups. These groups interact with states and their respective agencies on a frequent basis, but deny any primacy of central government authority. The passiveness of existing political institutions towards particular issues of public interest often creates the accurate playing field for civil society organizations (Lipschutz 1992).

CSOs rejection of state primacy may lead to the assumption that there is contention and rivalry between the state and its respective government agencies and the civil society. Civil society groups are often even sponsored and funded by public and state sources. Funding of projects through international organizations is common standard. That is the case because their operation structures are supposed to be less bureaucratic and more efficient, and also because states hope that their moral integrity can help them carry out certain tasks. Risse (2002) thus describes their relationship as either competitive or as one of intense cooperation, or even general mutual disregard. There is certainly no indication of them largely or wholly replacing state rule in the literature. Central for the argument is however that particular results in international politics are no longer explicable without taking civil society and their role in policy-making into account.

The significance of norms constitutes collective identities. By the means of those identities, civil society groups are seeking to claim influence. New norms seem most likely to achieve better reception if they are grafting on accepted norms. Further, scholars argue that the creation of weak norms through frameworks such as international treaties is an apt way to gradually facilitate a norm change. This notion remains contested among scholars however (Price 2003). The autonomous status from the state allows groups claiming to represent the civil society to create transnational political networks facilitated through conscious association of actors linked by shared political, social, cultural or economic purposes (Lipschutz 1992).

The growth of civil society groups and organizations has increased the overall density and visibility of civil society and thus their impact on the realm of international politics. Lipschutz (1992) attributes this to the fact that the number of states on the globe has risen significantly, which requires different forms of inter-state coordination. Furthermore, nation states are often no longer able to provide the sort of welfare assistance citizens demand, which creates a void that civil society groups can fill. In addition, new information technologies ease data flows. Civil society groups then often help facilitate the knowledge transfer needed. Price (2003) refers to this phenomenon as transnationalization of civil society, in which CSOs characterize privately structured agents distinct from the governmental and the for-profit corporate realm. Price further distinguishes between transnational networks and coalitions focused on advocating particular issue-based campaigns social movements, whose purpose is to use informal cross-border contacts to coordinate tactics in order to mobilize a large number of people to voluntarily undertake collective action in order to pursue and perform actions to the apparent likings of a wider public interest. Another important feature of civil society groups is their rejection of violent coercion, which is combined with their own inaptitude of executing any kind of violence themselves. NGOs are a very prominent representative of what is commonly subsumed within what civil society usually entails.

Since NGOs and other civil society groups lack assets of material power to steer global policy, they must find alternative modes of access into the international system. These

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include knowledge or the ability to influence public sentiment (Holzscheiter 2005). Discursive power is exerted through negotiating meaning in global policy discourses. NGOs' greatest asset as a normative authority is the credibility and moral integrity that stems from them seeming to not be targeted at making profits and their rejection of any form of violence. In their efforts, they make use of a language that encompasses emotions, rejection, and blaming to raise attention for a certain policy issue. This is just another way of describing a framing process.

Whether civil society groups effectively contribute to civic empowerment and democratization or not, is a controversial question for scholars. Stone (2008) argues, that global policy-making has been privatized by self-regulation and policy networks, leaving the vast majority of world citizenry uninformed about the venues and outcomes of global policy formulation and thus discharged from any influence. Moreover, there are doubts that these groups are actually legitimate representatives of the public or public interest respectively. This is mostly due to the lack of an actual transnational citizenry with a global collective identity. Their agenda and their interests might very well also run contrary to public opinion and merely be an expression of the loud voices of an influential minority (Price 2003). Second, their inherent character of being the product of Western liberal philosophy makes them vulnerable to accusations of serving an imperialist or neocolonialist cause and merely promoting Western ideas and values among groups and societies whose norms and beliefs differ from them. This can be particularly the case for groups advocating matters such as human or women's rights. The transnational character of a global civil society can therefore also pose an impediment to its credibility (Risse 2002).

What makes non-profit, non-state actors special in global governance is that they form networks more regularly and frequently than other types of organizations. They do this to broaden their access into spheres of influence. Price (2003) stresses the importance of elaborated and densely structured networks. They serve as vehicle for diffusion of information and ideas, and permit persuasion of a broad range of target audiences, also through the use of effective pressure tactics. This goes for both the global in a sense of transnational but also in the sense of an inclusion of a wide array of actor groups, not necessarily part of the non-state or civil society realm. In the following part, I will discuss the creation of such policy networks and their effect on global policy.

### **1.4 TRANSNATIONAL NETWORKS**

Transnational relations encompass a wide array of cross-border actor group interactions, flows of global capital, migration and the diffusion of ideas, values, and norms on a global scale. Transnational actors differ in their internal structure. Their interaction can be structured very formal and in elaborately structured and mostly hierarchical organizations. This is the case for most multinational corporations (MNCs) and international NGOs (INGOs). They can however also be structured more loosely resembling a network. In addition to this, transnational actors differ in terms of motivational grounds for their behaviour. While instrumental goals and the aim to ensure welfare for the organization itself and its members usually spur for-profit organizations, non-profit groups attain somewhat ideational *common goods*. This distinction reflects a continuum from instrumental to ideational (Risse 2002).

Networks are characterized by reciprocity as well as mutual trust and support among the various members (Powell 1990). They emerge out of an interest to gather and exchange knowledge and competencies freely and in a flexible and cooperative demeanour. Their triggers are thus the need for speed, trust and expertise. Transactions are indefinite and sequential, which creates long-term mutual reliance and interdependence. The parties depend on each other's respective resources and benefit from pooling them. Networks appear to be fairly suitable for situations in which information commodities are to be exchanged in an efficient and reliable way, particularly when commodities cannot or only barely can be measured in numerical and quantifiable terms. This is also the case for information, as well as ideas, which makes this conception of network quite accurate for describing interactions of cooperative schemes that include non-profit actors in global policy.

Initially, transnational networks were discussed from the perspective of an expansion of multinational corporations. The relationships that were transnationalized were thus mostly exchanges of economic activity and commodity and the subjects studied were firms and

corporations increasingly engaging in network-like modes of co-operation and organization. With conceptualizations on economic globalization starting grow in numbers in the early 1970es academic attention on transnational business networks also grew. INGOs were then initially described as *pressure groups*. Interest in studying the role of non-corporate and civil society actors surfaced with the onset of scholarly focus on institutions and the end of the cold war (Risse 2002). Political networks tend to be based on a shared vision of how the public order should look like.

### 1.4.1 FORMS OF TRANSNATIONAL NETWORKS IN INTERNATIONAL POLITICS

Political transnational network literature focuses on the non-profit sector and interactions of states with the transnational society. There are different ways in which such political networks are structured. They can comprise groups of individuals or even entire organizations. They share a main source of influence, which is the diffusion of knowledge and norms (Risse 2002). Focusing on the interactive patterns allows a more detailed study and understanding of what role the use of knowledge and information plays in international politics Networks formation can be spurred by different motivations that characterize what kind of network they are. Those are instrumental goals, shared ideas on causes of a policy problem, and shared wider principles, ideas, and values (Keck and Sikkink 1998).

The growing influence of experts and academics is captured in conceptions of epistemic communities (Haas 1992). Policy-makers increasingly turn to experts, whom they deem will have the access to the information needed and are thus capable of giving valuable advice to solve complex policy issues. Members of such an epistemic community have a shared set of normative and principled beliefs, adhere to the same notions of validity and often operate within a common policy enterprise. They influence state interests by hinting them to those dimensions they consider salient and relevant. The relationship between policy-makers and members of an episteme rests on mutual legitimization: while scientists gain credibility by being considered trustworthy by state officials, states can point to the fact that their policy is based on the evaluations of experts. The growing importance of epistemic communities was interlinked with the emergence of a policy elite of experts that are also international bureaucrats.

#### 1.4.1.2 TRANSNATIONAL ADVOCACY NETWORKS

Stone (2008) contributes by discussing the impact of experts and scientists on global policy. She underlines their role as gatekeepers for the definition of international standards. Decisive authority is disaggregated and regulated by a complex governance structure of different institutions and laws in the international political sphere. This has sparked the formation of transnational policy communities comprising transnational bureaucrats and civil servants. First, they may work as high-ranking officials on a national level that engage in intergovernmental networks to cooperate with their peers working in similar positions in other national entities. Second, they might be international civil servants as part of the staff of international organizations. They are not representing any nation state and are therefore described as loyal to an international cause. Third, there are transnational policy professionals embodying a complex set of consultants, business executives, experts and scientists, think tanks and NGO representatives (pp. 27-31). Seeing that such professionals are frequently linked to undertakings of the public sector for instance through contracted assignments, they are not confined to being private sector agents. There is considerable permeability between those different network types with network members continuously switching camps or being a member of more than just one community simultaneously. Experts' major source or power is their position, their access to and control of relevant information, their expertise or their professional experience. They engage in policy transfer by employing knowledge generated from a particular domestic or transnational realm and use it for the development of policies elsewhere and at a different point in time. Experts concur at international conferences or within sub-organizations or in especially established task forces and commissions. An example for this process would be policy templates used by the IMF for their structural adjustment programs.

The role of global advocacy emerging from networks of experts and activists is another important example of influential networks that shape global policy. Keck and Sikkink (1998) speak of Transnational Advocacy Networks (TAN). The elements that unify them are shared ideas and values. Actors embodied in a TAN can be (1) NGOs working with research and/or advocacy and operate both internationally and on the local levels, as well

as (2) social movements, (3) foundations, (4) media outlets, (5) organizations representing civil society entities such as unions, churches, etc., (6) bodies of regional and international intergovernmental institutions, and (7) parts of the legislative and/or executive branches of national governments (pp. 9f). NGOs tend to take a leading role in the formation of such networks. Advocacy, also in patterns of networks, is not a recent phenomenon. It has a lengthy history dating back several centuries. The abolishment of slavery in the Western world and women's suffrage are just two liberal projects that were fuelled by activist campaigns. However, their number and their extent as well as the density and complexity of their own inter-linkages have been significantly on the rise during the last few decades. Advocacy networks appear to emerge particularly in cases (1) where access to government channels is blocked for domestic groups, (2) activists believe in the effectiveness of networking for their campaigns, and when (3) international conferences or organizations feature ample conditions for network actors to gather (pp. 10ff).

Advocacy networks multiply access channels to the international governance structures by extending their own network and strengthening linkages among their network members. They are a communicative structure and targeted at increasing the reach of their own community to include actors working on issue areas from different institutional and normative angles to maximize access to leverage influence. They are further a political space themselves, where "actors negotiate (...) social, cultural, and political meanings" (Keck and Sikkink 1998: p. 3) produced within the realm of the network. Moreover, they empower domestic civil society actors by providing them with information and access to the international system by passing a traditional state monopoly of representation and thus transforming the practice of sovereignty. This can also facilitate boomerang effects, as already mentioned. Advocacy networks serve as an alternative source for information and provide facts, testimonies and narrative frames that help influence their audience to make a judgement about what is wrong and what is right. The information provided must further be well documented and reliable to enhance credibility. Campaigning is a central policy tool for advocacy networks that enables them to use information strategically to mobilize their own network, and persuade and pressure their target audiences, which signifies their novelty status within international politics. This

helps them to leverage influence over much more powerful organizations. Their ultimate goal is to alter the behaviour of their target audiences, hence states and IOs, and not just policy outcomes but also the overall terms of policy discourse (p. 31). Organizations and individuals that are part of an advocacy network are active political agents and are able to mobilize resources such as information strategically.

#### **1.4.2 TRANSNATIONAL NETWORKS AND NORM DIFFUSION**

Transnational actors have to consider the norms of the respective institutional environments in which they operate. Such norms are for instance domestic laws. This might lead to so some extent of diversion among their operations depending on where they are carried out. This diversion might be easier accomplished, when there is a certain extent of organizational flexibility, which a network-structure is much more likely to provide. Their operations and their embeddedness into a transnational institutional setting may however also adjust certain domestic norms and institutions (Risse 2002). The international system serves as an ample playing field for transnational network activities because international treaties and governance structures are much more based on norms than in the domestic systems, where there is a clear central government authority. Due to their access to both the domestic and the international realm, transnational networks can facilitate global norm diffusion. Access does however not guarantee impact, which is why they have to employ a range of activities to leverage influence. This is carried out within the stages of a policy cycle, including agenda setting as well as the creation and the implementation of international norms. In order to exert their influence in a winning way in the course of multilateral negotiations, they have to engage in pressure tactics. Essential for this is to build coalitions with international organizations to create pressure from above, and with smaller or less-influential country governments or their respective agencies to create pressure from below. On top of this, they have to carry out lobbying activities among the more powerful states - among their representative as well as and their constituents.

Next, they have to ensure that the norms rendered appropriate in a transnational setting get implemented on a domestic level in target countries. The tactics employed on a domestic level are similar, including building winning coalitions. In addition, the policies proposed have to resonate with already existing norms to some extent. The role of transnational networks is therefore to *frame* certain norms and issues in a way as to which there is resonance with pre-existing normative understandings and the local discourses (Risse 2002). Domestic and transnational actors can also work together in order to exert pressure on domestic governments or lawmakers from several angles. In terms of human rights advocacy, this marks a boomerang-effect (Keck and Sikkink 1998). Domestic civil society groups trigger such an effect by bypassing their respective governments and directly reaching out to prospective international organizations. These exert their influence on Western governments and international organizations. Their concerns get international attention and are channelled back into the domestic realm. As a result, the pressured governments need to take tactical concessions in order to not threaten its reputation. This can empower the domestic groups that initiated the movement and have them increase the pressure even further. However, boomerang-effect might not get accomplished if resonance is missing among the domestic audiences.

In order to be effective, there are several characteristics that are essential for transnational networks. Networks need to be dense, which entails that there is large number of actors that ensure a steady and reliable distribution of information among the network members. Moral integrity and strength in knowledge can serve as a strong base, which may even make up for shortcomings in terms of material sources, such as money and organizational capacity. Risse (2002) stresses that the impact of network activities is also reliant on features of their targets. Audiences, such as states, IOs or MNCs, need to be vulnerable or receptive to the effects of pressure tactics. Vulnerability can be given in terms of economic terms, for instance in relation to potential detriments to trade flows or foreign aid. There can also be reputational concerns in regards to the international standing of a target.

To realize their goals, transnational networks have a wide array of pressure tactics (Keck and Sikkink 1998). Their function is not restricted to just pressuring target groups, but also as safeguards for the mobilization of their own constituents. Among those tactics is the framing and re-framing of selected issues or the naming and shaming of their

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counterparts. Their intention is to engage their target groups into a public discourse, where practices and norms need to be justified. According to Risse (2002), they also put faith into the power of the argument, with which they seek to convince their audiences and the larger public of the rightfulness of their own principles and ideas. In the following, I will focus on the framing theory and how frames are successfully employed in order to shape policy and their outcomes.

### 1.5 FRAMES IN POLICY DEBATE

In Frame Analysis (1974), Erving Goffman aims at explaining how individuals make meaning of their environment. For this, schemata of interpretation are used, which he calls primary frameworks, allowing them to identify, locate and label certain events (p. 21). As an issue can be viewed from a myriad of perspectives, frames can serve as their respective proxies. The function of frames is therefore to organize experience and guide action (Benford and Snow 2000: p. 614). Schön and Rein refer to frames as "structures of belief, perception, and appreciation" (1994: p. 23) policy positions rest upon. Framing is the process of making sense of a complex situation by selecting and organizing information. Different frames are in competition with one another because a reality constructed through one frame can dismiss, disregard or even reinterpret the facts endorsed by the other (Schön and Rein 1994; Chong and Druckman 2007). Framing entails both agency and contention at the level of reality construction. Frames further constitute public opinion, and eventually modify it. Their resonance depends on the cultural and political environment, with media as major transmitter of meaning. Their potential to facilitate change has been of particular interest for the study of social movements (Benford and Snow 2000).

Deborah Stone (1989) has developed a typology of so-called causal stories with which she aims at explaining *"how political actors use narrative story lines and symbolic devices to manipulate (...) issue characteristics (...) while making it seem as though they are simply describing facts"* (p. 282). The function of causal stories is to move situations described as issues from the realm of fate to that of human agency, from being considered an accident to being understood as the outcome of intentional action and a particular human behaviour. There is an empirical dimension to it that explains how and

through whom these problems emerge as well as a normative dimension that serves to blame and judge the actions and agents identified as responsible. Policy actors engage in strategies to perform this shift by accusing the identified originator of an issue and wilfully having caused a certain condition understood as problematic either indirectly or with pure intent. They can also try to re-define something understood as adverse effect and thus indirectly caused. This would entail that the originator is accused of secretly yet intentionally generating effects and outcome that would then falsely be depicted as only adverse. Such causal stories can be a solid foundation to a framing process. Policy actors can employ such causal stories to raise the attention to a certain issue area and bring about change to it. Causal stories can demonstrate possible human control over issues understood as problematic. They can challenge and re-affirm prevailing social orders, assign responsibility to the actors identified as originators and thus trigger a change in behaviour or have them punished and compensate possible victims of their actions. They can empower another group as protector and advocate of victims and create coalitions among those people rendered part of those victimized groups. They can link those groups suffering from an issue to those claiming to have the solution and finally they can evoke political action.

Benford and Snow (2000) discuss frame generation as a three-folded process with overlapping stages. First, there are discursive processes that comprise actors' communication in relation to their activities. Frames are articulated by a compelling alignment of events and amplified. Discursive amplification refers to highlighting issues, events, and beliefs as more salient than others. Second, there are strategic processes aimed at linking interests and interpretive frames with those of prospective constituents. This includes:

(a) Bridging, as linking ideologically congruent but structurally unconnected frames,

(b) Amplification, which involves the idealization of beliefs possibly contradicting dominant cultural values,

(c) Extension, widening a frame beyond its original attention to include issues deemed important to potential supporters, and

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(d) Transformation, referring to changing understandings and meanings and/or the generation of new ones.

And lastly, contested processes, comprising counter-framing, internal frame disputes, and dialectic tension between event and action, generally referred to as framing contests (pp. 623-627).

Chong and Duckman (2007) explain framing as a "process by which people develop a particular conceptualization of an issue or reorient their thinking about an issue" (p. 104). In their work, they focus on the ability of certain frames to change the opinions and views of a specific target group of the frame creator(s), which can be triggered by even small alterations to the presentation of an issue. Such a change of opinions is referred to as *framing effect* (pp. 103f). Schön and Rein (1994) see discourses as venues of a frame conflict. A policy discourse signifies dialogue on policy issues. They are institutionally embedded in a larger social system. The institutional locus dictates how issues are framed and defines the roles, channels, and norms of the discussion. Public discourse is often performed through policy forums, such as legislation, courts, public councils and commissions, media, or academia. Specific rules on how debate is conducted apply and participants usually adhere to them.

Public policy is negotiated and executed based on constant contention in regards to what is best practice. Policy disagreements can often be resolved by examining and resorting to facts. There are however cases where parties appear to be unable to agree when assessing the facts. Rein and Schön (1994 and 1996) refer to these disputes as *intractable policy controversies*, where *"social science is not only unable to resolve (...) but tends to exacerbate (...) by providing information that can be used in opposing ways"* (p. 85). Parties to a controversy differ in regards to what facts they deem relevant based on their stance on an issue or their overall ideology. Moreover, even when resorting to the same facts, interpretations can diverge. This creates the ability to dismiss evidence brought forward by advocates of opposing facts or interpretations.

In policy controversies, the involved parties hold and employ conflicting frames. They communicate through stories about *problematic situations*. Specific aspects of the story are selected and adjusted to fit into a frame. This process stage is called *naming and framing*. These procedural stages not only construct a view of social reality but also identify the problem of the particular situation. They order the selected elements of the story coherently and describe what essentially is wrong. By further setting the direction for a possible transformation naming and framing lays the foundation for what Schön and Rein refer to as the *normative leap* from *is* to *ought* (1994). These stories can then eventually shape "public consciousness about [an] issue" and guide "legislation, the formation of policy, the design of programs, (...) the allocation of funds" (p. 25), as well as how evaluation and analysis shall be conducted.

Schmidt (2008) differentiates between discourses that refer to policy debate and the ones that refer to policy practice. The former are *communicative*, the latter are *coordinative*. Frames employed by the different actors of a discourse aim at persuading the audiences, as well as the justification and the display of apparent problems. They also influence and determine what policy actually does on a practical level. The location of the impact of a frame depends on its type. Schön and Rein (1994) distinguish between two types of frame: rhetorical frames use stories and arguments as means of persuasion. They have little influence on the design of actual policy but generate public attention for a particular issue. Action frames, on the other hand, give direction to policy in practice. There are frames that perform both roles. Action frames are further subdivided into three levels. Institutional actors use *policy frames* to point to a problem in a policy situation and decide what tools and measure are best to tackle a problem in this regard. They derive from frames used to structure a more extensive array of problematic situations, which are called institutional action frames. Policy-makers get familiarized with these frames through their professional experiences and wider socialization. Individuals' action frames may only be loosely coupled to those of the institution they represent however. Metacultural frames lie at their very root. They describe culturally shared schemes of values and principles. Meta-cultural frames can be connected to certain ideological beliefs (Schneider and Janning 2006). While rhetorical and action frames consist of loose ideas, meta-cultural frames capture institutions in the sense of ideas and norms internalized by

the audiences adhering to them. Ideas, whether they are institutionalized or not, are constitutive elements of frames.

Benford and Snow (2003) focus on the role of framing for the emergence of social movements and their execution of discursive power in policy controversies. The concept of *collective action frames* (p. 613) is central to their approach. Collective action frames are created based on the intention to mobilize potential supporters and demobilize antagonists. They emerge when movement activists come to agree on a shared understanding of a problematic situation that needs changing. They develop arguments on who or what is to blame for the problem. They define alternatives and urge others to act. In addition to the three-folded process of frame generation already discussed, collective action frames are the result of core framing tasks, grouped into:

(a) A diagnostic, directed at identifying sources and causes for a problem and *boundary framing* between protagonists and antagonists,

(b) A prognostic, describing strategies for the proposed resolution of the problem, and

(c) A motivational function, providing the rationale for concerted action.

They vary in terms of scope – with frames such as *rights frames* covering a wide array of interests, actor groups and thematic areas –, and resonance, illustrated through a frame's credibility and relative. Credibility has to be given empirically and in reference to the actors, as well as through frame consistency. Salience is qualified through centrality, meaning how relevant beliefs associated with the frames are for the lives of their targets, experimental commensurability, applying to the congruency of everyday experience and the frames, and narrative fidelity, referring to resonance of the frames with the targets' cultural values (pp. 614-622).

There is permanent contestation of frames, which are by no means static but continuously challenged, adjusted and modified. Their embeddedness into a sociocultural context also influences framing (Benford and Snow 2000). Changes in the institutional structure or the informal relations within a political system refer to political opportunities of movement mobilization. Frames are further based on a stock of meanings, beliefs, and practices that represent their cultural resources. Movements both adapt to existing cultural patterns and create new meanings. Framing processes thus reflect continuities and changes in culture. Lastly, the audience is a final source of frame modification by shaping form and content of the communication. Frames are not autonomous constructs but sponsored by institutions (Schön and Rein 1994). Policy controversies are therefore disputes of institutional actors sponsoring conflicting frames. The actors' interests and the frames they sponsor are in a reciprocal relationship. Frames are used to promote certain interests and also determine what actors actually perceive as their interest. Frame construction is an active process fostered by sponsors that do not come from a position of frame-neutrality.

Actors employing frames are usually unaware of their function, which means that frames are tacit (Schön and Rein 1994). Reflective frame analysis strives to identify the frames at work. This aims at de-masking the implicit dynamics that shape policy. It is however difficult to clearly assign a frame to a specific policy position. This is owed to several factors. There might be incongruence between the rhetorical frames of public comments and actual practice. The same course of action can be consistent with several frames. Policy might be understood and transformed quite diversely across different local levels. One way to overcome these difficulties is to see policy-making as a dynamic process and aim at observing changes over time and at different levels. Effectively, frames are a strategically selected bundle of information and interpretations that are being employed by actors and/or actor groups participating in a policy dispute or controversy.

#### 1.6 FRAMING IN TRANSNATIONAL ADVOCACY NETWORKS

Frames are of particular importance for the campaigning of global advocacy groups, hence TANs (Keck and Sikkink 1998). They help the TANs to generate and organize information, which may serve as the base of their political campaigns. By rendering information comprehensible to their audiences, TANs cast attention on particular issues and stimulate action, and eventually introduce new ideas and may thus alter entire policy discourses. As an alternative source of knowledge to the political elite, TANs aim at implementing new norms in international politics that potentially modify the identity and

interests of other policy actors and, ultimately, policy. Successful campaigning builds on the networks' ability to generate flows of information efficiently and applying that information effectively to the problems at hand. Hence, TAN's success is dependent on their access to the actors and institutions that provide them with the relevant knowledge. Framing efforts require very diverse sorts of information interpreted from multiple perspectives. Frame conflicts can also trigger discursive changes within the network.

TANs do not possess power in the traditional sense introduced above. According to Keck and Sikkink (1998), they instead exert their power by using discursive means through selected information and strategic ideas. Next to persuasion, their activities comprise pressure and shaming tactics. Keck and Sikkink further suggest a four-folded typology of tactics that TANs employ. Information politics positions TANs as alternative source of information. They use stories and testimonies and intend to assign responsibilities and propose credible solutions that appeal to their shared principles to ease communication with their target groups. This is essential for the construction of frames. In order to be effective and successful, frames must communicate that a particular state that is understood as problematic is neither accidental nor natural but has been inflicted intentionally by a clearly identifiable originator (pp. 16-22). Frames can also be a causal stories (Stone 1989). There may be a considerable gap between facts and different versions of the testimony that is being told, for they are adapted to fit into varying sociocultural contexts, instrumental meanings and languages. Benford and Snow (2000) have described something very similar in their approach to frame theory, which they have labelled as bridging, amplification, and extension, referring to the linking and the adjustment of different frames in order to make them more attainable for the respective audiences (pp. 623-627). Modes of communication aimed at catching the attention from the public and policy-makers need to be both dramatic and credible, which can be somewhat of a challenge in itself. Media is important when it comes to conveying the messages.

Symbolic politics help them create frames through explanations of powerful symbolic events. Through leverage politics they seek to influence powerful actors. TANs can employ material leverage, for instance by jeopardizing the reputation of a state in a way

as to have them change certain practices to avoid economic or political sanctions. Moral leverage mostly works through a so-called *"mobilization of shame"* (Keck and Sikkink 1998: p. 23), which is aimed at threatening the standing of a particular government within the international community. With accountability politics they can expose gaps between discourse and the actual practice of actors once they have committed themselves to a certain cause. Multiple tactics can work simultaneously in a campaign.

Influencing policy agenda takes place in five ascending stages. Those are (1) issue creation and agenda-setting, (2) influence on states' and IO's discursive positions, influence on institutional mechanisms, influencing policy change in targets as well as (3) influencing state behaviour. Actors must be able to transmit the right messages to targets vulnerable to persuasion and/or leverage. Issues involving bodily harm with a clear causal chain and issues addressing equality of opportunity appear to be particularly suitable for frame creation. Another aspect of the quality of a network is its density. The targets must be vulnerable to material incentives, sanctions from external actors, or sensitive to pressure addressing gaps between a stated commitment and actual practice. Targets are particularly receptive to messages if they are trying to upgrade their own standing (Keck and Sikkink 1998: pp. 25-32). This corresponds with Benford and Snow's (2000) idea of frame resonance through salience and credibility as an indicator of a frame's strength.

# Part II: METHODS

#### 2.1. INTRODUCTORY NOTE AND PRESENTATION OF THE RESEARCH QUESTION

How do ideas end up being turned into actual policy? Why do certain ideas appear as more feasible for policy practice? Who are the actors endorsing these ideas? All of these questions have been central to ideational studies within the social sciences ever since its genesis. As outlined above, there are many ways for ideas to enter the political discourse. Ideas are abstract and often travel through governance networks without being implemented, or even operationalized. In my thesis, I argue that transnational advocacy networks can contribute to how ideas enter the practical policy discourse. Through the

social process of framing, TANs can define and operationalize problems and offer concrete solutions to them. I show this process by studying the empirical case of the discourse on intellectual property protection and access to medicine. In the following, I will explain how I measure and analyze the concepts relevant to illustrating the framing power of TANs.

Frames generate a common idea or understanding of a policy situation and can suggest solutions to if they are understood as problematic (Rein and Schön 1994). An idea ends up being realized if a solution promoted through a certain framing is implemented into policy practice. Frames are also employed as tools of broader policy stories aimed at assigning clear causal chains and responsibilities to certain actors (Stone 1989). Different ideas continuously compete with each other and discourses are the venues of this contestation. Discourses are bundles of linguistic acts both in written and spoken form that are relevant for one or span across several topical fields and mediate mutual interferences of social relations and language (Wodak 2001b). Meaning is constructed by discourse actors' through the confrontation of different sets of ideas, which they then accept, re-interpret or reject. Discourses are powerful in the sense that they facilitate the diffusion of ideas among those participating in the discourse, which can be exclusive circles of policy makers as well as the general public (Holzscheiter 2005). Hence, analysing discourses serves as an accurate tool to assess the power dynamics that shape public opinion and determine which ideas become guideposts for actual policy.

There are two central questions I strive to answer through the analysis. First, how and through which means do TANs contribute to the promotion of certain ideas within a discourse? This includes questions about the different levels of a discourse whereon actors can exert their influence and the discursive strategies they employ when doing this. In addition, I will examine what qualifies ideas as being featured more prominently within TAN's campaigning. These questions reflect the notion that different policy actors can employ ideas as non-traditional means of power exertion. The literature has increasingly accepted their significance, particularly in comparison to traditional means, such as military force or central government authority (Holzscheiter 2005). Using Benford and Snow's (2000) two main quality criteria for a frame's strength

or resonance, salience and credibility, I would like to compare two policy tools directed at solving a certain problem and explain why one appears to gain less prominence within the discourse than the other does.

## 2.2. CRITICAL DISCOURSE ANALYSIS (CDA)

In critical discourse analysis, language is regarded as a social practice (Wodak 2001a). Discourses are constituted by the participants' confrontation with different ideas. Texts, as a semiotic embodiment of language, are then analysed in terms of an assumed relation between language and power. This can bee seen as an effort to uncover the dynamics of dominance manifested in language and shed light on how actors generate meaning through their interaction with textual devices. Analysing these dynamics thus facilitates an understanding of how ideas can become powerful tools and determine policy outcomes. This ultimately helps at finding answers to the research questions. There is a dialectical relationship between specific discursive practices and the venues they are embedded in – discourses both constitute and are constituted by the discursive efforts of its participants and/or the institutions they represent (van Leeuwen 1993 cf. Wodak 2001a). Powerful actors aim at obscuring how power and ideology produce meaning, which is eventually taken as given. Critical discourse analysis then strives to de-construct this process and studies the role of discourses as instruments of social control.

*Critical* refers to a distance to the analysed data and the relevance of its embeddedness into a particular social context, which factors concepts such as power, history, and ideology (Wodak 2001: p. 9). Key assumptions of CDA include language as social phenomenon, the inherence of values and meanings in institutions, the relevance of texts as units of analysis, the role of readers as active partakers of the discourse, and similarities in linguistic strategies of institutions. Language is not seen as powerful on its own – influential actors exert power through their specific use of language. The actors' agency is integrated into the conceptual framework alongside structural forces. There are multiple approaches and manuals on how to conduct a critical discourse analysis. I have chosen Ruth Wodak's discourse-historical model of CDA as my preferred method. I want to expose the dynamics behind the exertion of discursive power means the TAN employs,

and therefore endorse Wodak's approach as it emphasizes the significance of contextual factors.

#### 2.2.1 RUTH WODAK'S DISCOURSE-HISTORICAL CDA

Discourse-historical CDA is committed to three dimensions of critique. First, text- and discourse-immanent critique aimed at discovering internal inconsistencies. Second, socio-diagnostic critique directed at the exposure of the manipulative character of particular discursive practices. And finally, prognostic critique focused on the transformation of communication, such as an inclusive use of language or the avoidance of discriminatory phrasing (Wodak 2001b: p. 65). The discourse-historical approach further stresses the importance of a self-reflective and transparent research process, in order to solidify interpretations and arguments feeding off the evidence. Triangulation is a principle of the approach, which entails the endorsement of a trans-disciplinary research and the application of a variety of approaches.

According to Wodak (2001b), discourses consist of "simultaneous and sequential interrelated linguistic acts" manifested "within and across the social fields of action as thematically interrelated (...) tokens (...) that belong to specific semiotic types" (p. 66), which she labels as genres. A genre demarks a use of language that adheres to certain social conventions and is connected to a particular social activity. This includes examples such as legal texts or political speeches. Fields of action represent different functional areas within a particular social reality, such as legislation or public opinion. Discourses have macro-topics that somewhat delimit the scope of the issues being addressed. Discourses are open systems and allow for any number of sub-topics in reference to the macro-topic that can be created, added to, or removed from the overall discourse at any time. Wodak's approach is very much based on the notion of context, which is subdivided into four different levels (pp. 66f). This includes the immediate language or text. Next, the inter-textual and inter-discursive relationship between isolated utterances, texts, genres and larger discourses. Third, broader extra-linguistic variables and institutional frames, which Wodak also refers to as *middle range theories*. And fourth, the socio-political and historical context the discourse as well as the discursive practices and strategies applied are embedded in and relate to.

Wodak proposes a seven-step model of how to conduct a discourse-historical analysis (Wodak 2001b: p. 93). First, the researcher needs to gather information about the social and political context of the text(s) selected. Second, the genre(s) and the discourse(s) the text(s) belongs to have to be identified. In addition, further evidence has to be sampled in order to establish inter-textuality and inter-discursivity. This includes texts that deal with similar (macro-)topics or use similar arguments. Next, the researcher can come up with research questions and, as a fourth step, operationalize them into linguistic categories, which are, fifth, applied on the selected text(s). Following this, there is the possibility of creating visuals to better depict the links between different fields of action, genres, topics, and texts. As a final step, extensive and contextual interpretation that integrates the research question is required.

#### 2.3. DATA ACQUISITION

Taking Wodak's seven-step model as a template, a single text is the starting point of a discourse analysis. This is not so much the case for my analysis. I have instead selected a policy controversy already identified as discourse in the literature, namely the discourse dealing with how intellectual property protection impacts and potentially impairs access to needed medicine in the developing world. In order to contextualize the discourse and draw a wider political and sociological scenery, I have used secondary literature, including 't Hoen (2009), Sell and Prakash (2004), Sell (2001), Sykes (2002), and Morin (2011). In order to perform the second suggested step, I have gathered additional material, which means I have selected a number of texts and conducted a few interviews with experts. I will briefly explain the nature of my source material, how and why I have selected it and how I have conducted the interviews.

## 2.3.1 SOURCE DOCUMENTS

I have selected 9 text documents for my analysis. I consider them *typical*, since they are written by organizations identified by both the literature and the experts I have interviewed as members of the advocacy network campaigning for universal access to medicines in the developing world (Interview 3). Also, as I will outline in the analysis

chapter, the advocacy network mostly consists of groups representing the civil society and the international and domestic public sector. Therefore, I have decided to choose one organization representing each sector. This is MSF for the civil society, the WHO as international institution, and the South Centre as intergovernmental organization that represents the interests of domestic governments. In addition, I have defined the time frame relevant for the discourse, which is from 1995, the year that TRIPS was passed until today. I have decided to use the 2001 Doha Declaration as point of delimitation of three segments for the entire time frame. This is owed to the fact that the Doha Declaration has effectively changed the WTO's intellectual property regime, thus also altered the overall discourse. I will elaborate on this in the analysis of the political context in the following section. I have labelled the three sub-periods in relation to the Doha Declaration, meaning pre-Doha (1995-2001), the immediate aftermath of Doha (2001-2006) and the intermediate aftermath from 2006 and onwards. The source documents are shown in the box below.

	Civil Society Organization/NGO <b>MSF</b>	International Organization WHO	Intergovernmental Organization South Centre
Pre-Doha (1995-2001)	Globalization and medications: a new constraint for developing countries (1999)	Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement (1998)	Presentation of Carlos Correa from the South Centre at an Ad Hoc Working Group Meeting on the Revision of TRIPS (1998)
Immediate Post-Doha (2001- 2006)	Doha Derailed – A progress Report (2003)	Implications of the Doha Declaration (2002)	A Development Agenda for Intellectual Property Negotiations in 2004 and Beyond (2004)
Intermediate Post-Doha (2006- 2011)	Overcoming barriers to access to medicines (from MSF Homepage, last updated 2011)	The World Medicines Situation (2011)	10 years after Doha – State of implementation (2011)

FIGURE A: SOURCE DOCUMENTS / PRIMARY SOURCES

#### 2.3.2 INTERVIEWS

The expert interviews should serve as additional evidence for my analysis and help substantiate my argument. I have reached out to organizations representing all of the above mentioned sectors, and, in addition, to a pharmaceutical industry representative to test the networks claims on how the corporations see the case. This includes MSF, Health Action International (HAI) and Oxfam, as civil society organizations, the WHO and the South Centre. Unfortunately, I have only received answers from civil society and

industry representatives I have addressed. I consider their answers valuable evidence nonetheless.

Ellen 't Hoen	Expert on IP and Global Health, Former Director of MSF Access Campaign
Jørgen Clausen	Chief Economist at LIF (Danish Pharmaceutical Industry Association)
Yuan Qiong Hu	Legal and Policy Advisor MSF Access Campaign
Philipp Frisch	Coordinator MSF Access Germany

FIGURE B: INTERVIEWEES

The structure of my interviews followed Ullrich's Deutungsmusteranalyse im diskursiven Interview (1999) (analysis of interpretive frames through discursive interviewing), which aims at exposing some of the discourse actors' perceptions during the interview. Interpretive frames are the outcome of continuous social interaction. They are characterized by cognitive, evaluative, and normative components and help reduce complexity for the individual and ease communication among different actors. Interpretive frameworks can only be assessed through derivations, meaning particular and isolated argumentations that relate to certain events and phenomena. The discursive interview aims at provoking interview partners to express such derivations in order to set them into larger interpretive frames. Thus, specific questioning techniques and strategies are central to a discursive interview. At the evaluation stage, competing frames can be identified and then stabilized by contrasting different derivations. Evocation requires a structure that follows a certain chronology but also the interviewer's ability to intervene and make adjustments during the interview in order to enable follow-up questions and requests for additional reasoning of an answer. Thus, the interview is semi-structured and conducted via question guidelines. It is further necessary for the interviewer to provide a trusting environment for the interview to avoid distortions to answers. There are certain question types that have proved helpful for evocations and thus as stimulants for a discursive interview. This includes the simulation of hypothetic situations, so-called Persilscheine, which aim at indicating that any answer is socially acceptable, leading questions, conclusions and repetitions of things already stated in the course of the

interview, as well as confrontations with unpleasant facts or contradictions and polarizations. All of these questions types have to be used with precaution, for they can easily generate biases. Frames can be detected through the repeated employment of similar arguments by multiple interviewees.

#### 2.4. ANALYTICAL PROCESS

In the following, I will explain and deliver some background to what I intend to be doing in the analysis chapter. The order of steps taken in my analysis follows Wodak's (2001b) suggestion of a seven-step model of discourse-historical analysis. After having selected the discourse, which deals with the impact of intellectual property protection on the access to medicines in developing countries, I will provide the political and social context necessary for the reader to understand what the discourse is mainly about. Essentially, the passing of WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) marked a publicized starting point of the discourse. I will elaborate on how TRIPS came into being and how it was questioned soon thereafter by public health activists and their advocacy network. I will conclude this part by discussing the discursive events that marked a shift in how the public perceived the situation, which I argue is the result of the campaigning of a transnational advocacy network. This claim is supported by several authors as well, such as Sell and Prakash 2004, Sell 2001, and Olesen 2006 to name a few. This includes an explanation of the two policy tools that TRIPS considers safeguards mechanisms to secure access in the developing world that I am comparing. Following this, I will identify the actors of the advocacy network central to my analysis. I will do this by using the literature and through material I have acquired from interviews with network activists.

Next, I will describe the contents and topics of the discourse and how I have classified and selected them. Discourse topics can be identified by means of coding of the primary source documents, already mentioned above, and the interviews I have conducted. Before I have started coding them, I have read all of them in a non-systematic manner and tried to think of how they relate to one another in terms of them addressing similar topics and using similar arguments. For coding, I have used a software called Nvivo. My initial codes were the three thematic policy areas, public health, economic policy, consisting of trade and industry policy, and IP law. I have taken the three general themes or topical areas from the literature, particularly from 't Hoen (2009), Sell (2001), and Sell and Prakash (2004). My coding thus follows an abductive approach. After this initial classification, I have tried to sub-divide the text passages further and assign them more narrowly to a topic. Based on this, I came up with a total of seven topics. I have marked the text passages within the primary sources that reflect a certain topic or argumentation scheme as *nodes*. Nodes can signify intertextual connections since the nodes defined are being used for the coding of all the documents. They provide a very comprehensive overview of how the documents relate to each other. I have assigned a number to each topic, which do not indicate any sort of hierarchy or rank. An exception is topic number one Misconduct of the pharmaceutical industry that I consider a main or lead theme. This topic also has sub-topics in regards to different scopes of application, one related to false information in terms of legality under TRIPS and the other one in terms of R&D expenses. I have decided to make this distinction since they touch upon different policy fields, namely IP law on the one hand and health policy on the other. The relevance of single topics to the overall discourse varies.

I have identified the macro topic in conformity with the overall description of the discourse studied and labelled it as *Intellectual Property Rights and Access to Medicines*. Using Sell and Prakash's argument (2004: pp. 145f) that a global network of civil society advocates was able to introduce public health concerns into an originally trade-focused discourse into the realm gave me a clear direction to assign topical areas that the topics identified through coding could belong to. Moreover, the interviews helped me to select Industry Policy as additional topical area. I have therefore decided to group the topics into three topical areas, namely IP Law, Health Policy as well as Trade and Industry Policy. Due to plentiful thematic overlaps, I have decided to merge the latter two policy fields into one topical area. Due to interdiscursivity, discourses and topics are interrelated and thus often connected.

For the identification of the fields of action and genres relevant to the discourse I am analysing, I have used Ruth Wodak's proposal for the graphic depiction of selected dimensions of discourse as social practice (2001b: p. 89). I have adapted the dimensions

to the discourse analysed and grouped them into four fields of action. These are legislation, formation of public opinion, internal development of an informed opinion and the field of political administration. I have further assigned different genres to the documents discussed and published by the network actors.

Following this, I will identify the strategies that the TAN has been trying to employ through their campaigning. Wodak distinguishes between macro-strategies, aimed at particular outcomes of how the discursive shall be altered, and discursive strategies, describing the actual means the discourse actors employ in their efforts to modify the discourse. I have used the macro-strategies suggested by Wodak in her characterization of discriminatory discourses (2001b: pp. 71) and applied them to the discourse I am analysing. The ones I rendered applicable to the discourse are constructive, transformative, and destructive strategies.

Discursive strategies are linked to macro-strategies. Rather than a general agenda they describe the discursive means and practices discourse actors employ. To identify the discursive strategies at play in the discourse analysed, I have once again applied a template from Wodak's analysis of discriminatory discourses (2001b: p. 73) and selected the ones accurate. I have complemented this assessment with Keck and Sikkink's approach to persuasive strategies (1998: pp. 22-25). I have isolated indicators that provide evidence for particular strategies being employed and will elaborate on this in the analysis part. Lastly, I have applied different *topoi* on the discourse analysed. Topoi are conventionalized ideas that link an argument to a concluding claim. For this, I have used the list of topoi that also Wodak is using in her analysis of discriminatory discourses (2001b: p. 74). The list includes the following fifteen topos items:

1 Usefulness, advantage	6 Justice	11 Numbers
2 Uselessness, disadvantage	7 Responsibility	12 Law and Right
3 Definition, name-interpretation	8 Burdening, weighting	13 History
4 Danger and threat	9 Finances	14 Culture
5 Humanitarianism	10 Reality	15 Abuse

FIGURE C: LIST OF TOPOI (Wodak 2001b: p. 74)

Out of these topoi, I have selected nine items I deem accurate for the analysis of the case discourse, including Usefulness and Disadvantage (as one merged topos), Danger and threat, Humanitarianism, Justice, Responsibility, Reality, Law and Right, History, and Abuse. I have selected these based on whether they are relevant. Since the original list was used for an assessment of discriminatory discourses, topoi such as definition or culture have no relevance for this discourse for the core issues differ and can therefore not be applied. I have merged the first two topoi, for they represent somewhat of a topical pair that can also be captured within a single frame of a topos. I will then proceed with the analysis of how different actors within the network have strategized. I do this by giving some of the political context of the particular environments in which the actors operate and navigate and feed this with the knowledge acquired through the analysis already conducted at this point. In addition, I will argue why frames are relevant as a theoretical concept, how the advocacy network has been engaged in framing activities through the campaign, and why they were successful in constructing strong frames.

As the last part of my analysis, I am setting out to compare two policy tools that were introduced as safeguard mechanisms into TRIPS. These are the production of generic drugs through a legal scheme called compulsory licensing and parallel import. I have observed that the former is featured much more prominently than the latter. For this, I am discussing potential reasons for why this is using sources from the literature and the interviews conducted. Subsequent to this, I am going to apply Benford and Snow's (2000) approach to frame strength through resonance testing the two criteria salience and credibility on both mechanisms.

# Part III: ANALYSIS

## **3.1 INTRODUCTORY NOTE**

As I have already outlined, I conduct a discourse analysis using a selection of documents published by actors identified as members of the global advocacy network to be assessed, following a model of critical discourse analysis as described by Wodak (2001b). I will do this as an attempt to answer my research question on how policy actors, as participants of a discourse, frame issues within a discourse. As a second step to be able to answer the second part of the research question brought forward, I want to highlight selected mechanisms proposed in the analysed material and investigate why it appears that there is a discrepancy in terms of how they are perceived as useful in relevant documents. I have chosen generic drugs and parallel importation, both so-called TRIPS flexibilities. I argue that the use of generic drugs seems to attract much more prominence as suggested solution. In order to complete this task in a systematic fashion, I will be applying models of frame analysis (Rein/Schön 1994; Benford/Snow 2000).

I will apply Ruth Wodak's model of historical critical discourse analysis (Wodak 2001b). I endorse her approach seeing that it emphasizes the importance of studying the context in order to provide the soundness and validity needed for a profound analysis. As a first step, I will identify the advocacy network behind the access to medicine campaign as well as their formation and a summary of events that several sources from the literature have been pointing at as being crucial for the cause. I will then put the discourse into context with the theories already discussed in the first part and explain why they apply to this particular discourse. As a next step, I will look for intertextual and interdiscursive connections manifested in the genres and topics covered by the scope of the discourse. As the fourth and final step of Wodak's model, I will analyse the texts I have selected as primary documents. For this, I will code them into discourse topics or *topoi*, which help at understanding the meaning of the texts provided that the context has been outlined prior to this. After having finished my analysis of the discourse, I will continue analysing the role of two mechanisms defined as TRIPS flexibilities, in the advocacy network's framing of a possible solution.

#### 3.2 THE DISCOURSE ON ACCESS TO MEDICINES

#### 3.2.1 Case Description: Political and Historical Background

In order to conduct the analysis, I will start by outlining the historical development of the discourse and identifying its shaping discursive moments. As one of three pillars that serve as the foundation of the World Trade Organization (WTO), the Treaty on Trade-Related Aspects of Intellectual Property Rights (TRIPS) constituted a major cornerstone

for the regulation and governing of international trade. TRIPS was a result of the socalled Uruguay Round, whose conclusion in 1994 served as the official creation of the WTO. The treaty was largely seen as a milestone achievement when it took effect in 1995: it set out to harmonize intellectual property protection globally, which had been a matter of national discretion previously. It contained *"a code of minimum standards for copyrights, patents, [and] trademarks (...); an enforcement mechanism; and a dispute settlement mechanism"* (Sell 2001: p. 489). Further, it clarified that patents and their respective protection have to be granted for a period of at least 20 years and laid down their scope of application, covering all fields of technology. This meant that the exclusion of food and medicine from patent protection was no longer possible. TRIPS covers a wide array of means, including not just medical products but also processes and medical formulations leading to the actual invention. Initially, developing countries were given an extended transition period for the implementation until 2006 ('t Hoen 2009; Sykes 2002).

Activists started expressing criticism already while the negotiations lasted (Sell 2001). They eventually intensified their resistance after TRIPS' instalment and mainly addressed potentially adverse effects that a strict patent regime could have on developing countries. Since innovation stems from high levels of human capital and well equipped educational and research facilities, a big proportion of inventions were and still are filed in high-income countries. This is why IP protection appears to remain at the top of trade policy agendas of developed countries, while some of the developing countries would actually prefer a relaxation. This could help them to strengthen their own domestic industries. Representatives from governments of the developing world at the negotiations feared that such strict requirements might constrain the overall industrial development in Least Developed Countries (LDCs) as well as Mid-Income Countries (MICs), particularly in terms of "sectors of critical importance (...) such as food production, poverty alleviation, nutrition, health care and disease prevention" ('t Hoen 2009: p. 10 cf. WTO 2015)

It comes as no surprise that the pharmaceutical industry was heralding the struggle for a rigid enforcement of intellectual property protection (Sell and Prakash 2004). This is due to the high research cost the industry faces and their hopes to recoup the investments through monopoly pricing. This was further aggravated by the fact that pharmaceuticals

remained excluded from any form of patent protection in large parts of the developed world up until the 1980ies and in many developing countries at the time TRIPS took effect. The industry thus argued that potential inventors would be unwilling to make large investments. Their representatives successfully lobbied the US administration in the years prior to TRIPS and were very active participants of the Uruguay round negotiations. They argued that cheaper copies to their originator products would not only threaten their revenues but also put the overall industrial standing of the US in danger. As a consequence, the United State Trade Representative (USTR) started to create a Special Watch List that functioned as forerunner to trade sanctions and served as effective leverage to put considerable pressure on those countries with IP regimes incompliant with their own protection schemes. This was very much in line with the emergence of a neo-liberal paradigmatic discourse in economic policy, which favoured fierce protection of property rights, including IP, as major lever for facilitating economic growth.

Nevertheless and despite the criticisms, there are actually quite a few references to the safeguarding of public interests, particularly in relation to developing countries in TRIPS. These provisions are called TRIPS flexibilities ('t Hoen 2009). This includes the member states' right to issue a compulsory license on grounds of a national health emergency, allowing governments to license the production of generic copies of a patented product through domestic manufacturers – provided that the government is willing to remunerate the originate producer. Furthermore, there is the right to authorize the parallel importation of an originator product from another country, which can reduce medical prices (Sykes 2002). The prospect of a multilateral agreement with fewer possibilities of bilateral trade sanctions was in fact one of the main reasons why developing countries gave up their resistance during the Uruguay round and signed into the agreement. The vague and imprecise language used in TRIPS enabled the industry to legally challenge every domestic law they rendered detrimental for their businesses, which posed a considerable burden to developing countries that often lacked the legal expertise necessary to uphold their positions ('t Hoen 2009). To name an example, the term 'emergency' was not further defined in the agreement leaving countries contemplating to actually make use of such measures vulnerable to legal litigation.

An aggravating HIV/AIDS epidemic that climaxed over the course of the 1990ies and affected considerable parts of Asia, particularly in the South and Southeast, and the whole of sub-Sahara Africa, made the importance of universal access to needed medicine evident to large parts of the Western public, and even more so the detrimental impact TRIPS could have on developing countries' endeavour to tackle viral diseases. Activists of various public health and consumer groups started to publicly challenge the corporate notion of patents being a safeguard for economic growth by pointing at the adverse effects they could have on public health interests and urged the World Health Organization (WHO) to take a stand on the matter (Sell 2001). In 1996, the World Health Assembly (WHA) requested the WHO to work out guidelines for its member states to implement TRIPS in a fashion that guaranteed accurate drug availability ('t Hoen 2009). In the 1999 WHA, a resolution urging developing countries to make use of flexibilities under TRIPS to increase access to medicines was passed, including compulsory licensing to produce generic drugs and parallel importation. In the resolution, the WHO's willingness to provide developing countries with the necessary assistance and counselling was underlined. All this consolidated the WHO's role as stakeholder in IP affairs at international negotiations.

The pharmaceutical industry filed a case against the South African government accusing them of patent rights violation through the 1998 Medicines Act. The law allowed "generic substitution of off-patent medicines (...) and (...) parallel importation of patented medicines" ('t Hoen 2009: p. 21). International health activist groups, MSF, Oxfam and Health Action International (HAI) among them, joined local activists in their campaigning and supported them financially. They brought the issue to the attention of Western audiences in an effort to influence and pressure policy-makers to urge the industry to drop the case. After Western governments revoked their support for the industry and the legal foundation of the industry's charges turned out to be fairly thin, the 31 companies suing South Africa eventually withdrew from the case in April 2001. The court case turned into a public relations disaster for the pharmaceutical industry. Due to concerted effort and cooperation of civil society groups working both domestically and transnationally, Olesen (2006) considers it the discursive event responsible for the creation of the transnational advocacy network fighting for access to needed medicines.

Access to medicine became somewhat of an item at the 1999 WTO Ministerial Conference in Seattle, when president Clinton announced a change in US policy by stating that public health interests would be considered in the application of US trade-related IP legislation and that compulsory licenses were to given imperatively in cases of emergency, with special regards to HIV/AIDS (Sell and Prakash 2004). This was seen as direct response to fierce criticism against then Vice-president and Democratic presidential candidate AI Gore, who had come under heavy attacks from health activists. This was because of his reluctance to take a critical stand on the issue as a candidate in the light of a worsening situation in Southern Africa. Gore had initially hoped to secure funds from the pharmaceutical industry for his presidential campaign. Further, Doctors Without Borders/Médecins Sans Frontières (MSF) was awarded the Nobel Peace Prize in 1999, leading them to launch their Access (to medicines) Campaign in their then president's acceptance speech ('t Hoen 2009).

Further backing for the access campaign came from producers of generic drugs, when India-based Cipla committed to offer ARV (anti-retroviral) therapies to treat AIDS for less than the tenth of what the average market price was then ('t Hoen 2009). The average price of therapy could thus be lowered to roughly \$1 per year. In addition, the US was hit by a series of bio-chemical attacks with Anthrax viruses in 2001 and eventually considered to make use of their own right as WTO member to issue a compulsory license in order to pressure Bayer to lower prices. Given this, there were little grounds left to argue in favour of rejecting an extension of developing countries' possibilities of making use of public health safeguard mechanisms permitted in TRIPS.

Motivated by all these incidents, developing countries took the matter to the venue of multilateral trade negotiations. At the 2001 WTO Ministerial Conference in Doha, they requested clarifications to settle the legality of certain measures protecting public health interests. The result of this was the so-called *Doha Declaration on TRIPS and Public Health* ('t Hoen 2009). The declaration essentially stated a primacy of public health over commercial interests, which became a symbolic victory for all those campaigning for the promotion of access to medicines. Further, the relation between high medical prices and

barriers to access, which can be directly linked to patents, was acknowledged. The pharmaceutical industry has long fought this notion by arguing that domestic policy issues and a weak health care infrastructure were the only reasons for obstructed access. The right of member states to make use of the flexibilities, most notably compulsory licensing and parallel import, was reaffirmed and transition periods for LDCs were prolonged. Whether compulsory licenses could also be used for medicines produced for exportation could however not be resolved in Doha. LDCs often lack the facilities required for the production of medicines. This happened two years later in the 2003 August 30<sup>th</sup> decision. The parties agreed that compulsory licenses were to be given on a case-by-case basis, which included drug exportation of medicines produced under a compulsory license. Activists saw the complicated legal mechanism created to assess the case as a further disincentive for developing countries to seize their right of compulsory licensing.

Sell (2001) attributes the success in Doha to a well-prepared and unified group of developing countries and the loss of credibility the West suffered from their threats to issue a compulsory license when faced with attacks involving bio-chemical substances. A third reason is the emergence of a transnationally operating network of civil society and public health groups, which I will refer to as the access network. The focus of post-Doha campaigning was put on the industry's and Western governments' apparent attempts to limit the effectiveness of the declaration by questioning the clarity of some of the declaration's provisions and by circumventing TRIPS in its entirety through means of bilateral trade agreements that contain more restrictive IP laws ('t Hoen 2009).

## 3.2.1.1 Description of TRIPS Flexibility Mechanisms

## 3.2.1.1.1 Generic Competition under a Compulsory License

According to the WHO, generic drugs are "pharmaceutical product[s] (...) interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent" (WHO 2015), and then sold under a non-proprietary name, for instance a chemical ingredient of the medicine. The main advantage of generic drugs is that they are traded for much lower prices and thus available to the poor population. The WHO stresses governments' right under TRIPS to allow generic substitution and the positive impact of generic competition

on medical price reduction. Generic drugs are not to be confused with counterfeit medicine, which is criminal fraud through mislabelling of either the source of the identity of the product.

Generic copies can be produced for medicines whose patent has not expired and are therefore subject of protection through an exclusive right of manufacturing for the patent owner under regular conditions. Under TRIPS, Article 31, a government can issue a license, called compulsory license, to produce a product or process protected by a patent without the consent of the originator. Several requirements must be met for a government to be entitled to grant such a license (WTO 2006). These include unsuccessful antecedent negotiations with the patent holder for a voluntary license to copy and adequate remuneration. Cases of emergency, non-commercial public use or anticompetitive practices do not require negotiations however. Further, their main purpose shall be the supply of the domestic market. The latter provision has been relaxed through the 2003 August 30<sup>th</sup> Decision of the TRIPS council.

Compulsory licenses remain to be highly contested by the pharmaceutical industries and their lobbies in both legal and political forums. This is particularly the case in countries considered being growth markets, which is the case for most of the larger of the midincome countries. A further restriction of legal grounds for the issuing of a compulsory license enjoys a priority status on the pharmaceutical industries' wish list for TRIPS plus provisions ('t Hoen 2009).

## 3.2.1.1.2 Parallel Importation

The legal basis of parallel imports is the so-called right of exhaustion. Exhaustion means that the patent holders can no longer enforce their intellectual property right (Gallus 2004). An exhaustion of rights regime can be applied on a national, a regional or an international level. International exhaustion means that a product can be purchased and re-sold into a country other than where it has been initially marketed. Under a national exhaustion regime in the destination market however, parallel trade would not be legal since patent protection would still be given. Its legality is a matter of national laws and not

regulated by TRIPS. Article 6 explicitly states that principal prohibition is nowhere to be found in the TRIPS framework.

Due to price discrimination between different markets, which is common practice in pharmaceutical price politics, parallel trade is fairly frequent in the medical sector. This is due to the fact that the government heavily regulates the sector and regulations vary from country to country. At the same time, when government regulation is absent, pharmaceutical firms are very autonomous in their price setting thanks to the monopoly status that patents grant (Gallus 2004). Among the developing countries only Kenya has established a parallel import scheme on a larger scale. Just like restrictions on grounds for the granting of compulsory licenses, some of the TRIPS plus provisions negotiated in bilateral trade agreements also aim at the general prohibition of parallel imports ('t Hoen 2009). Due to the fact that the EU is a free-trade area, regional right of exhaustion is practiced in most of Europe. This is also the reason why parallel traders have significant market shares of over 10% in several countries, particularly in Northern Europe (Danzon 1998).

## 3.2.2 Discourse Actor(s)

I have identified a group of transnational and domestic NGOs and civil society groups, as well as international and intergovernmental organizations that campaigned for an improvement of access to medicines in developing countries or supported the cause as *Transnational Advocacy Network* (TAN) (Keck and Sikkink 1998). In my opinion, the access network qualifies as TAN for two reasons. First, they reached out to a variety of different actor groups representing very different spectrums of society, including the for-profit private sector, the civil society or non-profit private sector respectively and the public sector. Second, they have integrated both organizations and groups that operate on a trans- and international level as well as groups with a local or regional focus. This goes very much in line with the argument that these networks seek to extend their access to international policy-making by capturing a wide scope of actors that represent different societal spheres.

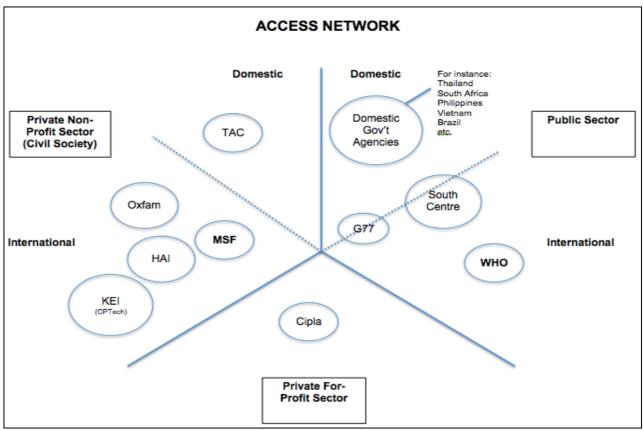


FIGURE D: ACTOR GROUPS OF THE ACCESS NETWORK

The networks' scope of actors includes international NGOs, such as MSF, Oxfam, Health Action Network (HAI), the Consumer Project on Technology (CPTech), which has changed its name to Knowledge Ecology International (KEI), and Act Up, as well as groups that operate locally, such as the South African Treatment Action Committee (TAC) (Olesen 2006). In terms of for-profit private sector actors, Cipla, a producer of generic drugs, helped the network to gain credibility by making an actual offer to deliver medicines at a lower price in countries severely affected by HIV/AIDS. Through the World Health Assembly (WHA), the decision-making body of the WHO, activists have influenced the WHO's policy, who has become the biggest public institution with a favourable stance towards the goals of the access network (Sell 2001). Lastly, intergovernmental organizations like G77, an association that represents developing countries in international settings and multilateral negotiations. Some of developing countries' governmental agencies, in particular administrative bodies and ministries responsible for health matters, have been in close connection with the network with changing frequencies over the years. Due to the many interests at stake within a country's

government and agencies with diverging views, it's not feasible to regard governments as network members (Interview 2; Interview 3).

## 3.2.3 Contents and Topics of the Discourse

The intention of the advocacy network was to alter the discourse and, by doing this, to introduce a new understanding of the function of IP protection. While at the time TRIPS was passed there seemed to be little interest for the matter, several factors led to an increase of public attention. As already outlined above, this is mostly prominent due to the emerging HIV/AIDS crisis in large parts of the developing world. Portraying the pharmaceutical industry and the governments of developed countries as the culprits who are to blame for millions of deaths in poor countries seems to be the most obvious story the access network could spread to trigger public discontent. This is however certainly not the only frame the TAN has employed. Initially, the discourse only covered the role of intellectual property protection. Public health was increasingly introduced into the debate, which also changed the macro-topic of the discourse.

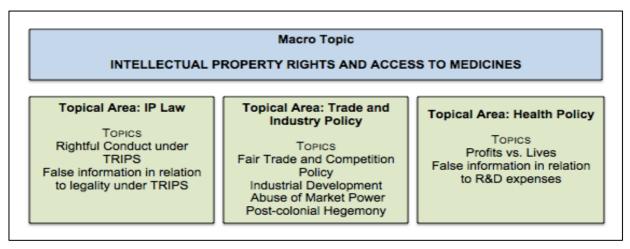


FIGURE E: DISCOURSE TOPICS, TOPICAL AREAS AND MACRO-TOPICS

Confronting the global public with an apparent hypocrisy of preaching free trade and fair competition but not living up to that standard in their treatment of developing countries proved to be a much more effective tool and also explains why the access network built a lot of their argument from a legal and a trade policy perspective. Accusing the industry and their allies as engaging in unfair and dishonest conduct stands as a ruling theme within the networks' discursive strategies. Sell and Prakash (2004) argue that they succeeded in introducing a public health narrative into the debate. This was a field where

they had significant expertise and were able to better steer the discussion than it would have been the case in a strictly economic and trade-focused discussion.

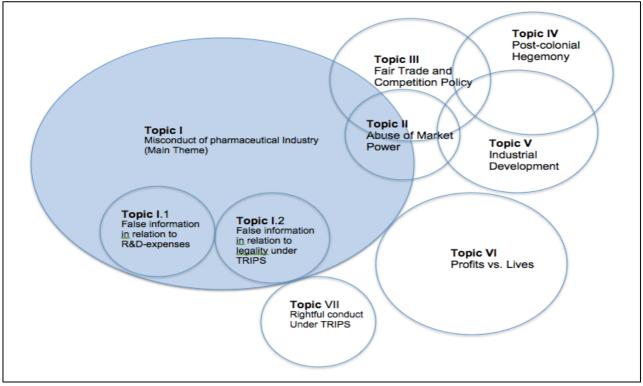


FIGURE F: INTERCONNECTIONS BETWEEN THE DISCOURSE TOPICS

Wodak (2001b) defines a discourse as a "bundle of (...) linguistic acts, which manifest themselves within and across the social fields of action as thematically interrelated (...) tokens (...) that belong to specific semiotic types" (p. 66). The most salient features of a discourse are macro topics. I have identified Intellectual Property Rights and Access to Medicine as the macro topic central to the discourse. They are often portrayed as opposites and their relationship to one another is a classical trade-off. Macro topics can have an indefinite number of sub-topics. Through my analysis of the literature, the texts I have selected as typical or primary, and the interviews I have conducted, I have counted and isolated seven individual topics and two additional sub-topics to Topic I. Some of them are more prominent and/or with a higher degree of interrelatedness than others. I have grouped them into three topical areas, which, in this case, are larger policy fields. This, of course, is only an attempt to categorize them. Depending on the perspective, there are aspects to every topic that can also be relevant for a policy field other than the one it is associated in the figure above. This is also an important feature of

interdiscursivity. Their relevance can depend on the frequency of their employment in public statements and other publicized linguistic acts, their position in these publications and the context they are used in. In the next section, I will explain how actors discuss these topics in a strategic endeavour to alter the discourse and where these efforts are to be located in terms of policy venues.

## 3.2.4 Discursive Venues and Strategies

A strategy is a somewhat intentional plan of particular actions directed at a certain political, social or linguistic outcome. The discursiveness of a certain strategy shows in the systematic use of a particular kind of language. Similar to topics, strategies also operate on different levels, which shows in the existence of macro- and sub-strategies. Discursive strategies are reflected and find expression "at different levels or linguistic organization and complexity" (Wodak 2001b: p. 73). Coming back to Wodak's definition of a discourse, the most elementary components are single linguistic acts that manifest themselves within and across social fields of action as "thematically interrelated (...) tokens" (p. 66). These tokens are captured in single utterances or, more compiled, in texts that then belong to particular semiotic types called genres. Genres are described as a distinctive use of language that belongs to a certain social activity or institution. A text must conform to particular social expectations in order to be understood and accepted by target audiences. Social fields of action are part of what individuals or certain groups understand as social reality. When applying Berger and Luckman's (1967) approach, one could understand fields of action as the institutional setting(s) of a discourse. Within politics there are several fields of action with different functions, such as legislation, the formation of public opinion or the expression of dissent. One discourse can take place in several fields of action and also other discourses simultaneously.

	FIEL	D OF ACTION	
Legislation	Formation of Public Opinion	Internal Development of Informed Opinion	Political Administration
Genre			

>> Multilateral Treaties	>> Press Releases	>> Internal Briefings	>> Public statements of
<ul> <li>&gt; TRIPS</li> <li>&gt; Doha Declaration</li> <li>&gt; August 30th</li> <li>Decision</li> <li>&gt; National</li> <li>Legislations</li> </ul>	>> Online Resources/ Information (Briefings, Reports)	>> Reports >> Speeches (Both at public forums and internal meetings)	national governments >> Reports issued by national governmental agencies
>> National Patent legislation (1997 South African Medicines Act, etc.)	>> Public Speeches (Speeches at formal meetings, demonstrations, etc.)	>> Mission Statement of the Campaign	

FIGURE G: DISCURSIVE FIELDS OF ACTION

Different discursive elements are interrelated. These relations can exist between different texts and other uses of language. Texts can also be located at the intersection of two or more discourses. Moreover, texts can be embedded in an institutional framework, and a wider social, political, or historical context (Wodak 2001b). Since the texts I have analysed were part of a sequential order of texts that were being published for the cause of a campaign, strong intertexuality is given. Across the different actor groups within the network, arguments are being used, repeated and/or slightly adapted to fit the expectations of the audience or to capture the events that alter the discourse over the course of the years. By bringing in arguments from the realm of trade policy into a formerly strictly public health-focused group or discourse, interdiscursivity is being established through means of argumentation. In terms of mid-range and grand theories, some of the networks' arguments clearly derive from the notion that the West acts as

hegemon and exploits the developing world, which is at the same dependent from trade relations with Western countries.

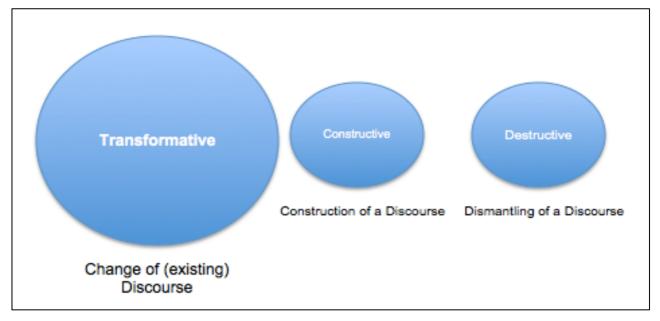


FIGURE H: MACRO-STRATEGIES USED

The intention of the network was to change a policy discourse from perceiving the role of intellectual property rights to safeguard economic growth, which could be achieved through the rigid enforcement of patent rights, to attributing special regards to public health interests, which were not to be harmed by intellectual property rights. They did this by employing discursive means, which was campaigning of the public and lobbying of policy decision makers (Sell and Prakash 2004). Their macro-strategy carried elements that are constructive, which means their intention could have been to create an entirely new discourse in IP policy, or elements that are destructive, which would have been directed at the suspension of an old discourse. Due to their use of topics and argumentative schemes stemming from the realm of trade policies, which was a field the discourse was mostly deriving its views from prior to the network's campaigning, I argue that their intention was mainly to transform an already existing discourse. In addition, the campaign never questioned the usefulness of IP rights protection. By introducing new elements into an already existing discourse, they have much rather transformed than (de)constructed or dismantled the discourse (Wodak 2001b)

By steering public outrage and concern over an access gap in Sub-Sahara Africa, the access network was also able to increase the communicative elements of the discourse. The multilateral negotiations of the WTO were fairly exclusive and restricted to government officials that were heavily lobbied by industry representatives and the outcomes were treated with secrecy. It appears that there was little interest to communicate policy proposals of this coordinative discourse in a Schmidtian (2008) sense. Through campaigning and bringing the issue to the attention of a broad audience that initially played no role in the negotiations, the discourse was effectively altered. This also changed the public expectations towards the work of the WTO and made subject of a much bigger public scrutiny. By demanding the consideration of public interests through civil society organizations in the discussions surrounding WTO conferences and negotiations, they did not just introduce communicative elements into the discourse but also increasingly entered the coordinative sphere of the discourse. This increased their influence on and significance for global trade and IP policy (Sell/Prakash 2004).

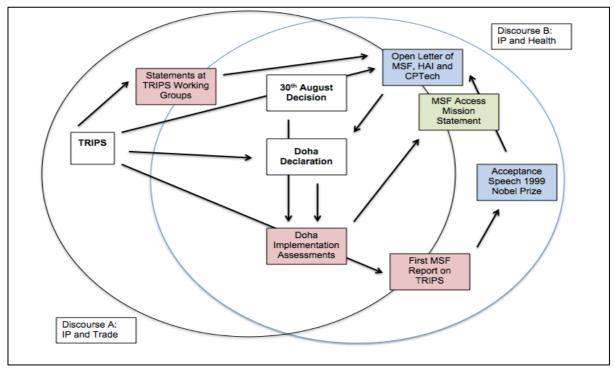


FIGURE I: INTERTEXTUAL CONNECTIONS

In their campaigning, the network employs simplifications and generalizations, which create a dichotomy between 'developing countries' and their respective populations and 'Western governments' and possibly disregard of more complex relations and similarities

between these categories. By doing this, network actors have a much easier task to portray one group responsible for a problem and victimize another. Wodak (2001b) has referred to this strategy as referential. The network actors engage in predication, which entails the assigning of negative or positive attributes to particular actors. As I have already outlined in the listing of the topics, it appears that the most prominent theme in the discourse are references to an unfair and dishonest conduct of the pharmaceutical industry and Western governments that support them. At the same time, sick people in developing countries in dire need of access to needed medicines are described as the group suffering from this prevailing malpractice. Their efforts are thus targeted at creating a causal chain for a policy problem, who is to blame and who is affected negatively by it. This is very much in line with Deborah Stone's (1989) concept of policy stories.

They justify their labelling through means of argumentation. By using a drastic language and citing the case of people dying because of an insufficient or entirely lacking access to medicine, the network further intensified the discourse. I deem all of these strategies as aiming at the creation of narrative frames. Frames serve to organize different events and make information comprehensible to respective audiences in an effort to raise awareness for a problem and stimulate action among groups interested or affected by it, which makes them a very effective tool of mobilization. Framing is used as a tool of representation within the discourse to invigorate values and positions within the network among its own actors and to mobilize both activist and policy maker audiences (Wodak 2001b).

Strategy		OBJECTIVE
Reference	>>	Constitution of groups, classifications, typologies
Predication	>>	Attribution of positive/negative characteristi referenced groups
Argumentation	>>	Justification for labels (through predication)

Representation	>>	Invigoration of views, framing, mobilization
Intensification	>>	Attention, mobilization
Accountability Politics	>>	Holding counterpart responsible and jeopardizing their credibility

FIGURE J: DISCURSIVE STRATEGIES USED

## 3.2.4.1 Topoi Used

Within an argumentation strategy, *topoi* are used as a crucial asset. Topoi are institutionalized premises or ideas that serve as the base for certain statements or arguments that link an argument to a conclusion that then turns into a claim. They can be either explicit or inferable from the implicit (Richardson 2004 cf. Žagar 2010). They overarch some of the implicit and institutionalized assumptions that serve as base for particular ways of understanding social reality. Implicit topoi can be compared with Schön and Rein's (1994) conception of meta-cultural frames that lie at the very bottom of an argument. A list of topoi can never be complete; they merely serve as template for suggestions as to what might be applicable to or relevant for a particular discourse. For my own analysis, I have used a selection of nine different topoi that are items of a list by Wodak (2001b), which is shown below (pp. 73-77).

Usefulness / (Dis-)Advantage	Reality
Danger	Law and right
Humanitarianism	History
Justice	Abuse
Responsibility	

FIGURE K: LIST OF SELECTED TOPOI

The *topos of usefulness or uselessness* respectively, can be applied on claims brought forward by the access network that contradicted a core argument of the industry, namely that patents would bring economic growth in all parts of the world, developing countries included. The access network saw evidence for this in the fact that the AIDS epidemics worsened and that the industry instituted legal proceedings against legislation that was set out to tackle that exact problem. The sort of patent protection established through TRIPS was thus rendered useless for anything other than protecting corporate profits, which doesn't serve public interest. The *topos of danger* finds itself reflected in the claim that the sort of patent protection stipulated by TRIPS could lead to the death of people. This topos is also closely connected to the *topos of humanitarianism*, which indicates that decisions or practice that do not conform with human rights should not be carried out, and the *topos of justice*, which promotes equal rights for all. The WHO has been very active in stressing the human right for health. Also closely connected to the previous three topoi is the *topos of responsibility*. It proved quite essential to the network's campaigning since they intended to assign causal responsibility for obstructed access to medicine to the pharmaceutical industry and Western governments. By doing this, they seek to address to conscience of the Western public.

Network actors employ the *topos of reality* when accusing pharmaceutical corporations of being dishonest in their denial of patents posing a barrier to access. Based on their depiction of reality that patents and, subsequently, high prices are the main reason for inadequate access, they ask for measures countering this. The *topos of law* influences the argumentation, whenever actors of the network stress the legality of measures that are covered as TRIPS flexibilities. Any attempt to limit the scope of the flexibilities is rendered unlawful accordingly and has to be dismissed. The *topos of history* is used when arguing for an apparent unfair conduct the West is engaged in, since many developed countries only managed to go through the process of industrialization by producing copies on a large scale. In addition, the fact that pharmaceuticals have long been excluded from patent protection is used as another historical argument against the application of strict patent enforcement for medicines. Finally, the *topos of abuse* is employed to argue against market monopolies for pharmaceutical products.

#### 3.2.4.2 Network actors and their strategies

The actors of the network all share a goal or principled belief, which is the idea that access to medicine to those who need it should be provided to everyone regardless of

their individual or their home country's government's financial capacity. Their individual communicative and discursive strategies aimed at realizing this goal differ however. This also shows in their usage of different topics and topoi. Topics and arguments from trade policy are featured most prominently across all actor groups. Policy-makers, regardless of them representing industrialized or developing countries, appear to be most responsive to arguments brought forward that focus on the economic well-being of nations. While civil society organizations feature potentially life-threatening consequences of inadequate access very prominently in their statements, the WHO is mostly concerned with stressing that TRIPS is a very flexible legal framework that is incorporating numerous mechanisms that safeguard domestic public health interests and encourages member states to make use of them. Intergovernmental organizations of mid-income and developing country governments stress public health interests as crucial aspect to a country's economic performance. Alongside civil society organizations they are also most likely to accuse the WTO and their industrialized member states of showing neo-colonialist behaviour by forcing a Western-style IP regime upon developing countries, which they render a distortion of fair competition and thus a contradiction of free trade principles.

The Doha Declaration altered some of the discursive strategies of the network. This is also due to the fact that the discourse on IP and access to medicine has been receiving much less attention since this milestone achievement. Civil society organizations seemed to be the least pleased with the achievements of the declaration and continued to point at efforts of the pharmaceutical industry to impede enforcement through litigation and lobbying for bilateral agreements with TRIPS plus provisions. Their discomfort can be elucidated by the fact that their role in the discourse feeds from the existence of a public controversy, which explains their interest in criticizing the declaration as outcome despite it factoring several of their demands. Moreover, they were interested in keeping the discourse under public scrutiny. NGOs were advocating for a general reform and re-thinking of the patent system and its economic incentives, which they rendered false and in no way catering to actual innovation. The presentation of the Doha declaration as a solution to all TRIPS-related controversy thus threatened their larger agenda. The issue was taken out of the political and transferred into a complex legal and technical realm,

where it was much harder for the access network to reap their expertise as political campaigners.

Further, the last two decades have seen rapid changes in the landscape of world economy. The emergence and transition of several former developing countries to growth markets makes labelling developing or mid-income countries as natural allies to the networks' goals increasingly difficult. Some of the countries originally opposing rigid IP enforcement are now often in favour of their incorporation in bi- or multilateral trade agreements. While domestic public health authorities might still be very much in line with arguments of the network, those in charge of trade affairs, who are usually much more powerful than their public health counterparts, might try to push policy into the opposite direction.

#### 3.2.4.3 Framing within the Discourse

Since framing theory studies discourses as the venues of frame conflicts, I consider frame analysis qualified as a type of discourse analysis. Benford and Snow (2000) have described frame creation as a three-folded process with discursive, strategic and contested elements. The network actors have aligned several events such as the aggravated HIV/AIDS epidemic and the fact that pharmaceutical corporations have taken legal steps against measures set out to mitigate this crisis. Hence, they have created the frame of a greedy industry insensible to health concerns as soon as they see their profits at risk. They have amplified the discourse by successfully counter-framing the dominant view of policy makers that trade had to be given priority over health matters (Sell 2001). By introducing health policy into a discourse focused on trade, they have extended their own health-oriented frame with arguments from a trade realm in order to gain additional support from groups that wouldn't have been motivated if the access network's frames had been less inclusive in terms of topical coverage. All of their framing efforts were directed to the creation of a counter-framing to the prevailing and previously dominant frames generated by the pharmaceutical industry and reinforced by Western representatives at the TRIPS negotiations.

The access network has created a very powerful collective action frame (Benford and Snow 2000) that urged network actors and allies to publicly denounce practices of the pharmaceutical industry and pressure political decision makers to change legislation and policies. The strength of a collective action frame stems from its credibility, based on empirical evidence, the status of the actors, and consistency in their argumentation, and salience, given through centrality and commensurability with the target audiences' experiences in life, and resonance with their cultural values (pp. 614-622). The worsening health care situation in AIDS-plagued regions and the hypocrisy revealed through Western governments' reaction to the Anthrax scare contributed the evidence needed for the networks' claims to be considered credible by a larger public. The active contribution of organizations like the WHO that were commonly regarded as pools of expertise as well as the integrity associated with organizations like MSF helped building additional credibility in reference to the actors involved. There was however not much commensurability since Western public weren't especially confronted with sick people suffering on an everyday basis, yet widely accepted commitment to help people that face emergency, especially in regions with high levels of poverty.

#### **3.3 FRAMING OF POLICY PROPOSALS**

After having showcased how networks create public attention for particular issues in the first part of my analysis by describing and analysing the discourse surrounding the policy controversy on how to safeguard access to medicine in the light of a newly emerged and Western-style global IP regime, I want to answer my second research question why particular ideas brought forward within the discourse get more attention than others. I have already discussed the significance of the Doha Declaration, which clarified the applicability of TRIPS flexibilities and left it to the member states to assess whether their use is adequate ('t Hoen 2009). The two mechanisms granted in cases of emergency are compulsory licenses and parallel importation.

It seems that the production of generic drugs (with or without a compulsory license being issued) remains to be featured as a more viable measure to tackle access barriers. This does not only show in a more frequent usage in relevant publications, but also in the

attributes that are associated to generic production of drugs. In the MSF access campaign's mission statement, generic competition is called *the most effective answer* to constrained medical access. Taking the antecedent analysis of the overall discourse, I will examine why that is. Initially, I will give a short explanation of both mechanisms and then continue with the analysis.

#### 3.3.1 Analysis

First, there is a very simple explanation for why generic competition is rendered more effective than competition through parallel import, which has little to do with how activists frame it as an issue. It is a strictly economic argument. The production of a copy is much cheaper than the purchase of original medicine in low-price countries through traders (Interview 2). The margins are therefore higher in the former, which means they can sell at much cheaper prices than their parallel trade counterparts. The effect of an introduction of generic versions of a product is often showcased by public health activists through the case of first line ARV therapies, which brought down annual prices from several thousand to a few hundred dollars. Apart from this explanation, I'd like to name several other reasons linked to the respective policy environment, the policy actors and problems with communicating the issue to the target audiences.

Economists have warned of negative side effects parallel trade could actually have on the medical supply of developing countries. Contrary to its intended use as TRIPS flexibility as means of establishing access to medicines, experts have argued that it might in fact impede it. Notwithstanding the case that medical prices might in fact be too high for the local populations in developing countries to afford access, the average price level is still lower in absolute terms compared to Western and mid-income markets. While most Western markets have safeguard systems to prevent this from happening, parallel trade could flourish between developing and mid-income countries if endorsed by policy makers on a large scale. Buckley (2011) suggests a trade area similar to the European Union in Africa, which would establish a policy environment that could ease parallel trade and improve access within this area. Gallus (2004) argues on the contrary that in such a scenario the countries with the lowest price level would face the highest risk of medicine shortages. This is certainly a reason for why there were no attempts to stimulate and institutionalize parallel trade on a larger scale. Representatives of MSF have however

stressed that parallel trade is perceived as some sort of second best solution and mostly used to leverage pressure on the industry (Interview 4).

Another reason for parallel trade being less significant is its complexity as a policy mechanism. As I have outline before, domestic laws and the choice of interpretation of the right of exhaustion determine whether parallel trade is legal or not. Since the concepts of parallel trade and exhaustion of rights are somewhat technical and complicated, they are not really suitable to communication to target audiences. This includes policy-makers, who tend to be more responsive to technical terminologies. However, this also goes for grounds for a compulsory licenses and some of the provisions involved in that. The end product of the policy – generic drugs – are however easier to explain as equal value copies and thus graspable by the target audiences (Interview 3; Interview 4). The rather technical nature of the discourse has been a major obstacle to the campaigning of the access network. The discourse started to be mainly coordinative and remained being one with the exception of a short period with more communicative elements, where a larger public actually considered IP rights as an essential aspect to poverty reduction and health policy. The public interest has decreased sharply after the Doha Declaration. This was partially due the media losing interest. The underlying notion for this has been that the problems were largely solved in Doha.

Further, there is somewhat of a dubious appeal of parallel trade. Their practice of buying stocks of an entity other than the producer and then re-selling the product under a different label can easily be deemed fraudulent and unlawful. This presumption is fuelled by representatives of the pharmaceutical industries, who have promoted a general ban of parallel import in TRIPS and continue to do so through bilateral trade agreements that include TRIPS plus provisions. The fact that in some countries and regions parallel trade is indeed already illegal due to the respectively applied exhaustion of rights principle doesn't exactly help the case (Interview 3).

In addition, parallel trade creates little or no incentives at all for the domestic industrial development in poorer countries. Generic production, including manufacturing under a compulsory license, on the other side, can contribute quite considerably to the industrial

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growth of a domestic industry. Several examples, most prominently India, deliver living proof for this. Governments in developing countries can thus support manufacturing of generic drugs for reasons other than health concerns, since it could additionally help their countries' industrial and technological advance. As I have already discussed before, a country's health administration is usually a weak player in intra-governmental power struggles, while industry policy plays a superior role (Interview 2; Gallus 2004).

A fifth reason is that the Doha Declaration already pretty much clarified that parallel imports are legal under TRIPS and therefore not much more campaigning was needed thereafter. This was not the case for compulsory license, since the case of exportation of products manufactured under a compulsory license was only resolved two years later. The fact that the hurdles to the granting of compulsory licenses were not really lowered even after the declaration, served as promising ground for the access network to continue campaigning. Parallel trade has never been a priority item on the network's wish list. I rather received the status of a second-best solution in cases where generic manufacturing was not realizable (Interview 2).

Having said this, it appears that there is more substance to creating a strong frame for generic drugs as possible solution to enhancing access to needed medicines. When specific ideas are incorporated into strong frames, they are more likely to become dominant within a discourse. I would like to apply this on a comparison between parallel trade and production of generic drugs. The criterion that best describes a frame's strength is its resonance. Frame resonance is defined by relative salience and credibility (Benford/Snow 2000). Compulsory licenses have been used many times already by many developing countries, and once even by Canada, whose government issued a compulsory license to produce drugs for Rwanda. Parallel trade on the contrary is only practiced on a large scale in the European Union. There is very little empirical evidence for its effectiveness in facilitating access to medicines and developing countries' hesitance to embark on it raises additional doubts. In terms of consistency of the frame, reports of medicine shortages in European source countries of parallel trade can pose a possible obstacle for the access network to use it as a part of a policy proposal. This

could very well also be an explanation why the access network does not seem too keen on further promoting parallel trade (Interview 2).

Salience consists of centrality and commensurability, which addresses that the stories told through frames apply to the target audiences' everyday experiences and are somewhat relevant for them, and narrative fidelity, resonating in the cultural values of the audience. Due to the complexity of parallel trade, it can be doubted that the audience can relate to the mechanism and link it to their daily experiences, provided they are not expert on the issue. Even though compulsory licensing is not less complex, at least most people know where to put generic drugs, which has already been said in one of the interviews (Interview 2). In terms of resonance to cultural values, parallel trade's slightly dubious bytaste, as I have already outlined briefly above, can be understood as theft and would therefore be condemned as practice by large parts of the world public. Explaining the legality of parallel trade would be a c complicated task for the access network.

## CONCLUSION

This thesis investigated the role the TAN played in the discourse on intellectual property protection and access to medicines and the way the network framed two policy mechanisms – production of generic drugs through compulsory licensing and parallel import – differently that were proposed as means to overcome barriers to access. The embodiment of a of wide array international and intergovernmental organizations of various social spheres qualifies the access network as TAN (Keck and Sikkink 1998). Through actively recruiting other organizations for a cause, the TAN was able to broaden its access into the discourse and thus its influence on international decision-making bodies, such as the WTO Ministerial Conference or the WHA.

As I show in the empirical analysis of nine constitutive documents of the TAN, the network succeeded in effectively altering the entire discourse. They did so by introducing elements of health policy into an originally strictly trade-oriented debate and alerting the public of the detriment an overly strict IP regiment could bring upon the developing world.

In addition, the network blamed medical patents for access impediments for poor people, which generated a direct link between patent law and access to medicines. The creation of clear causal chains and the identification of groups responsible for continued malpractice have helped the TAN in their mobilization of potential target audiences (Stone 1989) and shows that naming and shaming tactics were employed as leverage (Keck and Sikkink 1998). Seeming hypocrisy on behalf of governments of industrialized states in their refusal to accept relaxations of patent laws became evident when the 2001 Anthrax scare led public agencies to reconsider their own tough regulations. This enabled the TAN to utilize accountability politics (Keck and Sikkink 1998) intended to expose of gaps between stated commitment and actual practice of decision makers, which jeopardized the governments' public credibility ('t Hoen 2009). The introduction of public health concerns into the discourse further helped network actors gain credibility seeing that many of their advocates were seen as experts in their field. Moreover, promoting the fact that public health has implications on the overall economic performance and therefore also the trade policy of a country helped the access network to gain support from domestic policy-makers. In addition, the fact that expert organizations like the WHO joined the civil society's cause through the campaign, provided additional legitimacy and credibility to the access network's demands (Sell 2001). The TAN was not equipped with the same financial assets the counterparts from the industry and, initially, also lacked official political support. Their success, I argued in this thesis, thus stems from the strategic use of ideas.

The nine source documents I have selected to conduct the first part of the analysis represent the three network member organizations I have selected. Sampling was based on network members' social domains. This includes the civil society, as well as the domestic and the international public sector. The three organizations I have selected are MSF, the WHO and the South Centre, which as an IGO represents the domestic realm. In addition, the documents can be located temporarily either prior to the release of the 2001 Doha Declaration, in the declaration's immediate aftermath, or in its intermediate aftermath. I have selected one document per time period and network member. Following Wodak's (2001b) argument that the macro-topic is the most salient feature of a discourse, I have identified the theme of the documents as intellectual property rights and access to

medicines. Through manual coding I have identified and isolated seven discourse topics. These are (1) Misconduct of the Pharmaceutical Industry, (2) Abuse of Market Power, (3) Fair Trade and Competition Policy, (4) Post-colonial Hegemony, (5) Industrial Development, (6) Profits vs. Lives, and (7) Rightful Conduct under TRIPS. I subsequently analysed the TAN's use of these topics following Wodak's discourse-historical approach.

Discursive events take place within different fields of action, which describe the institutional settings of a discourse. They find expression through semiotic tokens, such as texts, and can be classified into different genres (Wodak 2001b). The analysed discourse spans across four fields of actions: legislation, formation of public opinion, the development of an informed opinion within the network, and the political administration. Text documents relevant to the discourse include genres such as the texts of treaties and national laws, as well as press releases, reports, or speeches. These texts can also be assigned to several discourses and relate to each other, which ensues the condition of intertextuality. A discourse can be influenced and affected by other discourses. In the case of the discourse analysed these are public health, as well as trade and industrial politics, and IP law. When multiple discourses refer and relate to each other, interdiscursivity is granted. The introduction of narratives from public health is an example for interdiscursivity in the case discourse, which can also be provided through links to theory. The notion of TANs as influential discourse partakers, who can shape policy through non-traditional discursive means of power exertion, roots in theoretical concepts such as global governance. Moreover, the access network's argumentation aimed at depicting Western governments and corporations as abusing their market power to exploit and bar people in developing countries from access to much needed medication feeds from notion of a Western hegemon in a post-colonial world.

My thesis produced several theoretical insights about the process of TAN framing. The network's overall goal is to change the public perception of patent protection in relation to medical access. Therefore, the network aimed at modifying the discourse through framing. Accordingly, their discursive macro-strategy can be labelled as transformative because they were seeking to alter an already existing discourse rather than constituting a new one or dismantling it in its entirety. Within the transformative character of their

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macro strategy, they have also employed a wide array of discursive strategies. These include referencing, predicating, arguing, representing, intensifying, and accountability politics. All these strategies are aimed at simplifying and generalizing complex phenomena in order to create dichotomies between different stakeholders and create clear causal relationships in order to blame or hold particular actors responsible for a situation rendered unfavourable. This has helped them mobilize potential target audiences. Lastly, discourse actors used different topoi, which are ideas that serve as link between an argument and a conclusive claim. Based on a list Wodak has used to assess discriminatory discourses, I have selected nine topoi. This list includes usefulness (and disadvantage), danger, humanitarianism, justice, responsibility, reality, law and right, history and abuse (Wodak 2001b: pp. 71-77).

There are discrepancies between how the different actors within the network discuss the problem. These disagreements also imply that different parties employ the discursive strategies dissimilarly. MSF is least likely to use arguments located in trade policy and most likely to talk about health concerns, while the South Centre mostly talks about the implications public health has on the industrial development and trade of its member states. This is also due to the fact that their target audiences vary. While the WHO and the South Centre are mostly interested in addressing government officials and policy practitioners, MSF is also interested in gaining support from a wider public. This also explains MSF's sometimes emotional and dramatizing story telling in the analysed documents. Further, a shift in argumentation has also occurred after the Doha declaration was passed. A lot of the criticisms against TRIPS in its pre-Doha state were tackled with the declaration. No more campaigning was thus needed in some regards.

Thanks to frame analysis, I was able to isolate several reasons for why the idea of producing generic drugs appears to be a better fit for TAN framing than parallel import. First and foremost, generic versions are cheaper than re-imported originator drugs. On the other hand, there are also more complex and policy-related issues for the relative prominence of generic drugs. This includes potential negative side effects for the medical supplies of the countries with a lower medical price average, which would be the attractive sourcing countries in a more formalized and better-established parallel trading

scheme. Another issue is the extreme complexity of parallel trade as a policy tool. It is therefore very hard to communicate as a feasible way to potential target audiences. Proponents of the instrument therefore face difficulties to communicate its feasibility. In addition, parallel import has in the past been perceived as a dubious business practice. This is partially owed to the fact that the pharmaceutical industry has put efforts into framing it as fraudulent and unlawful. In some countries, parallel import is in fact considered criminal due to the respective countries' exhaustion of property rights clauses. Moreover, parallel import creates very little incentives for the domestic industrial development of a country. The production of generic drugs requires accurate production facilities, whose construction has proved quite fruitful for some countries, as the case of India and its role as main medical supplier to developing countries most remarkably shows. The high barriers for entry are also the most probable reason why trade representatives respond more positively towards generic manufacturing. Lastly, little uncertainty remains about the legality of parallel import in TRIPS with the clarifications passed with the Doha, which renders it unnecessary to address legal concerns in the public discourse about IP and access to medicines.

Apart from the cost argument, the comparison aginst Benford and Snow's thesis is showing that the complexity of parallel import as mechanisms appears to be the most compelling reason for its relative underrepresentation in comparison with the production of generic drugs. Complex contents are hard to communicate to target groups and therefore also harder to frame within the discourse. The somewhat dubious appeal to public audiences due to the structure and considered appropriateness of the business model further renders parallel import a tough sell.

As with all empirical research, my thesis has some methodological shortcomings. For one, the scope of the project only allowed for analysing a limited amount of textual documents. A bigger amount of longitudinal source documents would have made it easier to document discursive changes over time within the discourse more comprehensively. Future research might also include media reports as illustration of how the public ultimately consumes the information broadcasted by the TAN. Owing to the fact that the defining events of the discourse took place over a decade ago access to more

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encompassing data is difficult. Therefore, a bigger interview sample including experts that have been involved in the debate before and at the time of the Doha Declaration might have yielded additional evidence for the framing power of the access network. A last limitation is that my text data is limited to successful framing attempts: the lack of being able to include evidence for unsuccessful framing strategies can introduce sampling bias. Based on my interviews, however, I am confident that the documents reflect all relevant attempts to influence the policy discourse on part of the access network.

Finally, my findings have a number of implications for policy. My data illustrates that parallel import might be an accurate short-term policy tool to overcome temporary shortages. As I have shown through my analysis however the access TAN only attributes minor importance to parallel import as an alternative policy tool to facilitate access. Moreover, as the European case shows, the benefits from parallel trade for national health care systems are ambiguous and specialized traders absorb most of the revenues (Kanavos/Costa-Font 2005). Nevertheless, a free trade zone with a regional exhaustion of rights regime among the LDCs of a region could have positive effects on short-term medical supplies and serve as a temporary solution during emergencies (Buckley 2011). Yet, fostering parallel trade is however not long-term solution to coordination the market for pharmaceutical products, because it does not question potential detriments a rigid patent regime can have on the overall society. One of the TAN's recommendations is therefore the establishment of a patent pool (Interview 4), where patent holders can voluntarily pool their patents via a multilateral agency that can then issue licenses for generic producers in developing countries. While the UN has thus established the Medicines Patent Pool in 2010 ('t Hoen 2009), the pharmaceutical industry has remained reluctant to consider such mechanisms as viable to established practice.

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#### Interviews

- INTERVIEW 1: Jørgen Clausen, Chief Economist of the Danish Pharmaceutical Association (LIF), June 9th 2015 at LIF Headquarters, Lersø Parkallee 101 in Copenhagen
- INTERVIEW 2: Ellen 't Hoen, Director of the Access Campaign 1999-2011, June 4th 2015 via Skype
- INTERVIEW 3: Yuan Qiong Hu, Legal and Policy Advisor at Doctors without Borders (MSF) International in Geneva, June 15th 2015 via Skype
- INTERVIEW 4: Philipp Frisch, Coordinator of the Access Campaign at MSF Germany, June 12th and 26th 2015 via Skype

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## **APPENDIX**

#### INTERVIEW 1 (JØRGEN CLAUSEN)

Jørgen Clausen is Chief Economist at LIF (Association of the Danish Pharmaceutical Industry).

Just to give me a little introduction - what is your role at LIF and how does your daily work look like?

JC: My name is Jørgen Clausen, I am chief economist. I'm working mainly with the hospital sector, with vaccines, and in general more or less responsible for all of our economic analyses of the market developments. Now and then we have a focus on generics and parallel import. But I must say that today we have learnt to live with it. In former days, PI was a really huge issue and generics also, but today I think it's fair to say that it's a part of the business conditions in Denmark even though we also have a quite huge share of PI in Denmark, you're probably aware about that.

Why is it that the situation has changed to the extent that pharma has learnt to live with it? What were the triggers?

JC: Well, I would dare to say the time. I mean the time aspect. And that's what you normally see in this area, when you're having new legislation and new regulation. We are always furious about what's going to happen, but now and then we will see that that's the way that the authorities want to save some money and so, well, that's the way we have to deal with and then the show must go on. Of course there must be different ways of how the original companies are dealing with PI, I mean some are partly financed by PI of their own products. You are probably aware of that also. So, it's not a direct competitor so to speak, because well some of the sales of the parallel importers are going back in the sales of the original manufacturers.

#### That works through reimbursement schemes?

JC: No, it's through the internal, how each company operates in Europe, I mean, they earn money, some earn money in Greece or Portugal for example, then by selling the products there and then the companies get compensated somehow in Denmark. And I

think there are different ways how companies are handling. So that's I think one of the financial reasons why some companies are not so eager to have a fight or a competition with the PI.

Can you quickly give me a quick explanation in your own words what PI actually means?

JC: I think it's basically it's quite simple. You have a Danish parallel importer going down these Southern European countries making deals with the wholesalers in different countries and all that. They're making a lot of different deals with the wholesalers in Greece, Portugal, Spain, and then, they will re-export it to Denmark and sell it in the Danish pharmacies, or I think it's quite an easy topic. And of course, I think one of the interesting questions is, what about the consequences of parallel import, I mean I think that's what you are going to make some conclusions also about. Does it stimulate competition, or what? I mean I have for some years back, I did have a rather tough dialogue with some guys in the York University because they issued a report and they said, well, look at Denmark and how effective PI is to stimulate competition and they showed it with several examples, that where, well at that point in time you might see that the parallel importer have the impact of increased competition and lower prices and my criticism was that well, dear academic friends, this drop in prices was due to a new legislation in Denmark, and not due to competition from parallel importers and I think that was a general conclusion they had that I was not agreeing with this conclusion. We did here in Denmark have a slightly different insight in the market and I allowed myself you have made a wrong conclusion.

But if, as you say, stimulated competition is not necessarily an impact of PT, what are impacts of PT, also for national health care sectors or patients.

JC: Yes, I think you might have some impact. When you have the price of the original products here, you will see that the price of the parallel imported product is slightly below. In Denmark they say, if the difference is less or more than a certain amount, I think 5% or 20 DKK, then the pharmacies are obliged to substitute to another product. This means if they are just 5% below the original products, then the pharmacies should deliver the cheapest product for the patient. Otherwise, if it's below this percentage or below 20DKK,

they have this triviality limit, so they can make their own decisions. You will see that the price of parallel imported products are quite close to the originals. My point is, well you have some price cap agreements, ensuring that the prices can't be raised for, well, a very huge part of the market, it means that we can't raise our prices normally for re-imbursed products, but if we could do that, you would see that if an original product has been raised by 1000DKK immediately you will see that parallel importers are going after. But due to those triviality limits. And my point is, well, if you would have the same saving just on a larger amount but, well, the real question is, if we see such a behaviour are you stimulating competition at all and thereby creating savings, I think this is more or less the very basic question for the Danish market for PI.

## Looking at the source markets. What effect does PT have on them? Are there any adverse effects?

JC: Yes, yes. I think now and then it has been argued, I can't remember this discussion recently but it has been argued indeed also from Norway that the re-export from those countries are so huge that they can't secure their own markets. In Norway, one of the richest countries in the world but with the lowest prices! They have had the problem that some cancer products because they are very tightly regulated by those international reference prices, so they have experienced the re-exports of the cancer countries and thereby leaving a hole in the Norwegian market because some of those products are somehow difficult to produce so the companies might run out of stock and it is not so easy just to fill into the gaps immediately, so there have been those problems, but you have also seen these problems in the Southern European countries.

So, to sum up, who benefits from this whole situation? Since trivial price raises and access countries, the patients and the health care sectors are not really benefiting from that scheme because they don't really save money on medication.

JC: No, I think it's questionable. Of course you can say that, well, if you have a difference in price, add it up to some amount, you could argue that there are of course some savings and of course if it's a little bit cheaper, added to the amount of course you will have some kind of savings, but the background mechanism, which I've raised here, well is it on a higher level, so to speak and thereby, is it a real saving or is it somehow artificial.

As you said before, the industry has learnt to live with this, are there any responses that the industry takes in facing this issue or have there been any sort of efforts?

JC: Yes, you have seen as far as I remember there have been a couple of cases, which has also been sent to the European Court, was it GSK? Was it them? Was it Pfizer? Bayer? They would only deliver packages to Portugal for instance of a certain amount of packages so that would ensure the Portuguese market. So they would put a limit on how many packages they were able to deliver in order to avoid the re-exportation to other countries and thereby PT. I think it was also in the European Court of Justice and there was a decision, it was allowable somehow to have this kind of rationing for each market but I think it's quite easy to find it. I think another mechanism was that one company did a two-tariff price structure, one price for those products being sold domestically and another higher price to those products being sold to PI, so I think that's the two mechanisms that I can remember we have seen that were used to defend your market position or to limit PI.

Have there been any initiatives, who decides what sort of steps there are taken? Is there some sort of common effort of the industry or is this always on a firm-level?

JC: It's on the firm level. I think it would be very dangerous if you saw that LIF as a branch organisation trying to make some steps, or trying to avoid the competition, it would be very problematic in a legal sense, we are representing the research-based companies, and of course that's our members which are parallel exported and imported around in Europe, so it would be a little bit dangerous. Of course we should ensure and we have discussions on whether safety is good enough when we're talking about PI products. We recently had a discussion about the need for some certification that each batch which will be parallel imported that you should prove from where these products were coming from. But they don't have - even though it is stated in legislation - some sort of control certification. We have also raised our concerns to the national board of health but it is also again a huge European issue, that it would be very difficult to have these things changed because you have, they have recognized that it is more or less impossible and the parallel importers will say that we can't get those certifications

because the original producers won't deliver them to the wholesalers around Europe. But again, basically we have learnt to live with it, it is the companies' own product. Of course the other issue about the access and I'm not sure of how big of a problem it is because it is basically quite simple to avoid parallel import, I mean having a flat European price would somehow limit PI, but of course it is difficult if you have such big differences and how you're regulating and also wealth differences. Of course you also have price negotiations in some of these countries, so it is difficult to set the price according a flat level, but you should somehow recognize that the ability to pay is different among the countries. In Greece, it doesn't matter, companies won't have their money at all from Greece, I can't remember how many billions the hospitals in Greece are owing the companies.

Now that you mentioned that in DK there is a scheme with a certain price cap where pharmacies are obliged to buy PT products, and a similar rule in Germany, so would you say that the states actively push PT?

JC: Yes, of course! I think it is the basic idea that at first sight you might have some savings to the in principal small price differences, but in reality you enforce a different pricing structure, but for sure it is the intention to stimulate the consumption of the cheapest products. One thing is generics, where you have quite huge differences especially compared to PI, where it's minor differences in the end.

Can you quickly give me a heads-up on the actual legal basis? Why is PI legal? Is this only across Europe, what is the basis for this?

J: I think it's more or less legal in all European countries. I think the argument is securing the free mobility of goods across countries, I think that's the goal they are trying to pursue and why they make this legislation that supports that. But I think it's also the official European statements you will see about PI, but I think they have more or less got it wrong because I mean, the goal behind the free movement of people and goods is to show the most efficient products in Europe, and I mean that's fine and of course. But in this area, I don't think you can argue that it would increase efficiency in the production. Not at all! In fact you would have a kind of waste, because you're moving goods from A to B and back again, where the profit is going into nothing, or to the owner of PI. So you

won't see re-investments in research and development. But I think basically it is based on the intentions of free movement of goods/persons.

You talked about two major issues, product safety and then access to medicine. Are there any contacts that LIF/the industry has to patients' organisations, are there any common initiatives, especially when it comes to the access problems?

JC: No, not really, not from our perspective.

Why do you think that is?

JC: Well, I think that might be the case in some of the Southern European countries, where you have problems in securing supply, but I'm not aware of any concrete example. Because, well, patient organizations are really concerned that you have the accessibility of products and it is of course a problem, when, well, all the cancer products are sold out because they are re-sold to Denmark or other richer countries. But, I think, well back in time, there might have been some concerns about the safety of when they're repackaging, etc., are the right products or pills going into the right packages but I don't think we have these kinds of dicussions anymore. Of course they can handle more or less both transportation and the re-packaging in a secure way, I mean, we would have probably heard a lot of stories if there would have been major problems in that area, but I don't think, I can't remember. There has been one example of falsified medicines, a little special issue. It was in fact a Danish parallel importer who sold some falsified medicine in Finland. But it was a special occasion.

Turning to Generic drugs, you already mentioned those, that they are significantly lower priced, what are generic drugs?

JC: It's copies of the original products. The same active ingredients in a chemical sense. We have some, perhaps you are aware of that, slightly different wordings when we talk about off-patent biologics, biosimilars, a very huge topic also today in Denmark. Perhaps you have heard about that. They have just decided recently to allow that doctors can change the medication of well-treated patients into another, biosimilar product, even though there is a lack of evidence about the patient safety issue. We are all very alert on that area. But it is a special occasion on the generic topic, but for sure in Denmark, the

generic competition is very effective. And it is due to the fact that we have these limits for substitution. If you are the cheapest product outside this limit you have the more or less whole market for a period of two weeks, this price period. So you will see in general, when a product goes off patent, the day after, so to speak, you will see a price decline of 80-90%, something like that.

### And is there any way the industry reacts to generic drugs?

JC: No. Well, now and then you are hearing some, well it's very rare, but some companies are trying to make a business out of the Generic segment and going into a price competition, and you will see that a small comment also in PI, well some companies are in fact trying to compete on prices with parallel importers but as we start to discuss, I mean, some companies are not so concerned about that.

### What is the effect of generic drugs on parallel import?

JC: You will see that, when you have generic entrance you will see the price drops, and second that the parallel importers are pulling out of the market. I mean, well immediately also, they are not going to compete with those generics. It's quite interesting, you will see that when generic competition the original product goes like that, parallel import like that, and generics go like that. It goes very fast.

Are you aware of parallel trade being an issue outside of the European Union?

JC: No, not really, no.

What would be your personal recommendations for the industry in how to face problems like PT?

JC: I think it is somehow a complicated game, because you as a company, you have the overview of the European market, you know quite well how to price and how to negotiate prices in different countries you know quite well that the risk of re-exporting to other countries and thereby somehow reducing your sales, and other countries, so I think that companies might have a quite good overview and of course it is should be in principle possible to say could we have our profit, do we gain a larger relative profit by selling it in Greece and then losing some sales in Denmark, a rather small country. So, I would think

that you can omptimize somehow looking at the European market as such.

You mentioned that the easiest way to tackle PT would be to have harmonized prices ...

JC: Yes, yes, yes, I mean that would be very simple but you will have the difficulties in, it would give so high prices in these Southern European countries that you won't sell anything and in addition you might have price negotiations, where it would not be accepted to have pan-European prices in Greece. But we have a problem, as I said Norway, they would have a very low price on the other side, they would also not accept a pan-Europe. They calculate their prices by using the three cheapest countries in a basket of comparable countries, the same basket that we are using. So it could be different to have one flat European pricing system, but I think some companies are giving it some thought, well indeed you should have this price curve going from a low price in Greece and a high price in Norway, according to the willingness/ability to pay, or Ramsey pricing. But we do have these international reference pricing system, companies and countries are comparing prices with each other and thereby you get artificial price development. And it is generally a problem, because I think we in Denmark we are also relatively, considering our wealth the price of pharmaceuticals is not that high either.

#### Even thought Denmark has one of the highest prices.

JC: Yes, I remember some of the prices, from OECD, showing that if you have somehow the wealth and the prices of medicines you should expect this, that they are moving along a line, and you will see this for a lot of countries. But in Norway, the prices are very low and Denmark is placed on the lower side of the curve, you will see this for nearly all goods. The wealthier a country is, the higher the prices are normally.

One more thing about the access problem, so when the industry tries to limit or restrict the amounts of exports to countries that a typical source countries - don't you think that that might actually aggravate access problems or does it actually change it effectively?

JC: Yes, I think if you can control it, can you ensure that the adequate number of packages gets delivered, then it should cover the national market in Portugal. I mean it

could be quite problematic and difficult to control it with the wholesalers, because if they can, in Greece there are sales and profits to sell large amount to a parallel importer every now and then, it could be, plus you have several wholesalers in those countries.

### So that might actually increase the problem?

JC: Yes, I think so. It's always difficult to control a lot of actors. In opposite to Denmark, where we have those two, it could be more easy if we had that problem. But I don't think it's that relevant here, with parallel exports.

Wholesalers are only allowed to buy from sources from within Europe?

JC: Yes, yes.

There's no parallel import coming from outside of Europe?

JC: No.

Because that's not allowed?

JC: Yes, I think so.

### INTERVIEW 2 (ELLEN 'T HOEN)

Ellen 't Hoen is the former policy and advocacy director of MSF's access campaign and an expert on medicines, law and policy.

You've been very much involved in the access campaign and you've been serving as the campaign's director of policy and advocacy, can you briefly summarize what the campaign is/was essentially about, who are other campaign actors involved, what are the main obstacles to access and what/were the milestones achieved by this campaign so far.

EH: A lot of that has been written up so I'm not going to spend a lot of time talking about things that you can find that have been published. You should have the article A Decade of Campaigning in relation to HIV medicines. So that gives you a lot of the answers to this. A quick summary of the access to medicine issues is that you can break it down in

following categories of problems, one is access to medicines that are new and expensive, those are mostly patented. Then there is the problem of access to medicines that are needed that did exist but stopped being produced, that's another category of access issues. Then there are the products we don't have access to because they are simply not developed, which is a research and development issue. And that was how MSF framed it about 15 years ago, and that was of course also very much against the backdrop of a rapidly emerging HIV pandemic, where people were dying at a very high rate in developing countries and while in the North the highly active anti-retrovirals had become available. Often when we talk about access to medicines, it's in the context of HIV/AIDS but the HIV/AIDS case has shown us what would of course subsequently happen with all newer medicines. And that situation that we are in now, in particular patenting has become widespread in countries where in the past pharmaceutical products were not granted patents and those countries were traditionally suppliers and producers of lowcost and also new medicines. That no longer is possible. So, there's been some progress on HIV/AIDS, also where companies now have acknowledged that they should license their patents but that is not happening in other diseases. That's the situation today as compared to let's say 15 years ago.

## Can you give me a definition in your own words of what Generic drugs are and what Parallel Importation means?

EH: A generic drug is a bio-equivalent, a medicine with or without its own brand that can be used as a substitute to an originator product can either be produced because the patent doesn't exist or because licenses are available either voluntary or compulsory that allow the generic companies to do so.

Parallel Importation is the importation of a patented product or originator product where it is sourced from a place where it is offered by the originator at a lower cost. There are some other definitions, that says parallel import is the importation of a medicine without the consent of the patent holder, which would include the parallel importation of generic medicine, that is for example the case in the Kenyan law.

Do you see that there might be any adverse effects to the access the medicine in developing countries through parallel importation?

EH: Negative effects? Well, if you look at the evidence where countries have used PI they have been able to access lower cost medicine, so, I don't quite see where the negative effects come from.

Looking at PI in Europe, pharmaceutical corporations have been arguing that this might impair access to needed medicine in source countries. Do you see that threat?

E: No. It hasn't really been a problem in Europe either. The companies manipulate the market and they might withhold supply, which I would think is rather dishonest and I think gov't should intervene when they do that. The beauty of the single market is precisely that we can purchase anywhere in Europe and that there are no barriers to trade within the common market. Companies are saying we can't offer our products at lower prices in countries in the EU where the income levels are lower and I can see that that is potentially a problem but the REAL problem is that the prices are set to high, period. And if they would be priced at more reasonable levels you wouldn't get the kind of PT within Europe that we have seen. You have to be very careful to not confuse the European common market debates on PT. It's also raging of our polls and other products with the use of a definition of a PI that has been used by developing countries to allow the importation of generic antiretroviral medicine despite the fact that they were patented. But again that has only been practiced at a very small scale. I think Kenya is the only one that has used that. But what has been used much more widely has been government use, the use of Paragraph 7, waiver for LDCs, these mechanisms have been used much more widely for the importation of generic medicines than parallel importation.

Looking at press releases and other briefings from MSF Access Campaign Webpages, it seems that generic drugs have a much more prominent role as a facilitator access. Why is that?

EH: Well, because the price is much lower.

### And there are no other policy-related reasons for that?

EH: Well, PI means you import the originator product that the originator has priced at a lower level, for instance if you look at the prices of the ARV offered by GSK in India, they

are much lower in India than in South Africa. In India they have to compete with the generics. Or had to compete with the generics. So, these products were patented in South Africa. Now, South Africa could do two things, either issue compulsory licenses or make gov't use and import further generics. Countries that are reluctant to do that, they can pay slightly more and parallel import the GSK product directly from India. That way, there are no patent issues involved. But then of course you pay slightly more, because the originator product is hardly ever priced lower than the generic.

Are there any policy barriers to PI? Do you think that Generics are treated lighter by national legislation or is that not really the case?

EH: I think it's very difficult to compare it. I think there are countries that have international exhaustion, and there are countries that do not. But the use of the wider TRIPS flexibilities that helped authorize importation of generic medicine has been much, much, much more widespread and has been very effective, I think the PI discussion is much more one that the industry doesn't like, because if you have international exhaustion, they lose control. People start to shop around on the globe for the best deal, which is by the way what free trade should be all about. The companies don't like that. They argued for a while that that type of PT was not possible under WTO rules and that would have further limited what countries could do. So it was very important to have that clarified. That was done in the 2001 Doha Declaration on TRIPS and Public Health, which made it absolutely crystal clear that there were no barriers whatsoever deriving from intl. Iaw or WTO law to PT of medicines. So that was a very useful clarification. So you should see that in the context of a pushback against one of the many attempts by the industry to limit what countries can do.

#### And there are no differences in qualities between generic drugs and PT drugs?

EH: No, well, you can have good quality PI drugs, you can have bad quality PI drugs, you can have good quality generic medicines and you can have bad quality generic medicines. That depends on very different things. In the field of HIV, because of the WHO pre-qualifications there are very reliable sources of generic medicines. When you do PI, meaning you're buying the GSK product that comes with a GSK regulatory dossier so you can assume that that is reliable source. Where you have to be careful, but that applies in

both situations, those who have the procurement have reliable supply chains and you need to know where the drugs come from. But that's the case in any scenario.

How do you see the role of developing country governments, is there some sort of unanimous stance on generics/PI?

EH: Taking into account that PI and Generic medicines are two very separate issues, countries have different approaches to generic policies, some are more rooted in health policy than in others. India's policy is very much an industrial policy while the South African actually also, the policy in Thailand is much more driven from a health policy perspective, where they go through rigorous process to determine which products they need and then figure out what the best way is to bring the cost down, so there's huge diversity. But there, is with regard to the need for generic, low cost generic medicines an intl. consensus, if you look at what comes out of the WHO, the WHA, the recommendations there, it is very clear also if you look at the price data, that robust generic competition provides the most effective way of bringing prices down. With regard to PT, there is a clear WTO consensus that can get any better than that. In the Doha declaration, which all member countries of the WTO have subscribed to.

With TRIPS+ Agreements that are being implemented through regional trade agreement and the US is also a fairly fierce stance on PI, so there might be some restrictions through regional...

EH: Oh, yes! As I said, the pharmaceutical industry they'll use whatever they can including the regional bilateral trade agreements, will always use these venues to further restrict and that's also why it is important to stand up against that, which is much easier in a multilateral forum than in a bilateral forum, developing countries can organize their positions much better and have a much stronger negotiation position in the multilateral trading system than they do in the regional or bilateral.

Do you see that there is a government that is kind of heralding access to medicine more progressively than other countries? Some sort of stand-out when it comes to establishing that sort of access?

EH: Well, it's mostly the countries that also have a good health policy that have stood out.

Thailand is an example, Philippines is another. South Africa came a little late, but is also on board. As I said, India is more of a industry-policy driven. But there are also within countries battles between the health ministry, which is usually a weak ministry, and the trade ministry, which is often a more powerful, or finance. So it will always be a subject in motion, so it's very difficult to say that this country takes that position, that country takes that position. Take a country like Brazil, which has been very outspoken on these issues, but there is a continuous internal battle going on about it. It can be fairly complex.

So even within countries there might be very different stances towards those issues.

EH: Yes, absolutely.

What are your proposals to best and most effectively facilitate access to medicine? What is the exact role of generics and PI in those proposals?

EH: Well, I think we need to move to changes in the way we finance R&D. And have a much greater demand on licensing coupled with the expenditure on R&D including the purchase of the medicines. Today, pharma really calls the shots, and they keep saying it costs so much to develop these drugs, we need these high prices. But if you would separate the R&D markets from the sales, you get an entirely different ball game, so you could actually have financing for the R&D, so market for the R&D but have products go to market as generics. A competitive generic market gives you the best price, everyone knows that. In a way, PI is second-best. If you have patent barriers to accessing the generic medicines, that's what you do. But even to be able benefit from better prices to PI you would need some generic markets, otherwise these originator products would not be offered at a lower prices elsewhere. So, key to solving the access and some of the innovation challenges is by separating the market for R&D from the marketing. And that's what some people call de-linkage. And that will also be the subject of discussions that are now ongoing or will we re-start at the WHO on a global treaty to make fundamental change happen.

Since PT has driven down medical prices in Europe, would you see that a similar scheme might work for developing countries?

EH: Well, they should make sure that they have that policy freedom but if you look at the African region, because the majority is LDC, they could, as a region, benefit from importing generic medicines and trade them within their regional trade area. I would not put the emphasis on PT as the way to go, it's something that they by all means need to protect as something that they want to have access to, but the most important thing for Africa is to organize themselves at the regional level is to make sure that they can import or produce generics and trade these generics within this region. Africa, actually has several legal options because the majority of their members are LDCs.

### So they have longer periods of implementing patent protection?

EH: There's the paragraph 6 that allows regional trade areas that have LDCs to purchase or produce generics for use within the area and they can then trade within the area. There are many options that will help increase access to the generics. And that's what you need, certainly, if you could make recommendations for a regional markets, which would have the benefit of an economy of scale creation, you should focus on the generics.

Since we have talked about definitions before, where you said that there's definitions that include generic trade in PI, so that would be a case for that. PI of generics within a regional trade zone.

### EH: Yes, except that you don't really need it.

Do you know of any position paper by MSF, where the actual stance on PI is laid down, because I haven't found that and maybe you know something. Or is there no real need to lay down.

EH: In a way the issue of PT was a bit put to rest with the Doha declaration. People in MSF were involved in operationalizing a creative interpretation in Kenya at the time. I think I wrote something about that in my book. I think there's something about that in there. And then the other person, who has written about that, is Carlos Correa. And Fred Abbott.

Why exactly is it that PT was put to rest with the Doha declaration?

EH: Well, the Doha declaration says that there are no restrictions on PT deriving from the TRIPS agreement. That is, I believe, paragraph 5 of the Doha declaration, if I remember correctly. Yes! (Reads out the paragraph.)

At that time PT was very much advocated by developing countries, or why is it implemented in the Doha declaration?

EH: It was clarified because there were people and a lot of pharma lobbyists who said that TRIPS prohibits exhaustions of IP rights, which means you can't do PI because of the TRIPS agreement, the Doha declaration clarifies that that is not the case.

### This was mostly pushed by developing country governments?

E: Hm. Well, probably the EU supported it also. I wouldn't say it was mostly pushed; it was an important item for developing countries to have that clarification but it wasn't the most crucial one.

### INTERVIEW 3 (YUANQIONG HU)

Yuanqiong Hu serves as Intellectual Property Advisor at the MSF headquarters in Geneva.

Just to start off with the interview, maybe you can tell me a little bit about what you're doing at MSF and what are your responsibilities?

YH: Okay. So as you see, I'm working as a legal advisor for the Access campaign, focusing on IP law. So my role is more a less a technical support in the team in terms of any advocacy at the international and national level. My role is to provide necessarily legal analysis and support giving advice, make sure our legal message is correctly formulated. This can be located in a broader advocacy strategy messaging. So that is a very broad introduction of my role. So in concrete terms I work with different teams within the campaign namely we have colleagues working at the national level focusing at different issues including patent law reform and any trade pressures, in term of using TRIPS flexibilities, I work with drafting necessary submissions, commentaries, press releases, I also support the global level advocacy in terms of getting messages

concerning medication we need across to different organizations, including WTO, WIPO, WTO, and others. So that's more or less what I'm doing.

So, what is the access campaign exactly working with. What is the underlying problem?

YH: Okay, so you probably heard from Ellen, the campaign started in 1999. It was started as a quite straight forward inspiration, because MSF delivers direct-house medical assistance to people who suffer from conflict and epidemics in the world, so in a simpler term we treat patients on the ground directly, so the launching of the campaign started with the increasing frustration of our doctors and practitioners in the field to say that a lot of essential medical tools which are available in developed countries are not available in developing countries because of different reasons. Either it's not registered, or it's too expensive or not available at all and, so there's a systemic fail of having equal access to the medical tools that can be used for life saving purposes. And one of the underlying systemic reasons at that time was the trend of globalization, of intellectual property, which put more and more developing countries under the international legal obligation to grant patent on pharmaceutical products, which is a kind of legal trend but is also being utilized to an unreasonable extent by pharmaceutical industries to maximize their profits without duly consideration for the consequences for the patients that we are working with. The basic scenario at the beginning when we launched the campaign. So in the past 15 years, the campaign as an integral part of the MSF movement has been focusing on servicing, so by nature we are a campaign, so the majority of our work is advocacy, campaigning and communication. So, basically, the basic scenario of our work is taking observations and experiences of MSF from the field to analyze it in a context of legal and policy environment at national and international levels. And to join the multi-national regional and national policy-making forums to voice our concerns in terms of the need to put patients need and put public health interests before profits, so that's a very broad messaging but in detailed terms, we try to use that evidence from the field in connection with legal and policy discussion. So we publish different publications, important fact sheets, and briefings every year, focusing on priority diseases MSF is treating and highlight the most pressing challenges we and our patients face in the field, which we think also effects patients beyond MSF clinics in the developing countries.

You already talked about this, voicing these concerns about access within policy forums. Who would you say are the target audiences of the campaign? In policy terms, is it mostly policy actors, is it the public, is it medical professionals?

YH: I think it's a mix of audiences. So, by campaigning we do aim to trigger policy change at the end of the day. So I would say our primary targeted audiences are policy-makers at different levels. Policy-makers have diversified faces in our work. It would include public health policy makers, IP policy and lawmakers. I think those are the two biggest categories. Depending on the topics and the context, we are sometimes also targeting policy-makers in the context of trade negotiations, science technology policy formulation in a country. Because as you probably also see, we are also tackling in recent years the failure of the current R&D system in pharmaceutical context, which is heavily relying on patents, and we think that this is one of the root causes, make the transformation very difficult and slow. So, yea, in a nutshell, target audience is policy makers at different levels, tackling public health policy, IP policy and law, and sometimes trade policies.

You have talked about this before, reaching out to different partner organizations, so with whom does MSF collaborate in relation to the access campaign.

YH: First of all, although we are a campaigning branch in the MSF movement, we are part of the MSF movement, so we have a quite wide collaboration with medical practitioner organizations, and public health agencies, like WHO, UNICEF, UnitAID, and so on. So, some of them are very like-minded, probably not completely, but some elements we have quite frequent dialogue and medical communities, and also have a very frequent collaboration with other NGOs that are working on a broader IP and development issues, because the access campaign is only concerned with the impact of IP on public health, but if you look beyond, the impact of IP has far-reaching impacts on other developmental issues, like national industry policy, environment, biodiversity, etc. So there's broader implications in the developing world, so they are other organizations working on those issues, so we have collaboration with them on public health-related topics and occasions, so those include international level NGOs, international think tanks, and also academic institutions, individual academics, like-minded professors and researchers, and in addition we also work with civil society organizations at the national level, especially when the topic is closely related to national patent law reform or specific

medicine accessibility on a national level, we're being working with patients' groups, CSO, different countries. These are the main partners I would say.

Can you name the most prominent ones in this NGO and civil society realm, but also international organizations?

YH: Yes, so multilateral organizations, not partners, but counterparts, some of them are targets of our advocacy, some of them may have like-minded aims, so as I said we have quite close dialogue with WHO, related to a number of public health policy they are making, and especially, I'm talking about my role only, especially only those policies, that may have IP components in their implementation, so we have dialogue with WHO, and we have communication and sometimes advocate towards some policy forums at WTO and WIPO, instead of collaborating with them we have dialogue with them. And in terms of NGOs, partners, there is quite a few of partners both nationally and internationally, for instance South Centre, Third World Network, KEI, this are the major ones we are working with, and, they are intergovernmental, UnitAID and MPP. So, in terms of patent licensing and some of the legal terms we normally have communication with them. Others, for instance, ICTSD, which is also an NGO based in Geneva, which is doing a lot of technical analysis, the other NGOs, which are more national or regionally focused, for instance in India because we have been working there for quite a long time and from the very beginning of the campaign until now, we have been working with local patient groups advocacy groups, like DMP+, in South Africa close collaboration with TAC and Section 27, a legal advocacy group on the national level, those are the outstanding partners we have. And, oh yeah, some others related to challenging the status quo of R&D, for instance Drug for neglected Diseases Initiative), is also a long-term partner.

## Talking about policy proposals and policy solutions, what are the main proposal of MSF to overcome those barriers to access to medicine?

YH: So, the basic assumption for our advocacy is that there is evidence that drugs can be more affordable and successful if there is generic competition present in a market. So, we've seen, as you've probably seen in our reports online, there is evidence of a dramatic reduction of cost of HIV/AIDS medicines, since the formulation of generic competition, so the price reduced 99% in a quite short period of time, so we think that is a sustainable

solution for longer term access for developing countries, in order to achieve that, I'm also talking about IP law, there are other issues, I will not talk about, so I will focus on IP issues. In order to achieve that, from a legal perspective, there are a number of things countries can do. So there's a package of flexibilities enshrined by international law, especially the TRIPS agreement in WTO that allows different countries to take into account public health needs, to use patent protection flexibly so facilitate access to medicines, either to local production or importation of generic drugs. Those measures include for instance strict patentability criteria, so that means strict criteria in law to determine whether anything deserves a patent protection, so technical criteria and patent law, every country has their flexibility to design their own detailed criteria, we already see, for example in India, which has adopted quite strict patentability criteria, so basically any small change of old drugs will not get patented very easily in India, which would be the case for instance in the US, because this kind of patenting small changes to old drugs is a strategy used by the industry to prolong their market monopoly. So those kinds of criteria is what we are in favor of. In addition to that one, there are also other things people can do. One of the backbone flexibility allow by TRIPS is compulsory license. Basically, it's kind of a mechanism, allowing the governments to temporarily suspend patent right on different reasons. So there's different reasons national patent law can adapt as a ground for issuing CLs, for instance CL can be issued on a patent when the patent holder does not use or work the patents sufficiently in the country, which is against the basic scenario of granting a patent, because the logic of patents, because that is that in order to encourage patent holders to disseminate the technology invention to the society, the government gave him some privilege as exchange, but if the patent holder abuses this privilege by holding up the patent without disseminating it's against the public interest and this privilege can be temporarily taken away. So, non-working of a patent can be a ground for compulsory license.

## Sorry to interrupt, if that is the case, if they do not sufficiently cater that patent, do they still get the reimbursement or not necessarily?

YH: They get some remuneration. Under the Paris Convention in WIPO, which many countries have incorporated in national laws, although it is not widely used, but that's one of the reasons. There are other reasons, for instance if the patent holder was found to

have anti-competitive behaviour, a CL can be used to counter this. That would require the collaboration between the patent regime and competition law, so if a country has a competition commission and then the patent holder gets sued, and they find out he's really showing anti-competitive behaviour, then the patent office can agree on CL, so that the other party can use this patent with certain remuneration depending on the decision of the national courts. So this ground has been used quite a few times in Europe, I think Italy has used this quite a few times. And there are also other reasons, cases are often documented in context of access to medicines, is the government use CL. If a government or a government agency determines they are facing a public health problem, that can not be solved, and they can decide to issue a CL on the medical product they need, so this has been used by quite a number of development countries, many African countries, Thailand, India, Brazil, a number of South-East Asian countries have been using this clause to facilitate public health needs, and public health-based CL also under the TRIPS amendment, which is an amendment to the original CL terms. In original CL law, a gov't can only issue a CL for predominantly for the use within their territory. So after issuing a CL the country can either import or produce the medicine within their territory primarily. But it doesn't really allow you to issue CL for exportation only under the original law. And the amendment of TRIPS was trying to kind of solve this issue, because many least-developed countries don't really have manufacture capacity, so even if they use CL, they can't really produce locally, because there is no industry, so in order to solve this dilemma, the amendment of TRIPS allows, in situations when a country has no manufacture capacity for neither drug, when the drug is patented in those countries, they issue a CL on that drug, and at the same kind request another country that has the capacity that also has a patent granted on that drug to produce and export to them. And another country has also issue a CL so that the CL can enable a bunch of products being manufactured for other countries only. So that's what TRIPS is trying to do, although the mechanism is quite underused so far, but the principle underlined in this context is trying to reinforce the message that a patent regime should be implemented that supports rather than undermines public health. So those are the CL mechanisms, the access campaign is supporting. We welcome countries to explore the maximum possibility that they can use to facilitate access to medicines. There are of course other measures as you mentioned in your initial question, as you have mentioned parallel import is one of the

flexibilities also allowed by international law. So, that means when the patented drug is sold in two different countries, often times we find that the two countries have different pricing schemes, according to the principle of exhaustion of patent rights, so once the patent holder for the first time in one country, he exhausted his patent right in that territory, so the re-selling of the patented medicine is no longer under his permit. Because of this exhaustion of right, the other country, which has a higher price on the same product, can buy the same medicine from the retailer of the first country without it being considered an infringement to patent law. So that's the basic logic behind parallel import. Which can also be used and in fact has been used in reality in certain instances to manage the price differences between different territories, but certainly the parallel import could be threatened by other legal means, used by patent holders for instance they can sign an agreement with the retailer to prohibit them to re-sell the drug outside of the territory, that can be done through contracts not through patent law. They can also have licenses with local producers to allow them to produce something but specify the territory they can sell, so in this case, they are taking away the flexibilities of parallel import for countries outside of the territory defined, and there were also other circumstance when laws other than patent law has probably restrictive provisions on customer rules or import-export regulation, they may cause problems in the reality when people want to exercise parallel import, so there is an advantage and a disadvantage. The advantage is quite flexible, when the first selling is done, people can already buy to individuals or organizations. A disadvantage is that because there is no clear legal mechanism on how to regulate the patent holder may contract. So they can circumvent or escape the flexibility by imposing restrictive contract terms in certain countries.

Despite having the legal base through TRIPS, where parallel import is clearly legal or clarified in legal terms, there are other measures how to undermine that legality?

YH: And for those undermining measure there's nothing available in TRIPS or, I don't think many national laws have the tools to tackle those things. The controversy is that if the contract is signed between you and me, it's more private law sphere and in many countries, the freedom to contract overrules other laws so the contract has a stronger binding force than other laws and that's the third party can prove the contract between

you and me has caused the evidential damage to the third party, then they can probably claim the contract to be invalid, but it is very hard to do so, because of the power relations between the contracting parties, which often are agreed on under confidentiality so the third party wouldn't really know what we would have said.

# Would you still consider the promotion of parallel import to be one of the goals of that access campaign?

YH: I think we still keep this messaging, because this is the very important flexibility people can pursue and we know that many individual patients are actually relying on that flexibility to get their medicines, not through us but at the individual level. So they go to a country, buy a drug and come back and they have also self-help channels to get the cheaper version of medicines, when there is limited generic alternatives in their country, they rely on parallel import mechanisms, so we still think this is very important and we would like to advocate for it, which is also why I mentioned, there are other means that could undermine parallel important, and that we are increasingly became visible now, especially many multinational companies increasingly use voluntary licenses, confidential agreements with generic companies, people see this shrinking of the spaces to negotiate. That's because of other measures undermining not only parallel import, but also other spaces of discussion to TRIPS flexibility.

# It seems that generic drugs are much more prominent theme in this campaign than parallel import. Can you tell me why that is?

YH: Yes. One of our assumptions is, looking at the history of HIV drugs, the dramatic cost reduction, and the dramatic diversification of options for procurement and for patients only happened when generic competition was formed. So we still think, in order to have this sustainable access, for longer terms, we need competition. And parallel import is an important flexibility however it's only concerned with patented medicine, therefore it's quite limited. First of all, even though you can manage price differences between countries, it would depend on a number of conditions, first of all, some companies would not market their product worldwide at the same time. There are physical or practical difficulties for patients living very far away to really do parallel import, if the drug is not

market in their nearby territory, so this causes practical difficulties. Secondly, the basis enabling parallel import is price differentials, which sometimes requires tier-pricing that's used by the companies. And if we look at how the tier-pricing is formulated, there are also a number of concerns that we have, first of all, nobody knows exactly the accurate, precise methodology companies use to set up their prices, they often heard argument is that they need certain markets to be high priced in order to cover the R&D costs, but again we also don't know what exactly are the R&D costs are. So if we look at the tier pricing, the methodology is questionable. And secondly, the tier-pricing is not a solutionoriented scheme, because it's still relying on voluntary willingness of the companies to determine the tiers and often time would see more and more middle-income countries with very high prices, whereas we know that within those middle-income countries, there are very poor patients, who can not afford that price and the health expenditure of those countries are also not sufficient to afford the prices of the companies. Then, it's becoming a superficial problem, a question asking people to use parallel import because then you need to have a very complex local pricing comparison, in order to determine where to go and to have sources, so there's a lot of limitations to rely on only one measure, which is parallel imports. So what we are in favor of, is we hope that every country can look at flexibility as a package and to use them according to different contexts, because the more of options, the more policy options a gov't has, the better and the more flexible it gets, when they are trying to tackle different problems. So that's the reason why we keep it as one of the flexibilities. We also always advocate the flexibilities as a package without focusing on just one measure as the solution, which would be risky for any gov't to stick with one solution.

In literature possible dangers inflicted through parallel import have been voiced. For instance access problems in source countries. Do you see this as a potential threat?

YH: So you mean large-scale exportation from a country with a lower price to a country with a higher price. I don't think so. Because back to the reality, there is different ways a company can prevent this from happening, which we often call anti-diversion measures, which I think many companies have been doing. I think there are two levels of this assumption. First, parallel import are still not widely practiced, even though it is legal, but

many developing countries haven't even integrated this into their patent laws. And even there are certain provisions in patent law where experts don't even have a clear understanding of how it works, because nobody has tried, apart from some patients. But when some patients are doing this, they probably don't know that this qualifies as parallel import, they just do as they do. It's only happening on a very small scale. So the large scale of diversion from low price countries to high price countries is not happening, and I wouldn't say it will happen in the foreseeable future, the mechanism is not widely known and used, it can be limited very easily by contracting and it can be easily undermined by other laws. However, if many multinationals do see this as a potential threat, there is a different measure other than contracting. They can ask the low price market products to be packaged differently, identifiably with different colours, use different size of pills or different packaging. So it's very identifiable in certain markets. So if they find this type of product is diverted to a high price market, well, that market probably has no parallel import law, they can enforce their IP very easily by tracking the product. So, one thing the company can do, is first to lobby against parallel import, or to limit the eligibility of doing parallel import, that's what I can do to influence the law. Or, as a company, I can also do private enforcement measures, by differentiating the packaging, signing contracts, lobby other authorities to limit exportation and importation of certain products. So, I don't think that assumption would really hold.

#### If Parallel Import to developing countries, what are the source countries?

YH: The price diversion mostly happens between a developing and a developed country because they need to secure developed markets. They don't want the drug to be diverted from an LDC back to Germany. If it happened, it would only happen between developing countries in fulfilling different conditions. First of all, if you want to justify a parallel import both the sourcing country and the importing country have to have the same law in regards to parallel import, so if one of the countries has a different scenario, for instance, because the parallel import is built upon exhaustion of patent rights, and there are different jurisdictions on exhaustion of rights in different countries, some exhaustion can be done at the international level, which we call international exhaustion, meaning the first sell can happen anywhere in the world, then you have exhausted your right. And some countries have a very restricted exhaustion of rights, which only recognizes the

exhaustion within the territory. If the country has a national exhaustion of patent rights it will have a direct impact on access to parallel import, so for instance between two countries, one has international exhaustion, one has national exhaustion. Then, the country with national exhaustion can not of the country with international exhaustion as a sourcing country, because of different legal systems. So the international exhaustion country can only source parallel imported drugs from another country with international exhaustion exhaustion, which further limits the scope of using parallel import. But if it would happen, I would say it would be among developing countries, from a lower price country to a slightly higher price country. But it's very unlikely that it would happen between European countries and developing countries, it's a highly protected market.

#### What are legal impediments to generic drugs in developing countries?

YH: That's a very broad question. I think there are a number of things. There are legal and practical complexities in relation to this. Back to our assumption, wider generic competition can facilitate access. There are a number of preconditions for generic competition. We need generic drug companies that can actually produce the drug in an acceptable quality, so it can be used, not any sub-standard drugs. We need one country to have a generic industry that can produce good quality drugs. We also know that within the developing world, some countries have more capacity than others, for instance India, China, Brazil, Thailand, Malaysia, probably have more capacity of having their own national generic industry that has already produced a lot of medicines to supply domestic and international markets, especially in the case of India, we also have other developing countries struggling to have a sustainable domestic industry. So there's industry policy. If in the context where the country does have generic industry, then, whether this company can produce drugs will depend two sets of law, which is patent and drug regulatory law. So the patent law would determine which product they can produce without infringing the patent rights in their country, which also links back the status of whether this country has joined TRIPS, meaning whether this country is issuing patents on pharmaceutical products. If the country only issues patents on pharmaceutical processes then the generic company has better changes, because then there is a bigger scope for them to produce something without infringing the patented product, but if the country has patent law granting patents on pharmaceutical products, then the changes are getting slimmer.

So, the generic company can produce if the patent is expired or the patent is invalid in the country, or if there's a voluntary license, allowed by the patent holder. Then they can produce certain products in the territory. There is a drug regulatory law, determining the quality, efficiency and safety of the product before it gets marketed to be used on the patients, so there are different laws governing the safety and quality. If the company produces certain medicines, can he export to other countries, then there's other legal complexities, first of all, they have to know whether the end market, the target market, has some patent barriers on the product he's producing, so he has to know the patent status from different countries, which is very difficult in regulatory terms, there is no world wide patent register and there's no database one can resort to, because the patent data is very complex to determine. And there are different database, many of them are commercial and to do an accurate patent search it requires a lot of resources, expertise, capital, so for developing countries it's difficult for generic companies to do this. That would add uncertainty when they look at global markets, knowing some but not all of them. If the targeted market has patent protection on the product he's producing, he can not export, unless there's is a CL issued in that country, or a voluntary license from the originator allowing them to export to this country, which is really case-by-case, so I think these are the basic complexities, generic companies would face. Of course some companies also choose to challenge the patent in their country, which means legal proceedings taking up to a few years, if they can successfully challenge a patent, then lift the ban for the production, they can start producing. If they fail, they have to go for license negotiations or just stop the production. So there's a number of legal barriers. And on the MNC side, in order to limit capacity for generic production, there are few things they can do. First is to lobby their government to ask for stringent IP rules through bilateral or regional trade negotiations, or bilateral property dialogue or collaboration, all kinds of different forums, they can penetrate their lobby forces asking for strong protection on their projects, their patents, so that the spaces for local generic producers shrink. They can also go for aggressive licensing strategy, to divide the generic industry into licensee and non-licensee, which also functions in a way of weakening the overall generic competition in a certain period of time.

Getting back to the campaign, is the campaign only focused on LDCs and developing countries, or do they include some mid- and high-income countries?

YH: We don't focus on countries. We focus on patients. So, when we do the campaign, of course we normally work in developing countries mostly, that's because the majority of our patients are located in developing countries, regardless they are in LDC, middle-income country, or wherever, they are all in developing countries. Our ultimate focus is patients, whatever legal tool, whatever policy measure used by the gov't, the ultimate goal is to benefit the patients who need medicine. Generally speaking, we don't focus on the countries; specifically this would depend on the topic of the cases. For some medicines, or some products, LDCs are more affected than others, we would have worked more way in messaging concerning LDCs and some medicines, then we may highlight the dilemma in middle-income countries. So, within the very broad developing country category, we have some tactics and strategic variations depending on the cases.

## Talking about developing countries, what sort of cooperation is there with the gov'ts of countries whose access is possibly obstructed?

Y: This again depends on a few things, even though we are a global campaign we actually have quite limited human resources, so in terms of gov't level collaboration we do it together with our medical missions in countries where we have medical operations. So, normally the starting point of doing any policy messaging is we are facing medical obstacles in the field, so, we would share our experiences in other countries, share the things we see, share our analysis about legal options the country can have, with relevant government agencies, if we have a chance and then if they would like to take that advise, we are welcoming this, but we can't really control what they decide at the end. In concrete terms, we just use what the national law provides us to do. For instance, if any national law revision, or policy reform is calling for commons or public participation or commentary, we use a chance to submit our comments. If we can have meetings joined with others to raise our concerns, we do so, and we also, in all of the cases, we discuss the legal issues always together with the medical challenge we're facing.

Would you say that different governments have similar interests with possible collaborations?

YH: Actually I don't know this. We hope they have collaboration because we see a lot of

dialogue and technical cooperation between developed countries, but the developing countries are working in silos, so there is no similar level of homogeneity among developing countries in terms of working out the common challenges as we sometimes see in developed countries, there is a certain level of homogeneity when talking about common interests. Such as G7 or similar forums, but there's nothing similar for developed countries. We don't really know, because of the lack of such a forum, we don't really know how governments talk to each other in terms of access to medicines. The only possibility for us to observe is probably in the multilateral forums, for instance in WHO or WIPO or WTO, we do see some countries talking about similar things when raising their concerns.

Would you consider International Organizations, such as WHO or the World Bank, as an ally for your cause?

YH: Certainly not the World Bank. WHO, I would say that we hope they are an ally, we see them as a counterpart, not totally aligned but we share some of the concerns. MSF is highlighting its independency when it comes to advocacy and operations, we have very regular meetings with WHO but we take independent decisions and actions regardless of what WHO thinks. I would see them as a like-minded counterpart.

# Do you know of any position paper, publications, that you would deem particularly representative for the campaign?

Y: We don't really have one position paper, but we have a basic framework outlining what we're doing online. But then the decision was taken to discuss this case-by-case and topic-by-topic, so you will find multiple position papers on different topics. You may find IP-related positions integrated in some of the documents. There is no single document outlining our position. But you will probably find a coherent position across different papers.

Particularly in regards to parallel import?

YH: No, I don't think so.

#### INTERVIEW 4 (PHILIPP FRISCH)

Philipp Frisch is coordinator of the MSF access campaign in Germany. The interview was thus held in German.

#### Was ist deine Rolle bei MSF?

PF: Ich koordiniere das Büro der Medikamentenkampagne, oder Access Campaign wie es international heißt in Berlin, und bin zuständig für Deutschland vor allem, deutschsprachige politische Entscheidungsträger, die in unserem Bereich relevant sind und konzentrier mich vor allem auf zwei große Fragen, nämlich einerseits Zugang zu bezahlbaren Medikamenten und anderseits Forschungspolitik.

Bei der Forschungspolitik geht es darum, dass es überhaupt die Medikamente bzw. Therapien gibt?

PF: Genau, Verfügbarkeit von lebensnotwendigen Medikamenten, das hängt ja ganz eng mit Forschungspolitik und wie die organisiert ist, zusammen.

Und die Medikamentenkampagne bezieht sich auf Entwicklungsländer oder auch mid-income countries oder Industrienationen?

PF: Es ist nicht so, dass die Kampagne irgendwas anderes wäre als Ärzte ohne Grenzen insgesamt, sondern im Gegenteil, es ist sozusagen integraler Bestandteil vieler MSF Programme und Aktivitäten und da MSF als Organisation eben sehr wohl viel in MIC und teilweise auch in high-income countries wie z. Bsp. in Russland oder in Italien, oder in Griechenland, ist es natürlich nicht so, dass wir zwangsläufig ausschließlich auf die klassischen LDCs konzentrieren, sondern gerade auch in Ländern mit mittlerem Einkommen arbeiten, wobei da es tatsächlich so ist, dass wir sogar noch mal einen größeren Schwerpunkt in der politischen Arbeit haben, weil die Probleme im Bezug auf den Zugang zu lebensnotwendigen Medikamenten in den MIC oft noch mal einen anderen Charakter haben, respektive einen deutlich politischeren, weil das auch damit zusammenhängt wie differential pricing mechanisms funktioniert, oder freiwillige Lizenzgebungen, usw. und welche Länder ausgeschlossen sind und so. Also ich würde sogar so weit gehen, dass vieles von dem was wir politisch machen einen größeren Schwerpunkt auf MICs hat.

Du hast jetzt schon angesprochen, dass es in deiner Arbeit um den Zugang und die Verfügbarkeit geht, also geh ich jetzt einmal davon aus, dass das der thematische Bogen ist, um den sich die Access Kampagne spannt. Kannst du noch kurz erklären wie das ganze entstanden ist, was die Milestones waren?

PF: Die Medikamentenkampagne gibt es seit 1999, die wurde ins Leben gerufen, die MSF für den Nobelpreis als Preisgeld bekommen hat, das war sozusagen die Anschubfinanzierung für die Kampagne und thematisch inhaltlich ist der Ursprung mit einem gewissen Schwerpunkt auf die HIV/AIDS-Bewegung und mit dem Faktum, dass eben viele Menschen, obwohl es die Medikamente gab um HIV/AIDS zu behandeln trotzdem keinen Zugang hatten, was eine klare und eine ganz reine Zugangsproblematik im Endeffekt war und eine reine Patentproblematik und daher kommt ein bisschen der historische Ursprung der Kampagne. Aber es hat sich dann letzten Endes doch relativ stark weiterentwickelt und wir arbeiten heute natürlich an anderen Dingen als vor 15 Jahren schwerpunktmäßig.

#### Wie zum Beispiel?

PF: Zum Beispiel jetzt neue Aspekte sind zum Beispiel ein zunehmendes Fokus auf Tuberkulose, also so ein bisschen weg von HIV hin zu Tuberkulose. Ein anderer Schwerpunkt ist die Verfügbarkeit von Hep-C Medikamenten, die wichtiger wird, grade eben durch die neuen Medikamente die man da eigentlich zur Verfügung hat, wo es auch wieder, ähnlich wie bei der HIV/AIDS-Problematik eine reine Zugangsproblematik entwickelt. Den ganzen MIC-Krams, ist eigentlich auch stückweit ein neuer Schwerpunkt, oder zumindest einer der immer wichtiger wird, genau.

#### Hat sich an der Grundproblematik was geändert?

PF: Erschreckend wenig. Ich hab letztens einen der ersten Newsletter gefunden, vom Januar 1999, wo auch das ins Leben Rufen der Kampagne verlautbart wurde, und wenn man sich da einige der Artikel ankuckt, dann sagen wir das heute immer noch. Also hat sich in 15 Jahren teilweise auch wirklich wenig geändert. Also zum Beispiel die Problematik von Zugang ist in vielen Bereichen die gleiche teilweise sogar schlimmer geworden über bilaterale Handelsabkommen, die sozusagen über TRIPS hinausgehen, also das hat sich eigentlich in manchen Bereichen sogar noch eher verschlechtert als

verbessert.

#### Und wen würdest du da als treibende Kräfte hinter dem ganzen identifizieren?

PF: Es sind vor allem die Industrienationen, die eine starke Pharma-Präsenz haben, die sich ggf. in Handelsabkommen mit ärmeren Ländern und auch MICs auf eine Art und Weise positionieren vor allem im Bezug auf die Frage nach geistigen Eigentumsrechten, die für sie selbst vorteilhaft ist. Das bedeutet dann in den allermeisten Fällen, dass eben genau diese Industrieländer sich für einen verstärkten oder ausgeweiteten Schutz geistigen Eigentums plädieren und sehr viel mehr auf Industriepolitik schauen, als auf den Zugang zu Medikamenten und auch die negativen Folgen, die das auf den Zugang hat. Das ist so ein bisschen der Spannungsbogen, würd ich sagen, wobei man das so pauschal für die MICs auch nicht mehr sagen kann, weil eben das Interesse an einem starken Schutzregime starken Eigentumsrecht in dem Moment ändert, in dem man als MIC selbst zunehmend an vorderster Front der technologischen Entwicklung steht. Geistige Eigentumsrechte sind vor allem etwas, was den Unterschied in der technologischen Entwicklung zwischen Ländern zementiert, das heißt immer die Länder, die weit vorne sind, haben ein größeres Interesse am Schutz geistigen Eigentums als die Länder, die ggf. technologisch aufholen wollen.

#### Welche Länder wären das in dem konkreten Fall bzgl. Medikamenten?

PF: Ich würde sagen, dass wir in den nächsten Jahren sehen werden, dass in Indien und China der Schutz geistigen Eigentums wichtiger wird für nationale Industrie- und Wirtschaftspolitik und die einen ähnlichen Entwicklungspfad nehmen werden, wie vorher auch schon Deutschland und Japan bspw. Japan war in den 80er Jahren ja bekannt dafür Industrieprodukte piraterisch nachzuahmen, die im Westen produziert werden und heute ist Japan ja mit an vordererster Front in der technologischen Entwicklung, man hat dadurch ja auch ein komplett anderes Interesse am Schutz geistigen Eigentums, und eine ähnliche Entwicklung hat ja auch Deutschland durchgemacht. Als Deutschland zu Beginn der industriellen Revolution im Bezug auf die technologische Ausstattung, Webstuhl zum Beispiel, den Engländern hoffnungslos unterlegen waren haben die Deutschen massiv kopiert und letzten Endes Produktpiraterie betrieben bis hin zu dem Punkt wo sogar die Engländer ein Warnsiegel, das explizit vor billigen deutschen Imitaten warnen sollten, das wir also heute noch verwenden 'Made in Germany', und interessanterweise hat sich ja über die Entwicklung Deutschlands und das Aufholen über Produktpiraterie ja auch die Bedeutung dieses Warnsiegels geändert, also quasi als Qualitätsgütesiegel. Das hat sich dadurch entwickelt, dass Deutschland die Möglichkeit damals hatte einfach bestimmte geistige Urheberschaft zu ignorieren und es einfach nachzubauen hat Deutschland gehabt industriell und technologisch sehr viel schneller aufzuholen, und wurde dann eben vom Piratenstaat viel mehr zu einem Land das einen sehr großen Wert auf den Schutz geistiger Eigentumsrechte legt. Und eine ähnliche Entwicklung ist durchaus in China und Indien möglich. Also eine sehr dynamische Entwicklung auch.

### Was sind die Maßnahmen bzw. Vorschläge für Maßnahmen, die MSF im Bezug auf Access ins Zentrum stellt?

PF: Wir sehen einen Zusammenhang zwischen engen Forschung, Gesundheitsforschung, wie sie organisiert ist und Zugang, weil in dem Moment in dem man Gesundheitsforschung anreizt über Monopole sagt man ja gleichzeitig damit auch, dass es dann am lukrativsten und damit am attraktivsten auch ist Gesundheitsforschung zu betreiben, wenn man hohe Preise verlangen kann und das dann auch tut. Das heißt, in dem Moment in dem es eine Verbindung gibt, zwischen dem Forschungsanreiz als solchem und dem Produktpreis des Endprodukts, und das ist genau diese Verbindung, genau in diesem Moment hat man zweierlei Probleme, zum einen Zugangshürden, durch hohe Preise, durch hohe Monopolpreise. Und zum anderen aber auch eine Forschungspolitik, die ganz klar in eine bestimmte Richtung geht, nämlich in die der kommerziellen Vermarktbarkeit von Gesundheitsprodukten, und daraus entstehen letzten Endes auch die zwei großen Probleme wiederum, dass wenn es Gesundheitsprodukte gibt, sind sie unerschwinglich und oft gibt es noch nicht mal welche, weil Gesundheitsbedürfnisse sind natürlich auch von geographischen Unterscheidungen, seien es zum Beispiel tropische Infektionskrankheiten oder die Erfordernis in bestimmten Kontexten angepasste Impfstoffe, Diagnostika, etc. zu haben und dass genau das dann natürlich zum Nachteil der ärmeren Länder ignoriert wird, tendenziell. Das heißt unsere Lösungsstrategien basieren also eigentlich immer darauf, diesen Zusammenhang zwischen hohen Produktionspreisen und Forschungsanreiz zu lösen. Das formiert sich dann unter dem Schlagwort 'de-linkage'. Also sozusagen, eine Trennung von diesen beiden Konzepten. So dass der Forschungsanreiz sehr viel gezielter das sein kann, was er sein soll, nämlich die Gesundheitsbedürfnisse, womit man gleichzeitig das zweite Problem gelöst hat, zu sagen man nimmt den Druck aus dem System, dass man sich nicht über die hohen Produktpreise refinanzieren muss. So das ist jetzt mal ganz vereinfacht gesagt, worum es eigentlich geht. Und de-linkage kann man durch verschiedene Maßnahmen implementieren, zum einen über Forschungsprämien, Meilenstein-Prices, push-pull-Finanzierung, direkte staatliche Finanzierungen von staatlichen Forschungseinrichtungen, etc. Wobei es in all diesen Fällen eben nicht so ist, dass es diesen Zusammenhang gibt. Und deswegen sagen wir auch nicht, wir kritisieren den Status Quo und die One-Size-Fits-All-Strategie die da implementiert wird über das Patentsystem und stellen dem gegenüber eine andere OSFA-Strategie, sondern es geht dann über verschiedene Bereiche, Kontexte, therapeutische Bereiche, in dem die eine oder die andere Maßnahme Sinn macht. Und es gibt ein ganzes Bündel an Dingen, die man machen kann, um eben diesen Zusammenhang aufzulösen und es kommt drauf an, um welche Krankheit handelt es sich und was macht wo am meisten Sinn.

In euren Dokumenten erkennt man einen Fokus auf Generika als Mittel. Woher rührt der? Geht der in der de-linkage Diskussion verloren? Wo würdest du Generika in diesem Zusammenhang einreihen?

PF: Generika sind ja insofern noch etwas anderes, als dass es sich dabei wirklich um die Frage des Zugangs handelt. Generika sind ja per Definition immer dann überhaupt relevant, wenn es kein Patent gibt oder das Patent schon abgelaufen ist. Das heißt es ist eigentlich erst nach Ende des Monopolschutzes oder eben in Situationen in denen es den von vornherein noch gar nicht gegeben hat überhaupt erst ein Thema. Und insofern ist es ein bisschen getrennt von der Forschungsfrage. Nichtsdestoweniger sind Generika ja letzten Endes ja nichts anderes als ein Synonym für Wettbewerb. Das heißt, es geht uns ja nicht darum Generika-Produzenten zu stärken, es geht uns darum, dass Generika eben für Wettbewerb sorgen, nämlich untereinander und ggü. dem Originalhersteller, was wiederum die Monopolpreissituation auslöst und untergräbt und für sinkende Preise sorgt. Und das ist letzten Endes auch eine Art von de-linkage wobei da die Forschungsfinanzierung erst mal nicht Gegenstand der Betrachtung ist. Sondern es geht erst mal nur darum, dass wenn wir ein de-linkage geschafft haben, wenn die Forschung finanziert ist und wenn es ein Produkt auf dem Markt gibt, wie kriegen wir dann den günstigsten Preis auch wirklich raus, wie kommt der zustande, und die Antwort darauf ist eben Wettbewerb, der Wettbewerb von verschiedenen Firmen, die sich gegenseitig preislich auch unterbieten, und eben versuchen möglichst effizient zu produzieren und niedrige Preise anbieten zu können, der zeigt uns letzten Endes erst wo eigentlich der Preis ist, der dann am nachhaltigsten auch tatsächlich gestaltet ist, so dass sich die Produktion weiterhin lohnt, dass die Kosten gedeckt sind, und ein schmaler Gewinn auch möglich ist, aber dass eben nicht irgendwelche gigantischen Monopolgewinne abgeschöpft werden an irgendeiner Stelle. Und daher ist es insofern ein bisschen eine andere Frage, aber es ist auf jeden Fall auch komplementär zur de-linkage Diskussion weil man natürlich sagen kann, ein durch de-linkage Maßnahmen durchgeführtes Forschungsvorhaben kann dann in der Produktion über generischen Wettbewerb den niedrigstmöglichen Preis rausfinden, vor allem dann eben schon von vornherein, weil ja eben durch de-linkage kreiertes Produkt gar nicht mehr erst auf Patente und Monopole zur Refinanzierung angewiesen ist.

#### Wie schätzt du die Rolle von Parallel Importen in diesem Zusammenhang ein?

PF: Also, noch einmal anders. Die erste Frage ist wie würde ein reformiertes System aussehen und funktionieren? Die zweite Frage ist, im jetzigen System, wie sind die Spielregel und halten sich alle dran? Und ich würde sagen, ursprünglich, oder immer noch, das Patent, um zu vergeben zu werden, hat eigentlich vom Gesetzgeber aus relativ hohe Hürden. Dazu gehört meistens dieses Dreigestirn an Novelty, Inventive Step und kommerzieller Vermarktbarkeit, also diese drei Dinge, die erfüllt sein müssen um ein Patent überhaupt gewähren zu können. Was wir jetzt allerdings in der jetzigen Situation sehen, ist dass es auch im jetzigen System eine ganze Menge an unrechtmäßigen Patenten schon gibt, unrechtmäßig im Sinne von nur ein geringer Erfindungsschritt oder frivole Patente, völlig ohne jeden Marktwerkt oder Evergreening, usw. Dagegen vorzugehen im Rahmen des jetzigen System und generische Produktion zu ermöglichen, wo sie ermöglicht werden muss, ist noch nicht etwas was ausschließt nicht trotzdem auch auf eine größere Form des Anreizsystems zu zielen. Das heißt das sind auch wieder zwei verschiedene Aspekte, deswegen muss man auch im jetzigen System auch vor der

Revolution, versuchen zu leben und das beste draus zu machen. Und dazu gehört beispielsweise auch die Ermöglichung der generischen Produktion von Medikamenten, mindestens im Rahmen von TRIPS und der Doha Declaration. Das heißt, dass die Flexibilität, die im Patentrecht international ohnehin vorgesehen sind, über die TRIPS Flexibilities auch tatsächlich maximal implementiert werden müssten in allen Ländern, um einen maximalen und mögliche guten generischen Wettbewerb bei so vielen Produkten wie möglich auch zu erreichen. Und die Parallelimporte, ich mein Parallel Import, ich bin ja kein Experte dazu, aber Parallelimporte sind ja immer vor allem dann interessant wenn man es hier mit einem System von tier-pricing zu tun hat, sonst würde es ja überhaupt gar keinen Sinn machen. Das heißt verschiedene Preisniveaus in verschiedenen Ländern. So das kann man jetzt entweder beim gleichen Produkt haben, was ja eine Strategie der Industrie ja auch schon immer ist und war, nämlich in unterschiedlichen Märkten unterschiedliche Preise fürs gleiche Produkt zu verlangen. Dafür gibt es ja auch diesen Big-Mac Index um die Kaufpreisparität international zu messen. Und da gibts ja zusätzlich darüber hinaus noch klinische Equvivalente, zum Beispiel Generika eines bestimmten Produkts, die auch wieder unterschiedliche Preisniveaus haben, in unterschiedlichen Märkten, teilweise sogar im gleichen Markt. So wie man hier eben, Aspirin kaufen kann, wenn man möchte, oder man kauft ASS-Ratiopharm, es ist letzten Endes das komplett gleiche Produkt mit den gleichen Eigenschaften in zwei unterschiedlichen Verpackungen zu zwei unterschiedlichen Preisen. Gerade in dem Fall, und um das aber als kommerzielle Strategie, und das ist tier pricing ja vor allem, um dieses System aufrecht zu erhalten, haben die Firmen natürlich ein genuines Interesse daran, die Märkte voneinander zu trennen, weil sonst würde das System ja nicht funktionieren, verschiedene Preise in verschiedenen Ländern tatsächlich zu nehmen. Und da ist natürlich dann, da geht ein Stück weit ein Problem mit einher weil wenn man im Sinne der kommerziellen Interessen den Import/Export von medizinischen Produkten versucht einzuschränken, dann kann das immer problematisch sein, also auch in Bereichen, die eigentlich gar nicht intendiert sind. Und ich glaube, dass es deswegen umso wichtiger ist, dass man im Bezug auf die Organisation von Parallelimporten oder Re-importen, versucht einigermaßen klare Regeln zu haben, die dazu gedacht sind, die Interessen auszubalancieren und eben auf keinen Fall dazu gedacht sein können, dass der Zugang zu bezahlbaren Medikamenten in irgendeinem Kontext eingeschränkt wird,

wenn das möglich ist. Es gibt ja die verschiedenen Definitionen von Erschöpfung zu tun, regionale, national, etc. Und ich weiß ehrlich gesagt gar nicht genau, wie da die aktuelle Interpretation von TRIPS ist, ich weiß nur, dass es da Unklarheiten gab, eine Zeit lang. Oder zumindest Diskussionen darüber, was denn im Falle von TRIPS da eigentlich gemeint ist, im Bezug auf Exhaustion und im Bezug auf Parallelimporte usw., deswegen kann ich dazu eben auch relativ wenig sagen.

#### In Sachen Kommunikation, spielt Parallelimport als Mittel eine Rolle?

PF: Nein, für die Kommunikation sowieso nicht, weil das versteht ja kein Mensch. Das ist viel zu technisch. Deswegen, die Kommunikation nach Außen findet sowieso auf einem ganz anderen Level statt. Da ist man ja froh, wenn man Schlagworte verwenden kann. Wir reden ja noch nicht einmal wirklich von Generika, wir nennen das qualitativ hochwertige Nachahmerpräparate. Also, ich mein sowas für eine klassische Kommunikatioinsexercise, da ist PI sowieso vollkommen over-the-top.

#### Wär aber in dem Fall auch de-linkage?

PF: Klar, deswegen, dass würde ich auch in einem öffentlichen Vortrag nie de-linkage sagen. Ich würde es immer umschreiben, und erklären, was es für konkrete Maßnahmen gibt, inklusive Beispiele. De-linkage versteht auch außerhalb des Public-Health-Sumpf kein Mensch. Eine Sache, was man natürlich hat, wenn man mit einer informierteren Öffentlichkeit ins Gespräch kommt, wird das oft als Einwand gebracht, gegen Generika, oder gegen das Erlauben von Generika-Produktion, dass durch die extrem unterschiedlichen Preisniveaus, ein Parallel Import, wobei das meistens verwechselt wird mit Schmuggel, das ist ja nicht das gleiche, dann ist eben immer so der Einwand, dass wenn das irgendwo billig produzierbar ist, dann kann man das ja immer wieder zurückholen in andere Märkte und auf der Straße verkaufen. Und ich glaub die Leute haben da ganz oft die Zigaretten, die im U-Bahnschacht von irgendwelchen Menschen verkauft werden im Kopf als Beispiel dafür. Das ist natürlich Unsinn. Aber was schon so ein bisschen in die Richtung geht, wie auch ja auch manchmal gedacht wird im Bezug auf die Segmentierung von Märkten. Je unterschiedlicher die Preisniveaus sind, desto lukrativer ist ja auch Schmuggel, also das ist jetzt mal jenseits von Parallelimportüberlegungen, also ich kann mir vorstellen, dass das auch ein Problem in

manchen Bereichen ist. Wenn du ein Generikum hast, musst du ja genauso - es sind zwei Prozesse, der Prozess geistige Eigentumsrechte zu schützen und der Prozess der Zulassung eines Medikaments, das sind unterschiedliche Prozesse, da sind unterschiedliche Behörden mit betraut, das heißt, auch wenn ich ein bioequvivalentes generisches Produkt habe, kann ich das zumindest legal nicht einfach deswegen vermarkten, weil es das entsprechende vermarktete Original auf diesem Markt gibt, ich muss das natürlich immer auch noch anmelden, um es überhaupt als Medikament vertreiben zu können, über die offiziellen Wege. Und dann immer dieser Vorwurf des Schmuggels, der immer so ein bisschen mitschwingt, der ergibt ja insofern relativ wenig Sinn, weil wenn man sich überlegt, warum sollte man denn versucht sein, sein Krebsmedikament im U-Bahnschacht zu kaufen oder auf sonstigen dubiosen Kanälen, das ergibt überhaupt keinen Sinn und keinen Anreiz. Das heißt die einzige Möglichkeit, wie Schmuggel funktionieren könnte, wäre wenn irgendein Apotheker daran mitverdient, sozusagen wenn er sich von der Krankenkasse die Erstattung von bestimmten hochpreisigen Medikamenten dadurch erschleicht, dass er die nicht selber kauft beim Originalhersteller, sondern auf irgendwelchen dunklen Kanälen. Das ist ja auch der Unterschied zu Zigarettenschmuggel.

Zurück zur Kampagne. Wen würdest du jetzt noch als relevante Stakeholder in diesem erweiterten Kampagnennetzwerk identifizieren? Mit wem spricht MSF, wenn nicht mit der Öffentlichkeit?

P: Es gibt natürlich eine Reihe von Netzwerken, die sich um bestimmte Krankheiten drehen wie das Aktionsbündnis gegen AIDS hier in Deutschland, eine Reihe von Organisationen die in diesem Bereich arbeiten, wie in Deutschland die Buko Pharma Kampagne, international KEI oder HAI oder - es gibt eine ganze Reihe. Und es gibt auch große Organisationen oft aus dem Entwicklungszusammenarbeitskontext nicht so sehr aus dem humanitären Bereich, die eine ganze Reihe von unterschiedlichen Dingen machen, und u.a. eben auch Gesundheit, und dass man da punktuell eben auch mit bestimmten Teilen von Organisationen zusammenarbeitet, und dazu zählt vielleicht so jemand wie Oxfam oder wie verschiedene kirchliche Organisationen und Träger, Brot für die Welt zum Beispiel, und dann gibts es natürlich auch bestimmte Netzwerke mit Einzelpersonen für andere Krankheiten, TB, da geht's auch immer wieder mal um

geistige Eigentumsrechte und Zugang zu Medikamente, und dann gibts ja auch noch mal Leute die das so ein bisschen von der handelspolitischeren Seite sehen, das sind dann aber oft auch eher die Deutungsmächtigsten sind dann eher Einzelpersonen, oft eben aus Academia-Kreisen mit denen man dann aber auch wieder punktuell bestimmte Dinge macht oder wo irgendwelche Forschungsgeschichten mit dahinter stecken. Ansonsten ist es ja letzten Endes ist dieses IP/TRIPS/Medikamenten-Thema auch keines wo sich die Zivilgesellschaft ballt. Das ist nicht irgendwie so was wie Wasser oder Bildung, wo ganz viele Organisationen zu arbeiten. Es ist schon ein bisschen ein Spezialthema und es ist ja auch technisch nicht einfach, insofern ist ja auch die Hürde daran mitzuarbeiten ein bisschen höher.

#### Direkt nachgefragt, was ist mit IOs oder Regierungsinstitutionen?

PF: WHO, WIPO, WTO natürlich auch im Zusammenhang von TRIPS. Was noch? UNCTAD hat was dazu gemacht. Also verschiedene UN Organisationen.

#### Würdest du die dann eher als Partner oder als Gegenüber?

PF: Tendenziell eher gegenüber. Wobei das natürlich, auch die WHO ist keine homogene Organisationen, verschiedene Departments haben unterschiedliche Herangehensweisen und Interessen, grade bei der WHO ist das sogar sehr offensichtlich und es gibt natürlich auch wieder verschiedene Einzelpersonen, aus diesen Organisationen, die sehr viel eher Verbündete sind als Audience. Aber das ist dann meistens informell. Man weiß wie diese Abteilungsleiter ticken, und man weiß dass man sich auf den verlassen kann, auch wenn der nicht zwangsläufig immer sklavisch an der wie auch immer gearteten Meinung der Organisation für die er arbeitet festhalten muss. Es gibt ja auch eine gewisse Flexibilität. Als Organisationen würde ich das eher als Audiences sehen, vor allem grade in diesem UN-Organisationsbereich sind das ja Organisationen mit Sekretariaten, das sind am Ende des Tages ja dann die Mitgliedsländer, die die Richtung bestimmen, und die Mitgliedsländer und damit die Regierungen sind ja auf jeden Fall Audience und nicht Ally.

Gibt's irgendwelche Einzelprojekte wo MSF mit Organisationen zusammenarbeitet, wenn es darum geht Verhandlungen zu beeinflussen. Gibt es hier einzelne Regierungen, die einen progressiveren Standpunkt vertreten? PF: Ich würde sagen, das kommt sehr auf das Thema an und auf die Interessenslagen der Staaten. Staaten, auch MICs und LDCs gehen nach bestimmten Eigeninteressen vor, das kann von Thema zu Thema unterschiedlich sein. In diesem Bereich von IP, ist die Interessenslage meist so, dass die Staaten, die an der Spitze der Innovation bilden weltweit, haben natürlich ein größeres Interesse am Schutz von IP als die Länder, die technologisch eher aufholen. Weil IP ist fundamental ja auch ein sehr konservatives Element haben, den Status Quo zu zementieren, in dem sie eine Art von Nachahmende Entwicklung, die es in der Menschheitsgeschichte immer gab, eher verhindern oder zumindest erschweren. Und deswegen ist natürlich auch so, dass je weiter ich das Gefühl habe als Staat voran zu schreiten, desto größer ist mein Interesse an einer Erhaltung dieses Status Quos, wohingegen eben Länder, die das Gefühl haben, sie würden gerne technologisch aufholen, tendenziell eher das Interesse haben, dass sich der Status Quo ändert. Insofern gibt's da auf jeden Fall ein Stück weit natürliche Verbündete und Gegner, und es ist schon tatsächlich auch die Spaltung zwischen Industrienation auf der einen Seite, die für auch wieder tendenziell, alles tendenziell, für den stärkeren Schutz geistigen Eigentums plädieren, im Pharma-Bereich dann natürlich auch die Länder, die eine größere Industrie haben, Schweiz, USA, UK, auch Deutschland, und eben die anderen Länder, die eher einen public health Gedanken haben, weil sie eine hohe burden of Disease haben, zum Beispiel im Infektionsbereich, HIV-Bereich, und natürlich ein Eigeninteresse daran zu haben bezahlbare Medikamente zu kriegen und damit tendenziell auch auf Generika setzen, und dazu zählen Indien, Thailand, Brasilien, Südafrika zu einem gewissen Grad, wobei das da auch immer so ein bisschen schwierig ist. Und dann gibt's natürlich einen großen Block von LDCs, die zum einen im Vergleich zu den anderen Ländern wenig Kapazitäten in solchen Verhandlungen verfügen, also personell, von der Expertise, usw. Dadurch von vornherein schon schwächer gestellt sind, wenn man sich vorstellt, die USA rückt zu einer Handelsverhandlung mit 150 Experten im Gepäck an, Kohorten von Anwälten, etc. und wenn am gegenüberliegenden Ende des Tisches dann Malawi sitzt, dann haben die halt nur 3 Leute da, und das wars dann. Das ist natürlich grade bei international Verhandlungen tatsächlich ein Problem, die Kapazität die Verhandlungen auch zu führen im eigenen Interesse, ist natürlich bei den Industrienationen deutlich stärker ausgeprägt, und grade bei den LDCs hängt das ncoh mal davon ab, bei den LDCs ist das dann so,

dass das Interesse vielleicht geringer ist an einer Generikaproduktion, weil man selber keine Produktionskapazitäten hat, und gleichzeitig ist die Abhängigkeit ggü. den klassischen Gebernationen, die ja wiederum Industrieländer sind, in vielen Bereichen sehr viel größer. Das heißt wenn ein Land X 30% seines Staatsbudgets von US-AID bekommt, dann werden die sich ja nicht in Verhandlungen um Trade Policies gegen die USA zu positionieren, weil sie sich das nicht leisten können.

Kannst du irgendwelche Positionspapiere, etc. von MSF nennen, wo du meinen würdest das wär repräsentativ für die Kampagne?

P: Im Bezug auf Zugang ist eine der wichtigsten Publikation 'Untangling of Web of ARV Productions', die kommt jedes Jahr raus und ist ein landscaping der Preise und Patente von HIV/Aids-Medikamente. Besonders wichtig für andere NGOs, die in dem Bereich arbeiten. Ansonsten gibt es eine für TB 'DRT Drugs under the Microscope', und für den Impfstoffbereich 'The Right Shot'. Also Schwerpunkt auf eine Mischung auf Zugang und Forschung.

#### Und so eine Art Mission Statement der Kampagne?

P: Ich weiß gar nicht ob es sowas wie ein offizielles Mission Statement gibt, am ehesten auf der Webseite mit der Selbstbeschreibung. Und dann, was vielleicht eine bessere Quelle für dich wäre, gibt es die Rede von Dr. James Robinski, der war 1999 Präsident von MSF und der hat den Nobelpreis entgegen genommen, und da muss man ja eine Acceptance Speech schreiben und die Acceptance Speech ist das Gründungsdokument der Medikamentenkampagne. Da stehen die Probleme im Bezug auf Zugang, im Bezug auf Forschungspolitik, und irgendwo steht dann der glorreiche Satz 'and this market failure is our next challenge' oder so, und auf diesen Satz gründet sich die Access Campaign. Und die ist ja tatsächlich auch danach gegründet worden, und die Anschubfinanzierung war ja das Preisgeld des Friedensnobelpreis. Das war das transformative investment das MSF damals getätigt hat, und gesagt hat wir müssen in diesen Patent und Zugangbereich, wir müssen dort Expertise aufbauen und mit dem Geld des Nobelpreises fangen wir an, das zu finanzieren. Das war der Gründungsmythos.