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International Legalization as a Challenge for Democratic Participation in International Institutions

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**The Politics of International Law
Using the Example of Biotechnological Patents**

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List of Abbreviations

APBREBES	Association for Plant Breeding for the Benefit of Society
ABS	access and benefit-sharing
ASEAN	Association of Southeast Asian Nations
ASTA	American Seed Trade Association
BIO	Biotechnology Industry Organization
CBD	Convention on Biological Diversity
CEWG	Consultative Working Group on Research and Development: Financing and Coordination
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
CIEL	Center for International Environmental Law
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
COICA	Coordinator of Indigenous Organizations of the Amazon River Basin
COP	Conference of Parties
DNA	deoxyribonucleic acid
DSB	WTO Dispute Settlement Body
DV	dependent variable
ECJ	European Court of Justice
ECOSOC	UN Economic and Social Council
ENB	Earth Negotiations Bulletin
EU	European Union
EWG	Expert Working Group on Research and Development: Coordination and Financing
FAO	Food and Agriculture Organization of the United Nations
FDI	foreign direct investment
FoE	Friends of the Earth
GATT	General Agreement on Tariffs and Trade
GMOs	genetically modified organisms
GNP	Gross National Product
GRAIN	Genetic Resources Action International
GRULAC	Group of Latin American and Caribbean Countries
GSPA-PHI	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
GURT	genetic use restriction technology
HIV/AIDS	human immunodeficiency virus infection/ acquired immune deficiency syndrome
IAEA	International Atomic Energy Agency
ICJ	International Court of Justice
ICTSD	International Centre for Trade and Sustainable Development
IFAD	International Fund for Agricultural Development
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations

IGC	WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
IIFB	International Indigenous Forum on Biodiversity
IL	international law
ILT	international legal theory
IMF	International Monetary Fund
IO	International Organization
IP	intellectual property
IPRs	intellectual property rights
IR	International Relations
ISF	International Seed Federation
ITPGR	International Treaty on Plant Genetic Resources
IUCN	International Union for the Conservation of Nature and Natural Resources
IV	independent variable
IWGIA	International Work Group for Indigenous Affairs
LDCs	least developed countries
LMMC	Group of Like-Minded Megadiverse Countries
MSF	Médecins sans Frontières
NAFTA	North American Free Trade Agreement
NGO	non-governmental organization
OECD	Organisation for Economic Co-Operation and Development
PCT	Patent Cooperation Treaty
PhRMA	Pharmaceutical Research and Manufacturers of America
PLT	Patent Law Treaty
R&D	research and development
RAFI	Rural Advancement Foundation International
RNA	ribonucleic acid
RoP	Rules of Procedure
SMTA	standard material transfer agreement
SPLT	Substantive Patent Law Treaty
TK	traditional knowledge
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
TWN	Third World Network
UPOV	International Union for the Protection of New Varieties of Plants
UN	United Nations
UNCTAD	UN Conference on Trade and Development
UNDP	UN Development Program
UNDRIP	UN Declaration on the Rights of Indigenous Peoples
UNEP	UN Environment Program
UNICEF	UN Children's Fund
UNPFII	UN Permanent Forum on Indigenous Issues
U.K.	United Kingdom of Great Britain and Northern Ireland
U.S.	United States of America

USPTO	U.S. Patent and Trademark Office
VCLT	Vienna Convention on the Law of Treaties
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSSD	World Summit for Sustainable Development
WTO	World Trade Organization
WWF	World Wide Fund for Nature

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Declaration

I hereby declare that this thesis is an independent work. All sources used are fully quoted to my best knowledge.

Cologne, 30 January 2015

TanjaAbendschein-Angerstein

Abstract

A deeper understanding of international legalization's effect on democratic participation in international institutions is urgently needed. Policies that were formerly regulated within the domestic context have been subjected to international law (IL). This has resulted in a growing number of international agreements and bodies. Some of these institutions gained new legal quality in terms of their legal obligations, procedural rules, and dispute settlement. With this trend of growing international legalization, also the normative expectations of IL have increased. In particular the key standard of democratic participation has to be met by international institutions to be considered legitimate in the long run. This crucial relationship between international legalization and democratic participation has been neither systematically theorized nor empirically researched so far.

The project forms part of a larger research strand on the interplay between law, politics, and democracy. By introducing a model of legalization's structure-inherent and actor-dependent effects, I demonstrate that legalization's costs cause powerful actors to restrict democratic participation in highly legalized international institutions. Only a formalization of membership rules tends to have a positive impact on democratic access.

Biotechnological patents serve as field of empirical research. Intellectual property rights (IPRs) have evolved into a resource of enormous economic value and a highly politicized issue area that make democratic participation indispensable. Four subject matters are considered: (1) access and benefit-sharing in the case of genetic resources, (2) protection of traditional knowledge, (3) IP protection of plant varieties, and (4) public health and IP. Six international institutions that address at least one of these issues are analyzed: the (1) Convention on Biological Diversity (CBD), (2) Food and Agriculture Organization of the United Nations (FAO), (3) International Union for the Protection of New Varieties of Plant (UPOV), (4) World Health Organization (WHO), (5) World Intellectual Property Organization (WIPO), and the (6) World Trade Organization (WTO). These institutions vary along the legalization dimensions so that the effect of lowly and highly legalized settings on democratic participation in international institutions can be compared.

The study contributes to an empirical and normative turn in research on legalization. First, I operationalize the two contested and elusive concepts 'international legalization' and 'international democratic participation'. International legalization encompasses 'legality', 'formalization', and 'delegation'. As to the democratic participation of states and non-state actors, I explore who (access) can on what terms (involvement) participate. As democratic standards serve congruence between decision-makers and mostly affected actors as well as contestation in deliberations. I further differentiate if these categories are fulfilled *de jure* and *de facto*. Yardsticks are presented in a transparent manner but also systematically applied to empirical cases. The results represent an important empirical foundation to analyze trends in international relations.

Second, my framework explains why legalization is currently more prone of becoming an apology of power politics rather than the utopia of an independent normative order. This finding has vital theoretical and policy-relevant implications. Neither scholars nor political actors can naively assume that international legalization is automatically accompanied by international democratization. The apparent allies in the domestic context might become at odds when transferred to the international playing field. Therefore, one has to be aware of the democratic trade-offs that legal commitments can demand.

Kurzzusammenfassung

Ein tiefgründigeres Verständnis des Effektes von internationaler Verrechtlichung auf demokratische Partizipation in internationalen Institutionen ist dringend notwendig. Viele Politikfelder, die einst national reguliert wurden, sind Gegenstand internationalen Rechtes geworden. Dies hat zu einer wachsenden Anzahl internationaler Vereinbarungen und Institutionen geführt. Diese Institutionen haben an rechtsstaatlicher Qualität hinsichtlich der rechtlichen Verbindlichkeit ihrer Vorschriften, ihrer prozeduralen Regeln und Streitbeilegung gewonnen. Mit zunehmender Verrechtlichung sind auch die normativen Erwartungen an internationales Recht gestiegen. Insbesondere der Grundsatz der demokratischen Partizipation muss von internationalen Institutionen eingehalten werden, um auf lange Sicht als legitim erachtet zu werden. Die zentrale Beziehung zwischen internationaler Verrechtlichung und demokratischer Partizipation wurde bislang weder systematisch theoretisch erörtert noch empirisch erforscht.

Die Arbeit ist Teil eines größeren Forschungsbereichs, der das Zusammenspiel von Recht, Politik und Demokratie untersucht. Auf der Basis eines Modells über die struktur-inhärenten und akteursabhängigen Effekte von Verrechtlichung, zeige ich, dass die Kosten von Verrechtlichung mächtige Staaten dazu veranlassen, demokratische Partizipation in stark verrechtlichten internationalen Institutionen einzuschränken. Lediglich die Formalisierung von Mitgliedschaftsregeln hat tendenziell einen positiven Einfluss auf den demokratischen Zugang.

Biotechnologische Patente dienen als empirisches Forschungsfeld. Geistige Eigentumsrechte (IPRs) haben sich zu einer sehr wertvollen ökonomischen Ressource und zugleich einem stark politisierten Feld entwickelt, wodurch demokratische Partizipation in diesem Bereich unverzichtbar geworden ist. Vier Themengebiete werden betrachtet: (1) Zugang und Vorteilsausgleich bei genetischen Ressourcen, (2) Schutz von indigenem Wissen, (3) IP-Schutz von Pflanzenzüchtungen und (4) öffentliches Gesundheitswesen und IP. Sechs internationale Institutionen, die sich mit mindestens einem der Themengebiete befassen, werden untersucht: (1) die Biodiversitätskonvention (CBD), (2), die Ernährungs- und Landwirtschaftsorganisation der Vereinten Nationen (FAO), (3) den Internationalen Verband zum Schutz von Pflanzenzüchtungen (UPOV), (4) die Weltgesundheitsorganisation (WHO), (5) die Weltorganisation für geistiges Eigentum (WIPO) und (6) die Welthandelsorganisation (WTO). Diese Institutionen weisen eine Varianz hinsichtlich der Verrechtlichungsdimensionen auf, so dass der Effekt von schwacher und starker Verrechtlichung auf demokratische Partizipation in internationalen Institutionen verglichen werden kann.

Die Studie leistet einen Beitrag zu einer empirischen und normativen Wende in der Verrechtlichungsforschung. Zum einen operationalisiere ich die zwei umkämpften und schwer greifbaren Konzepte ‚internationale Verrechtlichung‘ und ‚internationale demokratische Partizipation‘. Internationale Verrechtlichung umfasst ‚Legalität‘, ‚Formalisierung‘ und ‚Delegierung‘. Hinsichtlich der demokratischer Partizipation von Staaten und nicht-staatlichen Akteuren untersuche ich wer (Zugang) kann auf welche Weise (Mitwirkung) teilnehmen. Als demokratische Standards dienen Kongruenz zwischen Entscheidungsträgern und am stärksten betroffenen Akteuren sowie Kontestation in Diskussionen. Zudem unterscheide ich, ob diese Kriterien de jure und de facto erfüllt werden. Die Bewertungsmaßstäbe werden nicht nur transparent präsentiert, sondern auch systematisch an empirischen Fällen angewendet. Die Ergebnisse bilden ein wichtiges empirisches Fundament, um Trends in internationalen Beziehungen zu analysieren.

Zum anderen erklärt mein Forschungsrahmen warum Verrechtlichung gegenwärtig eher dazu tendiert, eine Apologie politischer Macht als die Utopie einer unabhängigen normativen Ordnung zu werden. Dieses Ergebnis hat entscheidende theoretische und politische Konsequenzen. Weder Wissenschaftler noch politische Akteure können naiver Weise annehmen, dass internationale Verrechtlichung automatisch mit einer internationalen Demokratisierung einhergeht. Die offenbar Verbündeten im innerstaatlichen Kontext können auf internationaler Ebene im Konflikt zueinander stehen. Daher ist es wichtig die demokratischen Einschnitte, die rechtliche Verpflichtungen mit sich bringen können, zu kennen.

Chapter 1

Introduction – An Empirical-Normative Turn in Research on Legalization

1.1 Background and Research Question

In April 1907, the then President of the American Society of International Law Elihu Root reasoned that “democracies are absolutely dependent for their existence upon the preservation of law” (Root 1917: 7). In his speech, which was delivered only two weeks after the USA entered World War I, Root explained why a democratization of states would lead to the adoption of more peace-securing international obligations and a greater respect of international law (IL).¹ Today, the analysis of the relationship between IL and democracy has to be reversed and elevated to the international arena. IL’s scope and complexity of IL have considerably expanded in the last sixty years (Armstrong et al. 2007: 61-62). Policies that were formerly developed within the domestic context have been increasingly subject to IL. This has resulted in a growing number of international agreements and bodies. Alone over 5.000 international treaties were registered at the UN secretariat by 2012.² IL no longer confines itself to setting the general parameters of international affairs but has regulated highly politicized areas that literally range from the seabed to the outer space. International institutions, which have often served as framework to develop and administer IL, gained new legal quality, for example with regard to their legal obligations or judicial review. By the end of 2011, there were at least 24 operational permanent international courts which had issued over 37.000 legally binding decisions (Alter 2014: 72-75). With growing international legalization, the normative expectations of IL have also increased.³ The widespread societal criticism that has been caused by the democratic deficiencies of international rule-making demonstrated that international rule-setting can no longer be legitimized purely by its output.⁴ International institutions also have to meet democratic principles such as transparency, accountability, and participation by all directly affected actors to maintain their legitimacy and stability in the long run (Brunnée/Toope 2000: 68; Franck 1995: 7; Krisch 2010: 264).⁵ In particular, the lack of participation represents a profound democratic deficit

¹ He later served as Secretary of War under President William McKinley (1899-1904) and Secretary of State under President Theodore Roosevelt (1905-1909). Available at: <http://bioguide.congress.gov/scripts/biodisplay.pl?index=R000430> (Accessed 17 December 2014).

² Available at: www.treaties.un.org (Accessed 17 February 2013).

³ Weiler 2004: 561; Wheatley 2010: 3-9, 13; Zürn 2004.

⁴ For authors who attest an international democratic deficit see for example: Alvarez 2007; Archibugi 2010: 86; von Bogdandy 2001: 618-622; Bodansky 1999: 596; Buchanan/Powell 2008: 327; Keohane et al. 2009: 2-3; Kumm 2004; Payne/Samhat 2004: 3; Peters 2009: 267; Scott 2008: 102; Zürn 2004; Zürn et al. 2006: 10.

⁵ See for example: Bodansky 1999: 606; Dingwerth 2007: 13; List/Zangl 2003: 375-378; Neyer 2004: 47; Yamin 2001: 155.

for it endangers individuals' self-determination.⁶ Therefore, it is explored *if international legalization promotes or impedes the democratic participation in international institutions*. Is international legalization a means of empowerment or power consolidation? Or in other words, is it part of the problem or the solution to undemocratic international institutions? Is IL a normatively desirable language for international relations as it was discussed by the UN Congress on Public International Law (UN 1996)? These questions are addressed by comparing the effect of lowly and highly legalized settings on democratic participation in international institutions.

1.2 Relevance for Research and Policy

Although both international legalization and the demand for international democratic governance are important empirical phenomena, their connection has neither been systematically analyzed by scholars nor adequately considered in the formulation of policies. This study tackles an untested relationship that is relevant for science and politics.

Academically, the project contributes to International Relations (IR) research by addressing three main shortcomings. First, it supports a normative turn in research on legalization and the institutional design of international organizations (IOs) by specifying the conditions under which international rules are democratically legitimate. For example, how does the democratic quality of negotiations on legally binding rules differ from those on informal rules? Does the formalization of processes within international institutions strengthen existing power structure or empower marginalized actors? If and how does the delegation of monitoring and sanctioning authority effect the participation of critical voices?

Concerning the consequences of international legalization, myriad of studies have explored international institutions' design, functions, and compliance with their rules.⁷ Also the re-engagement of international legal and IR scholars was driven by compliance questions (Brunnée/Toope 2010: 88; Diehl et al. 2003). This study, by contrast, addresses IL's impact from a democratic point of view. This change of perspective is crucial for democratic legitimacy is "the Achilles' heel of legalizing international politics" (List/Zangl 2003: 389; own translation). With a growing transfer of authority to international bodies and a bulk of vital decisions being agreed on at the supranational level, it is no longer satisfactory to demand the adherence to democratic standards only within the domestic context. Instead, it needs to be analyzed to what extent and under what conditions international institutions can be democratic. In particular in the light of the current constitutionalism debate it has to be explored if democracy is better off if it is legally backed up or if democratic governance should rather rely on other safeguards than law.

If international institutions' democratic quality is impaired, also their legitimacy suffers in the long-run with likely detrimental effects on actors' willingness to cooperate and comply

⁶ Bodansky 1999: 598, 617; Raustiala 1997a; Zürn 2000: 188.

⁷ For example: Alter 2003; Chayes/Chayes 1995; Checkel 1999; Downs et al. 1996; Guzman 2008; Guzman 2005; Ho 2002; Kahler 2000; Kingsbury 1997; Koh 1997; Koremenos et al. 2001; Lipson 1991; Mitchell 2007; Shelton 2003; Victor et al. 1998; Wettstad 2001.

(Buchanan 2006: 317). The neglect of normative considerations did not only create a blind spot but ignored that even a positivist conception of law requires legitimacy.⁸ Putting the discussion on a moral obligation to comply with democratic standards aside, a normative turn to IL is essential for the survival of the international legal project altogether. Even if one follows an instrumental argument, one has to take democratic quality seriously. Minimal legal principles, such as clearness and coherency of rules, do not suffice to guarantee a system's legitimacy. Access and involvement possibilities are a prerequisite to create incentives for state representatives to enter a dialogue because they increase the likelihood that the outcome is in their interest (Richardson 2008: 227). Likewise, states that were given the chance to play a serious role in negotiations are more likely to comply with the outcome. Even realists accept that international regulations are only legitimate if they represent participants' values and help them to pursue their interests (Posner 2009: 35).

Within the research on law and democracy, this project intends to provide a new perspective by using international legalization as independent variable (IV) and international institutions' democratic quality as dependent variable (DV). Most research in this context either has focused on the relationship between legalization and the democratization of states or has been descriptive by identifying international democratic deficits rather than explaining them.⁹

In order to comprehensively capture legalization's effects on democracy, it is also necessary to deviate from the dominant adjudication perspective in law-related IR research and legal theory (Raustiala/Slaughter 2002: 541).¹⁰ A democratic rule-making process is the precondition for legitimate rules in a democratic framework. Therefore, I focus on the decision-making process in my project.

Second, an empirical supplement to normative research on legalization and IOs is required (Besson/Tasioulas 2010: 3; Zürn 2011: 79-80). Democratic participation as a vital element of democratic governance is not only discussed theoretically here but was also empirically assessed and systematically compared across international institutions. If scholars proposed standards to assess the democratic quality or legitimacy of international institutions, they rarely put them to practice in order to demonstrate the empirical handling of their measurements.¹¹ This has been avoided most of the times since normative debates are based on disputed, difficult-to-operationalize concepts that easily render them vulnerable to criticism in empirical analyses. International democratic demands are also often instantly dismissed as utopian or subjects that are only relevant in philosophical debates. This line of

⁸ One of the most prominent exceptions is Robert O. Keohane (Keohane et al. 2009; Keohane 2002).

⁹ See for instance: Buchanan/Powell 2008; Keohane et al. 2009; Martin-Chenut 2008: 35, 39; Fox/Roth 2001.

¹⁰ See for example: Alter 2001; Cichowski 2006; Helfer/Slaughter 1997; Keohane et al. 2000; Posner and Yoo 2005; Romano 1999; Stone Sweet 2000; Zangl 2009; Zangl 2005.

¹¹ Among the rare examples that in fact empirically applied their proposals are the Discourse Quality Index (Bächtiger et al. 2010; Steenbergen et al. 2003), a study by Jens Steffek and his colleagues on the democratic quality of international institutions with regard to civil society participation (Steffek et al. 2008), and Cecilia Albin's and Daniel Druckman's justice standards in international trade negotiations (Albin/Druckman 2014; Albin 2008).

reasoning, however, ignores that empirical research on democracy at the international level is, first and foremost, directed to 'is' rather than 'ought' debates. Empirical analyses' main task is not to engage in the discussion on the determination of a desirable international setting toward we should work. Instead, it takes stock of and explains differences in the realization of democratic principles across international institutions. Sound empirical knowledge assists in further informing the empirical and normative debate on the democratic project by providing well-grounded criticism of the status quo and constructive proposals to improve it (Zürn 2011: 81). This endeavour requires transparent and measurable criteria of evaluation. My conceptualization will and should not end the contestation on democracy and its features.

Third, this project contributes to the debate on the interplay between legalization and politics. Many scholars have pondered if IL and legalization are independent from politics or rather represent politics by other means (Esserman/Howse 2003: 130).¹² In the debate if law is politicized or politics legalized, most academics concluded that both are interconnected in a sense that law creates the framework of political practices but is also a part of these practices. This provides no definite answer to the precise relationship between legalization and politics. One reason for this is that many studies remained vague with regard to legalization's precise nature and mode of operation. This made it impossible to locate what in legalization could have a certain effect on politics. In order to deepen the understanding of what legalization is and how it works, I developed transparent indicators and applied them for a systematic evaluation of institution's degree of legalization. On this basis, I analyzed what effects are inherent to legal structures that affect actors' behavior and ultimately democratic participation within international institutions.

For political actors, understanding the normative implications of legalization has important consequences for *policies*. First, the project's findings offer guidance for the design of future international institutions or the reform of current institutional deficiencies to increase legitimacy. This is especially of practical importance for many societal actors and policy advisors who promote international legalization as if they regarded IL as one institutional solution to international democratic deficits (Armstrong et al. 2007: 26; Charnovitz 2006: 348). If legalization involves in fact negative effects for democracy, this cannot be ignored by politicians who are interested in the legitimacy and hence stability and effectiveness of international institutions.

Second, even if an immediate and far-reaching reform of international institutions might not be feasible politically, the analysis shows how political actors strategically make use of institutional procedures with far-reaching effects for democratic participation. Consequently, it is crucial for politicians and activists to know in advance what form of bargaining mode they can expect if they enter soft or hard law negotiations. Is their voice likely to be heard or

¹² For example: Brütsch 2002; Habermas 2001; Koskenniemi 2005b; Krisch 2003: 155; Nardin 2008: 385; Onuma 2003.

excluded? The study underlines the importance of differentiating between legalization and normative considerations in terms of democracy, justice or morality in order to be not taken by surprise by legalization's forces.

1.3 Locating the Project in the Literature and Existing Points of Contact

The existing literature on the relationship between legalization and democracy is contradictory. Often, conflicting prospects of international legalization's effect on democratic participation are rooted in differences in the conception of democracy. Demanding democratic approaches that require a common demos or a catalog of substantial rights are in general more skeptical of the realization of democratic quality in international relations (Keohane et al. 2000). Since democracy can only be fulfilled within the state, international legalization in the guise of an increasing number of IOs undermines functioning democracies.¹³ Hence, lowly legalized international institutions are preferable since they interfere with state sovereignty and democratic self-governance to a lower degree (Posner 2009).

On the contrary, cosmopolitanism employs comprehensive democratic principles just because they are optimistic as to their international realization (Held 1995a).¹⁴ Legalization and democratic participation are considered to be closely connected to another, with law creating the foundation on which democracy and democratic participation can flourish (Archibugi 2010: 88; Weiler 2004: 562; Zangl/Zürn 2004: 32). While this is in many instances historically correct for the formation of the nation-state (Hurrelmann et al. 2007a: 4-5), there are also examples of undemocratic constitutional states (Habermas 1994: 83). Even more uncertain is legalization's impact at the international level. Supporters of international legalization consider it to be a crucial, if not the only means to enable fair deliberation and settle conflicts democratically (Ratner 2005: 40). Moreover, it is claimed that lowly legalized settings with their greater flexibility bypass democratic procedures and promote obscure cooperation (Klabbers 1998; Lipson 1991: 500).

Another perspective provides the general discussion on the impact that is ascribed to law. The clearest stance is held by realists who consider IL to be an epiphenomenon. If anything at all, it can only help to solve international coordination problems under rare circumstances but can by no means spur international democratization. Only already dominant actors avail themselves of legalization processes to lock in their privileges (Goldsmith/Posner 2005). Other approaches are less determined. While constructivism attaches a constitutive role to law, rationalist theories consider it to be regulative. In the former approach, legalization potentially possesses greater power by constituting and legitimizing actors' identity and behavior while it merely facilitates cooperation in rationalist theories. The norm- versus

¹³ Dahl 1999; Goldsmith/Posner 2005; Rabkin 2005; Rubinfeld 2004.

¹⁴ In this framework, international legalization cannot only promote international democracy but also mitigate domestic democratic deficiencies such as human rights violations (Buchanan/Powell 2008: 332; Keohane et al. 2009: 7-8).

interest-based differentiation, however, only examines legalization's magnitude but not its direction. Even within the same theoretical branch, one can derive contradictory assumptions that usually results from an uncertainty if legalization caters or constrains dominant actors (Abbott/Snidal 1998: 10; Simmons 2009: 126).

More insights can be derived from the critical theorists Jürgen Habermas and Martti Koskenniemi. They are torn assuming that law can promote both legitimate social norms and illegitimate power relations by establishing and structuring political power. Both authors shed light on the legalization-democracy relationship by exposing IL's dual character. IL oscillates between facticity and normativity in Habermas's words and apology and utopia in Koskenniemi's terms. On the one hand, IL attempts to establish a normative order that is capable of constraining international politics. On the other hand, IL depends on state power to be enforced. This creates a bootstrapping problem with an uncertain outcome. As Koskenniemi brought it to the point: "Law is a limit to power but it is also a means of empowerment" (Koskenniemi 2007b: 4).

Since a profound theory on international legalization's effects on the democratic quality of international arrangements is absent, this project draws on elements of several disciplines. Operating at the intersection of IR, normative theory, and international legal theory (ILT), several disciplines are considered.

Within IR research on international institutions, this project is placed in a more recent strand that is concerned with international institutions' normative implications.¹⁵ I chose an institutionalist framework for the theoretical analysis. Institutionalism's fine-tuned and comparative analysis of institutional features makes it very suitable to analyze the study's two main variables both of which refer to institutional characteristics.¹⁶ Institutionalists elaborated on how institutions can vary along various dimensions, for example, as to the choice of soft versus hard law, membership, voting rights, monitoring mechanisms, and dispute settlement.¹⁷ They explained how particular institutional design features affect state behavior. Although institutionalism has mostly been committed to clarify institutions' instrumental effects, such as compliance and effectiveness, it also illuminates states' incentives to behave (un)democratically in international institutions – be it consciously or unintentionally. On this basis, I developed a framework that takes into consideration legalization's structure-inherent and actor-dependent effects.

Within ILT, the discussion on various forms of legal arrangements has been prominent since the 1980s (Gruchalla-Wesierski 1984). Particularly relevant for this project is the debate on soft versus hard and informal versus formal law including their criteria of differentiation,

¹⁵ See for example: Binder/Heupel 2014; Breitmeier 2008; Dingwerth 2007; Keohane et al. 2009; Koppell 2010; Steffek/Hahn 2010; Zweifel 2006; Zürn 2010; Zürn/Stephen 2010; Zürn 2004; Zürn 2000.

¹⁶ Therefore, institutionalism has stimulated most interdisciplinary work between IR and legal scholars (for example: Abbott 2005; Abbott 2008; Guzman 2008).

¹⁷ For example: Abbott/Snidal 2004; Abbott et al. 2000; Koremenos et al. 2001; Lipson 1991; Lockwood Payton/Blake 2014; Zangl 2009.

the interactions between them, and reasons to establish a certain legalized setting.¹⁸ IR research can profit from this discussion for having been less sensitive to differentiate “between global governance through law and other forms of normative regulation” (Wheatley 2010: 276). In IR, this research strand became most prominent with the 2000 IO issue on legalization (Abbott et al. 2000). Moreover, the project intersects with ILT branches concerned with the future development of IL, such as the constitutionalism and pluralism debates, which also discuss under which conditions international democratic rule is feasible.¹⁹

As to the DV democratic participation in international institutions, one can draw from a bulk of literature on institutions’ democratic legitimacy and deficits.²⁰ The goal was, however, not to develop a new theory of international democracy but rather to use existing principles of democratic participation since my focus lies on the empirical analysis.

1.4 Empirical Analysis

Intellectual property rights (IPRs) and to be more precise biotechnology-related patents served as the issue area to empirically explore the legalization-democracy relationship. This field has two main advantages. First, it involves several institutions with variation across the legalization dimensions (Helfer 2004). This builds a methodologically sound foundation to compare the effect of highly and lowly legalized institutions. Second, both legalization and democratic participation are vital in the field of IPRs. IPRs are instruments of increasing economic importance and political salience. Legalization has influenced this process by harmonizing IP regulations and expanding their scope and depth. The large membership of IP-related international institutions increases the geographical scope of their rules’ validity. The number of patent applications filed worldwide under the Patent Cooperation Treaty (PTC) almost continuously grew from approximately 1.05 million in 1995 to around 2.14 million in 2011. Alone in 2011, almost 1 million patents were granted, more than 60% of which were filed by residents. It is estimated that around 7.88 million patents were in force worldwide in 2011 taking into consideration that the general patent duration is 20 years (WIPO 2012: 43, 45, 79). IP experts identified IPRs as the “key economic resources of the future” but acknowledged at the same time that “their very definition, scope and legitimacy remain uncertain” (Sell/May 2001: 468). Although this area might be considered very technical at first glance, it is in fact highly politicized owed to the high economic and social stakes involved in the settlement of IP standards. The resultant political conflicts can only be legitimately channeled and eventually reconciled via democratic participatory procedures.

Four subject matters are considered: (1) access and benefit-sharing in the case of genetic resources (ABS), (2) protection of traditional knowledge (TK), (3) IP protection of plant

¹⁸ See for example: Abbott/Snidal 1998; Helfer 2002; Klabbers 2001; Raustiala 2002; Shaffer/Pollack 2010; Skjærseth et al. 2006.

¹⁹ See for example: Brunnée/Toope 2010; Buchanan 2010; Dunoff/Trachtman 2009; Klabbers et al. 2009; Krisch 2010; Kumm 2004; Möllers 2008; Sadurski 2006; Tasioulas 2010; Walker 2007; Wheatley 2010.

²⁰ See for example: Buchanan/Keohane 2006; de Búrca 2008; Held 2009; Held 1995a.

varieties, and (4) public health and IP. Six international institutions dealing with at least one of the four issues are selected on the IV to explore in a first step if and which patterns can be observed between a certain degree of international legalization and democratic participation in international institutions. The institutions encompass the

- Convention on Biological Diversity (CBD),
- Food and Agriculture Organization of the United Nations (FAO),
- International Union for the Protection of New Varieties of Plant (UPOV),
- World Health Organization (WHO),
- World Intellectual Property Organization (WIPO), and
- World Trade Organization (WTO).

The timeframe covers the period between 1990 and 2010. In a second step, the CBD, WHO, UPOV, WIPO, and WTO are analyzed more in-depth to understand the causes of legalization's influence on democratic participation.

1.5 Outline of the Book and Major Results

The book is divided into a theoretical and empirical part each consisting of four sections. I start with an introduction of the main variables 'international legalization' and 'democratic participation'. Both are contested concepts and therefore require a clear definition and transparent measurement. In *chapter 2*, legalization is broken down into 'legality', 'formalization', and 'delegation' in order to be able to analyze the dimensions' specific effects on democratic participation. In *chapter 3*, I start with a discussion of different models of international democratic quality in order to locate my concept of democratic participation. In accordance with my operationalization, I explore who (access) can on what terms (involvement) participate. Participation is attributed with democratic quality to the extent that it achieves congruence between authors and subjects of decision-making and enables contestation in form of an open and fair exchange of opposing arguments. I further differentiate between the de jure provisions and de facto participation. Both states and non-state actors (NSAs) were included in the analysis. States are considered to remain the main representatives in democratic decision-making. At the same time, NSAs have been significant auxiliaries to improve democratic participation due to their various democracy-enhancing functions.

In *chapter 4*, I review existing approaches on the relationship between legalization and democracy and outline possible areas of harmony and tension. First, I argue for a thin understanding of the rule of law due to the drawbacks of collapsing law into morality. Second, I discuss the transferability of theoretical assertions on the domestic legalization-democracy relationship to the international arena. It is shown that the conditions under which law and democracy operate internationally are fundamentally different from the domestic context. As legalization's democracy-constraining effects have to be taken very seriously, I focus in the third part on the critical theorists Habermas and Koskenniemi who show that legalization oscillates between being a constraint on and the product of power

politics. Based on the lessons learned from the previous discussion, I introduce my theoretical framework of legalization's structure-inherent and actor-dependent effects on democratic participation. It is assumed that legality and delegation create costs while flexibility varies with the degree of formalization. These structure-inherent characteristics affect institutions' democratic participation by influencing actors' behavior and interaction within institutions. An institution's degree of legalization determines the costs to which actors are exposed. Depending on the scale of costs, actors behave differently to pursue their goals and possess different strengths of participation preferences. On account of these actor-dependent effects, powerful actors within an institution allow for or impede democratic participation. Generally, legalization's high costs are causes that impair democratic participation while a lack of formalization provides a means to circumvent democratic procedures. The theoretical part ends with an account of the methodology in *chapter 5*.

The empirical analysis starts with a brief explanation of what is understood by biotechnology and IPRs in *chapter 6*. This is followed by a summary of the main biotechnology-related IP regulations in the six analyzed institutions: the CBD, FAO, UPOV, WHO, WIPO, and WTO. In a third subpart, the general arguments of IP supporters and IP skeptics of biotechnological patents are presented before I discuss the specific interests, lines of conflicts, and mostly affected actors in the issue areas (1) ABS, (2) TK, (3) IP protection of plants, and (4) public health and IP. All four areas are highly politicized. Certain interests are irreconcilable and the stakes are high as the debates are concerned with the distribution of great economic benefits, fairness between the North and South, and eventually the importance of economic interests in comparison to social, environmental, and human rights in international relations. It is this constellation that makes democratic participation indispensable in these areas.

In *chapter 7*, the empirical application of the legalization concept shows variation of legalization across the institutions even though to different extents. Most common are lowly legalized institutions that are characterized by soft law, moderate formalization, and low delegation (CBD, FAO, WHO). The most legalized institution is the WTO with its hard law character, high formalization, and moderate delegation followed by UPOV. The results affirm the importance to consider legalization's individual dimensions in order to distill those elements that have a particular effect on democratic participation.

In *chapter 8*, I evaluate the institutions' democratic quality. The de jure state participation was democratic in all institutions with the exception of the WTO. By contrast, de jure NSA participation was less democratically regulated. De jure NSA access was undemocratic in half of the analyzed institutions (WHO, WIPO, WTO). The de jure NSA involvement was often only vaguely regulated and did not formally discriminate against NSAs with the exception of the WTO. The de facto dimensions of democratic participation differ considerably from their de jure counterparts in all institutions. This demonstrates that formal participatory rights do not lead to empowerment without proper enforcement. In general, non-democratic

trends concerning de facto state participation were mostly caused by the dominance of IP supporters in all institutions. Consequently, congruence was overall better satisfied than contestation. As to de facto state access, congruence was fulfilled at the CBD, FAO, WHO, and WIPO but violated by UPOV and the WTO. With regard to de facto state involvement, congruence was fulfilled by the CBD and WHO but not the WTO. State contestation was overall rather low. With regard to de facto state access, contestation could only be realized at the CBD, FAO and WIPO, only partly at WHO, and was imbalanced at WIPO and the WTO. As to de facto state involvement, by contrast, contestation was highest at the WTO, moderate at WHO, and lowest at the CBD. In contrast to the other dimensions, contestation with regard to statements' content was mainly driven by IP skeptics. Concerning NSAs' de facto congruence, most open were the CBD, FAO, and WHO in contrast to UPOV, WIPO, and WTO both with regard to access and if applicable involvement. De facto NSA contestation was most balanced at the CBD and FAO, intermediate at WHO, and most imbalanced at UPOV, WIPO, and the WTO. All in all, the CBD came closest to the ideal of democratic participation while the WTO was furthest away from it.

In *chapter 9*, I first bring together the results from both previous chapters and describe the patterns that can be observed between a certain degree of legalization and democratic participation. On this basis, I provide empirical illustrations to explain the legalization-democracy relationship by means of the theoretical framework developed in chapter 4. The cases yield five main results. First, IP supporters as dominant actors controlled participation in highly legalized institutions. Second, legality bolstered by high delegation impeded democratic access to international institutions due to its high costs involved. Third, legality strengthened by high delegation caused greater contestation in plenary sessions. However, a higher degree of contestation represented only a Pyrrhic victory as it was accompanied by IP supporters' evasion of formal procedures. Fourth, the lack of formalized participatory rights was used by IP supporters to the detriment of democratic quality. In comparison to legality and delegation, formalization represents the legalization dimensions with the lowest influence on democratic participation. Fifth, IP supporter USA took a prominent role in using and circumventing legalization to reach its policy goals and to this end also its favored participation constellation in the respective forum.

In *chapter 10*, I summarize the main results and discuss their implications for policy and research before I conclude with an outlook for further research.

Chapter 2

Legalizing International Relations

International legalization is undertheorized and -conceptualized in IR. Social scientists tend to underestimate the importance of IL and formality in international rule-making and rather consider legalization as a by-product of institutionalization (Brütsch 2002: 166; Klabbers 2009: 179). Yet it is precisely laws and the legal structure that political actors regularly intend to influence, enforce, and evade. This contributed to a one-sided research focus that neglected that law and legalized procedures form the rules of the game in most international institutions. Hence, social scientists – even institutionalists in IR – have often faulty and incompletely conceptualized their research objects. Legal theorists, on the other hand, tend to focus on law’s concept and content rather than the systematic conceptualization of a legal system’s entire institutional framework and processes. The different approaches of IR and legal analyses have often not been made fruitful for theoretical work and empirical research in a mutually supporting way.²¹

A more refined understanding of legalization is a precondition to capture and comprehend the functioning and consequences of legalized political interaction. Before I present my operationalization of legalization, I begin with a brief overview of the historical development and empirical evidence of legalization. Secondly, I take stock of previous attempts to conceptualize legalization to illustrate the insights and downfalls of grasping the phenomenon.

2.1 Legalization as a Change of International Political Conduct?

International legalization has accelerated after the Second World War and gained new speed with the fall of the Iron Curtain. But its roots are much older. Christoph Humrich and Bernhard Zangl describe three waves of international legislation that can also be applied to international legalization (Humrich/Zangl 2010).²² During the first phase of the ‘*law of coexistence*’ starting with the 16th century the medieval multi-level system of governance developed into the modern Westphalian system of sovereign and territorially separated nation states. The recognition of states’ ultimate external and internal sovereignty reduced previous political fights for supremacy at different levels and sites. The principle of non-interference in the internal and foreign affairs of other sovereign states established a clear differentiation between the national and international level. The international order remained a quasi-private one. It was characterized by customs and bilateral treaties that often focused on at-the-border conflicts and did not create obligations vis-à-vis the

²¹ There are a few exceptions like Abbott 2008, Abbott 2005, Alter 2011, Alter 2001, Armstrong et al. 2007, Brunnée/Toope 2010, Slaughter et al. 1998, and Slaughter Burley 1993.

²² In a previous version of their article, the authors even used legislation and legalization interchangeably (Humrich/Zangl 2009: 2).

international community. Law-making was hardly structured by procedural rules and only relied on a few fundamental principles, such as sovereign equality and state consent, to facilitate an order of peaceful coexistence. This period was marked by influential thinkers like Jean Bodin, Thomas Hobbes, and the ‘father of IL’ Hugo Grotius and important events like the Peace of Augsburg in 1555, the Peace of Westphalia in 1648, the Utrecht Treaties in 1713, and eventually the Congress of Vienna between 1814 and 1815.²³

Legalization’s second wave, ‘*the law of cooperation*’, began at the turn of the 19th century with the Hague Conferences in 1899 and 1907 and was later shaped by the establishment of the League of Nations and most importantly by its successor, the UN system. States increasingly codified international rules and entered into multilateral treaties. According to the World Treaty Index, over 55.000 international treaties were adopted between 1945 and 2000.²⁴ These treaties had gradually gone beyond the negative rules that refrained from the intervention in the affairs of other states. The interdependence of cross-border issues, like environmental damages or trade relations, required to address behind-the-border issues. International institutions haven often served as the institutional framework to develop, adopt, and implement treaties. The number of intergovernmental organizations (IGOs) increased from almost 40 at the beginning of the 20th century to nearly 7700 by 2012.²⁵ Law-making was specified and structured by procedural rules. The development of secondary rules was facilitated by bodies like the International Law Commission, which drafted the Vienna Convention on the Law of Treaties (VCLT), or the International Court of Justice (ICJ), which stated in its Statute IL’s sources and further elaborated on them in its findings (Humrich/Zangl 2010: 347-348).

Also sovereignty was no longer understood as an unlimited and independent exercise of authority but rather as submission to international legal norms such as human rights or *ius ad bellum/in bello*. With the emergence of a public order, sovereignty was no longer best expressed in a state’s autonomous and independent action but as equal participant in international negotiations that developed shared values and international principles of cooperation. Yet unaffected remained the principle that states can only be bound by international obligations to which they explicitly consented (Humrich/Zangl 2010: 347-349; Pfeil 2011: 76-99).

Some scholars argue that international legalization is currently in its third and still in-process stage of *constitutionalization* in the sense of an integration of separate legal systems into one vertically integrated legal order that is governed by higher basic rules and fundamental rights. Although its seeds were already planted with the UN charter, constitutionalization did not start to really unfold before the end of the Cold War. In the

²³ Held 1995a: 78; Humrich/Zangl 2010: 345-346; Shaw 2008: 23-27.

²⁴ Available at: http://worldtreatyindex.com/search.php?year0_0=1945&year1_1=2000 (Accessed 1 September 2014). For more up-to-date information consult: <http://treaties.un.org/Pages/Home.aspx?lang=eng> (Accessed 1 September 2014).

²⁵ Yearbook of International Organizations by the Union of International Associations is available at <http://www.uia.org/yearbook> (Accessed 2 June 2013).

course of this development, the original concept of unlimited internal and external sovereignty has been further weakened. Today, sovereignty is conditioned on the adherence to both international and domestic norms. In this framework of “authorized authority”, governments cannot rule as they wish. They have to uphold constitutional principles and follow human rights standards in relation to their own citizens. Also the international realm is in flux toward a cosmopolitan public order by embracing more and more commonly shared values that are not only *jus cogens* but also *valid erga omnes*. Last but not least, the procedural rules of IL have expanded in depth and scope. Rule-making changed in so far as state consent is at least formally no longer required for all decisions in international institutions. Also secondary rules have been further specified and comprise both law-making and law-enforcement. The latter is indicated by an increasing number of monitoring and dispute settlement mechanisms (Humrich/Zangl 2010: 349-352). While there existed six permanent international courts in the mid-1980s, there were at least 24 supported by over a hundred of ad hoc established tribunals and quasi-judicial bodies in 2011 (Alter 2014: 3-4; Romano 1999).²⁶ By the end of 2011, international courts have issued more than 37.000 legally binding decisions. 91% of them were released since the end of the Cold War. Most active are the European Court of Justice (ECJ) and European Court of Human Rights (ECtHR) with a share of almost 90% of all rulings, followed by the less well-known Andean Tribunal of Justice (ATJ) and Common Court of Justice and Arbitration for the Organization for the Harmonization of Corporate Law in Africa (ODAHA) (Alter 2014: 72-75). It is hotly debated if the current political-legal development at the international order can be indeed described as constitutionalization.²⁷ Nevertheless, scholars would agree that IL has changed international cooperation.

Three main insights can be derived from Humrich and Zangl’s historical typology. First, legalization is a dynamic process which is still in motion with no final destination in sight. Every attempt to conceptually grasp this phenomenon has to acknowledge its fluid character. Neither is legalization an automatic development. Legalization’s motor was a changing international environment. It was driven by the social, economic and political interdependence generated by globalization processes, far-reaching international political events, and the emergence of new norms. The precise connection and causality of these factors is far from being obvious and requires further research. The picture is further complicated by the fact that legalization’s advancement varies across issue areas. Generally speaking, it is most advanced in trade relations and lags behind in security matters while the areas of environment and labor range in the middle (Zangl 2005: 87-89).

²⁶ For a comprehensive overview of international judicial bodies, consult the Project on International Courts and Tribunals (PICT) at <http://www.pict-pcti.org> (Accessed 1 September 2014). Its taxonomy is explained and the results are summarized by Cesare P.R. Romano (Romano 2011). An up-to-date overview of international courts is also provided by Karen Alter (Alter 2014)

²⁷ This controversy is not only about empirical facts but also theoretical and ideological outlooks. Even the term ‘constitutionalism’ itself is contested. Prominent works in the debate include, for example: Dobner/Loughlin 2010; Dunoff/Trachtman 2009; Klabbers et al. 2009; Krisch 2010; Kumm 2004; Walker 2007.

Second, legalization does not only represent a mere quantitative increase in substantive rules but also a qualitative change of institutional structures and rules' legal quality. The broadening of IL's scope and density has been accompanied by more and more precise procedural rules of law-making and -enforcement. This development demonstrably changed international cooperation and even the understanding of IL's core doctrine – state sovereignty.

Third, legalization worked its way up to become a mode of governance that is indispensable in a complex globalizing world (Teubner 1985: 297). From a political-economic perspective, it reduces coordination conflicts and makes cooperation more efficient and effective. From a normative point of view, legalization has been heralded as pacifier with the potential to create a cosmopolitan world order. This point is discussed in greater detail in chapter 4. In any event, the legalization process is hardly reversible as it is bolstered by myriad of treaties and institutions. Therefore, the analysis of legalization will remain an important issue on the research agenda of IR and legal scholars.

There is no contention that an increase in international treaties and courts are signs of international legalization. Also most scholars would agree that both trends on their own are not sufficient to constitute legalization. A growing number of IL only indicates a trend of *regularization* (Wolf/Zürn 1993). By the same token, a growing number of international courts and quasi-judicial bodies only points to *judicialization*.²⁸ But little consensus exists on the precise understanding of legalization. Two approaches to delineate this concept are prevalent: *contra-politics* and national analogy. They are not completely separate from each other but emphasize different aspects.

The method of *contra-politics* intends to capture legalization by distinguishing it from politics.²⁹ It can be applied both at the national and international level. In this framework, politics is described as messy, irrational, and uncertain. By contrast, law is static, rational, and predictable. This perception is empirically grounded in the fact that institutions that are believed to be insulated from political struggle are among the most trusted ones in political systems (Moravcsik 2005: 374). Legalization is understood as an autonomous system with its own rationalized method rather than an instrument by politicians. The foundation forms the separation of powers doctrine according to which a political system consists of an independent legislative, executive, and judicative (von Bogdandy 2001: 610). Malcolm N. Shaw's important textbook on IL also takes up this view:

“Power politics stresses competition, conflict and supremacy and adopts as its core the struggle for survival and influence. International law aims for harmony and the regulation of disputes. It attempts to create a framework [...] moderating claims, and endeavouring to balance interests” (Shaw 2008: 12).

²⁸ For prominent research on judicialization see: Alter 2014; Alter 2001; Keohane et al. 2000; Romano 2011; Romano 1999; Shapiro/StoneSweet 2003; Zangl et al. 2011; Zangl 2009.

²⁹ Here, I focus on the elements that help to identify legalization's core elements. The relationship between legalization and politics is further discussed in chapter 4.

It is remarkable that even Shaw cannot detach himself from this black-white dichotomy despite recognizing that law and politics are connected via “inextricable bonds” and that expectations toward IL’s problem- and conflict-solving capacity should not be utopian (Shaw 2008: 11-13). Similarly, Richard H. Steinberg differentiates between law-based and power-based bargaining at the WTO:

“When GATT/WTO bargaining is law-based, states take procedural rules seriously, attempting to build a consensus that is Pareto-improving, yielding market-opening contracts that are roughly symmetrical. When GATT/WTO bargaining is power-based, states bring to bear instruments of power that are extrinsic to rules (instruments based primarily on market size), [...] and generating outcomes that are asymmetrical and may not be Pareto-improving” (Steinberg 2002: 341).

Also in this framework, law is portrayed as fair in the sense of being equally welfare-enhancing for all participants and efficient while the political and power-based approach is unfair and inefficient. What can be learned from this approach is that legalization changes the mode of inter-state cooperation due to its structuring effect on state behavior. States subordinate themselves to rules that govern the policy process and restrict their realm of legitimate action. The legality of rules is not determined by states’ will but by formal standards.

This strand’s asset can at the same time turn into its pitfall. The overemphasis on the differences between legalization and politics creates the false impression that these are completely separate modes of governance. Although both can be conflicting and tension-filled, they can also complement and strengthen each other. Political actors can use law and legalization as a means to spur their interests in the same way that lawyers and judges can utilize political bodies and techniques to further their goals. In other words, politics can be legalized and legal systems can be politicized. *Politics create law but is also subjected to law.* I keep addressing this finding throughout the next chapters. A further difficulty of this approach is its focus on legalization’s impact rather than its nature and rationale. Law is attributed with certain virtues without sufficiently clarifying how it should serve them.

The approach of *national analogy* distills the rule of law’s core elements as developed within the national context and transfers them to the international plane. The question what constitutes law and the rule of law has engaged myriad of legal scholars since centuries. Despite considerable disagreement, a minimum consensus on the rule of law’s core properties can be found in the debate. A suitable summary provides the legal positivist Joseph Raz with his eight principles derived from the basic idea of the rule of law.³⁰ Laws should be (1) “prospective, open, and clear” and (2) “relatively stable”. (3) “The making of particular laws (particular legal orders) should be guided by open, stable, clear, and general rules.” (4) “The principles of natural justice must be observed.” This includes, for example, fair hearings or unbiased decisions in court. Courts must be (5) independent, (6) have

³⁰ Raz’s set of principles substantially overlaps with the eight principles developed by the moralist Jon L. Fuller even though both legal theorists stem from opposite streams of legal thinking. Fuller agrees that law must be promulgated, not retroactive, clear, and relative stable over time (Fuller 1978: 49-65, 79-80).

review powers, and (7) “should be easy accessible”. (8) “The discretion of the crime-preventing agencies should not be allowed to pervert the law.” This list of principles, which according to Raz is “very incomplete”, enlightens different dimensions of the legal system, in particular law’s features and its enforcement mechanisms (Raz 1979: 214-218). Beyond these minimalist standards, most conceptions of the rule of law would add two standards to contrast it with despotic and arbitrary rule. The first is already partly suggested by Raz’s eighth principle: all people in positions of authority are subjected to the law. Second, people are treated as legal equals before the law without discrimination and regardless of their power positions. Simon Chesterman summarizes the rule of law as “government of laws, the supremacy of law, and equality before the law” (Chesterman 2008: 15). All of these features were attributed to the rule of law to attain certain goals: clarity, predictability, stability, and security (Franck 1995: 7).

In order to conceptually and empirically grasp the emergence of an international legal order, scholars have often applied the same yardstick of the domestic rule of law at the international level. Against this backdrop, IL and international legalization perform poorly. H.L.A. Hart termed IL as a “primitive legal system” because it lacks collision, decision-making and adjudication rules (Hart 1994). One potential drawback of the analogy is the risk of neglecting the different socio-economic and political conditions at the national and international level. Instead the focus is often on law only and not the structural environment in which legalization is embedded. Therefore, some scholars have criticized the application of the rule-of-law concept to the international order (Chesterman 2008).

On the other hand, there is no reasonable alternative to at least start with the analytical tools derived from the national context. It has to be acknowledged that international legalization is a novel and dynamic phenomenon. Nevertheless, it bears resemblance with structures that we know from national legal systems. Therefore, it is sound to use the domestic understanding of the rule of law as conceptual foundation without excluding the possibility to refine or even discard it with changing empirical realities. In recognition of certain obvious differences between the national and international legal order, the concept of international legalization is condensed. Its criteria are typically more minimalist and less normatively charged than the notion of the rule of law (Reinold/Zürn 2014: 245).

The discussion above illustrated the difficulties to arrive at a sophisticated operationalization of international legalization. I present my proposal in the following.

2.2 International Legalization – A Refined Understanding

International legalization is a hotly contested concept. One reason is that its conceptualization already indicates theoretical presumptions concerning its causes, consequences, and handling (Teubner 1985: 293-294). It comes therefore at no surprise that legalization was introduced as a fighting word in Germany during the Weimar Republic to protest against the petrification and depoliticization of working conditions and socio-political relationships (Pfeil 2011: 13-14; Teubner 1985: 298).

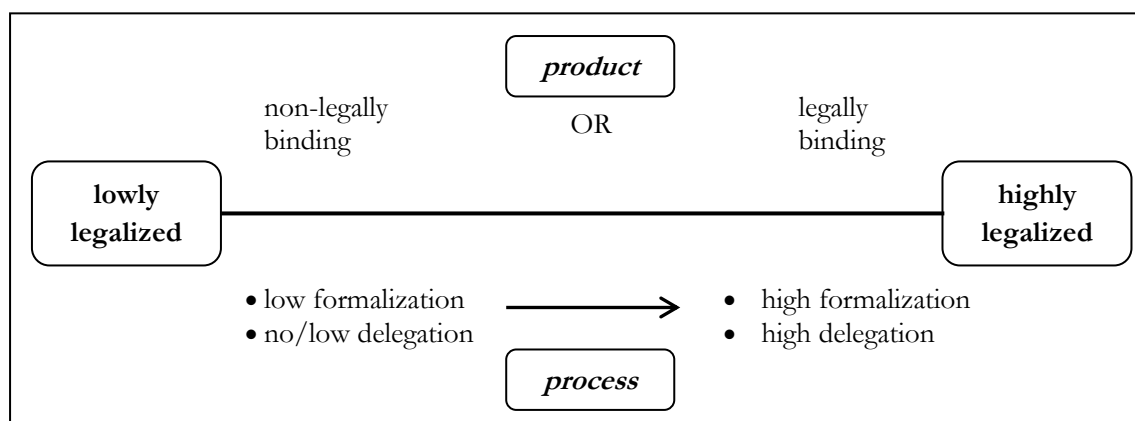
In the debate on the legalization of international affairs, one can refer to either individual institutions or the international system at large. The latter discussion is dominated by the question if we can observe an emerging international constitutional framework or rather a pluralist and fragmented international order. In this project, I focus on international institutions. Legalization not necessarily has to, but typically has been applied to international subsystems (Reinold/Zürn 2014: 245-246).

The dimensions of legalization are *legality*, *formalization*, and *delegation*. The higher the degree of legalization the more pronounced these components are overall. This conceptualization represents a synthesis and partly modified version of the frameworks by Kenneth W. Abbott and his colleagues as well as by Kal Raustiala (Abbott et al. 2000; Raustiala 2005). The dominant conception of legalization remains the one offered by Kenneth Abbott et al. in the 2000 IO issue (Abbott et al. 2000). They define legalization as a continuum along the dimensions ‘obligation’, ‘precision’, and ‘delegation’. Obligation denotes the degree of an obligation’s bindingness ranging from an explicitly legally non-binding character to unconditional legal bindingness. Precision indicates how clearly a rule specifies its objectives and the required conduct to achieve it. Delegation describes the extent of authority transfer to an international institution to implement agreements. It is low in the case of traditional diplomacy and high if courts and centralized enforcement exist (Abbott et al. 2000: 404, 410, 415-416). Although this concept of legalization has met with considerable criticism (Finnemore/Toope 2001; Fischer-Lescano/Liste 2005), it is still widely employed.³¹ In most cases, its usage is owed to its clear and transparent operationalization and often does not represent a theory-driven choice. I adopted ‘delegation’ and expanded it while rejecting ‘obligation’ and ‘precision’. ‘Obligation’ was replaced by what Raustiala terms ‘legality’ that refers to the binary divide between non-legally binding and legally binding agreements (pledges versus contracts). Raustiala’s other two indicators are ‘substance’ and ‘structure’. The latter refers to enforcement mechanisms and therefore overlaps with ‘delegation’. ‘Substance’ indicates to what extent a rule demands policy changes (Raustiala 2005: 583-585). In addition to these two concepts of legalization, I added ‘formalization’ as a new dimension.

³¹ For example: Faude 2011; Karlsson-Vinkhuyzen/Vihma 2009; Shaffer/Pollack 2010.

My conception of legalization encompasses both process and product based on the Hartian differentiation between primary and secondary rules (Hart 1994: 94-97).³² *Product* denotes the legal validity of a legal system's substantial obligations and rights or in other words the primary rules. Legality divides them into binding and non-binding provisions. *Process* refers to the secondary rules of the institutional framework according to which primary rules are concluded, implemented, and enforced (Guzman 2005: 583-584).³³ Process is more comprehensive than the secondary rules defined by Hart who confines his concept to the rules of recognition, rules of change, and rules of adjudication (Hart 1994: 94-97). Especially legalization's procedural dimensions formalization and delegation have to be spotlighted to avoid a narrow emphasis on only regularization. Since I concentrate on international institutions, a minimum of formalization has to be presumed.³⁴ Therefore, the study omits the analysis of very lowly legalized institutions. Legalization generally describes a development toward hard law combined with a high degree of formalization and delegation. An overview of legalization's dimensions is provided below

Figure 1: Dimensions of International Legalization



Three qualifications should be noted before the individual dimensions are presented. First, my goal is to grasp a real-life phenomenon that is oriented toward empirically realistic conditions at the supranational level. Therefore, one has to act with caution when differentiating between a high and low degree of legalization in order not to expect differences that are not consistent with empirically existing arrangements and hence entail no meaningful empirical implications. Second, this operationalization of legalization has to be considered as a snap-shot. Legalization is not a steady and uniform trend because

³² Legal scholars often do not apply their comprehensive set of analytical tools to legalization so that they are not sensitive to the different elements of legalization. Instead, they subsume everything under 'law' without differentiating between substantive regulations on the one hand and procedures as well as institutional settings on the other hand.

³³ Similarly, Paul F. Diehl and his colleagues differentiate between the operative and normative system of IL while the operative dimension refers to the secondary rules and the normative one to the primary rules (Diehl et al. 2003: 46-53).

³⁴ Delegation presumes a minimum of formalization so that the latter can be pronounced without the existence of the former but not vice versa.

institutional characteristics can change over time.³⁵ As the process of international legalization might take ways and turns in the future that cannot be foreseen today, also the concept might need to be adapted to a changing international environment. What is understood by legality and a high degree of formalization and delegation today might be only considered moderate tomorrow. Third, efficiency and effectiveness are neglected since my interest lies with legal characteristics. High legalization does not automatically imply or presuppose high compliance and vice versa. Instead, my intent was the development of a parsimonious concept of legalization that concentrates on legalization's essential characteristics.

2.2.1 Legality

Legality, as an indicator of commitment, is often considered to be the crucial element of legalization.³⁶ It denotes the legal quality of rules in a binary sense. Either a rule is legally binding or non-legally binding (Raustiala 2005: 583). The obligations and rights stipulated in hard law are legally binding. One key principle of international hard law treaties is *pacta sunt servanda*. This means that every "treaty in force is binding upon the parties to it and must be performed by them in good faith" (UN 1969: Art. 26). If a regulation contains no legally binding obligation but does also not completely lack legal force, it can still be soft law.³⁷ Not considered are tacit political agreements and purely private endeavors. Also excluded from the analysis of legality are acts of a so-called household nature. These decisions address institutions' internal operation and include administrative issues such as the approval of the budget or instructions for the secretariat like the compilation of information (Klabbers 2009: 182, 201-201). This notion of legality stands in contrast to Abbott et al. who refer to legal obligation as a continuum between soft and hard law (Abbott et al. 2000). I differentiated between the legal quality of the constituent documents and institutional framework (secondary rules) and policies (primary rules).

Hard law refers to IL's conventional sources as stated in Article 38(1) of the ICJ Statute (ICJ 1945). These encompass treaty law, customary IL, general principles of law, and judicial decisions. In this study, the focus is on treaty law as IL's prevalent source today.³⁸ Soft law refers to the not clearly defined area of informal and flexible rules that regulate

³⁵ Taking in consideration that legalization is not static, significant changes in one of the legalization dimensions of a selected institution would have made it necessary to divide the analysis of this institution into more cases or limit the period of analysis. This turned out to be not the case in my project.

³⁶ See for example: Aust 1986: 787; Dupuy 1991: 429; Hart 1994: 216; Heusel 1991: 290; Koivurova/Heinämäki 2006: 103; Klabbers 1996; Raustiala 2005: 586; Shaffer/Pollack 2010: 713; Shaw 2008: 117; Skjærseth et al. 2006: 104; von Stein 2008: 244; Woodward 2010: 125.

³⁷ The boundary between soft law and no law at all is difficult to draw. Nevertheless, minimum standards of soft law can be determined. Content-wise, soft law includes values, norms and standards that have already found significant recognition among actors who are usually states. Procedural-wise, law in order to be regarded as law in the broadest sense is concluded by an authorized legislative body (Humrich/Zangl 2010: 1). In that sense, soft law is not void of legal relevance but remains non-legally binding (Footer 2010: 246-247).

³⁸ This is necessary to limit the scope of the study. The formation of customary IL, for instance, can have other implications for democracy (Peters 2009: 291).

behavior. These include, for example, codes of practices, recommendations, guidelines, resolutions, declarations, and standards (Dunoff 1995: 251; Shaw 2008: 118).

The legal nature of an act is determined by formal criteria and does not depend on actors' compliance with the rule. For legality's empirical evaluation, two main indicators are key. One criterion is an *institution's powers*. Decisions of an international institution can only be legally binding insofar as its respective decision-making bodies are vested with the appropriate powers. Unlike states that are sovereign and possess a general competence, an institution has to operate within the sphere of its competence as it was defined by its member states. Pursuant to this dominant doctrine of attributed powers, it depends on the attributed legislative competences if acts of an institution can be legally binding or only recommendatory. Only if member states consensually delegate law-making power to an institution, its act can have legal force. The delegated competences are usually laid down in the founding treaties of an institution (Klabbers 2009: 178-179, 184-186; Schermers/Blokker 2011: 157-158).³⁹ Not only institutions but also the participants in international negotiations require the competence to create legal bindingness. The VCLT lays down that a treaty can only be adopted by state representatives with full powers to demonstrate that a state considers itself to be bound by a treaty (UN 1969: Art. 7).

Another important principle to distinguish between law and non-law is what Hart referred to as law's "internal point of view". In contrast to commitments or statements that only express political or moral promises, treaties have to be concluded by the parties with an *intention* to establish a legal act and thereof the belief of being under a legal obligation (Bernhardt 2000: 928; Klabbers 2009: 179). This is similar to the requirement of *opinio juris* in customary IL. In accordance with the VCLT, indicators for the intention to create an act of legally binding character are that

- a state affirms its consent to be bound by signature (UN 1969: Art. 12) or exchanges instruments (UN 1969: Art. 13, 16);
- the accord requires ratification (UN 1969: Art. 14) or accession (UN 1969: Art. 15);
- the treaty is deposited, for example registered with the UN secretariat (UN 1969: Art. 76-77).

³⁹ In addition to explicit powers, international institutions can also make use of implied powers. These are not expressly listed in the accord but are required to fulfill the 'effet utile' that are fundamental functions or in other words the mandate of an international institution. This principle was most famously formulated in the ICJ's advisory opinion in *Reparation for Injuries* (1949) and was later also strongly supported by the ECJ. While the doctrine of implied powers was influential until the 1990s, Jan Klabbers argues that its heydays are over. In order to underline this, he refers to the ECJ decisions in which the Court, which formerly upheld the doctrine, denied the European Community the exclusive competence to enter into international agreements and the power to accede to the European Convention on Human Rights. Another example includes WHO's request for an ICJ advisory opinion on the question if due to their health and environmental effects, the use of nuclear weapons constitutes a breach of the legal obligation under the WHO constitution. In 1996, the ICJ found that WHO was not granted the power to address this issue since it lied outside the scope of the WHO's mandate (Klabbers 2009: 60, 69-70, 216).

The scope of obligations laid down in treaties can be circumvented by states in hard law treaties by softening devices such as reservations, vague language, non-clarification of terms, and escape clauses.⁴⁰

Non-legally binding rules like soft law, by contrast, are of legally non-compulsory nature (Boyle 1999: 901; Heusel 1991: 42-43). Often these agreements are even explicitly non-binding that is reflected in titles such as memorandum of understanding, recommendation, and guideline (Abbott et al. 2000: 410-411). For not implying any legal obligations, soft law neither can be breached nor can deviators from soft law regulations be held responsible on legal grounds. Instead of establishing obligatory rules, soft law can serve as a normative instrument that creates standards of good behavior that can evolve into influential international norms (Dupuy 1991: 434; Koivurova/Molenaar 2010: 79). Nevertheless, soft law can be politically, culturally or morally binding (Klabbers 2001: 412; Koivurova/Heinämäki 2006: 103). In this line, the differentiation between soft and hard law shows no indication of an accord's effectiveness or compliance (Ellis 2001: 108; Young 1998: 12). Otherwise, law would only describe actors' behavior that would also be conducted in the rule's absence for it is either trivial, habit or enforced by powerful actors. Legal validity is subject to formal criteria of the negotiation and adoption process and not output-oriented. One case in point is the Organisation for Economic Co-Operation and Development (OECD) in which most rules are not legally binding but nevertheless exhibit high compliance rates (Klabbers 2009: 193). It was also shown for the North Sea Conferences that soft law triumphed over hard law in rendering effective results (Skjærseth 2010: 10).

Soft law is usually attributed with several advantages over hard law. It is generally said to be more flexible as it is not bound to traditional rules of law-making. First, soft law enables easier and more speedily negotiations. It does not require ratification and hence often less domestic discussion and justification (Boyle 1999: 903; Wolf/Zürn 1993: 20-22). Second, soft law is more apt to deal with uncertainty because it can be altered more quickly. Especially in policy areas that are prone to changing circumstances or new scientific findings, like environmental issues, politicians need a flexible and quickly adaptable policy instrument at their hands. This is of particular importance in international relations where information is often limited and problems are typically complex. In such circumstances, soft law allows states to test new policies from which they can learn and benefit if they turn out to be effective, but from which they can also easily depart if they lead to unintended consequences (Abbott/Snidal 2000: 441-444). Third, compromises can be reached more easily in case of divergent interests. Since soft law entails lower sovereignty and non-compliance costs, actors are more willing to depart from their initial demands. Fourth, the negotiation of soft law can also include the participation of actors who are not vested with

⁴⁰ Galbraith 2013: 316-323; Koskenniemi 2007a: 4-9; Shaw 2008: 913-915.

legal capacity (Abbott/Snidal 2000: 434-456; Kiss/Shelton 2007: 10-11; Raustiala 2005: 591-592).⁴¹

The term ‘soft law’ and its implications are hotly debated. Joost Pauwelyn differentiates between the ‘bright line’ and ‘grey zone school’ (Pauwelyn 2010a: 4-6). The latter group tends to use ‘soft law’ in a rather unsystematic way to describe rules that suffer from various imperfections (see famously Abbott et al. 2000). Either they just fall short of being considered legally binding, but they have the potential to obtain legal validity in the future, or they are ineffective, for example due to a lack of adjudication. In particular the latter usage is misleading for conflating rules’ legal quality and enforcement. Although the Austian or realist tradition argues that law for properly being called so requires independent enforcement, this does not adequately describe current legal practice and would deny most of IL’s legal force today.

From the ‘bright line’ perspective, the name ‘soft law’ is a contradiction in terms. Either something is law or not.⁴² In this line, soft law purports the existence of shades of legal bindingness which does not reflect reality (Klabbers 2009: 183). Soft law is accused of delusively inducing expectations of legal obligation and, in turn, causing the neglect or softening of legally binding norms (Harris 2004: 62). Although legal scholars have brought forward valid points that their discipline should not restrict itself to the study of legally binding norms (see for example debate on formalism: d’Aspremont 2011), it does not change the fact that the distinction between law and non-law remains crucial in daily politics and legal procedures. Judges, for instances, have to strictly decide which provisions of agreements are legally binding and therefore relevant for their findings.

As already indicated above, I side with the position that it is crucial for not only scholars, but most importantly for political and judicial actors to draw a clear boundary between legally binding and non-legally binding norms. This decision is frequently ambiguous but nevertheless made. Nonetheless, the concept ‘soft law’ should not be abolished all together because of its real-world importance. States frequently and consciously choose soft law as an additional policy instrument (Abbott/Snidal 2000: 423; Hillgenberg 1999: 515). For being a helpful analytical tool, however, soft law has to be used systematically by only referring to rules’ legal bindingness. Adherence to this standard evaporates most criticism about the concept of soft law.

Hard and soft law cannot be meaningfully distinguished solely with regard to substance-related criteria such as ‘depth’ or ‘precision’.⁴³ The concept of depth, being defined as the commitment of “serious changes in behaviour” of states (Raustiala 2005: 585), is problematic not only because it is difficult to operationalize and generalize across countries,

⁴¹ These are general assumptions with real-world exceptions. There are also examples of long negotiations on non-binding agreements like the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) that took 12 years (WHO 2012a: 118).

⁴² Fischer-Lescano/Liste 2005: 222; Heusel 1991: 29; Klabbers 1996: 181; Raustiala 2005: 586-590; Weil 1983: 417-418.

⁴³ Bernhardt 2000: 928; Finnemore/Toope 2001: 747; Hillgenberg 1999: 506-507; Pauwelyn 2010b: 5.

but also because the regularization of both the status quo and change can be concluded by soft and hard law. Because of using ‘precision’ as a criterion of legality, authors have tended to contradict themselves. Alan E. Boyle, for example, paradoxically assumes that soft law is often characteristic for detailed rules but at the same time also for being of general nature (Boyle 1999: 901-903). Unlike it is often assumed, soft law can promote very specific provisions because non-compliance does usually not inflict high costs on states (Abbott/Snidal 2000: 423; Koivurova/Heinämäki 2006: 107). On the contrary, there are various examples of hard law with no substantive content (Downs et al. 1996). By the same token, precision is not automatically more restrictive. More ambiguous rules can lead to greater self-restraint than clearly defined instructions since the former leave more space for interpretation and thereby greater uncertainty of how to abide by them (Abbott et al. 2000: 412). Exact rules can also lead to loopholes if they cannot be interpreted in a general way but only apply to specific circumstances (Chayes/Handler Chayes 1993: 189). Last but not least, imprecision loses its uncertainty in the case of mandatory jurisdiction. One should not forget that law – due to its indeterminacy – usually allows for different interpretations leaving a certain discretion to lawyers and judges (Koskenniemi 1999: 354; Shaffer/Pollack 2010: 750).

Precision is not a defining element of legality but rather a scope condition. Effectiveness and enforceability depend not only on monitoring and sanction mechanisms but also on a minimum of precision. Hence, it is reasonable to differentiate if rules entail substantive legal obligations or only announce very vague statements that do not create serious obligations that could be observed or sued. However, both elements have to be weighted differently. Legality represents the fundamental dimension while substance can intensify or weaken the effects of hard and soft law. Yet, a legally binding treaty with an escape clause remains hard law. As to the process-dimension of legalization, precision plays a stronger role in the concept of formalization since the latter would not be feasible without clearly defined regulations.

2.2.2 Formalization

Formalization refers to the degree to which rights and procedures are ex ante standardized by written procedural rules. Two elements are decisive. First, only if the rules of the game are a priori manifested in written form, clarity and transparency as fundamental elements of legalization can be fulfilled. This, in turn, creates stable expectations concerning participants’ rights and procedures to make, apply, and interpret rules. Such a formal framework is the foundation for due process and a legal system’s procedural legitimacy (Franck 1995: 7-8).

Second, formalization strives for conformity of behavior. It is characterized by a set of precise rules creating formally tight avenues of action accompanied by high institutional barriers to deviate from (Abbott et al. 2000: 412-413). They establish the legitimate social practices that at the same time reduce actors’ flexibility (Niederberger 2009: 232). A low

degree of formalization, by contrast, generally allows for more informal and flexible behavior (Aust 1986: 789; Boyle 1999: 901-902). Although informal procedures can be routinized, this is not sufficient to create formalization relevant for legalization as their alternation does not depend on a change of formal rules but of habit or tradition. Conform and consistent action yielded by formalization is intended to lead to the smooth operation of a legal system and the reduction of transaction costs. Conflicts seem to be at least superficially abolished. But formalization should not be confused with harmonization in terms of resolving all conflicts for good. Not all members are necessarily satisfied with the code of conduct. The inflexibility resulting from formalized rules' generalizing nature can also lead to a disregard of particularity. Under certain circumstances, a formalized procedure might not fulfill its intended purpose or cannot be employed if certain requirements are not met (Koskenniemi 2009a: 405).

One can analytically differentiate with regard to formalization of (1) membership, (2) decision-making, (3) monitoring, (4) sanctioning, and (5) dispute settlement.⁴⁴ The more these elements are standardized by secondary rules, the higher formalization and eventually legalization is. Each variable is classified in terms of high, moderate or low/no formalization.

Membership rules are the most constitutive norms in a legalized system. They are more than simple admission tickets to participate in a certain arena. They constitute the legal persons who exist within a legal community and are accorded with a defined set of rights. The formalization of membership rules produces transparency regarding entrance requirements for candidates. Membership rules encompass the accreditation rules of both full members and observers. Although access rules are often considered to be highly formalized in most international institutions (Breitmeier 2008: 185), they are frequently vague – in particular with regard to non-governmental organizations (NGOs) (Martens 2003: 8, 15).

Also *decision-making* is vital in legalized institutions. The decision-making rules determine the legitimate process of adopting rules that members should follow and that are legally-binding on all members in a highly legalized system. They structure deliberation by pinning down not only which actors can bring forward arguments, but also how and when they can make statements. The definition of a decision-making body's capacities delimits the scope of subjects that are allowed to be put on the table. By contrast, if decision-making remains lowly formalized, actors have less certainty of how they can engage in a debate.

Decision-making has various components that refer to both the setting and process of deliberation. It can be assessed to what degree the following elements are regulated:

⁴⁴ Implementation as another important part of the policy cycle is excluded because its formalization cannot be evaluated. The leeway that members possess in the implementation process is mainly driven by policies' precision. The only element of implementation that can be meaningfully assessed is the extent to which policy goals are accomplished. But compliance is independent of formalization. Connected with implementation is, however, monitoring and sanctioning which can influence the success of implementation. The formalization of these two elements is considered in the analysis.

decision-bodies' competences, delegations' composition, meetings' frequency, voting procedures and majority requirements, agenda-setting, amendment and revision procedures, and participatory rights such as the right to speak, number and length of speeches, and discussion of proposals.

Monitoring and *sanctioning* are two important features of enforcement that ensure that adopted rules are in fact implemented. Both can only be reliable and consistent if there are clear and comprehensive regulations that specify their procedures. This builds trust that the control of implementation and penalties for non-compliance are equally applied to all members. Detailed monitoring rules also facilitate exhaustive and in-depth surveillance that can deter non-abidance and again increase a system's credibility.

Monitoring and sanctioning are highly formalized if clear and stable mechanisms are in place to track implementation and to punish non-compliance. They are lowly formalized if there are only vaguely defined, lowly institutionalized or only represent ad hoc procedures. With regard to monitoring and sanctioning, one has to reflect if one evaluates a framework convention, constitution or a specific policy. The former two do typically not address enforcement and include it in follow-up policies. The formalization of monitoring and sanctioning is also connected with the precision of policies. If policies only state vague political objectives, also monitoring and sanctioning cannot be highly formalized.

Dispute settlement is the last element to complete the triad of legislative, executive, and judiciary. Actors choose legalized dispute resolution over traditional diplomatic conflict-solving if there are clear and reliable bodies to which they can turn. In order to have ample certainty of the proceedings, actors who consider filing a suit require knowing in advance who decides about the case on the basis of which rules, what is the decision's legal force, are there option to receive remedies, and eventually who can invoke proceedings. To this end, adjudication needs to be subjected to unambiguously regulated procedures. Dispute settlement is highly formalized if its process is clearly and comprehensively regulated. This includes the adjudicators' selection, the dispute settlement body's legal mandate, procedural rules, and standing. It is also important whether sanctions can be mandated or authorized if the other disputing party does not comply with the verdict. This element is included in the dimension 'sanctioning'.

How does formalization relate to soft and hard law? In the literature, scholars commonly characterize hard law as highly formalized and soft law as lowly formalized (Klabbers 2001: 411, 417). Hard law is governed by the VCLT that determines who is allowed to participate, vested with what rights and obligations (Goldsmith/Posner 2005: 95-97; Koivurova/Heinämäki 2006: 103). Although the VCLT is not sufficient to regulate international institutions in their entirety (Hafner 2003: 240), its rules set the "parameters of lawmaking" (Diehl et al. 2003: 46). Concerning membership, hard law can only be created by states – either by their behavior in form of customary IL or by international treaties (Koivurova/Heinämäki 2006: 102). Who is considered a state representative with

full powers to negotiate and adopt hard law is regulated in Article 7 of the VCLT. Generally this includes heads of states, governments, diplomatic missions, and ministers for foreign affairs. In addition to that, the interpretation and application of hard law are limited to legal reasoning (Green 1994: 208). This highly formal and technical mode of communication has to be differentiated from purely political argumentation (Koskenniemi 1999: 354-355). This subjects the law-making process to comparatively strict socialized rules (Abbott et al. 2000: 409-410). Therefore, hard law already entails a certain degree of standardization. By contrast, the scope of membership to non-legally binding accords is not legally restricted to traditional diplomatic actors (Slaughter 2004: 152). Concerning state actors, also “other ministries [than foreign ministries], domestic regulators, independent or semi-independent agencies (such as food safety authorities or central banks), sub-federal entities (such as provinces or municipalities) or the legislative or judicial branch” can be involved (Pauwelyn 2010b: 7). Nevertheless, one should not expect that soft law arrangements are generally characterized by a low degree of institutionalization and procedural rules. Although soft law can in principle be more flexible, many soft law organizations display a high number of secondary rules (Klabbers 2001: 409). Vice versa, also lowly formalized settings can yield hard law as exemplified by the informal and secret negotiations leading to the Anti-Counterfeiting Trade Agreement (ACTA).⁴⁵ In short, IOs do not necessarily have to be highly formalized (although this rarely occurs in practice) and international networks do not necessarily have to be lowly formalized.

2.2.3 Delegation

Delegation denotes the degree to which members of an institution authorize independent and well-resourced subgroups and third parties to monitor its rules, sanction non-compliance, interpret its rules, and resolve disputes. In a sense, delegation is another indicator of states’ intentions to legally bind themselves (Heusel 1991: 290).⁴⁶ It designates international institutions’ degree of independence from the control of individual states and ability to constrain state behavior (Haftel/Thompson 2006: 256-257). Delegation should not be confused with centralization. For example, regional and local offices can be granted greater autonomy and more authority than a central secretariat.

Among all legalization dimensions, delegation has been addressed with the most sophisticated measurement in IR research although not all of them are relevant for

⁴⁵ In this context, it is also problematic if the definition of formalization depends on institutions’ formal legal character. For example, the network Basel Committee on Banking Supervision (BCBS) was upheld as an example of “process informality” and contrasted with traditional UN-related IOs (Pauwelyn 2010b: 5). But as the research group headed by Pauwelyn rightly stipulated later on: networks can possess detailed rules of procedure (RoP) (Duquet et al. 2014: 82-83). The BCBS Charter proves this point (<http://www.bis.org/bcbs/charter.pdf>). The term “process informality” is therefore very misleading. Instead, the concept of formalization is better applied if it actually refers to the legal process and not only its legal institutional wrap.

⁴⁶ There can be other reasons for delegation, such as resource constraints (outsourcing), but these considerations are less relevant for the concept of legalization.

legalization.⁴⁷ Delegation as used here builds on Abbott et al. who only vaguely describe delegation's indicators as dispute resolution, rule-making, and implementation with a focus on the first criterion (Abbott et al. 2000: 401). My dimension goes beyond the original content to capture other essential aspects of a legalized system. So far, most research has considered adjudication as the central – frequently even the only – indicator of legalization. But also other elements and stages of the policy process are required for a sound legal system. For example, a well-developed adjudication is of little use if no appropriate procedure to monitor compliance and sanction defection is in place. Therefore, I add what Raustiala terms 'structure' which refers to monitoring and sanctioning mechanisms (Raustiala 2005: 585).⁴⁸ In addition to that, I include legal personality, legal commitment, bureaucracy, and financing.

In general, delegation is high if parties entrust bodies with significant powers and sufficient resources to fulfill core tasks of a legalized systems. These can be boards, councils, working groups, the secretariat, and under certain circumstances also individual members. Not all members need to be party to the organ that performs the delegated task. Besides internal delegation, states can also entrust external actors. This includes the outsourcing of implementation and monitoring to external private agents or other IOs as well as the submission of cases to international dispute settlement bodies (Koremenos 2008: 152). Some legal functions are better fulfilled if members have no direct influence on them to ensure independent and fair procedures.

In the case of low delegation, governments take the coordination of cooperation into their own hands and try to avoid the passing of authority to institutionalized and permanent third parties that might autonomously develop their own capacities and functions. In order to maintain their sovereignty, states retain the task of observing IL and punishing breaches of IL.

Relevant for legalization is delegation in the areas of (1) legal personality, (2) legal commitment, (3) bureaucracy, (4) monitoring, (5) sanctioning, (6) dispute settlement, and (7) finances.⁴⁹ Some of these elements resemble those of the formalization dimension but are explored from a different angle here. The focus is not on the preciseness of rules but the autonomy and resources with which an institution's bodies are vested to fulfill certain

⁴⁷ Brown 2010; Haftel/Thompson 2006; Hawkins et al. 2006; Koremenos 2008.

⁴⁸ It also shares some resemblance with 'centralization' in Barbara Koremenos et al.'s terminology (Koremenos et al. 2001: 771-772). They also address enforcement and adjudication. Nevertheless, it remains vague what they precisely understand by their variable.

⁴⁹ In contrast to the eight forms of delegation differentiated by Curtis A. Bradley and Judith G. Kelley (Bradley/Kelley 2007: 9-15), elements of decision-making (legislative, agenda-setting, and regulatory delegation) are not included here since these are not attributes of legalization. Commonly, decision-making is highly delegated if also sub-bodies, in which not all members are present, are allowed to agree on important rules, and usually simple majority voting – not consensus – is conducted in the plenary body. Institutions with majority rule are considered to be more independent because the number of veto player is downsized and unlike in the case of consensus voting, decisions can be reached against the will of certain states (Haftel/Thompson 2006: 258). Sub-bodies' competence and voting procedures are, however, no indication of the prevalence of the rule of law. This is different for the formalization dimension because legal systems require the existence of secondary rules that standardize and stabilize the rule-making process.

tasks. Similarly to the formalization dimension, delegation's indicators are measured along a continuum from low over moderate to high.

First of all, only institutions that are endowed with *legal personality* can be competent members of a legal society. It is a precondition to become party to a treaty or press charges against lawbreakers (Alvarez 2005: 129). In order for an institution to obtain the rights and responsibilities resulting from legal personality, state members have to be willing to endow it with a minimum of authority that can eventually restrict their own autonomy. Legal personality has a domestic and international dimension. Domestic legal personality denotes an institution's legal status within the territory of its member states whereas international legal personality also relates to non-members (Klabbers 2009: 44-50).

An institution's legal personality is usually regulated in its constituent documents. The international dimension of an international institution's legal personality was broadly recognized in the case 'Reparation for Injuries Suffered in the Service of the United Nations'. In its finding, the ICJ grants IOs a legal standing before certain international courts and makes them legally responsible for wrongful acts that they commit (Alvarez 2005: 130-139; Bederman 1996: 366-369). Commonly, the "functional necessity test" applies. The founding accord has not to expressly provide for international legal personality. It can be conferred if it is considered essential to fulfill the institution's duties (Klabbers 2009: 45; Shaw 2008: 1307). A case in point is Article 104 of the UN Charter in which it is stated that the "Organization shall enjoy in the territory of each of its Members such privileges and immunities as are necessary for the fulfilment of its purposes." Nevertheless, it strengthens an institution's legal status if a treaty explicitly grants international legal personality. Legal personality is strong if an institution expressly possesses both legal personality under domestic law and international legal personality. It is moderate if only one of them is granted and weak if both are absent.

By *legal commitment*, it is understood that members of an institution are equally bound to its rules and intend to continue their engagement within and for the institution. This is a precondition for a legal system's durability. In order for the rule of law to prevail, each member has to be equally subjected to the same rules. Otherwise the door for free-riding and differential treatment is opened. If states are allowed to withdraw from an institution's obligations – either by making reservations to specific paragraphs or leaving the institution, the delegation of any task can be circumvented and the institution's legal force is undermined. Legal commitment is considered to be high if the founding and subsequent agreements allow for no exit clause and reservations. Delegation of legal commitment is low if the possibility of reservations and an exit clause exist.

Also the enforcement process – *monitoring, sanctioning, and dispute settlement* – must be characterized by a high degree of delegation in a functioning legal system.⁵⁰ High delegation

⁵⁰ Like in the case of formalization, implementation is also neglected in the evaluation of delegation. The implementation of international regulatory policies is usually left to states so that there is not much variation with regard to international implementation mechanisms.

is a precondition for enforcement bodies to be vested with sufficient autonomy and authority to enforce legal rules independently, consistently, and equally. It is a vital element of legal systems that the abidance by law can also be enforced against the will of a member as long as the rule concerned was legitimately adopted. Otherwise, members of a legal community would not be equal before the law and powerful actors could abscond from unpleasant regulations. Following the law only in an opportunistic manner would drastically diminish fundamental legal principles like predictability, certainty, and fairness and render any legal system meaningless. The effectiveness of enforcement mechanisms is no indicator for the evaluation of legalization.⁵¹ Neither accountability problems that can result from delegation are discussed here.

Monitoring encompasses the information-gathering to review members' abidance by the rules. It is highly delegated if an institution obtains periodic, systematic, comprehensive, and independent data on members' implementation of its regulation. This is typically best executed by a third party or a central review mechanism – a 'police-patrol system' in Raustiala's terminology. It can be the secretariat, a body consisting of an institution's members or an external institution. Routine monitoring can be supported by a 'fire-alarm system' in which individual actors, including non-members and NSAs, can bring evidence of others' non-compliance to the attention of a monitoring body. They can assist in keeping track of implementation and increase the detection of cheating (Raustiala 2004: 393-394, 403-404). Special investigation can become important if unexpected crises make it necessary to examine the facts. Ideally, they can be initiated by actors without the approval of the suspected member (Brown 2010: 146). These complaint mechanisms cannot replace but only complement a separate monitoring organ as one cannot rely on other actors to be sufficiently affected or interested in a topic to obtain in-depth information on members' implementation of policies. Some members and issue areas might be more in the spotlight than others.

Delegation of monitoring can be impaired in several regards. First, states can retain the right to report on their progress of implementation or compliance is not evaluated for each member but only collectively (Raustiala 2005: 605). Second, monitoring can be limited geographically, temporally, technologically or resource-wise (Brown 2010: 146). In some cases, review mechanisms may also be non-existent.

Sanctioning refers to the consequences that follow from the detection of non-compliance during the monitoring process. Legally binding policies that were concluded within a perfectly legalized procedure are of little worth if they cannot be enforced. Also the credibility of dispute settlement procedures is bolstered if they possess the authority to enforce their decision by force if necessary. The sanction authority is highest if institutions provide for centralized and politically independent bodies that mandate and carry out

⁵¹ This should not deny the fact that a great political-science debate between 'managerialists' and 'enforcementalist' centers around the question if hard enforcement mechanism in fact increase compliance (Chayes/Handler Chayes 1993; Downs et al. 1996).

compulsory sanctions that cannot be blocked by the concerned parties. Moderate sanctioning delegation is observed if the institution can authorize at least limited sanctions that it can impose itself without further assistance and the concerned parties being able to obstruct them. This includes, for example, the restriction of voting rights or use of the institution's services. For more credible sanctions, states can be mandated to enforce sanctions on an ad hoc basis and are willing and capable to do so. There is low or no delegation of sanctioning if the institution is not granted autonomous sanctioning powers or it cannot authorize individual states to implement sanctions in the absence of states' willingness to execute them. In the case of dispute settlement, the disputing parties' decide about the exercise and scope of sanctions (Brown 2010: 147; Zangl et al. 2011: 18). Under these circumstances, sanctions depend on the unauthorized and unregulated initiative of individual states.

A well-functioning *dispute settlement procedure* is usually considered to be the flagship of any legal system (Zangl et al. 2011: 2). The judiciary is the body that usually receives most trust among all organs in political systems. It is also where law's ostensible fair character becomes most obvious. It is expected to be impartial, treat parties equally, and to be solely governed by legal reasoning. Adjudication can only be highly developed and hence highly judicialized if actors delegate a considerable amount of authority to the respective organ in order to vest it with important rights and capacities. This can include the adjudication of contentious cases and also the clarification of law's meaning. In not or lowly judicialized institutions, dispute settlement is impaired or absent. Bernhard Zangl and his research group developed an elaborate yardstick to evaluate the degree of judicialization of international dispute settlement procedures.⁵² The dimensions encompass (1) political independence, (2) legal mandate, (3) decision-making authority, (4) standing, and (5) authority to sanction.⁵³ The last criterion is separated and already covered by the above discussed dimension 'sanctioning'. Depending on the fulfillment of each of these dimensions, dispute settlement procedures can range on a continuum between diplomatic and court procedures. The former are lowly delegated while the latter are highly delegated. The focus on international dispute settlement procedures should not disregard the fact that IL can be brought before national courts. This is, however, not considered to be part of *international* legalization. National courts can play a role in IL's development. This then is a cause rather than a characterizing element of international legalization.

First, the insulation from direct political interference is a precondition to ensure unbiased decisions by the judges irrespective of disputing parties' economic or military capacities. In a court-like procedure, politically independent judges of a permanent judicial

⁵² This typology overlaps to a large extent with the one developed by Robert O. Keohane and his colleagues. They establish a spectrum between interstate and transnational dispute resolution depending on the adjudicators' independence (selection, tenure, legal discretion, financial and human resources), access to dispute resolution, and embeddedness (enforcement of decisions) (Keohane et al. 2000: 459-468).

⁵³ I use 'standing' instead of the authors' term 'access' in order not to create confusion with the dimension 'access' in relation to democratic participation which I present in the next chapter.

body perform adjudication.⁵⁴ Independence is still high but reduced, if independent experts decide about a case. It is further diminished if political representatives of third parties form the organ. It is completely politically susceptible if the disputing parties themselves or their representatives act as judges.

Second, legal mandate denotes the reasoning and procedure that are relevant for solving a conflict as well as the findings' legality. In a highly judicialized dispute settlement procedure the organ issues legally binding verdicts in accordance with binding and comprehensive procedural rules that only allow for legal reasoning. Hence, a strong legal mandate ensures that all actors are subjected to the same legal rules and have the same legal rights within a proceeding. The legal mandate is weakened if the decision is only recommendatory but concluded in compliance with a binding and legal procedure. The mandate is rather political if there are only vague procedural rules that nevertheless conclude with a juridical recommendation. A purely political mandate is characterized by a political decision that is the result of diplomatic negotiations in which political considerations prevail.

Third, decision-making authority refers to the possibilities of the disputing parties to block the proceedings or decisions. In a highly judicialized dispute settlement, the organ is vested with obligatory jurisdiction and neither proceedings nor decision can be blocked or vetoed. Decision-making authority declines if proceedings and decisions can be put on hold by a majority decision. Procedural obstructions further increase if the disputing parties themselves can block proceedings or decisions.

Last but not least, an open standing to dispute settlement procedures can enhance judicialization. It can be beneficial for the enforcement of law if the judicial organ can be invoked by all state members and also IOs, NGOs, and individuals. States tend to carefully calculate the risks and benefits of filing a suit against another state. This applies in particular to situations in which powerful actors violate rules that affect weaker states. By contrast, NSAs and individuals are not exposed to these considerations to the same extent and hence are more likely to bring a complaint against powerful states. Therefore, inclusive standing puts additional pressure on states to adhere to rules as their non-compliance is otherwise more likely to be sued. Standing is most open if also individuals may invoke dispute settlement proceedings. It is still open but more restricted if only states and NSAs can issue complaints. Access is restricted if only states have a standing and especially limited if no formal right of complaint exists (Helmedach et al. 2009: 41-49; Zangl et al. 2011: 18).

Last but not least, sufficient *resources* are a precondition for the sound functioning of any legal system. The two pillars of resources are finances and staff. As to finances, relevant are the absolute amount of budget and its source. In the absence of stable and sufficient capital

⁵⁴ The adjudicators' independence is even more strengthened if the judges are selected for long tenures (Keohane et al. 2000: 460-461).

by their members, international institutions depend on the good disposition of donors with their own political agendas. Financial autonomy is high if the budget is mainly composed of obligatory member contributions or if the institution is self-financing, for example, due to services that it offers. Moderate financial autonomy is characterized by dependence on voluntary but regular allowances. In the case of financial dependency, institutions are financed on an ad hoc or reimbursement basis.

A well-staffed and independent secretariat is necessary to effectively support an institution with the fulfillment of its tasks and ensure a bureaucracy's autonomy. Therefore, staffing is considered highly delegated if civil service is recruited independently with no possibility of state veto, moderate in the case of staff appointed by state members with no accounting responsibility, and low if staff consists of national civil servants.

Delegation is generally the least sophisticated dimension when comparing IL with domestic law due to the lack of a globally centralized world government, police, and court. Apart from questioning the practice of using national legal systems as prototypes against which international institutions have to be measured, states observe IL, often make violations public, and frequently punish them (Shaw 2008: 6). Therefore, the lack of international independent sanction mechanisms should not be overemphasized since states also often comply with IL in their absence (Wolf/Zürn 1993: 15). A quantitative study of 97 international agreements (\geq two states) across several issue areas revealed that states make use of delegation in more of the half of all cases with dispute resolution being the most frequently delegated task, both internally and externally (Koremenos 2008: 159, 164).⁵⁵

To what extent have these dimensions to be weighted differently? Legality certainly represents legalization's essential criterion. As it has already been mentioned, delegation is the empirically least pronounced dimension and cannot take center stage in classifying institutions' degree of legalization. An overview of the criteria to differentiate between high and low legalization is presented in the table below.

⁵⁵ Admittedly, Koremenos also found a significant and positive relationship between withdrawal clauses and delegation (Koremenos 2008: 176).

Table 1: Elements of International Legalization*1 Legality*

1.1 Formal powers

1.2 Intention

2 Formalization

2.1 Membership

2.1.1 Full members

2.1.2 Observers

2.2 Decision-making

2.2.1 Bodies' competences

2.2.2 Delegations' composition

2.2.3 Frequency of meetings

2.2.4 Voting procedures and majority requirements

2.2.5 Agenda-setting

2.2.6 Amendment and revision

2.2.7 Participatory rights

2.3 Monitoring

2.4 Sanctioning

2.5 Dispute settlement

2.5.1 Selection

2.5.2 Legal mandate

2.5.3 Procedural rules

2.5.4 Standing

3 Delegation

3.1 Legal personality

3.2 Commitment

3.2.1 Exit clause

3.2.2 Reservation

3.3 Monitoring

3.4 Sanctioning

3.5 Dispute settlement

3.5.1 Political independence

3.5.2 Legal mandate

3.5.3 Decision-making authority

3.5.4 Standing

3.6. Resources

3.6.1 Source of budget

3.6.2 Budget absolute

3.6.3 Staff number

3.6.4 Staff filling

Chapter 3

Democratic Participation in International Institutions

In December 2013, the General Assembly adopted resolution 68/175 that affirms that “everyone is entitled to a democratic and equitable international order” (UN 2013: para. 2). Why should international institutions require democratic legitimacy in the first place? This demand has mainly been justified with the growing transfer of authority to international institutions in order to exercise public tasks that have previously been fulfilled within the state.⁵⁶ Political regulation moved outside state borders while democracy’s main playing field remained within the national arena. In order for democracy to follow politics, also international institutions have to meet democratic standards in order to ensure that policies that deeply affect individuals’ lives represent a rule by and for the people. This becomes in particular important if institutions’ policies imply far-reaching distributive consequences. Citizens reject to carry the burden that such policies impose on them or are unwilling to dispense with certain benefits if they consider the procedures that arrived at these decisions to be undemocratic (King 2003: 23, 26). Therefore, technocratic models to govern complex societies are rebuffed by citizens’ increasing democratic demands (Warren 2002: 680-683). The distrust in politicians was epitomized by massive public protests that, for example, accompanied the WTO’s third ministerial conference in Seattle in 1999 and the G-8 summit in Genoa in 2001.

Although there is widespread support for democratic rule, its meaning is far from finding consent. While it is already contested what democracy means within the national context, this is even more complicated when applying the concept to the supranational level (Krisch 2010: 264-272). This difficulty is mirrored in the debate about the appropriate criteria of international democratic quality.⁵⁷ Problems to agree on international democratic principles are caused by various factors. First and foremost, the international arena displays a more complex actor constellation. We can observe a multitude of diverse actors in terms of their nature, geographical origin, and agendas. This raises fundamental questions about who represents the democratically legitimate actors in international meetings. Second, the international political structure is more intricate. Traditional modes of representation are challenged by citizens’ greater remoteness from the actual fora of decision-making, most subject matters’ transnational dimensions, and the multi-level structure of negotiations that forces state representatives to satisfy the needs of both their constituencies and their

⁵⁶ See for example: de Búrca 2008: 235-236; Ecker-Ehrhardt 2014: 28; Krisch 2010: 264; Kuyper 2014: 622; Zürn et al. 2012: 71. It is not presumed that democratic participation is required to a different extent varying with the level of legalization since all selected institutions in this project display a minimum of public authority that has often been considered as a precondition for democratic demands (de Búrca 2008: 233).

⁵⁷ I generally use the term ‘democratic quality’ instead of democracy because the latter often entails the presumption of state-like structures in the debate. This can create confusion as the focus here is on international institutions and their democratic performance.

negotiation partners (Buchanan/Keohane 2006: 416; Putnam 1998). Also democratic control is burdened by the greater physical distance between citizens and international political actors as well as the fragmentation of international political authority. The fulfillment of accountability is more difficult within international institutions than states due to longer and more diverse delegation chains, a diffusion of responsibility among a multiplicity of actors, and the paucity of effective enforcement and sanction mechanisms (Esty 2006: 1537; Koenig-Archibugi 2010: 1156-1158). Against this background, one has not only to consider what democratic standards are ideally desirable but also attainable.

Third, the international political issues that have to be tackled are wicked. The increased interdependence and complexity of problems accompanied with policies' unintended consequences complicate the settlement of international political conflicts. In addition to that, policy choices and risks are often unequally distributed (Warren 2002: 683-686). While policy choices often lie in the hands of Northern power-wielders, the risks are often beard by less affluent Southern countries. These circumstances complicate democratic decision-making, but make it at the same time even more necessary. If international policies inevitably affect a broad range of stakeholders with often unforeseen implications, affected actors need to be able to effectively participate in the formulation of these policies.

In order to tackle the contested concept of democratic participation, I proceed in three steps. The chapter starts with a brief review of different models of international democratic quality to locate and evaluate the role of international democratic participation. While for some international institutions' democratic quality can be measured by means of their utility and problem-solving capacity (output legitimacy), others consider the procedures by which policies are created and implemented (input-/throughput legitimacy) as pivotal. Therefore, democratic assessments can diverge considerably whereas I argue that democratic participation is the fundament of democratic governance. Second, I discuss who are the democratically legitimate actors at the international level. States remain the main representatives in democratic decision-making and are primarily in charge to ensure democratic procedures. Nevertheless, NSAs can be significant auxiliaries to improve democratic participation due to their democracy-enhancing functions. Last but not least, I present my conceptualization of democratic participation. It is explored who (*access*) can on what terms (*involvement*) participate. As democratic standards serve *congruence* between decision-makers and mostly affected actors and *contestation* in deliberations. In the light of the controversy on international democratic principles, I openly present the analytical yardstick to enable an informed and fruitful debate on the concept.

3.1 Models of International Democratic Quality and the Role of Participation

Democracy is on everybody's lips nowadays. But it is a buzzword that urgently needs clarification before it can be put to good use. This section starts with a sketch of six main strands of international democratic quality. The goal is to show important differences rather than the complete collection of international democratic theories. Apart from its utility, the latter would be a Sisyphean task as one could fill libraries with books on (inter)national democracy. International democratic theories can be differentiated as to their democratic standards and optimism to achieve them internationally. They can be grouped into *replicative* (containment and transfer), *compensatory* (technocracy, control), and *participatory* models (representative-moderate, direct-radical).⁵⁸ These labels are largely based on the work of Gráinne de Búrca and Nico Krisch (de Búrca 2008: 236-239; Krisch 2010: 14-16).⁵⁹ The brief overview exposes the models' benefits and pitfalls. Neither replicative theories nor the output-oriented standards of compensatory models alone can guarantee democratic governance. Due to its crucial functions for democracy, democratic participation has to be fulfilled to live up to democracy's core: self-government.

Most ambitious are *replicative* theories that see international democracy only fulfilled if domestic democratic institutions and values are replicated one-to-one at the international level. This strand usually presumes that democracy requires state-like structures to flourish. Only within a strongly state-like institutionalized framework, a political community that guarantees political and civil rights can be established (Görg/Hirsch 1998: 594-595). Consequently, international democratization premises an international constitutionalization in order to establish a political sphere analogous to the domestic constitutional framework.

Containment theories – the pessimist variant of replicative theories – deny that these conditions can ever be met beyond the state. Democracy depends on clearly demarcated political territories and confined sovereign political entities (Dobner 2010: 149; Maus 2007: 370). According to Robert A. Dahl, foreign policy has traditionally been non-democratic.⁶⁰ International relations are characterized by elitist negotiations of low popular control while citizens get only politicized and active in rare circumstances. This trend continues in international institutions that Dahl describes as “bureaucratic bargaining systems” with

⁵⁸ Many scholars who can be classified into one of these approaches do not offer democratic theories in the strict sense but rather convey underlying assumptions on international democracy with far-reaching consequences for their actual research objects.

⁵⁹ De Búrca focuses on the compensatory approach while Krisch distinguishes between the three strands ‘containment’, ‘transfer’, and ‘break’. There are myriad of other ways to distinguish different models of democracy. Fritz W. Scharpf differentiates between liberal and republican models (Scharpf 2010: 99-92). Andrew Moravcsik distinguishes between libertarian, pluralist, social democratic and deliberative democracy (Moravcsik 2004: 338-342). Magdalena Bexell and her colleagues use the trichotomy of representative, participatory, and deliberative democracy (Bexell et al. 2010: 83-85). Jan A. Scholte chooses the categories of statism, modern cosmopolitanism, and postmodern global democracies (Scholte 2014).

⁶⁰ Remarkably, even Dahl, who denies that international democracy is feasible, proposes to have a democratic yardstick against which international institutions should be evaluated (Dahl 1999: 34).

only a minimum of responsiveness (Dahl 1999: 33). A democratization of international relations is impeded by several factors of scale. In comparison to national systems, international institutions lack equivalent effective mechanisms of political education, participation, and accountability (Dahl 1999: 31-33). Long and opaque chains of responsibility render meaningful control impossible. Besides that, the plurality of interests is too fragmented to agree on common political positions and values in the absence of a transnational demos (Dahl 1999: 26), common culture and history (Maus 2006) or a global social compact (Dobner 2010: 149). Last but not least, most citizens are apathetic toward international affairs. Not only are they not sufficiently informed, but they show simply not much interest in international politics.⁶¹ One reason is that policies like health care and social security, which palpably address citizens' daily life at least in Western countries, are still dominantly regulated by national rules. A politically passive citizenry, however, cannot form the foundation of democracy (Moravcsik 2005: 374-375; Moravcsik 2004: 337, 342). Under these conditions, a global democracy remains a wistful utopia (Rabkin 2005: 245-248).

As democratic self-government is only possible within the state according to the containment approach, the democratic quality of international decision-making can only be strengthened by the internal democratization of states. This ensures that citizens are represented by democratically elected governments whose decisions are additionally legitimized by the ratification of national parliaments (Scharpf 2009: 251). By the same token, the fulfillment of democratic functions requires states to retain the sovereignty to self-determinedly shape their internal and external policies as it has been most explicitly emphasized by U.S. sovereigntists (Rabkin 2005; Rubinfeld 2004). The delegation of authority to supranational bodies should be restricted and revisable (Scharpf 1993). Since democracy's source lies within the state, international institutions can only be legitimate as long as they do not endanger states' internal democratic quality (Keohane et al. 2009: 23). International political participation is mostly carried out in traditional negotiations by foreign diplomats who follow the instructions of their national capitals.

Two main values come with containment theories. First, they remind us of states' vital democratic functions with which also international democratization cannot dispense. In the absence of a world government, states will most likely continue to structure political communities and aggregate political interests. Second, they stress democracy's demanding requirements and conditions and warn against the application of all too weak democratic standards.

Nevertheless, a democratic focus on state sovereignty is neither practically possible nor normatively desirable. Nowadays, thousands of international institutions are in place to assist states in the coordination of political action and its implementation. While some of

⁶¹ One recent example is Ebola that did not start to make big headlines in Western countries before their citizens began to worry about the spread of the virus into their immediate vicinity.

these institutions are of rather administrative-technical nature, many possess considerable authority and are engaged in the conclusion of high-stake policies. Even when – although unrealistically – assumed that states would reverse the trend of supranational cooperation, globalization processes and transnational movements will continue. Under these circumstances, no state can act as an autarkic island. National policies will neither affect only a state's own population nor yield highly effective outcomes in the case of transnational subject matters (Scholte 2014: 7-8). Both the democratic standard of congruence between affected individuals and decisions-makers and the responsibility to act to one's citizenry's welfare is violated in these situations (Krisch 2010: 21-22). Therefore, the transfer of national sovereignty to the supranational level is not a matter of choice but a question of the legitimate terms and conditions. Moreover, containment theorists tend to idealize states' internal democratic quality (Keohane et al. 2009: 4-5). In particular, their concept of participation is narrow-minded because it turns a blind eye to possibilities to adapt traditional national participations mechanisms to the international environment.

Transfer theories, like some strands of cosmopolitanism and constitutionalism, are more optimistic as to the establishment of an international democratic framework more or less analogous to the domestic context and even see it already partially accomplished (Held 1995b; Koenig-Archibugi 2011). They share most of containment approaches' democratic values but believe that an increased international institutionalization advances – and does not impede – their realization. Based on the belief that all human beings are of equal worth and dignity regardless of their nationality, ethnicity, gender, and age, cosmopolitans support universal human rights and democratic governance standards (Held 2009: 537; Pogge 1992: 48-49). The entire world society is committed to strive for the fulfillment of these rights. Characteristic for this group is the view that an international democratization is indispensable. Globalization processes establish interconnectedness across different fields and governance levels that challenge the traditional Westphalian system and increase the pressure to coordinate political action supranationally (Held 1995a: 267; Höffe 1999: 10ff). These growing transboundary movements are considered by liberal theorists in the Kantian tradition to have a pacifying and democratic effect on international cooperation, in particular among republican states (Tesón 1992).

As diverse as the group of cosmopolitans are, as much vary their proposals of institutional design. They range from a global pluralist order to a federalist world structure (Krisch 2010: 38-52; Zürn 2011: 82-96).⁶² Only the latter group clearly classifies into the category of transfer-thinking as the other agree to more or less extent with the concerns of containment scholars. David Held most prominently offers a cosmopolitan model of democracy. It includes in the long run, among others, a charter of rights and obligations, a global authoritative parliament, worldwide rule of law bolstered by international courts,

⁶² Most cosmopolitan theorists are not as utopian and radical as often portrayed and repudiate their association with a world state concept (Cabrera 2010: 521).

accountability mechanisms connected to global and regional parliaments, guaranteed basic income, a permanent shift of state's monopoly of force to regional and international institutions, and a standing international force with the goal of a universal demilitarization (Held 1995a: 270-280). Being more moderate, Jürgen Habermas does not believe in a democratic world state but proposes a multi-level system of democratic states. Democratic self-governance should be fulfilled and legitimized within states and strengthened by the international guarantee of human rights (Habermas 2008).

Participation plays an important role in transfer theories and is incorporated in many varieties. For instance, Held advocates representative participation via regional parliaments but also direct participatory means like the “extensive” practice of referenda although he does not consider them likely under current international circumstances. In addition to that, a vibrant civil society should organize itself in associations (Held 1995a: 273, 280).

Transfer models have several strengths. First, they treat democracy in all its facets and therefore come up with rich multidimensional democratic models. Second, they emphasize that the individual is the ultimate point of reference in democratic theories. This cannot be neglected even if democratic standards are established at the supranational level. Third, they acknowledge that state boundaries no longer define the communities of affectedness and adequate sphere of problem-solving (Scholte 2014: 9). But even if these scholars formulate their models with a long-term perspective, their visions depend on numerous ambitious conditions that cannot be expected to be met in the next decades to come. Besides practicality issues, cosmopolitanism has further conceptual pitfalls. It tends to overemphasize the global order and thereby neglects the need to democratize lower levels of governance (regional, national, and local). It bases its model on a universalist conception of the people and disregards that other forms of identity and solidarity – like class, gender, and race – still run deep (Scholte 2014: 10).

The second and most common group of *compensatory* theories is united by their stronger consideration of international constraints. This results in less demanding international democratic models.⁶³ They usually presume that democracy cannot be comprehensively or directly translated from the domestic to the international arena. Instead, only a few democratic core elements or some substitutes to guarantee democratic legitimacy can be transposed. The compensatory strand encompasses a heterogeneous set of approaches that range from considerations on efficiency over transparency to accountability (de Búrca 2008: 240-248). Since compensatory theorists already include the feasibility of international democratic standards in the formulation of their models, they are usually optimistic as to their realization.

⁶³ De Búrca divides the compensatory approach in accordance with democratic legitimacy based on (1) merits of the decision-makers (independent expertise and functional participation/participation of most-interested), (2) output of process, and (3) decision-making process (transparency and accountability). The first two are subsumed under technocracy while the last one is named ‘control’ here.

The *technocratic* approach emphasizes the output of political action. According to this management approach, international cooperation is democratically legitimized if it generates efficient and effective outcomes with usually welfare-enhancing benefits (Görg/Hirsch 1998: 596-597). This has been justified from two sides. First, policies' quality can serve as a democratic surrogate in the light of difficulties to ensure international procedural democratic standards. Second, national democratic procedures have come under criticism by elitist democratic theories à la Schumpeter for their ostensible irrationality. This irrationality is even more severe in complex international decision-making. Hence, the restriction of traditional democratic elements can be a necessary step to restore rationality and secure people's welfare. Instead of inclusive participation, expertise and efficient allocation of resources should prevail. This rationale of economic utility only relates to democracy in the broadest sense as it pledges to generate primarily socio-economic well-being. It may be a government *for* the people but by no means *by* the people (Brunkhorst 2003). Participation plays only a marginal role here. Experts might act as national delegates. However, their focus is not on the representation of their state's citizenry but on the weighting of ostensible rational arguments.

This technocratic framework can be alluring at first glance because it pretends to abolish political conflict and irrationality in order to reach the apparently best objective agreement. But technocratic decision-making can neither comprehensively foresee policies' outcome in highly uncertain and complex times nor can it solve political conflicts in which diametrical interests and logics, as for example in the case of environment versus economy, are involved. Eventually, also experts are not omniscient and face challenges to evaluate the scope and needs of all affected actors. Inclusive participation can mitigate this problem by gathering broad input on these issues.

Supporters of *control*-oriented democratic models agree with the efficiency strand that direct participation is not feasible on the international plane. If representation and delegation of tasks to international bodies is inevitable, then transparency and accountability become the central democratic prerequisites. Transparency defines to which degree what information is openly accessible or activities take place publicly.⁶⁴ Particularly in international relations, which are often said to be remote from the public, transparency plays an important role to assess international actors' performance. It enables citizens to reconstruct the policy process and subject it to public scrutiny. Transparency can serve different democratic functions. It can monitor actors' performance, adherence to rules but also their credibility.⁶⁵ Secondly, "transparency mechanisms institutionalize public discourse" (Hale 2008: 85). Based on the information made available, citizens can engage in a debate about certain policies or rules of conduct. Thomas Hale describes transparency as the crucial basis of accountability that can safeguard the latter even in the absence of strong

⁶⁴ Dingwerth 2007: 29; Hale 2008: 74; Payne/Samhat 2004: 58.

⁶⁵ Hale 2008: 85; Koppell 2010: 35; Slaughter 2004: 5.

formal enforcements mechanisms (Hale 2008: 74). Accountability ensures that delegates use authority in accordance with those on whose behalf they act (Héritier/Lehmkuhl 2011: 126). Accountability, can be summarized as (1) the obligation of delegates to disclose and justify their activities (2) according to a certain yardstick, and (3) the right of those having entrusted the power to evaluate the latter's conduct and if necessary impose sanctions on them.⁶⁶ The first element goes beyond transparency and additionally demands reporting and review mechanisms. The benchmark against which actors can be held accountable ranges from formal rules to meeting political goals. Sanctions can vary from non-reelection, dismissal, reputational harm to material penalties (Koenig-Archibugi 2010: 1156). Transparency and accountability are undeniably important features of a full-fledged democratic system. But these criteria alone cannot ensure self-governance as necessary condition for democracy.

Last but not least, *participatory* democratic models can generally be differentiated between moderate-representative and radical-direct variants. All of them do not settle for the minimalist standard of competitive elections but demand active participation. In opposition to an elitist approach, *radical theories* promote bottom-up participation to enable active and direct citizenship. This can materialize in form of social movements, transnational referenda or NSA access to international adjudication (Bexell et al. 2010: 84). The World Social Forum represents one example of an alternative initiative to democratize global governance (Teivainen 2002). In the EU context, EU-wide referenda and online consultations can be another departure toward supranational democratization. For radical models of direct democracy, both procedural and material considerations are relevant. Equal participatory opportunities have to be supplemented by socio-economic equality. Existing (inter)national structures and institutions are most of the times manifestations of power asymmetries so that their reformation is futile. Instead, these theories often recommend a fresh start of institution-building which can require revolutionary upheavals. More important than international institutions, however, is the strengthening of agency in international politics. Due to these demanding requirements to bring about international democratic change, radical participatory theorists are torn if these conditions can ever be met but appear to be optimists by necessity.

This approach's asset is the emphasis on self-determination as a core democratic value. But its disadvantage is the practical implementation of their models. Although their proposals are desirable from an idealist perspective, they remain utopian for the time being. These authors also remain rather vague as to the institutional implementation of their proposals. An example is the proposal by John Dryzek and his colleagues to establish a deliberative global citizens' assembly without a specification of its functions (Dryzek et al. 2011).

⁶⁶ Bovens 2007: 450; Buchanan/Keohane 2006: 426; Grant/Keohane 2005: 29; Keohane 2002: 12.

Less demanding are *moderate-representative* theories that also approve representative modes of participation and focus on the procedural dimension of decision-making. To the moderate-representative approach belong most discursive models. These also emphasize participation and demand deliberation to meet democratic standards. It should be an informed exchange of rational and well-justified arguments within a transnational public sphere (Dryzek 2006; Habermas 1984). Participants should be honest about their interests, respect and learn from others' arguments, and constructively work toward reaching the best outcome that takes into consideration the common good.⁶⁷

Participation, as sketched in deliberative theories, emphasizes democracy's active dimension. Democracy is "more about deliberation, reasoned argument and public reflection than voting and aggregation" (Bäckstrand 2006: 475). Democracy with passive and indifferent citizens cannot survive in the long-term. This lack of democratic agency exactly represents one of the great democratic challenges in the 21st century. I do, however, not side with the often made distinction between an aggregated model of democracy in which voting on fixed preferences represents the main democratic means and a deliberative model of democracy in which participants carefully weigh the different arguments before reaching an agreement.⁶⁸ Both forms of democratic participation are not mutually exclusive because intense deliberation can precede voting.

More flexible is de Búrca's democratic-striving framework which also belongs to the groups of moderate-representative models. Embracing the idea that the journey is the reward, one has to make every effort to achieve the most inclusive participation that is possible without impeding decision-making's effectiveness. In order to reach inclusive participation, all relevant stakeholders have to be identified and involved. Both the scope of stakeholders and policies can constantly be redefined due to a continuously open structure of "built-in provisionality and revisability" (de Búrca 2008: 248-254). The great strength of the democratic-striving approach is its procedural nature that allows its adaption to changing international conditions and moral standards while holding up core democratic values. Democratic participation beyond the state needs to be conceptually detached from a state-centered framework and therefore differs from its national counterpart. It acknowledges existing international challenges to democracy but also the inevitable necessity to democratize international governance. De Búrca therefore recognizes the "act of continuous striving itself as the source of legitimation" (de Búrca 2008: 237). This model's greatest challenge is that flexibility must not lead to analytical arbitrariness.

Not all models of international democratic quality are mutually exclusive. They rather differ in their emphasis of democratic values. For example, containment scholars also support international control mechanisms but would refrain from labeling their fulfillment as democratic. An overview of all models is provided in the table below.

⁶⁷ King 2003: 25-26; Nanz/Steffek 2005: 370; Steenbergen et al. 2003: 25-26.

⁶⁸ Dryzek 2000: 4; Nanz/Steffek 2005: 370; Warren 2002: 679.

Table 2: Models of International Democratic Quality

	Replicative theories		Compensatory theories		Participatory theories	
	Containment	Transfer	Technocracy	Control	Moderate-representative	Radical-direct
Core values	state sovereignty, national democracies	peaceful and democratic world society	socio-economic well-being	good office, responsiveness	self-determination	self-determination, political-economic equality
Means	state	global state-like bodies and structures, human rights, rule of law	expertise	transparency, accountability	discourse/inclusive participation by all affected actors, representative modes of participation	direct and active participation, social bottom-up movements, (extra-) institutional revolution
Role of international participation	marginal	important	marginal	marginal	central	central
Prospects for democracy beyond the state	grim	optimistic	optimistic	optimistic	optimistic	torn

In this study, I side with moderate-representative participatory theories in agreement that participation is a fundamental democratic value that by no account can and should be compromised. A radical approach of direct international participation is far from being realizable at present and therefore not appropriate to evaluate the current state of democratic participation in international institutions.

Essential benefits of participation are formulated by Thomas C. Beierle and Jerry Cayford with regard to public participation. Although their research interest lies on institutionalized mechanisms to include lay citizens in decision-making, their elaboration emphasizes the importance of participation in general. Participation's five functions are the:

- (1) "Incorporation of public values in decisions
- (2) Improving the substance of decisions
- (3) Resolving conflict among competing interests
- (4) Building trust in institutions
- (5) Educating and informing the public" (Beierle/Cayford 2002: 14-15).

First, the opinions of citizens and experts often diverge significantly (Beierle/Cayford 2002: 14). Therefore, the representation of public interests brings another dimension to decision-making. This is particularly important in the case of highly politicized issues for which no technically right decision is at reach and each choice entails great distributional implications. If citizens are involved – directly or indirectly – in deliberations, they are more willing to accept policies' unpleasant effects or that certain standards and interests take priority over others (Keohane et al. 2009: 8).

Second, fair and inclusive participation cannot only enhance procedural legitimacy but also output legitimacy both in a technocratic and just sense. Open participatory modes in which diverse interests can be represented yield a comprehensive and in-depth view on a problem. This includes various societal aspects ranging from economic over social to environmental ones as well as first-hand information and experience from locals. Such a rich collection of knowledge builds a solid foundation to reach decisions of high quality and broad acceptance. International institutions can reinforce this effect by bringing together even more information and subjecting national positions to external scrutiny (Keohane et al. 2009: 18-20). If all affected groups get a chance to make their case, a balanced distribution of benefits is more likely (Albin 2008: 760).

Third, bringing all parties to a conflict at one table to discuss issues in an impartial manner reduces tensions and assists in overcoming stalemates. The parties can increase mutual understanding and are more likely to accept a compromise if they can rely on the adherence to principles of procedural fairness.

Fourth, greater public participation helps to regain citizens' trust in political institutions (Beierle/Cayford 2002: 15). Citizens have become increasingly sceptical of political bodies in the last decade. Political work has been perceived as an ivory tower that is out of touch with citizens' everyday life. Politicians are believed to no longer represent the lay public's interests and cannot be held accountable. If citizens experience via greater participatory possibilities that their voice matters, trust in political institutions can be recaptured.

Fifth, participation has an educational and capacity-building function. It increases participants' understanding of a problem and the ways to tackle it (Beierle/Cayford 2002: 15).

Only few studies have attempted to empirically measure democratic participation. Among the few exceptions, discursive studies certainly take the lead. One of the few studies that provide clear criteria to empirically assess deliberation is the Discourse Quality Index (DQI) by Marco R. Steenbergen and his colleagues (Steenbergen et al. 2003). The index is theoretically grounded in Habermas' discourse ethics and encompasses seven indicators: (1) free participation, (2) level of justification, (3) content of justification, (4) respect toward groups, (5) respect toward demand, (6) respect toward policies' beneficiaries, demand of others and counterarguments, and (7) constructive politics. The DQI's main advantage is its great attention to participants' interaction. Its downfall is the narrowness of the coding categories used to conceptualize participation. Steenberg et al., for instance, define free participation as a binary variable that indicates if a speaker is interrupted or if normal participation is possible (Steenbergen et al. 2003: 27). This does not include if a participant was allowed to speak in the first place or if the speaking time was restricted in advance. It is also not comprehensible why the consideration of the common good is an intrinsic part of deliberation (Steenbergen et al. 2003: 25-26, 28-29). Democratic participation that aims for self-determination preconditions that participants

represent their self-interests (Mansbridge et al. 2010). Eventually, some of the authors self-critically admit several limitations of the DQI. It is difficult to measure respect and the level of justification, including the quality and persuasiveness of reasoning and communicative short-cuts, and to account for non-authentic language like sarcasm and irony (Bächtiger et al. 2010: 40-42). Nevertheless, this work stands out for presenting transparent coding rules that can be applied to observable behavior. A similar deliberative approach by Patricia Nanz and Jens Steffek concentrates on NSAs. They propose to assess the democratic quality of international deliberation by means of (1) access to deliberation, (2) transparency and access to information, (3) responsiveness to stakeholder concerns, and (4) inclusion of all voices (Nanz/Steffek 2005: 373; Steffek/Nanz 2008: 10).

My measurement of democratic participation differs from such discursive approaches. The latter take a Habermasian rational discourse in which truth-seeking and learning prevail as a baseline. I rather consider this form of deliberation as utopic because it does not take into consideration real-life constraints such as power asymmetries between participants that disadvantage certain groups, actors' cognitive limits to conduct a rational discourse, and problems to differentiate between communicative and strategic action (Bächtiger et al. 2010: 39).

More appropriate to conceptualize democratic participation are Cecilia Albin's criteria of procedural justice in international negotiations. These comprise (1) transparency, (2) fair representation, (3) fair treatment and fair play, and (4) voluntary agreement (Albin/Druckman 2014: 4; Albin 2008: 763-765). Since Albin's main concern is not democracy, the democratic standards of fair representation and treatment are more pronounced in my model.

As systematic empirical studies on normative concepts are still in their infancy, I use a parsimonious concept of democratic participation that can be empirically put into practice within this study's scope. This is not meant to be a full-fledged model of democratic quality. It is a starting point on which future studies can build and add further dimensions.⁶⁹

⁶⁹ Although participation is a vital necessary precondition for democracy, it is not a sufficient one. Democratic procedures also require transparency and accountability mechanisms to control representatives. In addition to these procedural criteria, substantive values of human and civil rights have to be enforced internationally and locally. The analysis of these dimensions has to be left to future studies.

3.2 International Actors' Democratic Legitimacy

Who are the democratically legitimate representatives at the international level? This question cannot be easily answered in the light of undemocratic states and unaccountable NSAs. Here, participation refers to both states and NSAs. At the international level, actors usually do not pursue their personal goals but represent a greater constituency of individuals. Therefore, democratic participation usually means *representative* democratic participation.

3.2.1 States as Major Holders and Responsible Actors of Democratic Legitimacy

States continue to be an important channel of representation given the currently lacking prospects for international direct democratic mechanisms and democratically elected international bodies. In democracies, elected governments and parliaments aggregate the 'national' interests that should be advanced in international negotiations. In general, only states can authoritatively implement international rules into the domestic system. But states can no longer govern their citizens as they wish and have to fulfill certain internal requirements. The weakening of state's right to territorial supremacy and non-interference is illustrated by the treatment of aliens, asylum and extradition law, and the responsibility to protect (Joyner 2005: 62; Shaw 2008: 47). Hence, states do not only hold the right to be legitimate representatives of their peoples. They also possess a duty to fulfill this task to the best of their capabilities (Pinto 1996b: 255).

In an international democratic framework, states cannot be equated with individuals in accordance with a domestic analogy. Whereas individuals are considered to be equal in democracies, states display different regime types, varying population sizes, and heterogeneous interests within one polity.⁷⁰ By bringing democracy to the international level, one can consider international legalization's horizontal effect on the democratic quality of cooperation among state representatives and vertical effect on the democratic quality of the relationship between states and their citizens (Wheatley 2010: 22-23). Regarding the latter, the question has to be raised to what extent domestic feedback mechanisms are affected by international legalization that, in turn, improve or impair institutions' democratic quality. Even if the domestic level cannot be completely shielded since the ultimate point of reference in the democratic framework is the individual, I focus on the horizontal dimension because international legalization's effect on international democratic quality has mostly been neglected so far. For this horizontal-international perspective, it is not differentiated between political systems like democracies versus non-democracies. Proposals that democratic states should have a greater say in formulating, interpreting and enforcing IL (Buchanan 2006: 315) suffer from important fallacies.

⁷⁰ The discussion of democracy between states came up with decolonization in the 1960s. For the newly independent countries the fulfillment of sovereignty and equality of states were not sufficient. Instead, they called for distributive justice after years of being exploited by Western countries (Pinto 1996b: 252-254).

Although democracies are in general more responsive than non-democracies, it cannot be taken for granted that democratic state representatives are always more successful in accomplishing their citizens' goals than their non-democratic counterparts. As it cannot be assumed that state representatives of autocracies never pursue the interests of their population, not all of democracies' state representatives always follow the will of their citizenry. Not only is it frequently complex for politicians to determine *the* people's will against the background of diverse national groups, but also require international negotiations occasionally to compromise certain national interests in order to close a deal. Also vertical accountability is restricted. Vertical accountability between state representatives and their constituency has traditionally been established by national elections. This is not completely unfeasible, however, more complicated at the international level. Elections have their limits since governments are usually not only re-elected or deselected for their foreign policy (Krisch 2010: 271). This is also impeded by the fact that voting records in international institutions are frequently not published so that citizens do not know for certain what agenda their government pursued (Ebrahim/Herz 2007: 15).

Moreover, who should have the authority to draw the line between democratic and non-democratic states? All states portray and defend themselves as democratic nowadays while there is no commonly accepted index to measure democracy (Coppedge et al. 2008). Even if states' democratic quality could be somehow objectively assessed, it is questionable that most democracies would meet all high democratic standards (Keohane et al. 2009: 5). In addition to that, depriving autocracies of their full participatory rights would most profoundly hit their peoples who eventually would lose all channels to be represented internationally. One cannot rely on democratic states to represent non-democratically governed individuals because democratic representatives concentrate on their own citizenry which decides about their re-election. Granting a certain group of states the interpretative authority to demarcate democracies from non-democracies risks perilous hegemonic implications such as normative hypocrisy or social-political conflicts between the insiders and outsiders of the 'democratic club'.

3.2.2 Non-State Actors as Auxiliaries of Democratic Legitimacy in Global Governance

The Panel of Eminent Persons on United Nations-Civil Society Relations notices a change from representative to participatory democracy:

“Representative democracy, in which citizens periodically elect their representatives across the full spectrum of political issues, is now supplemented by participatory democracy, in which anyone can enter the debates that most interest them, through advocacy, protest and in other ways” (UN 2004: para. 13).

While the Union of International Associations (UIA) reported 176 internationally active NSAs in 1909, the number rose to 5936 by 2002 (Martens 2003: 4). In this study, NSAs refer to organizations since individual participation in the form of direct democracy is hardly conceivable at the international level (Breitmeier 2008: 37). Generally, the group of

NSAs is divided into international intergovernmental organizations (IGOs) and NGOs. NGOs encompass both “formal (professionalized) independent societal organizations whose primary aim is to promote common goals“ (Martens 2002: 282) and business associations that promote economic goals. The terms IGOs and IOs are used interchangeably here. In accordance with the Correlates of War criteria, IOs consist of at least three member states and offer full membership predominantly to states.⁷¹

In order to do justice to the heterogeneity of IOs and NGOs, I differentiate them regarding their membership scope/geographical origin and nature. The criteria are specified in subsection 3.3.2.1.

NGOs are attributed with several democracy-enhancing functions. Besides the democratic potential of NGO participation, also its risks have to be taken into consideration. First, NGOs can play a significant role in giving marginalized actors a voice. These can be minorities or individuals from non-democratically organized societies. NGOs can also speak up for the interests of future generations in politics that is usually determined by short- and medium-term objectives (Charnovitz 1997: 274). But in a world in which IL is still exclusively adopted by states, NGOs can also represent transnational perspectives in counterweight to more narrow-minded state interests. In general, NGO participation has often been considered as a transmission belt to get a better sense of the public opinion that can deviate from governments’ priorities (Steffek/Nanz 2008: 8). NSAs have assisted in opening up new areas of legalization such as environmental protection, children’s rights, ban of landmines and international criminal prosecution, and in monitoring the compliance of these rules.⁷² Steve Charnovitz summarizes the position of UN expert Antonio Donini as follows: “had NGOs never existed, international law would have a less vital role in human progress” (Charnovitz 2006: 348). On the other hand, NGOs are also interest groups. They have to lobby for their members who are at the same time their donors (Anderson 2000: 116-118). The assumption that NGOs function as “conscience of the world” (Willetts 1996: 11) and always further the public good⁷³ is therefore deceptive, especially given that *the* good is most of the times far from being obvious. In global perspective, Northern NGOs are generally better equipped to campaign for their objectives because they are better financed and organized (van den Bossche 2008: 721). However, also Western-based NGOs can be committed to the interests and needs of developing countries (Commission on Intellectual Property Rights 2002: 165).

Second, NGOs can provide expertise. This, for example, can take place in form of gathering relevant information, conducting studies or organizing events. NGOs typically

⁷¹ In my empirical research, the NSA classification offered by the international institutions’ lists of participants is double-checked via Correlates of War and UIA. A small number of institutions that are listed in neither of the two databases but fulfill the threshold criteria, are classified as IOs. This includes, for example, the Carpathian Convention and the Permanent Interstates Committee for Drought Control in the Sahel.

⁷² Armstrong et al. 2007: 26; Arts 2006: 7; Charnovitz 2006: 348; Charnovitz 1997: 284; Martin-Chenut 2008: 37.

⁷³ See for example: Charnovitz 1997; Raustiala 1997a: 567; Yamin 2001: 154.

focus on specific issues on which they hold profound and often first-hand information.⁷⁴ In extreme cases, even a “resource dependency” from NGOs can develop. An example is the International Union for Conservation of Nature’s (IUCN’s) rich expertise on nature conservation that exceeds those of individual countries (Arts 2006: 8). As heterogeneous as NGOs are, as diverse are the information and perspectives they can provide. This comprehensive view and in-depth knowledge improves the quality of decisions. NGOs’ expertise is not only relevant for a general audience but can specifically help to enhance developing countries’ capacity. They, for example, brief delegations before and during meetings and inform them about their options. In some cases, NGOs also assist in the drafting of proposals. After the adoption of policies, they can provide technical assistance during the implementation process. Although NGOs’ input in negotiations can be very valuable, their participation can also be a further impediment to reach a deal if they add further opinions to an already complex constellation of positions.

Third, NGOs can increase transparency and accountability. Especially in the international realm in which international instruments often lack strong monitoring mechanisms, NGOs’ watchdog function is of special importance (van den Bossche 2008: 720). For instance, the WHO’s revised 2005 International Health Regulations stipulates that in the course of disease surveillance also reports from NSAs are considered (Lee 2010: 12). Monitoring can take place directly and indirectly by educating the public who then has a closer look at the action of international institutions and states. Under some circumstances, NGOs can bring cases directly to court (Dunoff 1998: 453-454; Yamin 2001: 159-160). A recent study by Jonas Tallberg and his colleagues found statistical evidence that NGO access to IOs is, among others, driven by IOs’ functional demand for NGO resources including their expertise and assistance in implementation and monitoring (Tallberg et al. 2014: 762). Nevertheless, it should not be neglected that also NGOs can have internal legitimacy problems.⁷⁵

Fourth, NGOs can contribute to the politicization of societal groups.⁷⁶ Besides serving as an upward channel of bundling and communicating citizens’ concerns, NGOs can educate the public about current political developments and policy options in international politics (Breitmeier 2008: 53; Nanz/Steffek 2005: 369). NGOs do not have to respect the diplomatic tone in the same way as politicians and civil servants have to. They can articulate their views and disseminate information in a more direct way that might be more appealing to the public. NGOs can raise awareness in the general public, for example

⁷⁴ Corell/Betsill 2008: 23; Oberthür et al. 2002: 3-4; Yamin 2001: 153.

⁷⁵ Jens Steffek and his colleagues suggested five criteria to measure NGOs’ internal democratic legitimacy: (1) participation, (2) inclusion, (3) transparency, (4) independence from state and market, and all four of them ultimately preconditioning the ultimate goal of (5) responsiveness (Steffek et al. 2010). This evaluation could not be accomplished in this project but is worth noting for future projects.

⁷⁶ Michael Zürn and his colleagues define politicization of international institutions as “growing public awareness of international institutions and increased public mobilization of competing political preferences regarding institutions’ policies or procedures” (Zürn et al. 2012: 71).

through information campaigns and media coverage, and also among politicians by pointing to certain problems that demand political action.⁷⁷

IOs can fulfill quite similar functions. In addition to the ones mentioned above, the participation of IOs in another international institution is especially warranted if both work on overlapping topics.

All of these functions can enhance an international institution's democratic quality. In order to fulfill these functions, it is considered to be democratically desirable that NSAs are formally granted access to international institutions. Although NSAs can supplement many state functions, they cannot completely replace them. There are also democratic risks if NGOs are included in international negotiations. Nevertheless, NGOs' potentially democracy-enhancing effects outweigh their possible democracy-impeding ones.

To sum up, the participation of both states and NSAs is democratically relevant. Considering mostly NSAs in the evaluation of international institutions' democratic quality has become widespread⁷⁸ but neglects the continuing, even if changed, importance of states. The group of affected actors who can be represented by either states or NSAs has to be identified in accordance with the issue at hand (see chapter 6).

3.3 International Democratic Participation

This project's primary aim is to explore the effect of international legalization on *international* democratic participation. More specifically, I concentrate on the democratic quality of international institutions, not the democratization of the entire international system. I stick to a normative conception of democratic legitimacy and neglect the sociological perspective of perceived democratic legitimacy. The former focuses on certain standards that an institution has to meet in order to be considered democratic while the latter centers on the subjective perception of the legitimate right to rule (Buchanan/Keohane 2006: 405).⁷⁹

Participation encompasses who (*access*) can on what terms (*involvement*) influence the international policy process. Access consists of both membership/accreditation and representation at meetings. Participation is democratic if the criteria of *congruence* and *contestation* are met.⁸⁰ First, congruence is the precondition to guarantee self-determination as one of the, if not the most vital democratic value. For self-determination to be met, it is crucial that there exists either a congruence between the authors and affected subjects of

⁷⁷ Oberthür et al. 2002: 3-4; Steffek/Hahn 2010: 5; Yamin 2001: 153.

⁷⁸ Breitmeier 2008; Steffek et al. 2008; Zweifel 2006.

⁷⁹ Although my concept of democratic quality is based on a normative understanding of legitimacy, the results of the analysis can have democratic implications in the sociological sense.

⁸⁰ These dimensions are semantically very similar to Robert A. Dahl's two dimensions of democratization that are 'inclusiveness' and 'contestation' (Dahl 1971: 6-7). Although they allude to comparable democratic values, their components exhibit great differences. The main reason stems from the fact that Dahl's indicators mostly refer to national democracies which cannot easily be transferred to international institutions such as the 'freedom to form and join organizations' and 'eligibility for public office' (Dahl 1971: 3).

international regulation or that those affected by rules are at least well represented in the decision-making process (Zürn 2000: 188).

Second, a democratic framework has to allow for contestation. This is a balanced and fair exchange of arguments that also allows for critical voices in a debate. Equality of means of engagement and decision-making power serve as preconditions for contestation. They ensure that participants have the same opportunities to bring forward their interests and arguments. Congruence indicates the scope of participants while contestation refers to the depth of their participation.

Both democratic access and involvement are not equally important for all international decisions. Democratic participation is particularly relevant in cases of politicized deliberation when highly politically sensitive issues – for example with distributive consequences or landmark decisions on political values – are at stake:

“Democracy is desirable where there is politics, but not all decisions are equally political and thus not equally deserving of the time- and attention-consuming mechanisms of democracy” (Warren 2002: 688).

Hence, democratic participation is vital when issues are contested, include diverse stakeholders and cultural diversity, and most importantly touch on actors’ distribution of power and other resources. By contrast, rather technical subject matters are of lower democratic necessity.

The empirical analysis of democratic participation focuses on decision-making as the heart of the policy process. There, participation’s democratic quality is essential because it lays the foundations for an institution’s work. Undemocratically negotiated decisions can hardly be ironed out in the later stages of implementation and adjudication. If a rule is adopted in accordance with an institution’s formal requirements – be they democratic or undemocratic, marginalized members have hardly a formal standing to either impede the rule’s enforcement or to successfully file a complaint against it.

It is also distinguished if the elements are fulfilled *de jure* and *de facto*. This differentiation is crucial since *de jure* treaty provisions can only unfold their value if they are *de facto* granted (Raustiala 1997b: 733). For each dimension, it is explored if in the case of democratic deficiencies the rules laid down in the accord are violated or if rules explicitly allow for the deviation from democratic principles. The *de facto* dimension can also reveal that institutional practices go beyond the democratic potential as provided by the formal provisions.

In the context of international institutions, participation in several fora can be relevant. This includes, depending on the institution, the representative body, intermediary bodies, and working groups. Due to the focus on participation in decision-making, I put particular emphasis on participation’s democratic quality in plenary sessions since only these bodies are usually vested with the formal powers to make authoritative decisions. Symbolic rhetoric in these fora cannot be ruled out but is not necessarily void of democratic relevance. The aggregated arguments serve, for instance, as politicians’ message to citizens.

Overall, my conceptualization of democratic participation is rather minimalist and realistic. It is comparatively thin because it makes no reference to a demos, common identity, culture, and human rights as preconditions for democratic participation. The concept, as used here, also avoids utopian requirements which cannot be institutionalized by taking account of the constraints at the international level. There, for example, the number and diversity of engaged actors is multiplied so that not all affected actors can be heard before an international decision is reached. Democracy is only meaningful if its values can be practiced and does not just amount to shared beliefs which are detached from real-world circumstances.

In the following, an overview of democratic participation's dimensions is provided. While the horizontal axis represents the democratic standards congruence and contestation, the dimensions on the vertical axis clarify who (access) can how (involvement) influence decision-making.

Table 3: Dimensions of Democratic Participation in International Decision-Making

		Congruence all-encompassing vs. restricted		Contestation balanced vs. biased	
		state	NSA	state	NSA
Access	de jure				
	de facto				
Involvement	de jure				
	de facto				

The elements are not weighted in numerical terms and aggregated to be located on a low-high continuum of democratic participation. Instead each dimension is treated separately. An index would create the false impression that a high score on one dimension could compensate for a low one on another dimension. It has become a trend in social sciences to quantify results in the hope that numbers would make evidence more scientific. This may work for some research objects, but it is problematic for normatively rich concepts like democracy (George/Bennett 2005: 19; Nanz/Steffek 2005: 373). For each dimension, it is differentiated between democratic, partly democratic and undemocratic results. The scale is adjusted to empirical realities so that in principle the value of 'democratic' can in fact be scored.

Two qualifications of my measurement have to be noted at the outset. First, there is a trade-off between scope and depth in every empirical analysis. I opt for scope at the expense of depth in some areas. For instance, I focus on statements' content and neglect the chain of arguments on which they are based. This is attempted to be grasped more comprehensively by deliberative approaches. These, however, do not differentiate between the different groups of affected actors who I consider to be a crucial element of democratic participation. Second, I consciously abstain from stating specific numerical thresholds that draw the line between democratic and non-democratic participation because the results

have to be treated context-sensitively. Special circumstances might democratically justify results that violate an a priori established borderline. In the end, also numbers are chosen within some range of arbitrariness despite deceptively conveying scientific precision.

In the following sections, I elaborate on the criteria to evaluate international democratic participation. With the application of democratic participation to the international level, this endeavor enters mostly uncharted territory because empirical studies on democracy have almost exclusively remained within the domestic context (Abromeit/Stoiber 2007; Lijphart 1999).

3.3.1 Congruence

The importance of congruence in democratic decision-making is affirmed by the General Assembly's resolution 68/175, which was already cited at the chapter's beginning. It declares that a democratic international order requires the "right of all peoples to self-determination" and the "right to equitable participation of all, without any discrimination, in domestic and global decision-making" (UN 2013: para. 5(a, h)). The standard of congruence runs like a scarlet thread through generations of democratic theorists. Already Immanuel Kant endorsed that men have the right to obey only those laws to which they themselves consented to (Tesón 1992: 61-62).⁸¹ In this context, democracy was defined as an "ideal of self-government" (King 2003: 25; Nanz/Steffek 2005: 369). Instead of congruence, other scholars used similar terms like "fair representation" (Albin 2008: 764), "collective self-rule" (Warren 2002: 678), "equal participation" (Kuyper 2014: 625), "inclusion" (Steffek/Nanz 2008: 12), "inclusiveness" (Dahl 1971) or only "representation" (Drahos 2002: 163) to denote a similar normative concept as part of democratic participation.

3.3.1.1 Access and Congruence

Access is an indicator of representation. Parties who can be and are present at international meetings have the greatest chances to influence their course and eventually their outcome. The congruence of access follows the four main principles of (1) affectedness, (2) voluntariness, (3) equal terms and conditions, and (4) veto possibilities within the limits of proportionality.

First, affectedness is the most essential and therefore a necessary condition of congruence. It is always a matter of degree. Obviously affected are actors whose life is significantly influenced by a political decision. The effect can be both positive and negative and can concern an array of fields like the economy, health, environment, family, and finances. The scope of affected actors can only be determined with regard to a specific issue. The dominant names in the debate are not always the most affected ones. Neither does affectedness respect territorial borders (Fraser 2008). In order to define and delimit

⁸¹ See for similar positions: de Búrca 2008: 249; Habermas 1992; Held 2009: 537; Held 1995a: 155; Görg/Hirsch 1998: 598; Keohane et al. 2009: 6; Scholte 2014: 3; Steffek/Nanz 2008: 12.

the group of affected actors, I focus on the *mostly* affected actors with regard to states.⁸² The mostly affected actors in the relevant fields of this project are presented in chapter 6. Affected actors usually have different financial, human and administrative resources at hand. Therefore, congruence can be spurred by providing assistance to disadvantaged actors. This can, for instance, be funding to attend meetings and administrative-technical assistance to participate meaningfully.

Second, it must be the free will of an actor to become party to an international institution in the absence of coercion. The problem of in-voluntary access is that states can be extorted into affectedness with negative consequences for their citizens. This occurs, for instance, if a state is forced into an institution that requires a substantial legislative and institutional adaption of its national system. The state that is thereon affected by the institution's rules can be represented at the institution according to the principle of congruence, but the affectedness could have been avoided.

Third, members must be treated equally and accepted upon equal terms. This does not exclude the possibility that some members must undertake greater policy changes than others. If candidates have to implement an agreement before they can become parties, policy action of different extent can be required because all states start from a different status quo. Nevertheless, they all have to meet the same criteria. Unequal entry costs can impede contestation later on due to path dependencies that have been created by the terms of access.

Fourth, barring actors from entering an institution is only democratically justifiable within reasonable limits. Reasonable demands include the adoption of agreements to which also existing members have committed themselves or the adherence to the rules of procedure (RoP) as long as they are not discriminatory. Actors should not be denied access only on the basis that a small group of members vetoed against it or that candidates do not echo the institution's dominant discourse on a certain policy. An exception for the latter is the recognition of fundamental democratic values like human rights that have to be respected by all states at all times. Good causes to exclude mostly affected actors from relevant international institutions are hardly imaginable. I start with the discussion of state access and then proceed to NSAs.

⁸² The evaluation of affectedness with regard to NSAs is more complicated as I explain below.

State Access and Congruence

In accordance with the four standards of congruence, an international institution is considered to have democratic state access if

- (1) full-fledged membership and access to the institution's bodies is de jure open to all affected states,
- (2) mostly affected states are de facto well represented at plenary sessions,
- (3) membership and representation take place on a voluntary basis,
- (4) the requirements of membership and representation are equal for all state members, and
- (5) membership and representation are only restricted under well-justified circumstances and cannot be hindered by a small number of veto players.

If some of these elements are not fulfilled, congruence is violated and can therefore be no longer regarded as democratic. The value of partly democratic only exists if one sub-dimension is evaluated by more than one indicator with different results.

First, state access is above all based on a state's full membership to an institution. Full membership is generally the admission ticket to an institution's plenary body and sub-organs. The exclusion of states from international institutions requires thorough justification given the fact that states remain the major representatives of peoples. Due to the interdependence and mostly transboundary nature of international problems, there are hardly any issues that do not affect all states. Although not all of them are significantly affected actors in the strict sense, they should be at least provided with the opportunity to comment. Therefore, the principle of congruence usually demands universal state membership and full access to bodies of an international institution.⁸³ In this line, the Declaration on Universal Participation, which was adopted together with the VCLT, emphasizes that

“multilateral treaties which deal with the codification and progressive development of international law, or the object and purpose of which are of interest to the international community as a whole, should be open to universal participation” (United Nations 1969).

A key organ that operates on a rotating principle can still be considered democratic if its governing members change sufficiently frequently, all state members get their turn, observer states have the possibility to express their view and get involved if necessary, and decisions are eventually decided or confirmed by a plenary body. For the evaluation of state membership's de jure congruence, I consult the institutions' formal accession rules.

Second, affected actors do not only require de jure membership and access rights but also have to be de facto well represented at plenary sessions. De facto access is explored on the basis of states' actual admission and representation at plenary sessions. De facto membership is analysed in terms of the actual membership scope in the institutions. In

⁸³ An exception to universal membership can be regional institutions as long as their regulations only affect their members.

order to measure if mostly affected states are well represented at meetings, I observe if they exhibit higher attendance rates and participate with greater delegation sizes than an average delegation. Although it is not assumed that delegation size directly transforms into negotiating power, delegation size gives an indication of state's capacity to participate in an institution's procedures (Horn et al. 1999: 15; Strasser/Redl 2010: 82). A greater manpower in negotiations has several advantages. It enables the attendance of parallel meetings and the consultation with more stakeholders on location in order to forge a compromise or (re)direct the debate in a beneficial direction. By the same token, a larger number of staff usually means more and differently specialized experts. They can gather more information and react faster to the course of deliberations by for example drafting new proposals or influencing the public opinion. Eventually, large delegations have used their dominance to endure longer in extensive negotiations that can last until the wee hours of the morning (Strasser/Redl 2010: 85). All in all, states would abstain from sending large delegations to meetings that were of no interest to them. In terms of measurement, there does not need to be a linear correlation between affectedness and attendance rate or delegation size for participation to be democratic. This is also hardly practical as many international institutions address a broad array of topics with changing groups of affected actors.

Third, the principle of voluntariness includes that the non-attendance of mostly affected actors does not violate the principle of democratic participation if these consciously choose to be absent. The fourth criterion is rather self-explaining. Access criteria must be equal for all states.

Fifth, membership and representation should not be able to be impeded for undemocratic reasons and by disproportional means. Approval of new members by plenary bodies is handled disproportionally if a minority can block the admission of a new candidate, for example, due to the requirement of consensus. This is especially problematic if veto players can misuse their position to exclude possible opponents in further negotiations.

For the empirical analysis, most attention is paid to affectedness as foundation of congruence. The other criteria are only explicitly discussed if they are not met.

NSA Access and Congruence

Similar to states, NSA access meets the requirements of congruence if

- (1) accreditation and access to plenary sessions is de jure open to all affected NSAs,
- (2) affected NSAs are de facto well represented at plenary sessions,
- (3) membership and representation take place on a voluntary basis,
- (4) the requirements of membership and representation are equal for all NSAs, and
- (5) membership and representation are only restricted under well-justified circumstances and cannot be hindered by a small number of veto players.

NSAs access is democratic if all of these indicators are fulfilled. It is undemocratic if one or more of these criteria are not met.

First, most international institutions grant formal access to NSAs but vary greatly in terms of accreditation status and participatory rights. The UN system of NGO accreditation has served as prominent point of reference. The UN Economic and Social Council (ECOSOC) differentiates between three NGO statuses depending on their reach, expertise, and scope of activity: (1) general consultative status, (2) special consultative status, and (3) roster status. Roster status applies to NGOs with a “a rather narrow and/or technical focus” that are occasionally consulted (ECOSOC 2009b).⁸⁴ An official relationship with an international institution is typically the precondition for a NSA to access meetings. In the absence of accreditation procedures, some international institutions allow for NSA access on an ad hoc basis.

Neglected in this study is NSA representation beyond formal direct participation. Besides accreditation, NSA representatives can be members of national delegations. This comes at the price of losing autonomy as NSA representatives usually have to commit themselves to certain guidelines.⁸⁵ Also public campaigns and protests outside the negotiating arena can give NSAs a voice (Oberthür 2002: 4). But this does not represent access in the strict sense and is therefore excluded. Formal participation has several advantages over informal venues. It improves access to information and facilitates the establishment of personal contacts with states representatives by meeting with them in the corridors or coffee breaks. Being an insider can strengthen NSAs’ expert status and give them an edge in influencing the public opinion (Oberthür et al. 2002: 67).

The definition of affectedness is even more intricate for NSAs than states. They are not the main legitimate representatives of citizens and most of them act transnationally. Depending on the issue and its stakes at hand, different NSAs need to be granted access to international institutions in order to ensure congruence. If a certain subject matter touches on the immediate rights or lives of a NSA’s members, the NSA has to be included in the negotiations. In some instances this can be clear-cut. In debates on TK, indigenous groups are obviously significantly affected and therefore should be present. If children’s rights are discussed, the UN Children’s Fund (UNICEF) as a specialized agency should be invited as participant in particular since children cannot represent themselves at international meetings. In other areas, the demarcation between affected and non-affected NSAs is more demanding. For example, myriad of NGOs are active in the field of environment. As no one can credibly possess the authority to make a decision on which of them should be granted access, one can only assess if a critical number of them can participate.

Moreover, the widespread black-and-white categorization of environmental, social welfare and human rights organizations as being inevitable ‘good’ and business actors as

⁸⁴ Out of the 3287 accredited NGOs in September 2009, over 65% possessed consultative status (ECOSOC 2009a).

⁸⁵ Åsa 2010: 124; Charnovitz 1997: 280-282; Oberthür et al. 2002: 44-45.

being 'evil' is premature. This form of democratic hypocrisy falls short of justifying why economic players should be denied participation despite their affectedness. Although I argue that also economic actors have a democratically legitimate interest to be represented, this does not imply that one should not exercise caution as to the dominance of economic interests in international negotiations and their frequently better material capabilities to get their way.

The members of NGOs and in particular of IOs are too diverse to make the demarcation between affected and non-affected groups feasible. Therefore, I base the analysis on the simplified assumption that all NSAs have a general right to be represented due to their potentially democracy-enhancing functions. Against this background, the proportion of NSAs is compared to those of states in order to observe if NSAs have de facto an inclusive access to international institutions.

Second, formal NSA access provisions are only relevant if they are not de facto undermined. Therefore, it is essential to explore to what extent de jure access regulations are in fact guaranteed or subverted. De facto NSA access must not necessarily be more restrictive than the de jure provisions. It can also be handled more generously than one would suspect based on the legal provisions.

As to the third and fourth criteria, NSAs should participate on a voluntary basis and be accepted on equal terms. Fifth, it is important under which conditions NSA access can be obtained or vetoed. Accreditation can depend on NSAs' internal organizational structure, geographical reach, expertise, scope of activity or accreditation fee. It is democratically reasonable to demand that NSA observers should be qualified in the field as it is generally the case in international institutions (van den Bossche 2008: 743). Expert or inside knowledge is a precondition that NSAs represent the interests of their members and fulfill their democracy-enhancing functions. By contrast, democratically questionable are financial requirements as democratic participation is not a matter of material affluence but of legitimate rights. National NGOs should also not be required to receive the consent of their national government like in the case of the 1979 Convention on the Conservation of Migratory Species of Wild Animals (Raustiala 1997b: 723). This endangers NGOs' critical potential and can prompt particularly non-democratic states to suppress domestic opposition. States can attempt to improve equal NSA presentation by funding crucial stakeholders who are financially disadvantaged (Oberthür et al. 2002: 7).

3.3.1.2 Involvement and Congruence

Access alone cannot guarantee meaningful participation which makes it also necessary to explore the involvement rights that are granted to the various actors. Congruence with regard to involvement is fulfilled if all mostly affected actors get the chance to meaningfully participate in international deliberations. This is analyzed by examining who can speak and according to which voting rights decisions are reached. The approach used here is input-,

not output-oriented. Therefore, the fulfillment of congruence does not imply that an actor's interest is necessarily mirrored in the negotiation's outcome.

State Involvement and Congruence

Democratic involvement of states fulfills the principle of congruence if

- (1) all mostly affected states have de jure and de facto the possibility to make statements,
- (2) mostly affected states exhibit higher statement rates than non-affected states, and
- (3) voting rights are democratic.

Among all involvement possibilities, the right to speak is the most essential one. It vests the speaker with the possibility to make an argument why her interests are important and should be considered in the negotiations. Democratic participation is about the fair bargaining of divergent positions. In particular mostly affected actors must have the chance to utter and explain their position because they have the highest stakes and depending on the negotiation's outcome, have to bear the greatest share of costs. As to the de jure dimension, I analyze if formal provisions impede mostly affected states to make a proper statement, for example in terms of time limits. As to the de facto dimension, it is analyzed if (1) all of the mostly affected states make a statement and (2) mostly affected actors make more statements than non-affected ones. With regard to the first indicator, a small proportion of non-speakers of mostly affected actors might be tolerable to account for mostly affected actors who have no interest to speak or are represented by like-minded members.

Besides making statements, voting rules are essential as they can have an effect on members' influence within international institutions (Koppell 2010: 105). They have often not been put into practice, but scholars have noted a trend of shifting away from consensual toward majoritarian decision-making (Krisch 2014). But what does democratic participation among states mean both with regard to voting procedure and weight? Given the controversy and complexity surrounding this topic, a balancing act between providing indicators to empirically differentiate among voting systems' democratic quality and leaving space for context factors is pursued. Depending on the context, such as actor constellation and cleavages, different voting procedures might be required to fulfill congruence. The goal of the following discussion is the formulation of at least minimal guidelines.

As to the voting procedure, there are certain criteria that can be easier declared (non-) democratic than others. Certainly to be considered non-democratic are voting systems that include special powers – usually for wealthy Western states – or deny certain members a vote at all. Also democratically dubious is unanimous voting that opens up the possibility for the tyranny of the minority. It is even said to further opaque agreements and horse-trading on the corridors (Klabbers 2009: 206-207). The traditional explanation that obligations under IL can only be created by state unanimity in order to ensure state

sovereignty is only limited applicable today. It seems to be outdated especially since the newly independent states after World War II had to accept the already existing international legal architecture (Shaw 2008: 9).

The discussion if majoritarian or consensus voting is more democratic is more difficult to settle. Consensus voting is formally less stringent than unanimous voting and usually suggests the “lack of strong disagreement” or “an overwhelming supermajority” (Koppell 2010: 156). In practice, consensus voting could not overcome the above mentioned drawbacks of unanimous voting (Klabbers 2009: 208). But there are certain situations in which consent voting or other high barriers are warranted. This includes, for instance, the change of fundamental rules like constitutional amendments. Generally speaking, it can be justified to demand greater majorities in international than national negotiations because international decisions tend to have further-reaching implications for a wider scope of actors.

Also qualified majority voting, which requires more than a simple or absolute majority of member states or population, involves disadvantages. Although this procedure intends to overcome the veto power of a small majority while securing the approval of a considerable amount of states, it has proved to conserve the status quo and empower the bureaucracy and judiciary (Tsebelis/Yataganas 2002).

Based on these considerations, there is no ready-made democratic voting procedure for all international institutions. Instead, it has to be accommodated to the respective context. Particular attention has to be paid to the de facto decision procedure because most international institutions do not make use of their official voting rules (Lockwood Payton under review: 2).

Concerning apportionment, the principle ‘one state, one vote’ is still dominant both in practice and scholarly debate. Most fundamentally, equal voting power is usually considered to be the foundation of sovereign equality. Since voting systems in which votes are weighted differently can advantage powerful states, a deviation from this standard has been regarded as an endangerment to states’ independence (Buchanan/Keohane 2006: 413-414; Schermers/Blokker 2011: 65). But one should exercise caution. First, the equality of individuals within states should not be equated with the equality of states. Since the international arena cannot represent a simple replication of domestic systems, the justification for equality of states and individuals has to be based on different grounds. Second, it is important to distinguish between equality before the law and equality in the rule-making process.

Proportional voting systems can be based on various criteria that can be more or less democratically justified. Classified non-democratic are voting systems in which the voting weight depends on financial contributions like in the case of the International Monetary

Fund (IMF) and World Bank.⁸⁶ In the IMF, the G-7 states possess about 43% of all votes (Ebrahim/Herz 2007: 13). By contrast, proportional weighting can be democratically reasonable in accordance with the principles of congruence. Congruence can be fulfilled by considering a state's population size and affectedness. If one takes it seriously that a democratic theory should ultimately refer to the individual, states representing more individuals should have a greater say than lower populated ones. In this line, opponents have criticized the procedure of 'one state, one vote' for disadvantaging populous countries while unduly advantaging small ones (Posner 2009: 35).⁸⁷ In order not to discriminate against smaller and at the same often less powerful states, the proportions have to be moderate.

In sum, there should be a balance between equal voting of sovereign states and equal representation of individuals. If an issue affects some states considerably more than others, it follows the logic of congruence that the voices of the former obtain greater weight in the decision-making process. Negotiations on the delineation of maritime borders, for example, do not directly affect landlocked states so that the latter's voice matters less than that of maritime nations from a democratic perspective. The discussion demonstrates that certain trends of (non)democratic apportionment can be delineated, but that decisions are context-dependent.

NSA Involvement and Congruence

NSA involvement meets the democratic standard of congruence if NSAs have de jure and de facto the possibility to make statements. NSAs can only unfold their democratic potential if they are allowed to form a meaningful opposition to state interests (Görg/Hirsch 1998: 606-607). Means of involvement can range from the submission of oral or written statements to voting rights (Beierle/Cayford 2002: 5-6; Brühl 2003: 126-30). NSAs can be vested with different competences. They can advise governments. Under some rare circumstances, NSAs may even possess negotiating capacity. So far, NSAs have been denied voting rights with the exception of the International Organization for Standardization (ISO) and International Labour Organization (ILO) (Oberthür et al. 2002: 206). This is democratically justified given that NSAs' representatives are often not accountable to a broad electorate. Therefore, the main indicator of NSA involvement is the possibility to make statements in plenary sessions in this study. Since NSAs' affectedness is difficult to assess as already explained above, I compare NSAs' statement rates to those of states in order to evaluate an institution's openness toward NSA involvement.

⁸⁶ It was argued that because of states' different responsibilities in terms of financial and military contributions weighted voting procedures are justified (Zamora 1980: 592). However, this does not represent a democratic justification taking into consideration congruence and contestation.

⁸⁷ An UN study from 1971 illustrates that in theory, mini-members that account for less than 0.2 per cent of the world's population can hold more than one-third of the votes (Jean 1971). Although the voting power of micro-states in international institutions still gets on the political agenda in recurrent cycles, the debate was most hotly debated from the 1960s to the mid-1970s (Schermers/Blokker 2011: 65-66).

3.3.2 Contestation

While congruence lays the foundation for democratic participation, contestation determines how meaningfully attendees can get involved. Contestation embraces the democratic standards of (1) fairness and (2) respect for diversity.

First, contestation includes procedural fairness. All participants should be treated equally and in an unbiased manner. No actor or group should be dominated or dominate others (Drahos 2002: 164). Each member's interest should be given equal consideration (King 2003: 25). Thus, every participant should have the same opportunity to present her position in democratic deliberation in order to have a chance to influence the outcome. But procedural fairness stands in contrast to substantive fairness. The latter can be based on criteria like the equal share of benefits and costs or the unequal distribution of benefits on the basis of merit or compensation (Albin 2008: 759; Zartman et al. 1996: 82).

Second, democratic participation requires a wholehearted debate. Politicized subject matters always entail distributional consequences. If some actors win, others lose. This prompts different groups of affected actors with typically opposing, often not reconcilable policy goals. Democratic deliberation has to respect and absorb this diversity and divergence before reaching a decision. Therefore, an open exchange of arguments has to be rendered possible in which conflicts are allowed as long as minimum standards of good conduct are respected. In particular, critical voices that are opinions that seek to change existing rules or challenge the dominant belief system in an institution have to be heard. Critical voices can be raised both by states and NSAs. In this study on biotechnological patents, I divide the group of mostly affected actors in IP supporters and IP skeptics (see chapter 6).

In an ideal deliberation situation, all actors are open about their interests (Rojo et al. 2004: 619) and argue constructively (Steenbergen et al. 2003: 26). As desirable as these principles are, they cannot be presumed in real-life negotiations and therefore are not considered in the empirical analysis. In this project, contestation is limited to the debate on policies and excludes contestation over the international institutional architecture at large (for the latter see for example Stephen 2012). The analysis of contestation applies similar indicators as used for congruence but evaluates them from a different angle by differentiating between the groups of mostly affected actors. I discuss state and NSA contestation together for access and involvement.

3.3.2.1 Access and Contestation

With regard to access, contestation is fulfilled if

- (1) the access rules of mostly affected actors are de jure and de facto the same and
- (2) the attendance of the different camps of mostly affected actors in plenary sessions is de facto balanced.

Access allows for contestation if all mostly affected states have de jure and de facto the possibility to become member to an institution and attend plenary sessions irrespective of their critical potential. Mostly affected actors of different, maybe even diametrical views have to be able to participate in negotiations. The question suggests itself why critical actors want and should be allowed to be present at an institution the rules of which they might put into question. The simple answer is because they are affected. The weighting and bargaining of the different positions on a subject matter is best feasible if the affected actors can directly represent themselves. If a group of mostly affected actors is excluded from the negotiation, it increases the chances that its position is neglected. The adopted policy can still affect the group even though they are formally not bound by it. If, for instance, the WTO would decide that the use of TK is not permitted to be an obligatory requirement in patent applications without consulting with indigenous groups, the latter would nevertheless be affected by the outcome. Consequently, actors seek to access institutions that deliberate on policies that affect them. This provides them at least with the possibility to influence negotiations from within even if they risk that the outcome runs counter to their interests.

The first criterion demands that no mostly affected state and NSA should be barred from relevant debates. The non-discriminatory treatment between mostly affected groups echoes congruence's standard of equality. The focus is slightly shifted. While congruence addresses the access conditions for all mostly affected actors without differentiating between them, contestation takes a closer look if certain actors within the mostly affected groups are marginalized de jure and de facto.

Second, the representation of the various affected groups should be balanced. Concerning states, I compare the attendance rate and delegation size of IP supporters and IP skeptics. For NSAs, the distinction is less clear-cut. An IO, for instance, often cannot speak with a single voice as its members usually have different opinions on a subject. In order to still differentiate between actors within the heterogeneous groups of IOs and NSAs, I present information on their nature, IOs' scope, and NGOs' geographical origin. This information shows some indication of which goals are advanced by a NSA. This approach certainly generalizes a complex empirical constellation of actors and interests but nevertheless provides essential reference points to evaluate contestation.

IOs' nature is differentiated between (1) environmental organizations, (2) social welfare and human rights organizations, (3) indigenous peoples' organizations and local communities, (4) economic organizations (trade and finances), (5) scientific organizations, (6) organizations of comprehensive scope, (7) and other organizations. In addition to that, I identify if an IO has international or regional membership. If the latter is the case, I specify the region: (1) Africa, (2) Asia, (3) Europe, (4) Latin America, (5) Oceania, and (6) USA and Canada.

NGO's are distinguished between (1) environmental organizations, (2) social welfare and human rights organizations, (3) indigenous peoples' organizations and local communities, (4) business actors, (5) scientific organizations, (6) parliamentarian organizations, (7) local authorities, and (8) other NSAs. Furthermore, I classify NGOs with regard to their headquarters. Like in the analysis of IOs, the regions encompass (1) Africa, (2) Asia, (3) Europe, (4) Latin America, (5) Oceania, and (6) USA and Canada.

3.3.2.2 Involvement and Contestation

Democratic contestation of involvement requires that there is a balance between

- (1) the frequency of statements made by the different camps of mostly affected actors and
- (2) positions raised by the different camps of mostly affected actors.

In accordance with the standard of fairness, mostly affected groups should have equal opportunities to be heard and make their case. To this end, I compare the frequency of statements between mostly affected groups. Since it is not only important if actors speak, but also what actors can say, I code the content of statements to analyze if the representation of the various positions is balanced. I only code which standpoint is brought forward and neglect if statements are rational, well-justified or constructive for a political solution. Both states and NSAs are considered.

Like (inter)national democracy, also its components are contested. Although analytical arbitrariness should be avoided, the democratic nature of participation cannot be measured solely by a priori theoretical considerations. Ultimately, one has to keep in mind that democracy is an "interpretative and integrated ideal". Not only is disagreement about democratic values in itself an intrinsic element of democracy, but also is the value of democratic principles context-dependent (Sadurski 2006: 394). The absence of a consensus should not prevent scholars from empirically assessing institutions' democratic quality. Without empirical data on the state of democratic affairs, debates on international institutions' democratic deficits and democratization remain shallow. The aim of this chapter is not and cannot be to give a definite answer to what we should mean by democratic participation. It is both a starting point and a snap-shot.

Chapter 4

Legalization, Democracy, and Politics – A Harmonious or Tension-Ridden Relationship?

The relationship between legalization and democracy is neither self-evident nor well researched. In this section, I provide an overview of the possible areas of harmony and tension in the legalization-democracy relationship and conclude with a framework to analyze it. Important questions that are tackled include:

- What precisely in legalization's and democracy's nature is said to cause a positive or negative relationship?
- Most theoretical accounts on the legalization-democracy relationship refer to the domestic context. But how do the political and structural conditions at the international plane alter the legalization-democracy relationship?
- Given the multitude of positions on this topic, it is important to evaluate and compare their substance. How persuasive is each side?
- What framework can be used to analyze the legalization-democracy relationship?

Since a profound theory on this topic is absent, this project draws on elements of several theoretical frameworks from IR, normative theory, and international legal theory. Providing an overview of the different views on legalization's impact on international institutions' democratic quality is complex. Neither is the connection between both concepts in many instances explicitly discussed since it rather serves as an underlying and unproven ideological background. Nor do most of the theories, especially across disciplines, directly address each other. Besides a lack of systematic empirical research, conflicting prospects of international legalization's effect on international institutions' democratic quality are rooted in differences in the model of democracy and its fulfillment at the international level (see also section 3.1 above) and understanding of legalization's nature, functions, and consequences.⁸⁸

Given the broad range of issues covered by legalization and democracy, a few specifications have to be made in advance. First, the focus lies on codified public IL. Since it differs in important respects from private law, the latter entails other implications for democracy and thus deserves a separate analysis. Second, my main focus lies on the *international* or in other words horizontal dimension of democratic quality. I thus neglect international legalization's impact on the *national* democratic quality.⁸⁹ Third, the term 'democracy' is often used as an umbrella term for different democratic standards that are not analytically differentiated in the legalization-democracy debate. Therefore, I refer in the first part of the discussion to democracy in general and turn to my specific interest of democratic participation in the presentation of my theoretical framework. Fourth, the

⁸⁸ In many theories, law is not clearly separated from legalization.

⁸⁹ See Steven Wheatley for a literature review on the vertical dimension (Wheatley 2010: 23-28).

groups according to which I classify the different assumptions on the legalization-democracy relationship are neither strictly selective nor do the categories' boundaries clearly run along certain theoretical schools. Some scholars are torn while others imply implicit normative beliefs and commitments rather than clear theoretical justifications.

I argue that legalization's effect on democratic participation in international institutions has to be surveyed in a more differentiated way. This can be best conducted by an institutional approach that takes into consideration legalization's structure-inherent effects and the cost calculations of actors interacting within the institutional framework. The argument unfolds in four steps. First, the drawbacks of collapsing law into morality are illustrated on the basis of which I advocate for a thin understanding of the rule of law. Second, I provide a brief overview of theoretical assertions on the domestic legalization-democracy relationship and discuss to what extent positive national experiences can be transferred to the international arena. It is shown that the conditions under which law and democracy operate internationally are fundamentally different from the domestic context. The debate also illustrates the diametrical positions on this topic. At the one extreme are scholars who consider an intrinsic democracy-enhancing effect of legalization. At the other end, a negative impact of legalization on democracy is asserted due to law's oppressing nature or by considering law as epiphenomenon of brute power politics. A closer examination of the opposing arguments suggests that legalization's democracy-constraining effects have to be taken very seriously. In order to clarify these implications, I focus on critical theorists' approaches that emphasize legalization's power dimension in the third part. Critical theorists show that legalization is both a check and means of power. Law oscillates between being a constraint on and the product of power politics. Based on the lessons learned from the previous discussion, I then present the model of structure-inherent and actor-dependent effects. It does not only take into consideration that legalization is an instrument of power but adds which actors make use of it with what effect on democratic participation. This is understood as a theoretical-analytical framework to explore the legalization-democracy relationship rather than a full-fledged theory.

4.1 Law, Morality, and Analytical Accuracy

The relationship between law and normative standards of legitimacy – such as morality, justice, or democracy – has been conceptualized in various ways.⁹⁰ One great dividing line can be drawn between positivists who strictly separate between law and morality and a more heterogeneous group of scholars who consider moral considerations to be internal to law. Although positivism is said to be the prevailing understanding of law nowadays, normatively charged views on IL are surprisingly common in theory and political practice. As to theory, one does not need to go back to natural law to find supporters of a morally demanding legal system. In a manner of ‘that which must not, cannot be’, a just society is set as indisputable goal that all modes of regulation, including law, have to serve. The normative requirements can be either substantial (Alexy 2002) or procedural with the latter being preponderant. The examples of Jutta Brunnée/Stephen J. Toope and Bernhard Zangl are cases in point.

Brunnée and Toope offer an interactional model of IL according to which law is based on shared understandings and practice. With reference to Jon Fuller’s principle of reciprocity, Brunnée and Toope claim that law is no exercise of authority that is understood as imposed hierarchical power:

“Law is ‘authoritative’, but only when it is mutually constructed. [...] The formation of a simple contract provides a useful example. If the imbalance of power between the parties is great, if there is no real opportunity for negotiations, and if no true reciprocity is evident, then one really has not created a contract at all, but has merely acted in the form of ‘contract’” (Brunnée/Toope 2010: 24-25).

In other words, law can only be credibly called so if it results from and is applied via a meaningful interaction between law addressees and the different political branches. In the absence of broad social agreement, no legal validity exists. Formalism, understood as the reliance on IL’s traditional sources, is not adequate to differentiate law from non-law. Instead, the congruence between a norm’s substance and a shared understanding that is expressed in common practice generates fidelity to law. This fidelity legitimizes the legal system and creates a sense to obey the law. The felt obligation is crucial to determine legality and differentiate law from other social norms (Brunnée/Toope 2010: 46-47).

⁹⁰ Justice and morality are concerned with the right reasons to act in a certain way. Different schools within and across the disciplines of philosophy, political and legal theory have defined both in diverging ways and put them in different relationships to each other. More often than not, they are used interchangeably and are not clearly defined. Generally, morality rather belongs to the personal sphere and concerns normative principles and obligations between individuals. Justice, on the other hand, rather relates to the problem of fair social organization. Morality is usually inquired by ethics while justice is usually the subject of political theory and philosophy. But this distinction is not hard and fast. Often morality and justice are differentiated and immediately collapsed again. So follows Terry Nardin first the above classification and then argues that morality represents a source to establish principles of justice: “‘just’ is merely a synonym for “morally justified”” (Nardin 2010: 595). As another example, Thomas M. Franck sets out that justice is attributed to persons, not collective entities like states (Franck 1990: 208) while Hart assumes the opposite (Hart 1994: 167-168). In the discussion, I stick with the terms as used by the respective authors who more frequently refer to morality than justice.

Zangl differentiates between a simple and developed legal order. In addition to a simple legal order which only consists of primary and secondary rules as proposed by H.L.A. Hart, a developed legal order includes tertiary rules to normatively justify procedural rules and legitimize rules' validity. Operating with a Habermasian framework, rule-setting in a developed legal order ensures congruence between the authors and affected subjects of international regulation. This form of self-determination should be achieved within a discourse of equal participants that is free of force (Zangl 2006: 32-40). Only if deliberative participation among all addressees of law is fulfilled, legalization is considered to be high (Zangl/Zürn 2004: 35).⁹¹

Both theories consider a legal system only as fully developed if it guarantees participants at least a minimum of fair social interaction on par with each other. They vest legalization with an inherent inclusive and equalizing force that subsumes to a democratizing effect. Other scholars consider democratic legitimacy as an essential and at the same time undeniable feature of IL even if the international legal system or international institutions currently exhibit certain democratic deficiencies.⁹² An effective international legal system enables and promotes welfare-enhancing cooperation, contributes to checks and balances, enhances freedom of individual actors, and balances out power asymmetries: "Under the principle of legality, less powerful states tend to be more effectively protected against impositions by powerful states" (Kumm 2004: 918-919). IL is said to "serve the common interest" and to be an "action which is subject to moral duty and which gives rise to moral responsibility" (Allott 1999: 31, 34). Christian Tomuschat summarizes this perspective:

IL "is not an objective in and for itself and that, instead, it has a general function to fulfill, namely to safeguard international peace, security and justice in relations between States, and human rights [...] International law has a mandate at the service of humankind in general" (Tomuschat 1999: 23-24).

And even more pointed, Martti Koskenniemi entitles his book on the history of IL "The Gentle Civilizer of Nations" (Koskenniemi 2005a) and elaborates on "[l]aw's civilizing mission" (Koskenniemi 2011: 324).

But also policies often praise legalization as a panacea for goals of various kinds. The General Assembly proclaimed the period between 1990 and 2010 as the "United Nations Decade of International Law" (UN 1989). In the context of a conference that was organized within this program, the Under-Secretary-General for Legal Affairs Hans Corell argued that "the effective application of the rules and principles of international law is the surest way toward peace and harmony among nations" (Corell 1996: 3). The General Assembly considers the rule of law of "fundamental importance" to achieve international peace and security, human rights, and development. The "rule of law and democracy" is

⁹¹ In a more recent article, by contrast, Zangl clearly differentiates between democracy and the rule of law at the international level (Kreuder-Sonnen/Zangl 2014).

⁹² Steven Wheatley argues that the "idea of a democratic rule of international law is inherent in the idea of global governance through *law*" (Wheatley 2011: 548). Vice versa, Loren A. King considers "binding collective decisions" to be an integral part of democracy (King 2003: 25).

even described to be “interlinked and mutually reinforcing” in Resolution 67/1 (UN 2012). Resolution 68/175 declares that democracy requires the „universal adherence to and implementation of the rule of law at both the national and international levels“(UN 2013: para. 4). The rule of law rhetoric also has frequently been invoked by Western countries to illustrate their moral and economic superiority over other countries. The USA, for instance, employed their self-image of a law-abiding nation to distinguish itself from the communist bloc during the Cold War (Ohnesorge 2007: 102). The American Bar Association generally claims that the “rule of law promotion is the most effective long-term antidote to the most pressing problems facing the world community today, including poverty, economic stagnation, and conflict”.⁹³ The former WTO Director-General Mike Moore requests that “[o]ur dream must be a world managed by persuasion, the rule of law, the settlement of differences peacefully by the law and in co-operation” (WTO 1999c: 5). Last but not least, it is worth mentioning that most democracy indices – such as the Bertelsmann Transformation Index, Freedom House, and the Democracy Barometer – subsume the rule of law under democratic quality.

In all of these examples, the distinction between ‘is’ and ‘ought’ is blurred. Thick models of the rule of law have three severe shortcomings. First, the theories, as developed by Brunnée/Toope and Zangl, struggle to tie up with legal practice. It is debatable if a broad and shared understanding of IL has always existed. Consent is required but not in a way that Brunnée and Toope envisage it. It does not need to be unanimous as most international institutions formally require only majority voting for most decisions (Lockwood Payton/Blake 2014: 11-12). Also IL’s validity is formally not bound to compliance. The divergence of a state’s formal approval of a legal provision from its subsequent practice does not impair the provision’s legal quality. By the same token, the three authors disregard that unequal power positions in negotiations are the general rule rather than the exception. IL is rarely concluded among equals in the democratic sense that each party has in fact the same chances to advance one’s interest. Consequently, the outcome always advantages some actors while others are sidelined. International relations provide ample evidence that law does not need to be moral and law is not in any case the most suitable means to enforce moral values.

Second, a conceptualization of law and morality as inherently connected principles is not only empirically questionable, but it can also create a dangerous hope as to the strength of morals’ normative force. As Hart admits, law and morals share certain resemblances like are a similar vocabulary of a rights-and-duties language, some substantial overlaps, and the demand for adherence. Nevertheless, there are important differences. Treaty law can be altered faster than moral norms according to predefined secondary rules, and usually not by

⁹³ Available at:

<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CDEQFjAB&url=http%3A%2F%2Fwww.ibanet.org%2FDocument%2FDefault.aspx%3FDocumentUId%3Df1b855c4-9a45-47df-8a1b-8058dedf06e6&ei=KXKKUZ6zBOiQ4gSU3YGIBA&usg=AFQjCNGRZPyjgkhJ9e79iGi27Ze79i-BqA&bvm=bv.46226182,d.bGE> (Accessed 3 June 2013).

a shared understanding or practice. Compliance is evaluated according to externally observable behavior while, unlike in the case of morals, subjective will is disregarded. And most crucially, law can be backed up by a state-run institutionalized enforcement mechanism in contrast to social and more informal pressure that morals employ (Hart 1994: 175-180). Although non-legal norms do not necessarily have to be less effective (Skjærseth 2010; Young 1998: 12), actors cannot rely on the state to implement these norms nor do they have a legal standing to enforce them in court. The ICJ argued in the South-West Africa case with regard to humanitarian interventions:

“It is a court of law, and can take account of moral principles only in so far that as these are given a sufficient expression in legal form. Law exists, it is said, to serve a social need; but precisely for that reason it can do so only through and within the limits of its own discipline” (ICJ 1966: para. 49).

These considerations do not deny that there is overlap between law and justice/morality (Hart 1994: 206-207). There is a core of just and moral norms that law has to respect in order to be legitimate in the broadest sense. This includes procedural standards of fairness like impartiality, equality, and generality as well as substantial requirements like the protection of human rights. However, law that is perceived as unjust by certain groups or individuals is still valid law if it was concluded by authoritative bodies.

Third, a thick understanding of the rule of law impedes the differentiation between legalization and its effects. They erroneously couple legalization with a desired normative order that the former should bring about (Skaaning 2010: 451). As Hedley Bull writes in a review on Robert Falk’s work:

“The blurring of the distinction between “is” and “ought” imposes a grave obstacle both to the work of identifying what rules are law, and to the work of establishing what rules are good rules” (Bull 1972: 585).

A thick understanding of the rule of law turns a blind eye to the possibility that IL might – even with some adjustments and reforms – not be capable of delivering the envisaged normative goals. Most of the time, assumptions on the legalization-democracy relationship are not openly presented but constitute underlying beliefs or theoretical presumptions with far-reaching consequences for the studies’ models. However, assuming such effects from legalization a priori can obscure legalization’s drawbacks. Therefore, legalization’s de facto consequences for democracy need to be strictly analytically distinguished from normative visions of how they should play out. This is especially important in an empirical-normative project like mine. For these reasons, I use a minimalist and positivist conception of legalization so that “it follows that conformity to moral values or ideals is in no way a condition for anything being a law or legally binding” (Raz 1979: 38). A formal-procedural model also assists in distilling legalization’s most essential attributes. Excluding irrelevant features represents an important step toward parsimony and theory-building.

4.2 The National Experience and its Transferability to the International Plane

Normative approaches to law have been most comprehensively developed for domestic legal systems. Many authors have been convinced that law has already proven its democratizing value within the state – at least within Western Europe. Achim Hurrelmann and his colleagues embrace a four-staged model of Western modern state development that has been echoed in similar versions in other projects. In a first phase, territorial states with internal sovereignty were established in the 16th and 17th centuries. They attained the monopoly of force and other key resources like a functioning bureaucracy and the capability to impose taxes. In a subsequent step, the political struggles of the 17th and 18th centuries led to the constitutional state. State authority was subjected to the rule of law to guarantee individuals liberty and legal certainty. On this basis, a democratization of the state followed in the 19th and 20th centuries. The legal-administrative entity became a political one. Citizens demanded individual self-determination and on this account also effective participation. These newly introduced standards of legitimacy were accompanied by a nation-building process that formed a *demos* with a collective identity and governed by representative democracy. The project of the modern nation-state was eventually completed with a growth of state interventions to secure economic welfare. This last stage started in the late 19th century and reached its heyday in the 1960s/70s (Hurrelmann et al. 2007b: 3-6). In this narrative, democracy requires legal safeguard to constrain political power.

The backbone of this model is what Judith Shklar coins as legalism.⁹⁴ This term denotes a belief that law is a mode of social action that is superior to morals and politics. According to this Western idea of law, legal rules are first of all impartial and not susceptible to political and moral pressures. Law is accepted as something naturally given that is disconnected from its social and political context and is not seen as the result of political struggles. The technique of legal reasoning exercised by trained professionals and an independent judiciary guarantees an unbiased application of rules. Legal rules are clear and predictable which creates certainty as to what constitutes legitimate behavior.⁹⁵ This stability stands in contrast to the uncertain and changing rules of tyrannies. Justice is created by equally subjecting individuals to legal rules. These attributes make legal systems capable of regulating and solving complex social issues in an ostensibly fair and harmonious manner (Sinclair 2011: 1096-1098, 1107). This popular perception of law is also said to be widespread among IR scholars who tend to have a simplified understanding

⁹⁴ 'Legalism' is usually not a self-chosen name but is used by various scholars to criticize a certain view on law. Examples encompass Judith Shklar (Shklar 1986) and Eric Posner (Posner 2009). It is similar to what I call the contra-politics approach in chapter 2.

⁹⁵ Similarly but without the moral underpinning, system theorists, like Niklas Luhmann and Gunther Teubner, consider one essential function of law to stabilize expectations and reduce complexity. In contrast to legalism, they define law as a self-referential system of communication that is normatively closed.

of law because they are less concerned with law's nature and logic but more interested in the compliance with law (Onuma 2003: 112; Sinclair 2011: 1095-1096).

Even if most scholars agree that law is not inevitably democratic,⁹⁶ many consider the rule of law as necessary precondition to build up a national democracy. Petra Dobner concludes that the democratic state

“depends on the constitution, for there has thus far been no other means of regulating in a binding manner both the democratic practices and the legitimation of rule in secular societies” (Dobner 2010: 143).

Similarly, Guillermo A. O'Donnell argues that “the rule of law is among the essential pillars upon which any high-quality democracy rests” (O'Donnell 2004: 32). Likewise, Richard A. Posner defines “law and democracy” as the “twin pillars of the liberal state” (Posner 2003: ix). Also former U.S. Secretary of State Elihu Root considers law as an “essential condition” for democracy:

“the only atmosphere in which a democracy can live between the danger of autocracy, on one side, and the danger of anarchy, on the other, is the atmosphere of law” (Root 1917: 7).

Nevertheless, legalization's democracy-enhancing effects are not confirmed by all scholars who have researched the relationship between the rule of law and national democracy. The different logics according to which democracy and law operate can bring both into conflict. One strand emphasizes the danger of judicialization or the politicization of the judiciary that refers to the rise of the more or less unconstrained rule of judges beyond their original remit (Hirschl 2008). It has not only been criticized that judges try to augment their own power, but also that politicians readily transfer their political responsibility to courts to let them decide about politically controversial or uncomfortable issues (Vorländer 2006). Unlike politicians in democracies, judges are not elected and are not bound to a set of accountability mechanisms to ensure responsiveness. Therefore, it is problematic if judges take over a legislative function (Ferejohn/Pasquino 2003). By contrast, politicians can use the judiciary as a political weapon against opponents of who they cannot get rid of otherwise (Maravall 2003). While they can use law to confine their adversaries, dominant political actors can free themselves from legal constraints. O'Donnell finds empirical evidence for this in Latin American countries where powerful actors circumvented or twisted law in their own conduct, but at the same time insisted on a strict application of law to their (weaker) opponents. A statement of the former Brazilian President Getúlio Vargas highlights this: “For my friends, everything; for my enemies, the law.” Therefore, O'Donnell acknowledges at most a rule *by* law, but not a rule *of* law (O'Donnell 2004: 40, 43). Eventually, law depends on being interpreted and enforced. Both can be controlled by powerful actors.

Adriana Sinclair adverts to the origins of the rule of law to illustrate the oppressive potential it has carried from the onset. The legal discourse held sway in the Western world in the 17th century when capitalism started to supersede feudalism. In order for the rising

⁹⁶ See for example: Dobner 2010: 142; O'Donnell 2004; von Bogdandy et al. 2008: 1389.

bourgeoisie to conduct their trading business, a system of contracts and property was established. The legal protection of property by the state represented the precondition for capitalism's expansion. The structuring of social problems in legal rights and duties assisted the merchant class to lock in their privileges. This ostensible empowerment, however, led at the same time to the oppression of other social groups. Besides the fact that women themselves were considered property of their fathers or husbands, small landowners and the working class lacked the material power to make use of their formal rights so that they were exposed to bourgeois exploitation (Sinclair 2011: 1099-1102). In a similar vein, Jürgen Habermas criticizes that the liberal-bourgeois paradigm of an equal distribution of rights proved insufficient to guarantee equality in practice (Habermas 1998). This also concurs with the Marxist-Leninist tradition of considering democracy as a sugarcoated obfuscation of the bourgeois dictatorship (Maravall/Przeworski 2003: 8).

What can we learn from the national experiences and what are the implications for the international arena? Those scholars who have already detected tensions between legalization and democracy domestically remain their grim outlook for the international arena. The others who share the view that the rule of law has often provided the foundation on which democracy could flourish within states disagree about the transferability of the positive domestic relationship beyond the state. One group believes that the mutually reinforcing connection between law and democracy can be transformed into an international project. In its extreme version embodied by some cosmopolitanists, the rule of law can – analogically to the domestic model – support global democracy. In short, the “rule of law is an essential counterpart of any democratic system” (Archibugi 2010: 88). A ‘democratic public law’ entails not only civil and political rights but also ensures health, social, cultural, civic, and economic entitlements to ensure freedom and equality among individuals (Held 1995a: 190-200). Empirical evidence for an emerging global democratic legal order is believed to be found in the rise of human rights treaties and the growing influence of civil society actors supporting legal democratic norms.

Lawyers in the tradition of Immanuel Kant and Hans Kelsen like Georg Scelle and Hersch Lauterpacht have high expectations of law as it should establish an order of peace and human rights (Fischer-Lescano/Liste 2005: 213-214). Kantian liberalists believe in the gradual improvement of international institutions working toward the strengthening of individual rights and world peace. IL takes up a civilizing function by legalizing human rights and structuring cooperation so that it can be carried out in a peaceful and fair manner. International relations are based on commonly shared fundamental values of which many are codified in the course of time. To guarantee individual freedom, international democratic relations can only be sustained if they are accompanied by national democratization (Tesón 1992: 54, 60-61, 70-74; similar: Martin-Chenut 2008; Slaughter 1995: 509).

Many assertions of IR and legal scholars have only referred to IL's impact on national democracies. Robert O. Keohane and his colleagues argue that international legalization can mitigate domestic democratic deficiencies by (1) improving the protection of individual and minority rights, (2) curbing special interest groups, and (3) improving the quality of democratic deliberation by introducing additional technical expertise to national politicians and publics (Keohane et al. 2009; see also Buchanan/Powell 2008: 330-332).

Also IL's procedures have been said to serve national democratic quality. In contrast to informal and legally non-binding regulations, hard law treaties usually require ratification by national parliaments. These obligatory domestic approval procedures can enable a domestic feedback mechanism that "can and should serve as a 'transmission belt' of accountability to the national electorates" (Peters 2009: 272; Shaw 2008: 912). In domestic deliberation, it can be agreed on the specific tasks and limits of an international institution (Ulfstein 2009: 55). Within a state, informal arrangements can shift power from the legislative to the executive and judicative and hence, infringe on the domestic checks and balances (Buchanan/Powell 2008: 327). Ostensibly benefits of lowly formalized soft law, such as flexibility and speed, can turn out to be impediments to accountability. This argument can only partly justify a democratic advantage of hard law given that states display various requirements for legislative approval and consultation (Alvarez 2007: 171). A survey by Beth A. Simmons shows that 108 out of 177 countries request at least the approval of the majority by one legislative body (Simmons 2009: Appendix 3.2).⁹⁷ The demand of ratification, however, is not more pronounced in democracies than in other regime types.⁹⁸ Furthermore, the requirement of ratification can restrict state representatives' room for maneuver to successfully complete negotiations.

Others assert that democratic rights became or should become international legal obligations. For instance, Thomas Franck, Michael Reisman, and Fernando Tesón have advocated a "democratic entitlement" in IL (Franck 1992; Reisman 1990; Tesón 1988). They contend that states can no longer be indifferent to states' internal governance but have to respect and protect citizens' right to political participation that is grounded in human rights treaties such as the Universal Declaration of Human Rights (UDHR) and the International Covenant on Civil and Political Rights (ICCPR). If a government denies its own citizens this right, for example by impeding free and fair elections, it can no longer rely on the doctrine of state sovereignty. Also other states have an international obligation to ensure people's sovereignty abroad (Fox/Roth 2001: 335-336).

Despite their differences in the institutional design of supranational democratic governance, the previous authors share a belief in law's impartiality (for instance in form of

⁹⁷ Available at: http://scholar.harvard.edu/bsimmons/files/APP_3.2_Ratification_rules.pdf (Accessed 30 April 2011).

⁹⁸ This was tested by comparing the average of countries' degree of freedom according to the Freedom House Index (2010) and regime type according to the Polity IV Index (2009) with the different categories of ratification rules established by Simmons.

independent international adjudication), its strong taming force of sheer power politics, and the possibility of effective international enforcement and sanction mechanisms.

The critiques of the transferability-thesis strongly doubt that these conditions can ever be met internationally and claim that the positive relationship between law and democracy holds only true domestically. This position has been most notoriously and clearly advanced by realists. They deny an autonomous role of IL in international relations and the possibility to realize democratic principles internationally. Given realism's gloomy outlook of a Hobbesian international state of nature, stable long-term cooperation is rare since mistrust can never be surmounted (Mearsheimer 1994-1995: 12). States cannot rely on legal commitments in this conflict-driven international self-help system in which compliance with rules cannot be reliably observed and breaches cannot be effectively sanctioned by an international centralized authority (Morgenthau 1940: 275-276; Posner 2009: 31-32). Realism warns against a "legalistic-moralistic approach" which, on the basis of a naïve equation of domestic and international conditions, assumes that IL promotes international peace (Kennan 1951: 95-96). While domestic politics are characterized by the rule of law backed up by a centralized monopoly of force, international relations are "a struggle for power [...] and the modes of acquiring, and demonstrating it determine the technique of political action" (Jackson/Sørensen 2007: 67 citing Hans Morgenthau). Therefore, both law and democracy can only be meaningful within the state. States may enter international treaties but depart from IL if compliance is not in their national interest. Unbounded trust in legal precepts, as it is imputed to a Wilsonian idealism, is therefore dangerous because IL turns out to be extraneous in the case of conflict in which war serves as a last resort (Steinberg/Zasloff 2006: 71-73). Even if institutions exhibit *de jure* democratic features, they are *de facto* rendered worthless because members do not consistently comply with institutions' procedural rules.

Among the currently most prominent spokespersons of this strand are Jack L. Goldsmith and Eric A. Posner. The authors avail themselves of a rational choice approach to develop a theory of IL in which state power and state interests take center stage (Goldsmith/Posner 2005: 3-4). States are rational actors who strive for maximizing their interests and therefore never comply with IL for non-instrumental reasons (Goldsmith/Posner 2005: 13). Consequently, IL is endogenous to state interests. For IL reflecting the distribution of power among states but not being capable of altering it in favor of less powerful actors, international institutions are dominated by powerful actors who determine the terms of contract and can force weaker states to enter treaties that are unfavorable to them.⁹⁹

Given this framework, it might come at surprise that Goldsmith and Posner devote almost one third of their book to draw "normative lessons" from their theory (Goldsmith/Posner 2005: 4). First, they argue that legal rhetoric is costless so that everyone

⁹⁹ Goldsmith/Posner 2005: 10, 87-88; Mearsheimer 1994-1995: 7; Morgenthau 1940: 275-276.

engages in it rendering legalization practically ineffective (Goldsmith/Posner 2005: 173-174). Second, states have no moral obligation to comply with IL for the latter never represents *the* world public's interest but the compromise of egoistic states that care more about their own citizens than individuals living outside their jurisdiction (Goldsmith/Posner 2005: 185-203). Third, strong cosmopolitanism is not only utopian but also incompatible with domestic liberal democracy since the latter demands state heads to take care of their own people rather than to be other-regarding (Goldsmith/Posner 2005: 205-223).

Despite several theoretical pitfalls¹⁰⁰, realism illustrates the significantly different conditions under which law and democracy operate internationally and domestically. The three political branches of an independent judiciary, a democratically elected legislative, and an effective executive do not exist at the international level like also other authors have stressed (Alvarez 2007; Dobner 2010).

In addition to the rather simplistic realist model, other authors add democratic deficiencies of the international system. IL's legitimacy has traditionally been bound to sovereign states' consent. If one takes democracy seriously, the principle 'one state, one vote' violates the democratic principle of the individual as the primary normative unit of democracy because states' populations differ (Alvarez 2007: 160). By the same token, the fragmentation of international legal regimes disrupts important principles of the rule of law. This can be an impediment to democracy because neither unified and equal application nor legal certainty can be guaranteed under these circumstances.

Even if one accepts a fruitful liaison between legalization and democracy within the state, a simple analogous application to the international realm seems to be out of reach. If the relationship between legalization and democracy has already dangled on a string within the state, it is even more precarious on the international plane. Therefore, the theoretical

¹⁰⁰ Realism fails to explain why states increasingly codify and institutionalize their cooperation, states take great pains to differentiate between pledges and contracts in the first place, and powerful states obey the law even if it is not beneficial to them. Even the security area – realism's dominant field of concern – exhibits important IL such as *ius ad bello* (see Article 2(4) of the UN Charter) and *ius in bello* (Geneva Conventions and Protocols with almost universal membership). The realist critique that the formal outlawing of the use of force did not prevent wars from breaking out does not rule out the possibility that IL assisted in preventing and mitigating conflicts.

By the same token, realism cannot explain the variance of institutions' democratic quality. If moralistic and legalistic talk is, as claimed, en vogue and almost ceremonial but ineffective (Goldsmith/Posner 2005: 88), one should observe that dominant states within institutions grant more rights to less powerful actors to appear democratic and to satisfy normative claims. It is also left in the dark why domestic audiences settle for empty democratic talk (Goldsmith/Posner 2005: 178-179) when they want their governments to be committed to promoting democratic standards internationally.

Furthermore, realists accuse mainstream IL scholarship of being "under the spell of a legalistic ideology" (Goldsmith/Posner 2005: 202). However, realism itself is prone to fall into a self-constructed trap by envisaging an overly pessimistic world view that, when intimidated actors adhere to it, becomes a self-fulfilling prophecy. At the same time, realism lacks transformative guidance which would enable the escape from the 'anarchic game'. Neither IOs' distributional consequences nor the compliance with IL can always be traced back to the distribution of power among states (Hathaway/Lavinbuk 2006: 1430). In this line, it also contradicts realist hypotheses that IOs continue to exist after the decline of U.S. hegemony (Slaughter Burley 1993: 218).

arguments for a tensions-ridden international legalization-democracy relationship deserve further considerations. This justifies a closer look at critical (legal) theory that emphasizes law's power dimension in a more sophisticated way than realism. Realism is certainly correct to emphasize the importance of power in international relations and therefore to warn of blind faith in law. Breaches of IL are sometimes willingly accepted if law no longer suits in particular powerful states' needs (see for instance the unauthorized U.S. invasion into Iraq). However, realists all too often regard law and power as opposing concepts rather than two sides of the same coin and therefore take the shortcut to stigmatize IL as an epiphenomenon. Critical theorists, on the contrary, often attribute a democracy-impeding impact to law precisely because it represents an enormously influential means of power.

4.3 Legalization between Emancipation and Power Consolidation in Disguise

Being receptive to law's power potential, the heterogeneous group of critical theories scrutinizes and challenges legal principles and structures.¹⁰¹ Critical legal theories depart from the determination and interpretation of legal doctrines. Instead, they explore and denaturalize the discursive and structural setting of legal arguments (Beck et al. 1996: 227). They criticize and deconstruct legal principles, such as impartiality, sovereignty, and equality before the law, by locating them into their social context (Koskenniemi 2005b). Two authors are highlighted here: Jürgen Habermas and Martti Koskenniemi.¹⁰² Both provide valuable insights on the operation of law as well as its capacity to influence democracy. Out of the scholars' rich work, only some points can be raised here.

One of the few studies that explicitly and elaborately deals with the relationship between law and democracy is Habermas's opus "Between Facts and Norms" (Habermas 1992). He argues that law and power are connected via an internal relationship in full-fledged democratic systems. Both depend on each other to exercise their respective intrinsic functions. In functionally differentiated modern societies, law represents a crucial medium to integrate modern societies.¹⁰³ First, law enables individual self-fulfillment by guaranteeing actors fundamental rights of liberty and political participation (laws of freedoms) on the basis that actors' scope of allowed behavior is limited (laws based on coercion) (Habermas

¹⁰¹ In order to facilitate the discussion, I do not differentiate between critical theory of different disciplines such as IR, legal theory, and sociology.

¹⁰² To include Koskenniemi's theoretical considerations in an IR study seems to be an audacious endeavor considering his distinct antipathy against IR research. He has frequently accused the scholarship of a "managerial" approach that simplifies IL and has criticized its rationalist methods and language. Managerialism depicts IL as a practice of legislating and managing instrumental rules. This usually involves no critical potential to reform existing structures and serves dominant interests and powers (Koskenniemi 2011: 324-325; Koskenniemi 2009a: 410; Koskenniemi 2007a: 23). Therefore, Koskenniemi is very skeptical of a fruitful joint endeavor between legal and IR scholars because "[i]nterdisciplinary" seemed always to be less about collaboration than conquest" by the IR discipline (Koskenniemi 2011: 319).

¹⁰³ Similarly, Koskenniemi diagnoses an international legal fragmentation (Koskenniemi 2007a: 4-9) and agrees on law's important social functions (Koskenniemi 2009a: 415).

1994; Habermas 1992: 47). Second, law – due its generality, abstractness, publicity, and procedures – serves as a common language across different subsystems which creates stable expectations (Habermas 1992: 68-69, 77-78).

Law can only effectively fulfill its role if it is binding and self-imposed. First, this requires that political power confers social facticity to law. Political authority's sanction mechanisms secure the implementation and enforcement of legal rules that lead to legal certainty. Second, law only possesses validity and a legitimizing force in the long if it serves democratic self-determination that corresponds in Habermas's framework with a public deliberative process. This denotes an ideal speech situation in which all affected actors freely and equally exchange their arguments on the right means to reach certain ends (pragmatic) or the right ends themselves (ethical/moral) and eventually agree on the scope of laws that grant and limit individual freedom. This should be supplemented by a public sphere rooted in an active civil society. Political power, in turn, needs to be located in a legal framework to fulfill its main task that is the realization of collective goals. In other words, democracy can only be realized within a legalized system.¹⁰⁴ Consequently, law and democracy are mutually necessary conditions that positively complement and reinforce each other in a circular relationship. Nevertheless, these are not sufficient conditions to create legal and factual equality. Although Habermas is more engaged in elaborating on the positive association between law and democracy, he also emphasizes that law can be misused to conceal the usurpation of power in guise of legalized privileges (Habermas 1992: 59, 181): "Often enough, law provides illegitimate power with the mere semblance of legitimacy" (Habermas 2001: 40). Habermas's strength is to come to grips with law's complex role in modern societies by seizing the middle ground between legal positivism and natural theory (Zurn 2011: 204). He acknowledges that law requires both the facticity provided by political authorities and the legitimacy derived from democratic procedures.

Habermas is skeptical if law's democratizing function can be transferred to the international arena. First, there is no monopoly on the coercive use of force to back up the international legal order and its stabilized expectations (facticity). Second, it is more difficult to accomplish an international democratic process of deliberation by all affected actors who would legitimize the legal order (legitimacy). The even greater multitude of values that have to be regulated and balanced internationally creates difficulties for law to fulfill its function of social integration. This is especially relevant as common values have to be built from scratch. In this context, international institutions and the international system in general lack a constitution and a common legal community on which the national model relies (Habermas 2008: 368).

These doubts are mirrored in Habermas's proposal of a multi-level system to democratically constitutionalize the entire international system. Although he supports a world organization that protects human rights and secures international peace, democratic

¹⁰⁴ Habermas 1992: 57-58, 177-180; Niesen/Eberl 2006: 5; Zurn 2011.

self-governance remains mostly within the state. The main source of legitimacy is channelled bottom-up via democratic states and is only safeguarded top-down by a universal charter. The role of a world parliament in form of a reformed General Assembly, which could consist of democratically elected national parliamentarians, would be restricted to elaborate and interpret the universal charter. Transnational institutions, located between the global and national level, are left with technical and other less political issues that have to be coordinated in a transparent deliberative process (Habermas 2008). Habermas's model, consequently, is located between a world state and a world of states. Given his reflective analysis of international legal and political imperfections, Habermas's continuous support for IL seems to result from a calculated optimism in the absence of alternatives that could take over law's integrating and pacifying functions. Legalization in its complexity and variety is not discussed, but rather considered as an unchallenged default setting and development.¹⁰⁵

The tension between legalization's democracy-enhancing and -deteriorating effects is also well-illustrated in Koskenniemi's work. He describes his approach as a holistic, formalistic, and critical deconstruction of the legal argument. The traditional opposition between theory and doctrine should be avoided by taking into consideration law's social character (holistic) and analyzing both facts and ideas as parts of an argumentative structure (formalistic). This exposes both legal grammar's deeply underlying liberal code that restricts what can be legitimately argued and the oppositional structure that opens up a critical potential (critical) (Koskenniemi 2005b: 6-14).

In a similar analytical vein as Habermas, Koskenniemi expounds the constant antagonism between apology and utopia in IL. The legal structure forces lawyers to choose sides in their defense of a legal argument. States discard IL as utopian if it is detached from political realities and interests. But at the same time, IL is considered as an apology for the existing dominant power structure if it only reflects the current international power constellation and does not promote higher normative values that can be enforced independently from politics. This tension is caused by IL's dual necessity to require state consent and at the same time legally bind states. Therefore, a legal argument has to oscillate between an 'ascending' and 'descending' mode. The former relies on a positivist law conception of state practice and consent (concreteness) while the latter refers to higher moral principles of impartiality and equality (normativity). Both principles contradict each other for the former emphasizes political realities and actual state behavior while the latter distances itself from states' political interests (Koskenniemi 2005b: 17-70; Koskenniemi 1990: 7-8). As a consequence, the project of promoting an international rule of law has only been rendered possible by IL's dependence on formal standards and processes in the absence of substantial rules (Koskenniemi 1990: 28, 30).

¹⁰⁵ For a critique of Habermas's multilevel order see Humrich 2007.

Moreover, Koskenniemi emphasizes law's indeterminacy understood as the absence of a fixed consensus on legal norms' content. IL is not decoupled from moral, political or economic pressures. Instead, IL is a hegemonic "technique of articulating political claims in terms of legal rights and duties" (Koskenniemi 2004: 197). The ultimate objective in this process of hegemonic contestation is to universalize one's subjective interpretation of a legal norm and stabilize this meaning in the legal discourse as *the* only legitimate and universally applicable version (Koskenniemi 2011: 324; Koskenniemi 2004: 199, 202). Given the competition on the interpretation of legal norms, they are never objective and always serve certain political agendas (Reus-Smit 2004: 23; Venzke 2009). Every legal argument remains ambiguous and depends on the interpretation by a politically privileged rationality that has to face criticism in terms of concreteness and normativity. Also the underlying liberal assumptions of modern IL provide no guidance to reach a final interpretation (Koskenniemi 2005b: 5). Therefore, the currently dominant ideology of managerialism, which portrays IL as a technical instrument determined by regulation, efficiency, and compliance, cannot dissolve conflicts within and between different legal systems by relying on expert decisions.

In his appeal to rescue IL from functional vocabulary, Koskenniemi does not expressly refer to democracy but proposes to bring back in a normativity of which many parts overlap with the concept of democracy as presented above. Referring to Kant, Koskenniemi argues that law should be a "project of freedom" that allows for contestation and offers a universal mindset – "a shared standard of criticism" – to evaluate interpretative judgments as to their capacity to fulfill peace in a political world community and what we consider the meaning of life (Koskenniemi 2009a: 413-416). Instead of degrading IL to "strategic games to realise self-interest", Koskenniemi

"often think[s] of international law as a kind of secular faith. When powerful states engage in imperial wars, globalisation dislocates communities or transnational companies wre[a]ck havoc on the environment, and where national governments show themselves corrupt or ineffective, one often hears an appeal to international law. International law appears here [...] as a placeholder for the vocabularies of justice and goodness, solidarity, responsibility and – faith" (Koskenniemi 2007a: 30).

In this way, IL as a mode of international regulation to solve conflicts has not to be jettisoned altogether. Law's indeterminacy can offer a window of opportunity for alternative, more democratic interpretations. At the same time, members of a legal and hence political community are vested with rights and duties. If these are violated in individual cases, it is of concern to the entire community (Koskenniemi 2004: 214-215). Since IL is a very powerful technique of international politics, it is not only a threat to freedom. At the same time it represents the only effective means to save it.

Although Habermas and Koskenniemi have different theoretical backgrounds, they are joined in their endeavor to expose IL's dual character. IL depends on facticity and normativity in Habermas's words and oscillates between apology and utopia in Koskenniemi's terms. Bringing the two authors together, two main findings are worth

being highlighted. First, IL is a restraint on the free exercise of power and concomitantly depends on power to be enforced and applied. It therefore depends on states to voluntarily subject themselves to international legal rules and on powerful actors to back them up (facticity and apology). Second, IL confers legitimacy and at the same requires legitimacy (normativity and utopia). IL legitimizes international relations in so far as it is assumed to be vested with a stabilizing, equalizing, and pacifying function and be the outcome of fair and formalized procedures.¹⁰⁶ This is perceived as normatively desirable because it is hoped to lead to fair cooperation and other normative goals. But IL is only legitimate in the long term if it in fact lives up to these high hopes. This is a daunting challenge as IL is intrinsically indeterminate and therefore does only create the semblance of unity and certainty. Both points are interrelated because IL's power-restraining effect ultimately depends on its legitimacy.

Altogether, critical approaches seem to be torn in their evaluation of the legalization-democracy relationship. On the one hand, they analyze law's underlying power structure and map how it can be misused in undemocratic ways. On the other hand, they acknowledge law's crucial communicative and integrative function in a fragmented world that could pave the way to emancipation. The authors are overall still hopeful about legalization's democracy-promoting effect. In particular, Koskenniemi seems to be very critical of deviating from full-fledged legalization in favor of softer forms outside public IL (Koskenniemi 2009a: 407-408). Koskenniemi raises concerns that new forms of informal rule-making in combination with the heterarchical nature of the international legal system increase the influence of illegitimate bureaucracies and special interest groups. In his eyes, this postmodern deviation from the intergovernmental law-making process endangers accountability and checks and balances (Koskenniemi 2004: 210-212).

At the same time, both authors do not oversee legalization's imperfections and do not consider it as an automatic and linear process.¹⁰⁷ What remains is a tensions-filled international legal structure with uncertain democratic implications. In the following, I present a model that sheds light on the question if legalization's pendulum swings more in the direction of apology or utopia. Central to the answer is the clarification of how powerful actors behave in highly legalized settings.

¹⁰⁶ With regard to the latter point, Habermas is more specific than Koskenniemi since he explicitly adds democratic procedures as a requirement for law's legitimacy. Koskenniemi remains on a more general level and notes that IL requires in addition to its formality "essentially contested – political – principles to justify outcomes to international disputes". "[S]ocial conflict must still be solved by political means and that even though there may exist a common legal rhetoric among international lawyers" (Koskenniemi 1990: 7).

¹⁰⁷ More pessimistic are, for instance, critical theorists like Michael Hardt and Antonio Negri who consider IL as a powerful means to disguise undemocratic procedures (Hardt/Negri 2001).

4.4 Model of Structure-Inherent and Actor-Dependent Effects

Most of the theories presented above only describe the legalization-democracy relationship by general assumptions and beliefs. They, however, lack mechanisms that could explain in-depth the assumed causal relationship, or in other words, isolate legalization's specific effects on democracy. Critical theorists like Habermas and Koskenniemi go further and specify legalization's mode of operation and relationship with democracy. Although their theories provide a good starting point for further analysis, they remain unclear on how the tension and at the same dependence between legalization and democracy specifically plays out in international institutions.

In order to overcome the deficits of these theories, I use an institutionalist framework for the theoretical analysis. Although institutionalism has not explicitly dealt with normative considerations, it suggests itself in many respects. Institutionalists had long avoided explicit references to law. But their main research topic considerably overlaps with the one of international legal theorists. International institutions represent institutionalized rules of varying legal quality. They are usually founded by an international contract. At least a minimum set of procedural regulations establish the rules of the game that serve as a framework to produce further policies (Scott 2008: 102).

Institutionalism's fine-tuned and comparative analysis of institutional features makes it very suitable to analyze the study's two main variables, legalization and democratic participation, both of which refer to institutional characteristics. On the basis of a complex understanding of the interplay between power, interests, and international constraints, institutionalists explain why it is rational for states to behave in a certain way in accordance with an institution's design. They elaborate on how cost-benefit considerations influence state representatives in structuring agreements that oscillate between a desire to make credible commitments and to avoid the costs of non-compliance (Abbott/Snidal 2000; Guzman 2005). Such an approach sheds light on states' incentives to behave (un)democratically in international institutions – be it consciously or unintentionally.

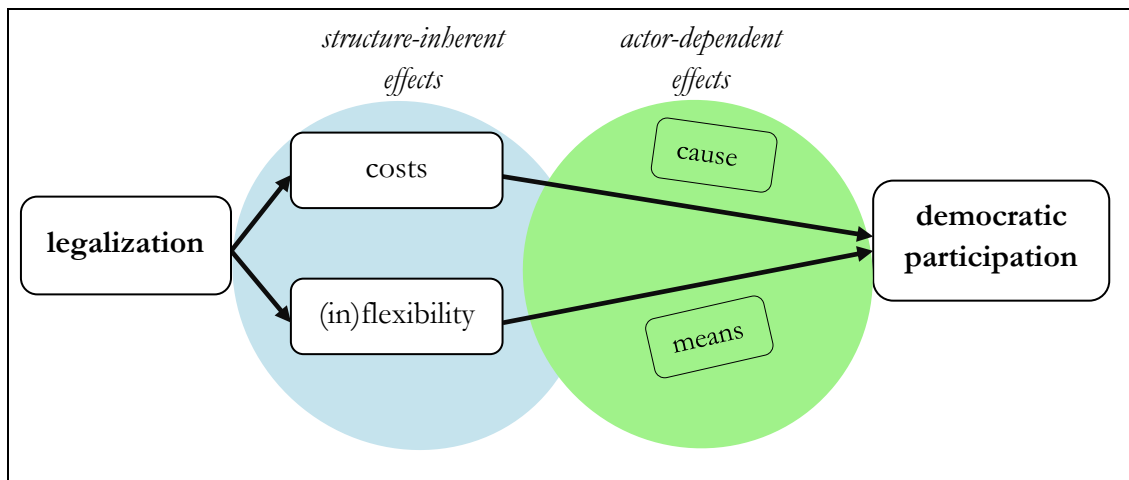
Last but not least, institutionalism allows for an unprejudiced and less ideologically charged analysis of the legalization-democracy relationship. Its drawback redounds to its benefit here. Since it considers democratization merely as a possible by-product of an institutional design, it comes with no ideological package that forecloses any direction or scope of legalization's effect on democratic participation. While the institutional design approach forms the skeleton, the insights from the previous discussion assist in putting flesh on this framework.

The model is derived inductively and does not serve as a blueprint to test certain hypotheses. It is nevertheless presented prior to the empirical analysis to maintain the conventional divide between the theoretical and empirical sections. The independent variable (IV) legalization is disaggregated into the three dimensions legality, formalization, and delegation in order to explore the impact of its specific features (see chapter 2). This

makes it possible to illustrate that legalization’s individual dimensions have different effects with varying force on international institutions’ democratic participation. For similar reasons, I differentiate between the democratic standards of congruence and contestation (chapter 3) because they can be differently affected by legalization’s dimensions.

My model can be briefly summarized as follows. The discussion on the benefits and downfalls of low and high legalization frequently centers on the two categories costs and flexibility.¹⁰⁸ It is assumed that costs are mostly created by legality and delegation while flexibility varies with the degree of formalization. These structure-inherent characteristics affect institutions’ democratic participation by influencing actors’ behavior and interaction within institutions. An institution’s degree of legalization determines the costs to which actors are exposed. Depending on the scale of costs, actors behave differently to pursue their goals and possess different strengths of participation preferences. On account of these actor-dependent effects, powerful actors within an institution allow for or impede democratic participation. Generally, legalization’s high costs are causes that impair democratic participation while a lack of formalization provides a means to circumvent democratic procedures. The theoretical framework is illustrated in the figure below and subsequently described in greater detail.

Figure 2: Analytical Framework of Structure-Inherent and Actor-Dependent Effects



I want to make one note in advance. The term ‘powerful’ in the discussion predominantly refers to actors’ economic resources. Economically powerful states have typically most leverage in international negotiations.¹⁰⁹ Being very influential, they usually must be part of an agreement to deal successfully with a matter. This applies to financial and trade accords as well as environmental and social agreements. In the former ones, the participation of great economies is decisive to (re)structure international economic relations. In the latter ones, they determine to what extent these issue areas prevail over economic concerns by

¹⁰⁸ Abbott/Snidal 2004; Abbott/Snidal 2000; Skjærseth et al. 2006.

¹⁰⁹ This assumption does not deny that military power can trump economic power. But this only applies to extreme cases and not international negotiations at large.

subordinating immediate national monetary benefits to the achievement of global environmental and social goals. Also their financial support conditions the success of implementing these policies.

4.4.1 Structure-Inherent Effects

Structure-inherent effects are institutional design features that have a clear-cut impact on democratic participation. This can be either directly or indirectly by influencing the behavior of actors who, in turn, attempt to affect participation within an institution. Actors can only alter structure-inherent effects by converting the respective legalization dimension. For instance, if states conclude hard law, it requires legal capacity and mostly national ratification (UN 1969: Art. 7, 14). Both can only be circumvented by the return to soft law. Structure-inherent effects are evidence of legalization's utopian facet. They prove that legalization is more than an apology of politics and a mere sociological description of states' behavior but remains its validity even if states' interests change. The structure-inherent effects can be divided into costs and flexibility.

4.4.1.1 The Costs of Commitment

Both legal obligation and high delegation are costly in sense that they (1) limit states' sovereignty, (2) make breaches of provisions costly, and (3) require legal expertise (Shaffer/Pollack 2010: 717-719; Sitaraman 2009: 33). Although states can have different motives to support or reject legality and delegation, I argue that the effect of both dimensions in terms of costs they create is similar.¹¹⁰

Sovereignty costs refer to a state's constraint or loss of authority to an international institution. They vary across issues and states, for instance concerning hard law treaties' status within states (Abbott 1998: 62; Alvarez 2007: 171). Sovereignty costs increase with a state's extent of loss over its decision-making and the scope of binding policies that are regulated within an international institution.

Sovereignty costs are highest if IL directly touches on the Westphalian pillars of external and internal sovereignty or in other words a state's relationship with its citizens. The breadth of sovereignty costs cannot always be anticipated because states cannot foresee the pathways that autonomous institutions might take over time (Abbott/Snidal 2000: 437-438).

Delegation transfers tasks that were previously fulfilled by and within states to international institutions. Although delegation to international institutions can increase states' problem-solving capacity, at the same time, it restrains states' scope of autonomous action. The room to maneuver is further limited by concluding international legally binding accords in which states pledge to take certain action or avoid certain behavior.

¹¹⁰ Guzman 2005: 588; Shaffer/Pollack 2010: 717-719; Sitaraman 2009: 33.

Costs of non-compliance refer to material and reputational costs. Both forms are increased by legality and high delegation. Legality holds states legally responsible so that breaches of hard law can be brought before (inter)national courts. In the case of soft law, states do not incur legally binding obligations that they have to implement in a given period of time and for which they can be held responsible on legal grounds (Betsill/Corell 2008b: 40). Also reputational costs are higher in the case of hard law since the readiness to accept legal bindingness signals a more serious commitment.¹¹¹ A high degree of delegation in the form of court-like procedures and sanction mechanisms increase the costs of non-compliance because it improves the detection of non-abidance and enables more effective sanctions against violators (Guzman 2002; Shaffer/Pollack 2010: 718).¹¹²

These often self-imposed costs of sovereignty and non-compliance are a precondition to ensure the independence of IL and legalization from brute power politics. Why would states accept these costs? Hard law and delegation are tools to strengthen one's own commitment and assure other countries of one's intent to abide by the law (Abbott/Snidal 2000: 426-430). A credible commitment forms the foundation of effective cooperation.

Hard law also demands *legal capacity*. To construct and defend a legal argument is a special practice that requires technical expertise as provided by lawyers. As O'Donnell notes:

“strictly speaking there is no “rule of law”, or “rule by laws, not men”. All there is, sometimes, is individuals in various capacities interpreting rules which, according to some preestablished criteria, meet the condition of being generally considered law” (O'Donnell 2004: 34).

Likewise Koskenniemi observes:

“[T]he legal argument inexorably, and quite predictably, allowed the defense of whatever position while simultaneously being constrained by a rigorously formal language. Learning to speak that language was the key to legal competence” (Koskenniemi 1999: 354-355).

In order to make a legitimate legal argument, a situation has to be examined for applicable legal rules or precedents that support a case. It can require the reformulation of the problem in order to make it fit into a category of illegal action. But this does not imply that anything goes. Lawyers need to adhere to IL's formal procedures and practices (Koskenniemi 2009b: 9). As a consequence, legal rules can only be interpreted and applied in accordance with legal principles while courts usually have the final interpretative authority in a highly legalized system (Abbott/Snidal 2000: 427, 429).

In international hard law negotiations, states depend on legal experts to evaluate their options and strategies. To this end, their lawyers have to be familiar with the relevant international legal regimes that are often very complex not least because of the fragmented

¹¹¹ See: Goldsmith/Posner 2005: 83; Keohane et al. 2000: 467; Shaffer/Pollack 2010: 713. Reputational costs can be limited by the existence of “multiple reputations” and a lack of transparency (Simmons 2009: 117-118).

¹¹² Of course, breaches of soft law can also be sanctioned in non-legal ways. This is especially correct given the fact that sanction mechanisms both of soft and hard law are more credible if they are backed up by powerful states. Nevertheless, it is assumed that IL is vested with a stronger legitimacy to justify non-compliance.

international legal architecture. At the same time, they need to be acquainted with the respective national legal system as domestic laws can influence a country's policy space in international negotiations and IL can have considerable consequences on domestic laws. The legal expertise that is demanded in hard law institutions is more than general acquaintance with IL's principles. Usually specialized legal knowledge of the respective policy field is required. This knowledge might only be held by a handful of well-trained experts. Also the greater legal complexity in connection with the higher costs that result from hard law often make negotiations tedious and resource-consuming.

Legal capacity is not only required for the negotiation process but also in the stages of implementation, enforcement, and adjudication. The implementation of IL has to be executed by professional and trained staff on the basis of sufficient administrative, financial, and human resources. Cases against other states can only be lodged if the claimant can afford experts that are familiar with the legal procedures and the precise regulation in question. Studies illustrate how a lack of resources impedes the de facto access to litigation in the cases of the EU and WTO (Börzel 2006; Busch et al. 2009: 576). Therefore, legal capacity's inherent costs structurally discriminate against less affluent states with few full-time professional staff and a lack of legal resources.¹¹³

As already indicated, delegation and legality cause structure-inherent costs to a different extent while legality represents the crucial dimension to generate costs which can be intensified by delegation.

4.4.1.2 Flexibility – Cui Bono?

Formalization's major structural effect is stabilization. It standardizes and institutionalizes procedures in order to foster stable expectations, reduce transaction costs, and regulate behavior according to predefined rules.¹¹⁴ The substantial specification of this effect depends on the content of procedural rules and the respective actor constellation. Formalization can both strengthen already powerful states or countervail the unequal power distribution among actors (Abbott/Snidal 1998: 10). However, IL "pulls toward equality" (Krisch 2003: 152). This can be explained by state sovereignty as one fundamental principle of IL. Furthermore, formalization leads to transparency in form of written rules. Under these conditions, states face inhibitions to openly discriminate against actors. This applies in particular to procedural rules where unequal treatment becomes more easily palpable than in complex substantive regulations. Formalization, especially in connection with legality, is often considered to be a fair form of organization attributed with neutrality, transparency, and procedural fairness that tames state action and goes beyond power politics.¹¹⁵

¹¹³ Abbott/Snidal 2000: 432; Busch et al. 2009: 565-566; Kim 2008: 661-662.

¹¹⁴ Kim 2008: 658; Neyer 2004: 56; Niederberger 2009: 232; Onuma 2003: 123.

¹¹⁵ Buchanan/Powell 2008: 333; Klabbers 2001: 419; Schneiderman 2001: 522; Scott 1994: 8.

In addition to that, formalization in combination with legality has some direct structure-inherent effects on democratic participation by establishing certain rules that reduce flexibility within political interaction. These impact both access and involvement. Concerning access, IL recognizes only states as full-fledged members in the international public arena. This is most impressively illustrated by the fact that IL limits the full powers of concluding legally binding rules to states. Other actors, such as transnational NGOs and indigenous groups, are denied this right. By contrast, lowly legalized settings can allow for more unregulated and flexible participation and a greater range of participants (Koivurova/Heinämäki 2006: 104; Oberthür et al. 2002: 9). Less legalized processes are less formally structured (Abbott/Snidal 2000: 445-446). This flexibility can undermine the due process of rule-making and lead to informal accords in camera (Klabbers 2001: 419; Pauwelyn 2010b: 6) that “escape the public controversies” (Lipson 1991: 500).

Legalization’s structure-inherent effects have direct ramifications on actor-dependent effects as I discuss in the next section.

4.4.2 Actor-Dependent Effects – Agency within Legalization’s Structure

Actor-dependent effects are shaped by legalization’s structure-inherent effects such as cost calculations associated with legalization. Altering actor-dependent effects on democratic participation requires a change in actors’ behavior or the modification of rules’ substance but not necessarily a change in the degree of legalization. The inclusion of actor-dependent effects in the analysis of legalization closes an important gap. Raz found four primary functions of law:

- (1) “Preventing Undesirable Behavior and Securing Desirable Behaviour”,
- (2) “Providing Facilities for Private Arrangements between Individuals”,
- (3) “The Provision of Services and the Redistribution of Goods”,
- (4) “Settling Unregulated Disputes” (Raz 1979: 169-173).

Without adding agency to the legal picture, it remains unclear for whom “desirable behaviour” is achieved, who profits from the redistribution of goods, and if the settling of disputes means pacification in a fair manner or rather silencing of conflicts by dominant actors.

The following discussion is based on two main presumptions. First, it is assumed that state agents are rational actors who strategically pursue their – not necessarily material – interests when they design and act within international institutions. These interests are rarely obvious for state actors have to accommodate various national and international requests and even state agencies of the same country can pursue different interests. Nevertheless, presuming rational actors, it is expected that negotiating state agents calculate the above presented structural effects when designing and acting within international institutions.

Second, states, once having entered into an accord, have a tendency to care about compliance. Skeptics counter that IL merely represents “cheap talk” and therefore neither

influences state action nor bears any costs on states (Guzman 2008: 12). This perspective fails to explain why states meticulously differentiate between non-legally and legally binding agreements, often invest a considerable amount of resources to negotiate rules, frequently refer to IL to justify their behavior, and utilize legal rhetoric to convince the international community of their adherence to IL (Chayes/Handler Chayes 1993: 184). For example, the lengthy negotiations of the UN Convention on the Law of the Seas (UNCLOS) illustrate both the effort that states make to agree on legal rules and that states refrain from adopting a treaty if they consider its rules to be unfavorable to their interests. So rejected the USA UNCLOS although it had substantially financed it (Chayes/Handler Chayes 1993: 182). In the same manner, states withdraw from an institution if they object to its growing legalization (Helfer 2002). Hence, many scholars have concluded that states have a “sense of obligation” (Young 1979: 23) and “general propensity” (Chayes/Handler Chayes 1993: 178) to comply with law. In other words, IL has a “compliance pull” (Franck 1990: 26). This does primarily depend on IL’s legal validity rather than its substance (Koskenniemi 2011: 323-324).

4.4.2.1 Legalization’s Costs as Cause for Undemocratic Participation

Actors across and within states have different cost calculations depending on their interests and different possibilities to enforce them in accordance with their power position. Generally speaking, it is assumed that dominant states are particularly determined to avoid breaches of rules in the costly environment of legal and highly delegated institutional settings. At the same time, they attempt to decrease the chances of discovering one’s own non-compliance that can be very costly due to the rules’ binding character. Because of these compliance considerations, dominant state actors opting for a highly legalized setting are particularly interested in controlling the policy process and outcome in the first place (Abbott/Snidal 2000: 427-428). Due to the threats of high costs, negotiations on hard law accords, especially in connection with delegation, represent *hard bargaining* in which powerful states are less inclined to compromise their interests. In an environment of hard bargaining two scenarios for state participation are conceivable while both have a democracy-diminishing effect.

First, powerful state actors restrict participation to avoid disagreeable influence from the onset by limiting access and if this is no longer possible involvement. This measure often does not suggest itself because powerful actors have an interest that also others are bound by IL. This applies in particular to legal regimes that are beneficial to powerful actors.

Under these circumstances, a second option concerning access becomes more likely. Powerful actors force candidates to assimilate according to the formers’ will before they can become member to an institution. Adversary states can be best curbed prior to their admission. This is especially effective if entrance depends on policy conformity with the international institutions’ rules or negotiations with existing members. At this stage, key

actors can pressure candidates to structurally adapt to the formers' needs and tame them before they even had a chance to influence the institution's policies and operation. Members can therefore suspend the logic of reciprocity and act in a take-it-or-leave-it attitude when requiring concessions. The right to participate can be paid at a high price by new members while it is highly uncertain that the necessary cooptation pays off (Charnovitz 1997: 284; Herr 1996: 107-108).

Nevertheless, access and involvement are differently affected by hard bargaining. After having been granted access to an institution, states have more means at their disposal to influence events. Once members are allowed to speak, it is almost impossible to constrain them. This has a positive effect on contestation with regard to involvement. In hard law negotiations, contestation is intensified because the stakes are higher due to the greater costs involved. Therefore, affected actors have a strong interest to bring forward their argument in a clear and pressing way. This especially concerns affected actors who aim to change current rules because it is easier to maintain the status quo in international institutions. Negotiating a new compromise is time- and resource-consuming and intricate in the case of complex interest constellations. By the same token, decisions are usually taken by consensus rather than vote so that opponents of new policies possess a greater veto power. But one should be cautious about the sustainability of higher contestation in highly legalized institutions as it can quickly turn into a Pyrrhic victory. Powerful actors cannot avoid critical voices in formal debates but can shift the crucial stages of negotiations to informal and more exclusive fora. Consequently, high contestation in plenary debates does not necessarily materialize in the policy outcome. Due to hard bargaining within the framework of high legalization, no highly legalized institution is assumed to run counter to the interests of powerful states.

Legalization's effect is generally more severe on contestation than on congruence. Powerful actors themselves are often strongly affected by policies. Their usually secured participation improves congruence. Instead, the participation of less powerful and at the same time critical actors is at risk that impairs contestation.

In contrast to negotiations in highly legalized institutions, more harmonious and less politicized debates are conducted in lowly legalized settings. Although it can be assumed that states always pursue their interests, dominant actors are more inclined to make concessions with regard to democratic participation in soft law negotiations that not only inflict lower non-compliance costs on them if they cannot live up to their pledges but also can be modified faster and more easily. In the end, these non-binding commitments can merely represent symbolic talk and action for powerful actors.

NSA participation can be easier curtailed by states. NSA access and involvement are expected to be more restrictive in the case of hard bargaining in highly legalized institutions than in lowly legalized institutions. As already described above, soft law negotiations induce more inclusive participation and greater compromises than would have been possible in a

more costly environment. The broad presence of societal actors does not represent a threat to powerful actors in these settings because the outcome cannot legally demand a change in their behavior. In general, NSAs face greater constraints than states since NSAs possess a less protected legal status in international relations. Their presence can already be denied on grounds that their work is not sufficiently relevant for an institution. The accreditation of NSAs is also sometimes not permanent so that states have several chances to prohibit the renewed approval of unpleasant NSAs. By contrast, negotiations on soft law expand the range of actors who can legitimately compete in the debate. This opens the gates for NSAs (Koskenniemi 2004: 211-212).

4.4.2.2 Flexibility as a Means for Undemocratic Participation

Formalization is vested with structural power to create institutionalized procedures of which actors cannot legitimately deviate from. As already described above, formalization possesses an equalizing force on participatory rights with regard to both access and involvement in international institutions. Highly formalized procedures are less insusceptible to discriminate against affected and critical participants since their transparent character would easily expose inequalities. Therefore, a high degree of formalized participatory rights is expected to promote democratic participation. This does not imply that states cannot circumvent formalized procedures if they run against their interests. But if they do so, other states can more easily debunk their undemocratic behavior as they violated clear and transparent rules on which participants agreed beforehand. By the same token, they can insist on the adherence to the collectively accepted procedures.

By contrast, less formalized participation allows for more ambiguity as to the legitimate criteria of membership, channels of communication, procedures in deliberation, and decision-making. This leaves more wiggle room for powerful actors to revert to informal and exclusive forms of negotiations without explicitly violating shared rules of the game.

Formalization's nature differs from legality and delegation. Not only has it a positive effect on democratic participation. It also represents a means rather than a cause that influences democratic participation. But taken alone, formalization is the legalization dimension with the presumably lowest influence on democratic participation.

All arguments on legalization's effects on democratic participation are systematically compiled in the table below.

Table 4: Legalization's Effects on Democratic Participation

		Effects		Participation	
		structural	actors-dependent	CG	CT
Legality	yes	high costs	hard bargaining: dominance of powerful actors	U	access: U/ involv.: D
	no	low costs	compromising: greater chances of less powerful actors	D	access: D/ involv.: U
Formali- zation	high	stabilization	equality	D	D
	low	flexibility	ambiguity	U	U
Delegation	high	high costs	hard bargaining	U	D
	low	low costs	compromising	D	U

[Legend: CG=congruence; CT=contestation; D=democratic; U=undemocratic; involv.=involvement.]

Most legal scholars would agree that a major function of IL is to regulate human behavior. Yet the ways and direction in which IL operates differ considerably as the chapter has shown. The discussion highlights that law is inextricably linked with politics and therefore also subject to power (Habermas 2001: 40; Shaw 2008: 11-12, 68). Actors are aware of law's power both in terms of regulating and legitimizing behavior. Therefore, powerful actors utilize legalization to manifest their dominant status by codifying and institutionalizing their relations to their advantage (Rajkovic 2010: 1).

Chapter 5

Methodology

In this chapter, I present the methodology used in this study. I first introduce the case-study design followed by the sampling strategy, data collection and evaluation.

5.1 Case-Study Design

The project's main purpose is to explore since a profound theory on the relationship between legalization and democratic participation is missing. To this end, the research design represents a forward-looking comparative case study analyzing the relationship between the independent variable (IV) 'international legalization' and the dependent variable (DV) 'international democratic participation (Ganghof 2005: 4-6; Ragin 1989: 4, 6). The study is divided into two parts. It starts with a descriptive *what*-question exploring if and which patterns can be observed between a certain degree of international legalization and democratic participation in international institutions. This requires assessing the IV's and DV's values for the selected institutions according to the prior operationalized yardsticks. On the basis of these results, I take stock if and where the IV has a negative or positive impact on the DV. This rather quantitative part is followed by an explanatory *how*-question that is addressed in a qualitative manner (Yin 1989: 17): How can the observed patterns between low/high legalization and high/low democratic participation be explained? The combination of quantitative and qualitative data makes it necessary to find a balance between a sufficiently large number of cases in order to be able to detect reliable patterns across institutions and an adequately small number of cases in order to be able to explore the legalization-democracy linkage.

A case-study design represents an appropriate strategy in several respects. Accounting for a phenomenon's context, case studies are particularly suitable for exploratory and explanatory work of contemporary events like in my project (George/Bennett 2005: 21; Gerring 2007: 39-41; Yin 1989: 23). Instead of traditional theory-testing, I explore the legalization-democracy relationship in order to develop a theoretical framework. In adherence to conventions of academic writing, I nevertheless present the theoretical framework prior to the empirical results. By the same token, the case-study design is conducive for the investigation of causal mechanisms with a high degree of internal validity (George/Bennett 2005: 19-21; Lijphart 1971: 683-684). Also I intend to demonstrate at least initial evidence of causality. Last but not least, case studies allow for a high degree of context-sensitivity and conceptual clarity that are crucial in the analysis of contested concepts like legalization and democracy. My interest lies in disaggregating these complex variables to analyze which attributes have an effect and are affected respectively.

Two limitations of this project have to be noted in advance. First, it is presumed that international legalization serves as an important IV rather than the only or necessary IV to

influence institutions' democratic participation. Therefore, I am certainly not able to eliminate all indeterminacy and create laws in the manner of 'if A, then always B' (Hovi 2004: 73). Since other context variables are at play and no linear relationship between legalization and democratic quality can be presumed, generalizations from my results to other international institutions can only be made cautiously. Other interdependent and conditioning variables are noted in chapter 9 but were not systematically analyzed.

Second, the high demands of identifying mechanisms in the sense of "linking specified initial conditions and a specific outcome", for instance by means of process tracing, cannot be completely met (Mayntz 2004: 241). Instead of empirically tracing a causal chain, I settle for illustrating possible fields of tensions and harmony between the IV and DV. In the endeavor to explore legalization's effect on democratic participation, I face the trade-off between the generalizability of results and depth of causal investigation. I opt for a middle ground to profit from the benefits of both approaches. But as a consequence, I cannot investigate the individual cases as detailed as I could have done with only one or two cases.

5.2 Sampling

I employ a heterogeneous sampling strategy (Boehnke et al. 2010: 109-110). The design is based on the selection of institutions with varying degrees of legalization. The purposeful choice of cases on the IV avoids selection bias by not predetermining the study's outcome (King et al. 1994: 108, 137; van Evera 1997: 46). Furthermore, the purposive sampling of contrasting cases often represents the first step toward the development of a theory. This is in particular appropriate for this study as no ready-made theory can be tested. The pitfall of purposive sampling, in contrast to random sampling, is its limited generalizability from the selected cases to the entire population.

The sampling consists of three layers. In a first step, IPRs and to be more precisely biotechnology-related patents are chosen as an issue area because it involves several institutions with variation across the legalization dimensions (Helfer 2004). It also represents a highly politicized field with great economic and social interests at stake so that democratic participation is inevitably required in this area. I further focus on biotechnology applied to agriculture (green biotechnology) and to medical processes (red biotechnology). This yields four main topics:

- (1) access and benefit-sharing (ABS),
- (2) protection of traditional knowledge (TK),
- (3) IP protection of plant varieties, and
- (4) public health and IP.

I consciously focus on one, even if broad, subject matter to control for important variables like actor and interest constellation that would considerably diverge in a comparison across issue areas.

On a second level, I select institutions that vary across the three dimensions of legalization. Preconditions are institutions' (1) sufficient engagement with IPRs, (2)

minimum of autonomy, (3) being active for most parts of the research period (1990-2010), and (4) relative consistency with regard to the legalization criteria within a case.¹¹⁶ This reduces the sample to six institutions:

- Convention on Biological Diversity (CBD),
- Food and Agriculture Organization of the United Nations (FAO),
- International Union for the Protection of New Varieties of Plant (UPOV),
- World Health Organization (WHO),
- World Intellectual Property Organization (WIPO), and
- World Trade Organization (WTO).

Concerning the cases' boundaries, I do not to detach sub-bodies, such as FAO's Commission on Genetic Resources for Food and Agriculture (CGRFA) and WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) from the broader institutional framework. Otherwise, the requirement of possessing a minimum of autonomy would have been violated.

As the field of biotechnology itself, the selected institutions span different issue areas. The fields of activity range from environment (CBD) over human welfare (FAO, WHO) to economy (UPOV, WIPO, WTO). Due to the complexity of most topics, spheres – such as economy, environment, and development – often cannot be strictly separated leading to interdisciplinary subject matters. The interaction between the institutions has to be controlled for in the empirical analysis. But at the same time, the fragmentation that follows from regime complexity is characteristic for many areas of IL today (Koskenniemi 2007a: 4-9).

Third, the time period between 1990 and 2010 is selected. The early 1990s serves as an adequate starting point since not only is the end of the Cold War commonly accepted as a turning point in international cooperation but also IPRs increasingly appeared on the international agenda during this time (Helfer/Austin 2011: 34). By the same token, I do not have to account for a general greater international acceptance of democratic norms as I would have needed if I included previous periods. Exploring a more recent period also considerably facilitates the access to documentation. The time period has to be further limited for the CBD and WTO both of which were founded later. The CBD started operating in 1994 and the WTO in 1995. Since the focus lies on legalization's effects on

¹¹⁶ Against this background, I omit from the sample the G-8/20, the UN Industrial Development Organization (UNIDO), and the UN Conference on Trade and Development (UNCTAD) due to their lack of engagement with IPRs. For autonomy-related reasons, the UN Commission on Human Rights and its successor – the UN Human Rights Council – are excluded because members were selected by ECOSOC in the case of the former and are selected by the UN General Assembly today. The UNDP is not considered since it carries out coordinating functions rather than rule-setting. The International Treaty on Plant Genetic Resources for Food (ITPGR) is excluded for having been active only in the last years of the selected research period between 1990 and 2010. The ITPGR entered into force in 2004 and held its first plenary session in 2006. In total, only three meetings could have been analyzed for the time period. In addition to the special interaction and socialization effects taking place at the early stages of an international institution, generalizations would have been very problematic. Since the ITPGR was negotiated under the auspices of FAO, it is nevertheless mentioned in the FAO context.

democratic participation after an institution was founded, institutions' pre-establishment phase including founding members' institutional considerations are omitted from the analysis.

With regard to the use of cases, all of the six institutions are considered in form of a comprehensive database to identify patterns between the IV and democratic access. The analysis of democratic involvement is restricted to the CBD, WHO, and WTO (chapter 8). For the exploration of the legalization-democracy relationship, the CBD, UPOV, WHO, WIPO, and WTO are analyzed more in-depth (chapter 9).

5.3 Data Collection and Evaluation

For the assessment of the variables, I use different data sources.

The *degree of legalization* is mainly assessed on the basis of formal documents such as founding documents, RoPs, treaties, guidelines, and decisions. I evaluate legalization's dimensions legality, formalization, and delegation according to the yardstick developed in chapter 2.

The empirical analysis of *democratic participation* is carried out in several steps. Information on the de jure access and involvement is collected from founding treaties, RoP, and guidelines on participation.

Data on the de facto access is gathered from the plenary meetings' lists of participants. The bodies encompass the CBD's Conference of Parties (COP), FAO Conference, UPOV Council, World Health Assembly (WHA), WIPO Assemblies, and WTO Ministerial Conference. In the case of the WTO, the TRIPS Council does not offer lists of participants. The analyzed documents yield information on states' membership, attendance rate, and delegation size as well as NSAs' attendance rate. In addition to that, NSAs' nature, IOs' membership scope, and NGOs' geographical origin are tracked down by further literature and internet research.

As to the de facto involvement, I code statements made in the institutions' plenary sessions by means of MAXQDA. Systematic coding has to be restricted to the CBD, WHO, and WTO. UPOV and WIPO are excluded because they did not provide meeting documents for all years and did not mention all individual speakers. FAO is dropped from this part because the other cases already provided for sufficient variation on the IV.

For the CBD, I use the final reports of the COPs. Concerning the WTO, the minutes of the TRIPS Council are coded because they deal more specifically with IPRs and biotechnological patents than any other WTO body. Besides that, the WTO does not offer minutes for the meetings of the Ministerial Conference. In the case of WHO, all statements in the WHA plenary sessions are coded but only those for the WHA Committee meetings that deal with IP-related matters.¹¹⁷

¹¹⁷ The WHA Committee meetings take place in parallel to the WHO plenary sessions.

The plenary bodies' meeting reports differ with regard to the precision of their content. Most detailed information can be derived from WHO's verbatim records followed by the summary reports of the TRIPS Council and WHO's Committee meetings. The CBD is very comprehensive in listing all interventions but sometimes does not specify the statements' content. This especially has to be kept in mind for the results on contestation at the CBD. In general, one has to be careful when comparing the results of the individual institutions. These differences in the documents' nature are not ideal from a theoretic point of view but cannot be avoided in empirical research.

Idea units are chosen as units of coding due to my focus on thematic codes. Hence, the unit of analysis is the individual statement within an actor's speech. A statement refers to one argument or position in a speech. Therefore, more than one statement for each speech is possible. At the minimum a statement possesses the length of one sentence, at the maximum of one entire speech that can take up to several paragraphs. The documents are analyzed sequentially from the beginning to the end (Boyatzis 1998: 64; Mayring 2003: 53). The following general coding rules are obeyed to ensure consistency across institutions:

- The repetition of the same argument(s) within one speech is counted only once.
- If a statement's content is not clear, it is coded as 'miscellaneous'; for instance: 'country X supported statement by country Y'.
- I exclude statement by chairs, the Director-General/Executive Secretary, and the institutions' own staff.
- If a country speaks *also* on behalf of other countries that do not form a special group, only the speaker's country is coded. If an actor speaks on behalf of a regional group, the group – not the individual speaker – is coded as actor.

Each code includes three sets of information: (1) forum, (2) statement-maker, and (3) actor's position. The coding scheme for the content of actors' statements is derived inductively for the four issue areas. It is data-driven to ensure that all positions are comprehensively captured. If not stated otherwise, each category can assume the values (1) supportive, (2) opposing, or (3) general/vague. An abridged version of the coding scheme for the dimension 'position' is provided below. The complete coding scheme including the frequency of the individual codes can be found in figure 11 in the appendix.

Figure 3: Abridged Coding Scheme for Dimension 'Position'

Access and benefit-sharing	Traditional knowledge	IP protection of plant varieties	Public health and IP
ABS in general	benefit-sharing	form	public health vs. IP
access to genetic resources: • disclosure of origin • prior informed	IP protection of TK	breeders' rights	generics: • compulsory licensing under Art. 31 TRIPS • Art. 30 TRIPS
	TK database	farmers' rights	

consent <ul style="list-style-type: none"> • state sovereignty • identification of TK 			(Bolar provision) <ul style="list-style-type: none"> • Art. 39(3) TRIPS • generics
	inclusion of indigenous peoples in policy process	scope of IP exemptions under Art. 27(3b) TRIPS	parallel importation
benefit-sharing	forum	review of Art. 27(3b) TRIPS	Doha Declaration: <ul style="list-style-type: none"> • beneficiaries of flexibilities • suppliers • safeguards • scope of exemptions • legal implementation • functioning
form	other/vague TK	GURT ¹¹⁸	
forum		ex situ collection	drug price: <ul style="list-style-type: none"> • differential pricing • IP effect on drugs
biopiracy		other/vague plant protection	use of flexibilities
			Art. 70(8-9) TRIPS (protection of pharmaceutical & agricultural products)
			Art. 7 TRIPS
			Art. 8 TRIPS
			forum
			other means to protect public health
			other/vague public health and IP

Miscellaneous categories: participation (admission of new members, NSA inclusion, participation constraints, RoP); IP vs. public interest; inter-institutional relationship; IP-related (for example: patent criteria, duration of protection, transitional periods, assistance); technology and science; implementation and monitoring.

¹¹⁸ GURT=genetic use restriction technology.

The intra-rater reliability of both the coding and the classification of units of coding are tested. The value of Cohen's kappa is 0.75 so that the reliability is regarded as satisfying.

In order to measure contestation, I aggregate the statements in terms of being pro, contra, or indifferent/vague with regard to (1) a strong ABS system, (2) strong TK protection, (3) strong IP protection of plant varieties, and (3) prioritization of public health over IP protection. A precise categorization of codes across these issues is provided in table 32 in the appendix.

The dimensions of democratic participation are evaluated in accordance with the democratic standards of congruence and contestation as developed in chapter 3.

In order to investigate why legalization influences democratic participation (chapter 9), I make use of official documents such as meeting reports, secondary literature, and NSAs' reports like the Earth Negotiations Bulletin (ENB) that is published by the Canadian-based International Institute for Sustainable Development (IISD). For further background information serve four interviews:

- (1) NGO representative, 31.7.2012 (Skype)
- (2) Senior Advisor at WHO, 19.6.2012 (telephone)
- (3) NGO representative, 26.7.2012 (Skype)
- (4) NGO representative, 10.7.2012 (telephone)

Legalization's impact is explained based on the analytical framework presented in chapter 4. I do not use statistics as I have only appropriate quantitative data for some dimensions of the DV but not the IV. An overview of the data collection and analysis for legalization and democratic participation is provided below.

Table 5: Data Collection and Analysis

Variable	Data Collection	Data Analysis
Legalization (chapter 7)	formal documents: founding documents, RoP, guidelines, decisions	evaluation in accordance with chapter 2
De jure access/ involvement (chapter 8)	formal documents: founding treaties, RoP, guidelines on participation	evaluation in accordance with chapter 3
De facto access (chapter 8)	List of participants of plenary bodies: <ul style="list-style-type: none"> • CBD: COP 1-10; 1994-2010 [10 meetings] (not detailed list of participants for all years)¹¹⁹ • FAO: FAO Conference 26-36; 1991-2009 [11 meetings] • UPOV: Council 33-44; 1999-2010 [12 meetings]¹²⁰ • WHO: WHA 43-63; 1990-2010 [21 meetings] 	evaluation in accordance with chapter 3 taking into consideration: <ul style="list-style-type: none"> • states' <ul style="list-style-type: none"> - membership - attendance rate - delegation size • NSAs' <ul style="list-style-type: none"> - attendance rate

¹¹⁹ EXCOP 1 (1999) is excluded from the sample due to its focus on biosafety that is not directly related to biotechnological patents.

¹²⁰ Extraordinary meetings are excluded from the analysis.

	<ul style="list-style-type: none"> • WIPO: WIPO Assemblies 22-26, 28-48; 1991-2010 [26 meetings] • WTO: Ministerial Conference 1-7; 1996-2009 [24 meetings] 	<ul style="list-style-type: none"> - membership scope/ geographical origin - nature
De facto involvement (chapter 8)	Reports/verbatim records of meetings: <ul style="list-style-type: none"> • CBD: COP 1-10; final reports; 1994-2010 [10 meetings] • WHO: <ul style="list-style-type: none"> - WHA plenary sessions 43-63; 1990-2010 [21 meetings] - WHA Committee sessions 43-63; 1990-2010 [21 meetings] • WTO: <ul style="list-style-type: none"> - attendance: Ministerial Conference 1-7; 1996-2009 [24 meetings] - statements: TRIPS Council minutes 1-64: 1995-2010 [64 meetings] 	<ul style="list-style-type: none"> • coding of statements • evaluation in accordance with chapter 3 taking into consideration states' and NSAs' <ul style="list-style-type: none"> - statement rate - statements' content
Legalization's influence on democratic participation (chapter 9)	<ul style="list-style-type: none"> • official documents • secondary literature • NSAs' reports • interviews 	exploration in accordance with chapter 4

Last but not least, *affectedness* is a key concept in this study to locate the relevant actors for the assessment of democratic participation. The mostly affected actors of each issue area are determined by quantitative data that serve as a proxy. I differentiate between IP skeptics and IP supporters.

With regard to *ABS*, IP skeptics are biodiversity-rich countries and IP supporters are countries with most biotechnological patent applications. To identify biodiversity-rich countries, I use data from the 2002 UNEP World Atlas of Biodiversity (Groombridge/Jenkins 2002: 295-305). The data is based on the WCMD database which “derived information from a large number of published and unpublished sources, including country reports and regional checklists”. The most biodiversity-rich countries are the same that joint forces as the Group of Like-Minded Megadiverse Countries (LMMC). IP supporters are detected by means of applications for biotechnological products under the Patent Cooperation Treaty (PCT) as provided by the OECD iLibrary.¹²¹ The countries are ranked in accordance with applicant(s)'s country(ies) of residence and priority date based on their average ranking between 1990 and 2010.¹²²

Concerning the *protection of TK*, IP skeptics are indigenous-rich countries and IP supporters are countries with most pharmaceutical patent applications. The mostly affected indigenous-rich countries are confined by the figures of the IWGIA's¹²³ Indigenous World

¹²¹ Available at: <http://www.oecd-ilibrary.org/> (Accessed 25 February 2012).

¹²² There is not much variation across the years.

¹²³ IWGIA=International Work Group for Indigenous Affairs.

Report of 2013 (IWGIA 2013).¹²⁴ The numbers are based on various sources, usually nationally censuses. In some countries, indigenous groups doubted the credibility of the numbers and usually estimated them to be higher than stated in the report. Where only percentages are provided in the report, I convert them into absolute numbers by using the World Bank's 2010 population figures.¹²⁵ I consider the ten countries with the largest absolute number of indigenous peoples and the five countries with the largest relative proportion of indigenous population. I combine the two forms as they both are relevant for affectedness. Since TK has mostly been utilized for the development of pharmaceuticals, IP supporters are determined based on the proportion of PCT applications for pharmaceutical products worldwide between 1990 and 2010 (OECD iLibrary).¹²⁶ Like in the case of ABS, the data is ranked in accordance with applicant(s)'s country(ies) of residence and priority date.

As to *IP protection of plants*, IP skeptics are agricultural countries and IP supporters are countries with most holders of seed titles. IP skeptics are identified by means of World Bank data on countries' percentage of employment in agriculture.¹²⁷ An average is formed for the period between 1990 and 2010. IP supporters are localized by seed patent applications filed under the UPOV system in 2010 (UPOV 2011b). The data is ranked according to applicant(s)'s country(ies) of residence.

As to the debate on *IP and public health*, IP skeptics are countries that depend on generics and IP supporters are countries with most pharmaceutical patent applications. As the surging HIV/AIDS crisis represented one main cause for the debate on public health and IP to gain momentum, IP skeptics are identified based on the prevalence of HIV/AIDS among adults aged 15 to 49 as provided by the WHO Global Health Observatory Data.¹²⁸ The data is ranked in accordance with the average for the time period between 2001 and 2006. IP skeptics are the same as for the debate on TK. The data used for the determination of affectedness is summarized in the table below.

¹²⁴ The World Bank provides only estimates for regions (World Bank 2010).

¹²⁵ Available at: <http://data.worldbank.org/indicator/SP.POP.TOTL> (Accessed 25 February 2012).

¹²⁶ Available at: <http://www.oecd-ilibrary.org/> (Accessed 25 February 2012).

¹²⁷ Available at: <http://data.worldbank.org/indicator/AG.LND.AGRI.ZS/countries?display=default> (Accessed 25 February 2012).

¹²⁸ Available at:

http://apps.who.int/gho/athena/data/download.xsl?format=xml&target=GHO/MDG_0000000029&profile=excel&filter=COUNTRY:*;REGION:AFR;REGION:AMR;REGION:SEAR;REGION:EUR;REGION:EMR;REGION:WPR (Accessed 25 February 2012).

Table 6: Affectedness According to Issue Area

Issue area	Measurement of Affectedness	Relevant institutions
Access and benefit-sharing	<ul style="list-style-type: none"> • <u>IP skeptics</u>: biodiversity-richness according to UNEP World Atlas of Biodiversity (Groombridge/Jenkins 2002: 295-305) • <u>IP supporters</u>: PCT applications for biotechnological products; average number for period 1990-2010 (OECD iLibrary) 	CBD, FAO, WIPO, WTO
Protection of traditional knowledge	<ul style="list-style-type: none"> • <u>IP skeptics</u>: indigenous population (IWGIA 2013) • <u>IP supporters</u>: PCT applications for pharmaceuticals; average number for period 1990-2010 (OECD iLibrary) 	CBD, FAO, WIPO, WTO
IP protection of plant varieties	<ul style="list-style-type: none"> • <u>IP skeptics</u>: World Bank data on percentage of employment in agriculture • <u>IP supporters</u>: applications of seed titles in 2010 (UPOV 2011b) 	FAO, UPOV, WTO
Public health and IP	<ul style="list-style-type: none"> • <u>IP skeptics</u>: prevalence of HIV/AIDS among adults 15-49 (%); average number for period 2001-2006 (WHO Global Health Observatory Data) • <u>IP supporters</u>: PCT applications for biotechnological products; average number for period 1990-2010 (OECD iLibrary) 	WHO, WTO

Chapter 6

Biotechnological Patents – Regulation, Interests, and Affectedness

We encounter biotechnological patents in our daily life. They impact the assortment of our grocery stores as well as the price of our medicine. Despite their importance, biotechnological patents hardly make the headlines. Better known recent examples include the 2013 U.S. Supreme Court ruling that isolated human genes as can be found in nature may not be patented¹²⁹, the EU proposal to reform the seed regulation with the Plant Reproductive Material Law in May 2013¹³⁰, or India's Supreme Court decision against the evergreening of pharmaceutical patents in April 2013¹³¹. Pursuant to IPRs' low-profile media coverage, IP policies have only rarely led to a public outcry like in the case of the Anti-Counterfeiting Trade Agreement (ACTA) at the beginning of 2012. One reason might be that most individuals consider IPRs as arcane and highly technical. And yet their complexity is part of IPRs' economic power. IPRs were coined as “new capital” (Muzaka 2009: 1343) and the “key economic resources of the future” (Sell/May 2001: 468). The USA annually spends \$1 billion on its Patent and Trademark Office (USPTO). In the case *Polaroid vs. Kodak*, each party paid over \$100 million for litigation (Love 2002: 76). In the smartphone patent wars, the main competitors are involved in hundreds of lawsuits that are sometimes worthy over \$1 billion.¹³² Without being acquainted with the actors and their interests at stake, it is difficult to understand these conflicts and their far-reaching consequences. Therefore, this first empirical chapter lays the foundation for the further empirical analysis. I start with an explanation of what is understood by biotechnological patents. This is followed by an overview of the most important biotechnological IP regulations in the six analyzed institutions. In a third part, the general arguments of IP supporters and IP skeptics concerning biotechnological patents are presented before I discuss in greater depth the lines of conflicts in the issue areas (1) access and benefit-sharing (ABS), (2) traditional knowledge (TK), 3) IP protection of plant varieties, and 4) public health and IP. Based on the clarification of interests, the mostly affected actors are identified. The determination of affected actors in an issue area forms the foundation to evaluate democratic participation in chapter 8.

¹²⁹ AMP vs. Myriad Genetics, available at http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf (Accessed 15 July 2013).

¹³⁰ Available at: http://ec.europa.eu/dgs/health_consumer/pressroom/docs/proposal_aphp_en.pdf (Accessed 1 June 2013).

¹³¹ Novartis vs. Union of India & Others, available at: http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?pagewanted=all&_r=0 (Accessed 2 April 2013).

¹³² Available at: http://www.nytimes.com/interactive/2012/10/08/business/Fighters-in-a-Patent-War.html?_r=0 (Accessed 2 April 2013).

6.1 Biotechnological Patents – An Underrated Economic Resource

Generally speaking, IPRs are

“rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his creation for a certain period of time” (WTO 2008f: 3).

In other words, IPRs are property rights over knowledge that allow the inventors to benefit from their investment in the creation of a new commodity. Already the Universal Declaration of Human Rights lays down that everyone

“has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author” (UN 1948: Art. 27(2)).

Likewise, the Charter of Fundamental Rights of the European Union recognizes the human right to property and explicitly requires the protection of IP (EU 2000: Art. 17).

Usually, IPRs are classified into patents, copyrights, trademarks, and geographical indicators. Here, only patents are of interest.¹³³ Generally speaking, patents are defined as ideas and products that are new, non-obvious, and applicable for industrial use. Biotechnological inventions have not easily fit the traditional patent criteria. The standards' practical meaning is debated. For example, the criterion of non-obviousness has sparked controversies about the scope of patentable subject matters (May 2010: 5-6). Where does common sense or discovery end and innovation start? Is the isolation of a gene a discovery or an invention?

What makes IPRs profitable? According to basic economic principles, a commodity's price is regulated by supply and demand. Knowledge, unlike material goods, is a non-rivalrous resource. In order to extract a price from the use and transfer of knowledge, IPRs artificially and legally construct a scarce and tradable commodity by making the access to knowledge dependent on payment (May/Sell 2006: 5). Law is key to create a market for such knowledge:

“property is constructed and reproduced by state legislation to protect *not* something previously existing, already recognised as property, but rather to protect certain current interests and in doing so codify their protection as ‘property’” (May 2010: 16). “Property in a legal sense can only be what the law says it is; it does not exist waiting to be recognized as such. Property is the codification of particular social relations, those between owner and nonowner, reproduced as the owners' rights” (May/Sell 2006: 17).

The state provides the institutional framework to legally protect IPRs. It holds national offices where IPRs can be registered and offers judicial mechanisms to sanction the unauthorized use of protected knowledge. In return, states expect IPRs to stimulate the

¹³³ The other categories can be explained as follows: *Copyrights* refer to the form of knowledge. They encompass literary, musical and other artistic works and also computer software. The rights of the creator are infringed if another person produces her work in the conscience that it is already protected by copyright. Under TRIPS, the duration of copyright protection is at minimum granted for an author's life plus fifty years. A *trademark* distinguishes a company and its products from others in terms of design. This can include numbers, words, graphics and other forms of visual expression. Trademarks are of economic value for they attach a certain reputation to a company and its products. *Geographical indicators* are appellations of origins and distinguish local from generic products or other variants. These include, for example, Champagne, Parma, and the Thuringian Sausage. Other forms of IPRs are industrial design protection or trade secrets (May 2010: 6-9).

development of new technologies from which their societies profit. The history of IPRs, in particular of patents, has been shaped by the tension to what extent IPRs should serve private benefits or public welfare. On the one hand, companies need incentives to spend their money on research and development (R&D). As compensation for their investment and in order to make a profit, they demand the exclusive right to charge fees for the use and transfer of their inventions. On the other hand, IPRs create information asymmetries that prevent individuals from utilizing all available knowledge and technologies to improve their lives or advancing scientific progress. The limitation of the protection period for IPRs should strike a balance between these two poles. The duration of protection should be shorter for goods that are vital to promote public goods, such as pharmaceuticals, and longer or even open to unlimited renewal for ideas whose free use would run counter to public interests. An example for the latter is a trademark that represents a company and its products. It steers competition of which customers can profit in terms of price and product quality (May 2010: 4-6, 10).

The range of patentable items is manifold as the field of biotechnology itself. Biotechnology has drawn the interest of the IP sector since the 1970s. It integrates biology and engineering. The OECD famously defines biotechnology as

“[t]he application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services” (OECD 2011: 184).

As the definition already indicates, biotechnology is a wide-ranging field of interdisciplinary breadth. Depending on the research focus, one can differentiate between biotechnology applied to agriculture (green biotechnology), medical processes (red biotechnology), marine and aquatic applications (blue biotechnology), and industrial processes (white biotechnology). This project is restricted to patents on green and red biotechnology.

Biotechnology is considered to be an innovative sector of wealth production. By manipulating and controlling nature, it is hoped to address the pressing challenges of malnutrition, famine, sustainable energy supply, and health care (WCED 1987: 182). Important milestones in the more recent history of biotechnology include the cloning of organisms, such as the sheep Dolly (1996), or the development of high-yielding grain seeds that contributed to the Green Revolution of the 1960s and 1970s. The origins of biotechnology, however, go back to zymotechnology, which is the industrial fermentation with brewing as its most famous type (Bud 1993: 6-26), and even further to plant breeding when farmers consciously started to crossbreed plants to strengthen certain traits over 10,000 years ago (FAO 2004: 9-10). Modern science and industry cannot be imagined without biotechnology. It is used for the production of antibiotics, microbial rennet as used for cheese, insulin, lactase, and genetically modified organisms (GMOs). GMOs, for example, can be found in about 70% of processed food sold in the USA (Kloppenburger 2004: 292)

The absolute number of biotechnological patents had continuously increased from the 1990s to the turn of the millennium and had subsequently slightly decreased until the late 2010s. On average, the number of patents filed each year under the Patent Cooperation Treaty (PCT) dropped from 12,254 in 2000 to 9,584 in 2010 (OECD iLibrary).¹³⁴ The surge of biotechnological patents in the late 1990s has been attributed to the myriad of patent applications on the human genome while stricter patent criteria led to a decline in this field in the early 2000s. Also the establishment of TRIPS contributed to a growing number of patents in the 1990s. In the period between 1994 and 1996, biotechnological patent applications made up on average 10.3% of a country's total patent applications (van Beuzekom/Arundel 2009: 70, 75). The decline of newly filed biotechnological patents has not been detrimental to the revenues arising out of biotechnological products and should not hide the fact that large parts of biotechnological progress have already been covered by IPRs.

Patents are subjected to the principle of territoriality. Inventors have to apply for them in every single state for which they seek protection. The granting state decides about the conditions of protection such as the duration or the patent holder's rights. But international agreements have harmonized patent requirements and procedures and thereby have considerably restricted states' domestic leeway to design IP policies and balance it against other public interests.

6.2 Overview of Main Regulations – Conflicting Rules for Conflicting Interests

Regulating IPRs is not a new phenomenon. International IP coordination kicked off with the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Work which were adopted in 1883 and 1886 respectively. In this sub-section, I provide information on the selected institutions' main biotechnology-related IP policies with regard to ABS, TK, IP protection of plant varieties, and public health. The overview shows that each institution privileges certain interests over others. The institutions are also not completely independent from each other. They overlap in their scope and even partly contradict each other. These struggles have reinforced the politicization of the debates on these issues that makes democratic participation even more important. In the following, the focus is on the institutions' regulation until 2010. The institutional setting is described in the next chapter on the institutions' degree of legalization (chapter 7).

¹³⁴ The numbers refer to inventor's country of residence and priority date. Available at: <http://www.oecd.org/science/inno/oecdpatentdatabases.htm> (Accessed 17 April 2013).

6.2.1 Convention on Biological Diversity (CBD)

The CBD was adopted in 1992 and entered into force in 1993. It is the most comprehensive accord to conserve biological diversity. *Biodiversity* describes the variety and frequency of living organisms from all sources and ecosystems in a given area (CBD 1992: Art. 2; McNeely et al. 1990: 17). *Genetic resources* means “genetic material of actual or potential value” while genetic material contains “functional units of heredity” (CBD 1992: preamble). The CBD Convention lists three objectives that are

“the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources” (CBD 1992: Art. 1).

Its framework is fleshed out by two protocols. The Cartagena Protocol on Biosafety¹³⁵ was adopted in 2000 and entered into force in 2003 and the Nagoya Protocol on Access and Benefit-Sharing was adopted in 2010 and entered into force in 2014.

The CBD had to reconcile the diametrical interests of industrialized and at the same time biodiversity-poor countries with those of developing and frequently biodiversity-rich states. Concerning genetic resources, some of the former demanded administratively eased and low-priced access to genetic resources, while the latter insisted on technology transfer and financial compensation for providing genetic resources as basis of technological innovation (Helfer 2004: 28). In the end, the treaty put a greater emphasis on the rights of biodiversity-rich countries at the expense of their low enforceability. The CBD has been in particular used as a forum to negotiate issues pursuant to ABS and TK.

ABS. The CBD Convention affirms that states retain their sovereign right to exploit the resources and protect the environment within their jurisdiction (CBD 1992: Art. 3). Access to genetic resources should be based on prior consent of the providing state and mutually agreed terms (CBD 1992: Art. 15). In return for granting access to their genetic resources, developing countries should profit from facilitated technology transfer (CBD 1992: Art. 16(3)). The fifth COP established the Ad Hoc Open-Ended Working Group on Access and Benefits-Sharing in 2000 to address several ABS matters as foundation for future measures (CBD 2000c: para. 11).¹³⁶ The result was the 2002 Bonn Guidelines on Access and Benefit Sharing that represent more specific but voluntary principles and measures for ABS.¹³⁷ They recommend the creation of focal points and competent authorities to facilitate the implementation of ABS systems. ABS agreements between providers and users of genetic resources should be conducted under mutually agreed terms and contain

¹³⁵ The Cartagena Protocol is not part of the further analysis as its primary goal is not directly relevant for the four issue areas. It intends to ensure “safe transfer, handling and use of transboundary movements of living modified organisms resulting from modern biotechnology” (CBD 2000e: Art. 1).

¹³⁶ The Ad Hoc Open-Ended Working Group on Access and Benefits-Sharing is a reconvention of the Panel of Experts on Access and Benefit-Sharing that was established by the fourth COP in 1998 (CBD 1998a: para. 3). The Panel could not reach consensus on the role of IPR in the implementation of ABS arrangements (CBD 2000c: para. 15).

¹³⁷ The official name is “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization”.

prior informed consent. Benefits can be either monetary or non-monetary (CBD 2002h). The Working Group on ABS was reconvened by the sixth COP in 2002 to engage in further terminological and exploratory work on ABS (CBD 2002a: para. 8). Having identified the capacity constraints of developing countries and local communities as impediment to implement the Bonn Guidelines, the seventh COP meeting adopted the Action Plan on Capacity-Building for Access to Genetic Resources and Benefit-Sharing in 2004. Mechanisms to increase capacity encompassed, for example, the assistance with the development of adequate national strategies, technology transfer, information exchange, and regional and international cooperation (CBD 2004b: Annex). In the same decision, the Working Group on ABS was mandated to negotiate an international regime on ABS (CBD 2004b: para. D.1) which led to the Nagoya Protocol on ABS. The protocol adds legal obligation and clarity. In addition to the ABS principles of the CBD Convention, countries have to facilitate the access to and usage of their genetic resources by providing for legal certainty, clarity and transparency of their domestic ABS legislation (CBD 2010g: Art. 6). In return, user measures are added to assist in the monitoring of ABS standards. Countries have to ensure that genetic resources used within their jurisdiction follow the provider country's ABS requirements (CBD 2010g: Art. 15). In order to deal with transboundary situations in which no prior informed consent can be obtained, members are encouraged to establish a Global Multilateral Benefit-Sharing Mechanism (CBD 2010g: Art. 10).

TK. The Convention also emphasizes TK's significant value for biodiversity. According to Article 8(j), TK is "relevant for the conservation and sustainable use of biological diversity" and therefore should be preserved. Also its wider application should be promoted "with the approval and involvement of the holders of such knowledge". At the same time, states should "encourage the equitable sharing of the benefits arising from the utilization" of TK (see also: CBD 1992: Art. 10(c), 17(2), 18(4)). A working group on Article 8(j) and related provisions was established in 1998 to advance the role and involvement of indigenous and local communities in the implementation of the CBD's goals. The major outcome of its work was the adoption of the voluntary Akwé: Kon Guidelines in 2004.¹³⁸ It proposes a cultural, environmental and social impact assessment for locations traditionally occupied by indigenous and local communities. Paragraph 60 specifically calls for respecting indigenous communities' IPRs by making the use of TK dependent on the prior informed consent of their owners (CBD 2004c: para. 60). In 2008, the CBD established the Group of Technical and Legal Experts on Traditional Knowledge¹³⁹ to assist the Working Group on ABS in the negotiation of the Nagoya

¹³⁸ The full name is "Akwé Kon Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessment regarding Developments Proposed to Take Place on, or which are Likely to Impact on, Sacred Sites and on Lands and Waters Traditionally Occupied or Used by Indigenous and Local Communities". The indigenous term originates from the Mohawk tribe meaning "everything in creation". Available at: <http://www.cbd.int/traditional/guidelines.shtml> (Accessed 3 December 2012).

¹³⁹ Its name is "Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing".

Protocol. The latter stipulates that the ABS system should be extended to TK (CBD 2010g: Art. 7, 12). Demands to include also public available TK in the ABS regime were successfully averted by developed countries (Wallbott et al. 2014: 38). By the same token, derivatives, which are estimated to account for 90% of currently commercialized TK, are not explicitly covered by the Nagoya Protocol (Crookshanks/Phillips 2012: 75). Other COP decisions include, for example, the assistance of indigenous groups with the documentation and collection of their TK in form of databases (CBD 2008a: decision C).

Even though the CBD recognizes the adherence to IP standards (CBD 1992: Art. 16(2)), IPRs were initially not its primary concern. Some of its provisions were reinterpreted and others, such as Article 16(5), which requires IPRs to be in conformity with the Convention's goals, gained currency after TRIPS's consequences generated growing criticism and attracted the shifting of IP policies into the CBD forum (Helfer 2004: 27-29, 32).

6.2.2 Food and Agriculture Organization (FAO)

FAO was established in 1945. Its objectives encompass the raising of living standards, increasing the efficiency of the production and distribution of food and agricultural products, and contributing to an expanding world economy (FAO 1945a: Art. 1). FAO's work has been relevant for all three biotechnological issues on plant genetic resources: ABS, IP protection of plant varieties, and TK. The first two matters are especially intertwined at FAO so that they are treated together here.

ABS and IP protection of plant varieties. FAO has been used as a platform by developing countries to regulate the use of plant genetic resources since the early 1980s. Negotiations resulted in the voluntary International Undertaking on Plant Genetic Resources for Food and Agriculture of 1983 (Resolution 8/83) which also led to the establishment of the Commission on Genetic Resources for Food and Agriculture (CGRFA). The Undertaking designates plant genetic resources as common heritage of mankind that should be accessible without restrictions for plant breeding and scientific purposes (FAO 1983: Art. 1, 5).¹⁴⁰ This corresponded to the original demands of developing countries to apply the principles of common heritage and free exchange to all categories of germplasm (Kloppenburger 2004: 172). In the long run, however, this ran counter to the interests of both seed corporations and farmers. The industry has claimed private ownership over their cultivars. At the same time, farmers and gene-rich Southern countries have asserted sovereignty over their natural resources and has been increasingly reluctant to make their plant genetic resources available free of charge to Northern seed companies that transformed them into commodities of private ownership (Kloppenburger/Lee Kleinman 1987: 23-24).

¹⁴⁰ It also mandates that primitive cultivar and wild species and "elite and current breeders' lines and mutants" are considered plant genetic resources and hence fall within the heritage of mankind (FAO 1983: Art. 2(1)).

In the course of the so-called “seed wars” at FAO, the Undertaking was annexed with three Agreed Interpretations between 1989 and 1991 in order to strengthen farmers’ rights and states’ sovereign rights over plant genetic resources. Farmers who domesticate, conserve, and improve plant genetic resources should be better compensated and benefit from improved plant genetic resources (FAO 1983: Annex II). It also emphasizes that “free access” to plant genetic resources should not be understood as free of charge and states were asked to more seriously finance the International Fund for Plant Genetic Resources with the aim of more effectively supporting the conservation and utilization of the plant genetic resources particularly in developing countries (FAO 1983: Annex I). At the same time, the reaffirmation of states’ sovereign rights over plant genetic resources within their borders could be used by developing countries to claim higher benefits for making plant genetic resources accessible (FAO 1983: Annex III; Helfer 2004: 38).¹⁴¹

In order to overcome deficiencies of previous models, the FAO Conference adopted the International Treaty on Plant Genetic Resources (ITPGR) after seven years of negotiations in 2001. The treaty entered into force in 2004 and its Governing Body held its first regular session in 2006. Its objectives are sustainable agriculture and food security (FAO 2001: Art. 1(1)). Although this organization was excluded from the sample due to its short existence, its main achievements are worth mentioning to understand the discussion on the IP protection of plant varieties. The ITPGR’s core elements are the Multilateral System of ABS and the standard material transfer agreement (SMTA). They endorse the rights of farmers and indigenous communities to partake in the benefits arising out of the products developed on the basis of plant genetic resources. The Multilateral System covers 64 major crops and forages “established according to criteria of food security and interdependence” and the ex situ collections of the Consultative Group on International Agricultural Research (CGIAR) and other international institutions in accordance with Article 15(5) (FAO 2001: Art. 11(1)). Access to ex situ collections shall be provided via a SMTA. It denotes a bilateral agreement between the provider and recipient of plant genetic resources while FAO’s Governing Body serves as the third party beneficiary. The SMTA should facilitate access and prevent costly bilateral negotiations. Access to in situ collections shall be governed by national legislation (FAO 2001: Art. 12(3h)). Expedient and low-cost access to plant genetic resources within the Multilateral System is restricted “for the purpose of utilization and conservation for research, breeding and training [...],

¹⁴¹ Another point of tension was raised over the patentability of new plant genetic resources based on material from international gene banks. Gene banks are ex situ collections that store plant genetic resources to make them available for R&D. The major gene banks are the international centers of the Consultative Group on International Agricultural Research (CGIAR) that conserve approximately 600,000 seed samples (Jungcort 2008: 117). FAO and CGIAR negotiated a form that can be used to conclude bilateral agreements between FAO members and CGIAR’s research centers to hold “designated germplasm in trust for the benefit of the international community” by placing them under the auspices of FAO (FAO and CGIAR 1994: Art. 3). In practice, they could not prevent the granting of patents on plant genetic resources based on raw plant material received from the CGIAR (Helfer 2004: 38).

provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses” (FAO 2001: Art. 12(3a)). Furthermore, the scope of patentable subjects is restricted. Users cannot patent matters that would “limit the facilitated access to the plant genetic resources [...] in the form received from the Multilateral System” (FAO 2001: Art. 12(3d)). In order to avoid undesirable constraint of national IP protection, Australia, Canada, Japan, and the USA added interpretive statements that they see no conflict between ITPGR and (inter)national IP law (Helfer 2004: 40-41).

In exchange for receiving facilitated access via the Multilateral System, recipients who utilize these plant genetic resources for developing commercial products with restricted access have to pay a share of their profits to a fund (FAO 2001: Art. 13(2d)). This trust, in turn, invests in projects supporting farmers in developing countries to conserve crop diversity and to adapt crops to an environment shaped by climate change. The responsibility to enforce farmers’ rights, however, rests with national governments (Gerstetter et al. 2007: 263-264). Despite its legal ambiguities, the ITPGR has been heralded as improvement of farmers’ rights not least because it challenges TRIPS and UPOV.

TK. Since one of FAO’s main objectives is the improvement of living standards, it has also been active in promoting the rights of indigenous peoples as they belong to the poorest groups in the world (FAO 2010: 2). In accordance with FAO’s core principles, indigenous peoples should be included in the consultation processes of activities that directly affect them and should give their prior informed consent before these projects are launched. Indigenous peoples should also be granted collective rights over their TK, land, and natural resources that they have traditionally occupied and used (FAO 2010: 5-6). In 2002, FAO established the Indigenous Peoples Working Group to guide the organization’s work with and on indigenous peoples. The ITPGR recognizes the “enormous contribution that the local and indigenous communities and farmers [...] have made and will continue to make for the conservation of plant genetic resources” (FAO 2001: Art. 9(1)). Members are requested to protect TK relevant to plant genetic resources for food and agriculture (FAO 2001: Art. 9(2a)), but TK is not formally incorporated into the ABS system. Besides that, FAO’s engagement with TK has not led to any noteworthy policies so far.

6.2.3 International Union for the Protection of New Varieties of Plants (UPOV)

UPOV was the first international convention dealing with the IP protection of plant genetic resources. The original convention of 1961 entered into force in 1968 and was revised in 1972 and 1991. With each round of revision and amendments, breeders' rights were further strengthened. Due to its special focus, actors have used UPOV mainly as a forum in the discussion of the protection of plant varieties. UPOV aims to incentivize investment in the development of new plant varieties by granting breeders exclusive rights of commercial exploitation. Breeders' rights bear great resemblance to patents but are in legal terms another form of IP protection – a so-called *sui generis* system.¹⁴² Both grant the breeder monopoly rights over the use of a plant variety for commercial purposes for a given period of time. They differ, however, concerning the protection requirements, rights, and duration (Cullet et al. 2006: 131; Dewan 2011: 133). *Variety* is defined as a

“plant grouping within a single botanical taxon of the lowest known rank, which grouping, [...], can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged” (UPOV 1991: Art. 1(vi)).

In contrast to previous versions, the 1991 Act not only requires the protection of certain but all plant genera and species (Basso/Beas Rodrigues 2007: 196-203). New members have to initially protect 15 plant genera or species and all others within ten years at the latest (UPOV 1991: Art. 3). The minimum duration of protection is in general 20 years and 25 years for trees and vines (UPOV 1991: Art. 14, 19). UPOV's requirements to grant IP protection are novelty, distinctness, uniformity, stability, and an appropriate denomination (UPOV 1991: Art. 5). A plant variety is considered novel if

“at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety

- (i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and
- (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date” (UPOV 1991: Art. 6).

It is worth nothing that novelty does not depend on the previous existence of a variety but only its commercialization (Cullet et al. 2006: 131). The UPOV principle of a plant variety to be clearly distinguishable from “common knowledge” is at least intricate. Distinctiveness can be adduced if the variety is not contained in a country's official register of varieties (UPOV 1991: Art. 7). A more general form of evidence is to demonstrate on the basis of

¹⁴² To simplify matters, I use the term ‘biotechnological patent’ in this study in a very broad sense that also includes the IP protection of plant varieties.

the breeding history that a variety was not known before (Ravishankar/Archak 1999: 3667). Additional requirements for protection besides novelty, distinctness, uniformity and stability are prohibited (UPOV 1991: Art. 5(2)). This stands in conflict with the CBD that also calls for the disclosure of origin, prior informed consent, and benefit-sharing. Alone in 2010, UPOV issued over 11,000 titles to breeders (UPOV 2011b: 13).

There are three important exceptions that can curtail breeders' rights while only the first two are compulsory for member states (UPOV 1991: Art. 15). First, *private and non-commercial acts* are exempted from IP protection (UPOV 1991: Art. 15(1i)). This rule can justify the use of protected plants for subsistence purposes and creates some flexibility for member states to permit informal non-commercial seed exchanges between farmers (Twarog/Kapoor 2004: 138). Second, the *breeder's exemption* permits the use of protected plant varieties for experimental purposes and the breeding of new plant varieties (UPOV 1991: Art. 15(1ii-iii)). This provision intends to remove impediments to scientific progress. Third, the *farmer's privilege* allows farmers to save harvest for propagating purposes on their own holdings (UPOV 1991: Art. 15(2)). The latter only represents an optional exception that has to be explicitly guaranteed by national law. Some authors see in these provisions an endeavor to balance the rights of breeders and farmers (Twarog/Kapoor 2004). However, farmers' rights, which – in contrast to farmers' privileges – are more than mere restrictions of breeders' rights, are not mentioned in the UPOV Convention (Ravishankar/Archak 1999: 3662). On the contrary, one can observe a trend of increasingly limiting the exceptions for farmers to use plants without the breeders' authorization. While the 1978 version of the UPOV Convention set no limitations to farmers' use of plant varieties that they have legally obtained for propagating purposes on their holdings, the current version also protects breeders' rights on the harvested material and makes the guarantee of the farmer's privilege dependent on national regulation. Also the general minimum duration of the protection period has been extended to five more years and seven years for trees and vines. It is also worth noting that the 1978 Act allowed only one form of IP protection – either by a special title of protection or a patent (Art. 2(1)). The recent version also accepts double protection of breeders' rights (Cullet et al. 2006: 132; Safrin 2004: 246). UPOV's business focus stands in stark contrast to the ITPGR's multilateral system of ABS and concern of farmers' participation in national decision-making (Jungcort 2011:183).

6.2.4 World Health Organization (WHO)

WHO was established as a specialized UN agency to improve public health in 1948. In its constitution, the “enjoyment of the highest attainable standard of health” is recognized as a “fundamental” human right (WHO 1947: preamble). Its scope of action has grown despite a declining budget while its mandate has oscillated between technical and normative activities (Lee 2009: 16-21). WHO’s engagement in biotechnology-related IPRs was sparked by TRIPS. Starting with the Revised Drug Strategy in 1996 (WHO 1996), WHO served as a forum to debate IP consequences on the access to essential pharmaceuticals.¹⁴³ The 1996 Revised Drug Strategy initiated a review of WTO’s impact on national drug policies and pursued a collaboration with the WTO (WHO 1996: para. 2(10)). Since then, WHO has observed TRIPS’s impact on public health and assisted countries in making use of TRIPS flexibilities, including transition periods and compulsory licensing (Helfer 2004: 42-43). The organization has portrayed itself as the leading technical expert on public health implications in areas of the trade-health intersection. The then WHO Director-General Gro Harlem Brundtland stressed in her speech at the Ad hoc Working Group on the Revised Strategy in October 1998:

“When trade agreements affect health, WHO must be involved from the beginning. We need to analyse and monitor how new international agreements can support public health” (WHO 1997a: 70).

This comment also gets to the core of WHO’s focus that is review and monitoring rather than leadership in terms of concrete policy action.¹⁴⁴ The Revised Drug Strategies of 1996 and 1999 do not contain concrete political acts. Both vaguely urge members to ensure “equitable access to essential drugs” (WHO 1999b: para. 1(1); WHO 1996: para. 1(1)). The tone of the 1999 version is only slightly more pressing. It directly refers to TRIPS and encourages its members to use the possibilities under TRIPS to protect public health under international trade agreements (WHO 1999b: preamble and para. 1(3)). In 2001, two WHA resolutions specified that the use of generics for poor countries should be facilitated (WHO 2001d: para. 1(10); WHO 2001e: para. 1(5)). In the same year, a WHO bulletin on TRIPS flexibilities with regard to public health was published. It recommends developing countries to be “cautious” about accepting TRIPS-Plus standards (WHO 2001b). Later WHA resolutions reaffirmed TRIPS flexibilities to protect public health and advocated their usage.¹⁴⁵ The WHA, for instance, urged members to reach a solution at the WTO to enable developing countries to make use of compulsory licensing under paragraph 6 of the Doha Declaration (WHO 2003c: para. 1(3)). Also bilateral trade agreements, which indirectly hints at TRIPS-Plus agreements, should respect the flexibilities contained in

¹⁴³ WHO also rarely mentions the need of fair ABS from the use of TK (see for example: WHO 1998a: para. 2(5)) and the protection of TK (WHO 2009a; WHO 2003a). But its engagement in this issue area remains of comparatively low importance and is therefore not further mentioned in the analysis.

¹⁴⁴ See for example: WHO 2006d: para. 4(4-5); WHO 2003c: para. 2(2-3); WHO 2002c: para. 1(5); WHO 2001e: para. 2(4).

¹⁴⁵ WHO 2008b: para. 8, 12, 38; WHO 2007d: para. 1(5-6); WHO 2007a: para. 1(8); WHO 2006d: prelude; WHO 2005a: para. 1(10); WHO 2003c: para. 1(2).

TRIPS and the Doha Declaration (WHO 2006d: para. 2(4); WHO 2004a: para. 2(6)). The WHO secretariat should assist countries that intend to make use of the TRIPS flexibilities with technical and policy support (WHO 2007e: para. 3(2)).

WHO's work on public health and IP was conducted in a series of bodies. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was established by the Director-General in 2004 as decided by resolution WHA56.27. During its operation until 2006, the CIPIH's mandate included the review of existing R&D instruments that disproportionately affect developing countries, analysis of IP's role on innovation and public health, evaluation of stakeholder proposals, and production of concrete proposals for action (WHO 2006a: iv). In order to implement the CIPIH's 60 recommendations, the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) was set up in 2006. Its negotiations resulted in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), which was adopted by resolution WHA61.21 in 2008. The GSPA-PHI emphasizes that the protection of public health has to be considered in the implementation of TRIPS and other IP policies (WHO 2008b: para. 8, 34(5.2b)). This can also require the adaptation of national legislation to use TRIPS flexibilities (WHO 2008b: para. 36(5.2a)). Developing countries should be assisted in using these flexibilities if they face obstacles to do so (WHO 2008b: para. 12, 35(5.1-2), 38). The Strategy also proposes new ways to increase R&D for neglected diseases (for example: WHO 2008b: para. 5(3a), 38-40). Remarkably, WHO is excluded as explicit stakeholder in the "further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development" (WHO 2011c: Annex: 2(3c); WHO 2009c).

Upon the recommendation of the IGWG, the Expert Working Group on Research and Development: Coordination and Financing (EWG) was established in 2008. Its report was rejected by the WHA in 2010 (Velasquez 2014: 71). The EWG's work was reviewed by a Consultative Working Group on Research and Development: Financing and Coordination (CEWG), which was set up in 2010. In its 2012 report, they recommended the adoption of an international treaty to strengthen R&D for the health needs of developing countries. IPR should be applied "in a manner that maximizes health-related innovation" and access to all health products and devices should be improved (WHO 2012a: 122).

WHO has never become tired of emphasizing the importance of public health in the context of trade, but it rarely adopted policies that demand concrete political action. Although WHO has frequently raised a cautiously critical voice against TRIPS¹⁴⁶, it has sought a close cooperation with WIPO and the WTO and other involved institutions from the beginning (WHO et al. 2012).

¹⁴⁶ See for example: WHO 2009d; WHO 2008b; WHO 2003c; WHO 2001b.

6.2.5 World Intellectual Property Organization (WIPO)

WIPO became a UN agency in 1974. It currently administers 26 treaties of which four are particularly relevant for this study.¹⁴⁷ The oldest of them is the 1983 Paris Convention for the Protection of Industrial Property. It provides for the right of priority¹⁴⁸, substantive patent requirements, administrative and financial provisions, and like the WTO demands national treatment (WIPO 2004d: 242-261). The WIPO Convention as constituent document was signed in 1967 and entered into force 1970.

The PCT was adopted in 1970, entered into force in 1978, and was amended in 1979, 1984 and 2001. The PCT facilitates and centralizes the filing of patent applications across countries via an international patent application. The latter only has to be filed with a single patent office in one language and has effect in all designated states that are listed in the application.¹⁴⁹ An application under the PCT does not lead to the granting of an international patent in the sense that once an intervention is recognized by one member country, it becomes automatically valid in all other member countries. The right and responsibility to grant patents rests exclusively with the national or regional patent offices.

The Patent Law Treaty (PLT), which was adopted in 2000 and came into force in 2005, further standardizes and streamlines the patent application procedure to reduce costs and formality errors that can lead to the unintentional loss of rights (WIPO 2004d: 301-305). It establishes a maximum set of formal requirements for patent applications – for instance with regard to mandatory representation, required evidence, copies, and communication – and standardizes application forms (WIPO 2000). So far, the PCT and PLT only have dealt with procedural parts of the application process. Therefore, WIPO formally sets no substantive requirements for patents. In general, it refers to the common principles of

¹⁴⁷ For the up-to-date number see: <http://www.wipo.int/treaties/en/> (Accessed 3 February 2013).

¹⁴⁸ The right of priority refers to the time period (six or 12 months) that is granted to an applicant who filed a patent application with a member country to apply with the same patent in other countries whereas the filing date will be considered the same day as her earliest application (WIPO 2004d: 243).

¹⁴⁹ Since 2004, all states are automatically considered designates. The subsequent procedure is centralized. The application undergoes

- a formal examination by a single patent office (a national or regional office and the WIPO International Bureau can act as ‘receiving office’);
- an international search by an international searching authority (a national or regional office which concluded an agreement with WIPO to act as an international searching authority) reporting the relevant prior art which can be used by both the applicant and the designated Offices to assess the prospects of obtaining a patent; and
- a centralized international publication.

Afterwards, the International Bureau, WIPO’s secretariat, transfers the international application to the designated states. Optionally, the applicant can demand an international preliminary examination that reports on the patentability of the invention. For the application, only one single fee has to be paid to the receiving office. Payment of national fees to the designated patent offices is delayed. After this international phase, the national one starts. Without the PCT and under the national patent system of the Paris Convention, the applicant had to file separate applications with every single national office in countries in which she sought for IP protection and had to pay for national applications and translations – all within 12 months after the priority date. (WIPO 2004d: 277-284).

novelty, invention, and practical use.¹⁵⁰ Negotiations to harmonize material aspects by means of the Substantive Patent Law Treaty (SPLT) have been dragged on since 1995.¹⁵¹

Reflecting growing concerns that comprehensive IP protection does not lead to the promised economic benefits, WIPO adopted the Development Agenda in 2007 (WIPO 2007a). Its 45 recommendations emphasize a holistic approach to IP protection taking into consideration the special needs of developing countries and least developed countries (LDCs). The Committee on Development and Intellectual Property was established to develop and monitor the program (Choer Moraes/Brandelli 2009: 34, 40, 44-45; Woodward 2012: 57-58). With regard to the four issue areas of this study, WIPO has been especially used as a platform to debate ABS and TK.¹⁵² Both topics are also very much interconnected at WIPO.

ABS. In 2001, the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) was founded to address IP-related aspects of TK and generic resources. In its 2013 Draft Guidelines on ABS, the IGC recognizes the CBD's ABS principles of prior informed consent and benefit-sharing (WIPO 2013: 4). The policy options that could lead to an international legal instrument vary considerably. Disagreement exists, for example, on the question whether ABS should be integrated as a mandatory requirement into the international IP regime or if its implementation should be executed nationally and outside the patent system (WIPO 2014). Also the Working Group for Reform of the Patent Cooperation Treaty discussed if the PCT should be amended to also require under certain circumstances the notification of the source of genetic resources and TK (Lawson 2012: 44). Besides these discussions, WIPO has worked on establishing an online database of biodiversity-related ABS agreements since 2001 (WIPO 2010a).¹⁵³

TK. WIPO's work on ABS is strongly connected with TK. WIPO established its Traditional Knowledge Program in 1998. It has organized roundtable discussions and fact-finding missions. By the same token, training is offered to patent officials to create awareness for TK. The IGC has been working on Draft Provisions for the Protection of

¹⁵⁰ See for example: http://www.wipo.int/patentscope/en/patents_faq.html#patent_granted (Accessed 3 January 2014).

¹⁵¹ Available at: <http://www.wipo.int/patent-law/en/plt.htm> (Accessed 2 July 2013).

¹⁵² Only at the end of my research period, WIPO started to discuss the need of facilitating access to medicine. During the negotiations leading to the Development Agenda, developing countries emphasized the importance of applying IPRs without damaging public health. Nevertheless, the Development Agenda makes no direct reference to 'health' or 'medicine' but only calls members "to promote fair balance between intellectual property rights and public interest" and to "intensify its cooperation" with WHO (para. 40) (Helfer/Austin 2011: 126). In 2009, WIPO launched the Global Challenges Program to understand the interplay between IP, innovation and dissemination of technology in areas like climate change, food security, and public health (<http://www.wipo.int/globalchallenges/en/>). In 2011, the WIPO Re:Search was formed as a cross-sector partnership between actors from business, science, and civil society (<http://www.wipo.int/research/en/>). The database seeks to improve research on neglected diseases that are of particular relevance to developing countries. All products developed under a WIPO RE:Search Agreement must be sold free of charge to all LDCs (WHO et al. 2012: 123-124).

¹⁵³ Available at: <http://www.wipo.int/tk/en/databases/contracts/> (Accessed 9 October 2014).

Traditional Cultural Expressions and Traditional Knowledge since 2004.¹⁵⁴ In 2009, the WIPO General Assembly renewed and extended the IGC's mandate to table a draft for an "international legal instrument [...] which will ensure the effective protection of GR, TK and TCEs" (traditional cultural expressions) by 2011 (WIPO 2009b: 217). This could eventually result in a sui generis IP regime for TK. But the negotiations reached an impasse owed to the very diverging positions and proposals of IP-friendly and IP-skeptical countries (Andana 2012: 551; Janewa 2011: 172-173).¹⁵⁵

6.2.6 World Trade Organization (WTO)

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is part of the reformed trade regime that entered into force in 1995 as successor of the General Agreement on Tariffs and Trade (GATT). Due to the sluggish negotiations at WIPO, developed countries led by the USA pressed for the inclusion of IPRs into the Uruguay Round. Developing countries were allured by a package deal in which they agreed to strong IP standards in exchange for greater access of their agricultural products, textiles and other goods to the markets of developed countries (Helfer/Austin 2011: 38).

The objectives of the TRIPS agreement are "the promotion of technological innovation and [...] the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge" by harmonizing and promoting effective IP protection (WTO 1994d: Art. 7). To this end, the principles of non-discrimination and most-favored-nation treatments hold for IPRs in the same way as for the other areas regulated by the WTO (WTO 1994d: Art. 3-4). TRIPS formulates minimum standards of IP protection in terms of substantive requirements and enforcement. In the course of national implementation, states can adopt stricter IP regulations or expand them to new areas as long as it is in harmony with TRIPS (WTO 1994d: Art. 1(1)).

Concerning patents' scope, TRIPS confers exclusive rights to the patent holder. It is distinguished between product and process patents. If a patent refers to a product, the patentee is guaranteed the exclusive rights "to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product". Process patents cover the protection of both process and the products directly obtained by the process. Moreover, patent owners have the right "to assign, or transfer by succession, the patent and to conclude licensing contracts" (WTO 1994d: Art. 28). The duration of IP protection has to be granted for at least 20 years calculated from application's date of filing (WTO 1994d: Art. 33).

In an attempt to accommodate the needs of developing countries, TRIPS provides for technology transfer, capacity-building, longer transitional periods for non-industrialized

¹⁵⁴ For the latest version see:

http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_27/wipo_grtkf_ic_27_4.pdf (Accessed 10 February 2014).

¹⁵⁵ Available at: http://www.wipo.int/tk/en/igc/draft_provisions.html (Accessed 5 December 2012).

countries to implement TRIPS, and some limited discretion to restrict IP protection. The obligations concerning technology transfer and capacity-building remain rather imprecise. Developed countries shall assist developing and least developed members in building and strengthening their IP infrastructure (WTO 1994d: Art. 67).

Due to its comprehensive scope and membership, TRIPS has enormously contributed to IPRs' political visibility. This represents one reason why the WTO has been used as a forum to address all four issue areas of this analysis: ABS, TK, IP protection of plant varieties, and public health and IP.

ABS. In order to be patentable, Article 27(1) requires a subject to be “new, involve an inventive step and [be] capable of industrial application”. In principle, these criteria can be applied to all products and processes. As in the case of UPOV, the CBD's ABS requirements for products based on genetic resources could be considered as illegal trade barriers if they were expanded to the WTO's IP system (Jungcurt 2011: 180). It has caused great debates at the TRIPS Council if the CBD and TRIPS are in conflict with each other. Similarly, the ITPGR's requirement of transferring a percentage of financial benefits to its fund can violate TRIPS (Helfer 2004: 41). Demands to incorporate ABS standards into TRIPS and make them mandatory conditions of a patent application have been successfully diverted by developed countries.

TK. Although TK issues have been extensively discussed at the TRIPS Council, its policy outcomes show little proof of it. The Doha Declaration just vaguely calls members to consider TK protection in its review of TRIPS's implementation pursuant to Article 71(1) (WTO 2001d: para. 19). The 2001 Doha Work Program requests the examination of the connection between IPRs and TK. In the subsequent years, it remained a permanent issue on the agenda if TK can be best protected by patents or a sui generis system as well as if regulations should be national or international and recommendatory or legally binding (Brody 2010: 241). Through TRIPS lenses, it is challenging to grant TK IP protection because the agreement associates innovation with commercial utility (Crookshanks/Phillips 2012: 72).

IP protection of plant varieties. In contrast to other areas, the IP protection of plant variety under TRIPS leaves some leeway for member states. They can choose between a patent regime, sui generis system, and a combination of both (WTO 1994d: Art. 27(3c)). This has caused considerable discussion in particular because no further specification has been made as to what constitutes an *effective* sui generis system. The U.S. has promoted UPOV as the most effective model to protect plant varieties although TRIPS does not make any reference to UPOV (Sell 2003: 143).

Public health and IP. TRIPS requires patent protection in “all fields of technology” (WTO 1994d: Art. 27(1)). TRIPS only allows for exemptions from its regular patent obligations under very restricted circumstances. Article 27(3a) permits to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”. In addition to that, patents might not be granted in cases of emergencies when it

“is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment” (WTO 1994d: Art. 27(2)).

Similarly, Article 8(1) authorizes Members to

“adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.”

Also Article 30 approves

“limited exceptions to the exclusive rights [...] provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.”

As clarified by a WTO panel, it does not constitute a patent infringement if a patented pharmaceutical is used as an act of testing to obtain market approval of a generic under the condition that the generic enters the market after the original patent has expired (Bolar provision). But if products, like pharmaceuticals with new chemical entities, require the submission of undisclosed test or other data to obtain marketing approval, the data must be protected against unfair commercial use except when the public has to be protected (WTO 1994d: Art. 39(3)). Article 31 more specifically lays down the conditions for *compulsory licensing* that is a state’s authorization to use a patented product or process against a patent holder’s will. The issuance of such license is subject to certain conditions. The issuing state must have attempted to acquire a voluntary license on “reasonable commercial terms” within a “reasonable period of time”. This requirement may be relaxed in cases of emergency and for public non-commercial uses. The right holder has to be paid adequate remuneration. Other restrictions, for example, refer to the license’s limited scope and duration and the opportunity to subject the decision’s legal validity to judicial or other independent review by a distinct higher authority. Most contention caused paragraph f of Article 31 that stipulates that the use should be “predominantly for the supply of the domestic market”. This requirement is problematic as high drug prices usually hit predominantly developing and LDCs that possess not sufficient manufacturing capacities to produce generics within their borders.

Closely related in the discussion on public health is the exhaustion of the patent holders’ exploitation rights. Initially, TRIPS was equivocal if international or national exhaustion of rights can be legally applied (WTO 1994d: Art. 6). IPRs are exhausted once a protected item is launched on the market with the IP owner’s permit. In other words, the IP holder loses its exclusive right of commercial exploitation for a given product with its first sale (first sale doctrine). As the product is then treated as second-hand, the IP owner can no longer control resale or any other form of commercial use. National exhaustion of commercial rights for the IP owner is reached once a product is circulated for the first time with the IP owner’s consent on the domestic market. Nevertheless, the IP owner remains the rights to control the sale and import of original goods. The latter refers to so-called *parallel imports*. Parallel imports are imports of IP-protected goods that are produced with the IP owner’s consent in a foreign country, but imported or resold without with the

authorization of the patent owner. This practice can save the importing country a considerable amount of money. In the case of international exhaustion, the IP owner loses her control of commercial exploitation once she consented to the sale of the product either nationally or internationally.¹⁵⁶ The differentiation is crucial because an international exhaustion regime allows for parallel imports while a national one prohibits it.

The 2001 Doha Declaration on the TRIPS Agreement and Public Health settled ambiguities concerning compulsory licensing and parallel importation for the promotion of public health. It clarifies that each member is free to establish its own national regime of exhaustion (WTO 2001c: para. 5(d)). Also it explicitly notes that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” (WTO 2001c: para. 5(a)). Paragraph 6 of the Doha Declaration left it to the TRIPS Council to decide before the end of 2002 how members with insufficient or no manufacturing capacities in the pharmaceutical sector can make effective use of compulsory licensing. In 2003, the TRIPS Council waived the domestic use obligation under Article 31(f). It allowed WTO members to export generics treating to countries with insufficient or no manufacturing capacities under well-defined conditions and procedures. For example, the process has to be accompanied by several notifications from the importing and exporting country (WTO 2003c). TRIPS contains general safeguards (WTO 1994d: Art. 41). For example, border measures, like the control of goods in transit, can be used to control the infringement of IPRs (Micara 2012: 76; WTO 1994d: Art. 51).

In 2005, the TRIPS Council approved Article 31bis which will replace the 2003 ‘paragraph 6’ waiver with a permanent amendment as soon as two-thirds of WTO members have accepted it. The original deadline of 1 December 2007 has been extended to 31 December 2015 by the General Council at the end of 2013. Until then, the waiver will continue to apply (WTO 2013a; WTO 2005c).¹⁵⁷ One decade after the Doha Declaration’s adoption, the mechanism has only been used once by Rwanda to import an ARV drug, an HIV/AIDS medicine, from a Canadian manufacturer (Morin/Gold 2010: 564; Muzaka 2009: 1355-1356).

Another means of flexibility represent the longer transition periods that are offered to non-industrialized countries. As a general rule, WTO members have to implement TRIPS one year after it entered into force (WTO 1994d: Art. 65(1)). A transition period of four additional years are granted to developing countries and countries in transformation to a free market economy, with the exception of obligations resulting from the national and most-favored-nation treatment (WTO 1994d: Art. 3, 5, 65(2-3)). In areas for which a developing country has to build IP protection from scratch, it has five more years to

¹⁵⁶ Available at: http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (Accessed 5 December 2012).

¹⁵⁷ For a current list of members that accepted the amendment see: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (Accessed 18 February 2014).

comply with TRIPS (WTO 1994d: Art. 65(4)).¹⁵⁸ A deferral of ten years until 1 January 2006 was initially granted to LDCs under Article 66. For the establishment of a pharmaceutical patent regime and the protection of undisclosed information, the Doha Declaration grants LDCs a separate transition period until 2016. Nevertheless, the commonly called ‘mailbox provision’ requires members who have not provided for pharmaceutical IP protection yet to already accept the filing of patent applications (WTO 1994d: Art. 70(8)). Pending the final patent decision, exclusive marketing rights have to be granted to the patentee under Article 70(9). The latter obligation was waived for LDCs by the General Council in 2002 (WTO 2008f: 18). The initial transition period for LDCs was extended twice: first until 1 July 2013 and afterwards until 1 July 2021 (WTO 2013b). This decision leaves the IP protection of pharmaceuticals unaffected.¹⁵⁹

Additional flexibility to control for the scope of patentable pharmaceuticals can be gained by adopting a narrow definition of novelty to exclude second-use patents. The latter, also known as evergreening, refer to either already patented drugs for which new applications are discovered or patents on a new modification of a known substance that does not enhance its efficacy (Helfer/Austin 2011: 120-121).

Industrialized countries pushing for stronger IP standards have successfully curbed built-in flexibilities and transition periods by so-called TRIPS-Plus treaties. By means of bilateral and regional free trade agreements (FTAs), developing countries have been pressured into bilateral agreements in which they have committed themselves to shorter implementation periods and domestic IP protection that have exceeded TRIPS standards (Helfer/Austin 2011: 40; Helfer 2004: 5).

Although the WTO embarked on an area that was previously mainly within WIPO’s competence, TRIPS formally recognizes WIPO’s continuing importance and intends to “establish a mutually supportive relationship” with it (WTO 1994d: introduction). In this vein, the WTO signed a Cooperation Agreement with WIPO in 1995. The two organizations agreed, among others, to collaborate in the technical assistance of developing countries to support their compliance with TRIPS.

The previous overview illustrates the upstream harmonization of IPRs. IP expansion in terms of scope and depth has also evoked a backlash of critics who have warned about IPRs’ negative side-effects on fundamental public matters like environment, food, and health. The subsequent conflicts of IP supporters and IP skeptics are presented in the next section.

¹⁵⁸ In return for longer transition periods, developing countries agreed to comply with their obligations in agriculture and textiles (Correa 2000: 9).

¹⁵⁹ Available at: http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm (Accessed 18 February 2014).

6.3 IP Supporters versus IP Skeptics – IP as a Politicized Field of Conflicting Interests and Asymmetrical Positions of Power

IPRs always involve certain costs and benefits. These diverge for the consumers and right-holders of patented products as well as for the users and providers of genetic resources on the basis of which patents are developed. The stark differences in interests concerning biotechnological patents have led to the politicization of the field. For a better understanding of this development, I first introduce the general arguments of IP supporters and IP skeptics. In the subsequent sections, I specify the dividing lines between actors in the fields of (1) ABS, (2) protection of TK, (3) IP protection of plant varieties, and (4) public health and IP. For every field, I state the main lines of conflict, mostly affected actors, and the relevant fora of the discussion. The debates demonstrate the irreconcilability of certain positions and the enormous losses and gains that are at stake. These factors have prevented an easy settlement of the conflicting interests and make democratic decision-making process even more important.

6.3.1 General Arguments in the IP Debate – Balancing Economic and Public Interests

6.3.1.1 IP Supporters

Several factors contributed to the rise of IPRs and have established IPRs as a vital part of the political-economic agenda. One can distinguish between a set of philosophical and empirical reasons. The philosophical narratives have served as the underlying meta-justification of IP protection. Susan K. Sell and Christopher May characterize in their critical account of IP history two important approaches that justify the existence of property and its protection.¹⁶⁰

The first strand argues that labor invested in the improvement of nature needs to be rewarded. This is based on a Lockean understanding of property. According to this merit-based framework, things that exist in nature can usually not be owned. If the value of natural resources is, however, increased by individual efforts, the previously ownerless objects can become property. Although John Locke has never directly addressed IPRs, the notion that ownership is a necessary prerequisite to create incentives for progress is the dominant justification for IPRs today. Only if expenditures in innovation are compensated and free-riding is prevented, the argument goes, the private sector is willing to invest in R&D. The resulting technological progress stimulates economic development. This makes IP protection not only beneficial for the inventor but society at large.

¹⁶⁰ The authors also mention a third approach which is not relevant here. It emphasizes a state's duty to protect individual property as the foundation of its freedom and sovereignty. Following Georg Hegel, free individuals identify themselves and distinguish each other via property. It is nothing less than an expression of their autonomy vis-à-vis the state. In contrast to John Locke, property is regarded as a legal construct. Ownership is not the reward of labor in improvement but part of individuals' membership to a society. This conception supports the widespread view that property is an empowering institution that requires state enforcement.

Second, an economic and functional set of arguments considers the institution of property as the most efficient way to allocate resources. Commodification enables the quantification of the benefits and costs that arise out of a resource's use. To this end, also knowledge needs to be transformed into a tradable good. Putting a price tag on knowledge and legally protecting its ownership creates an artificially scarce resource. This is the basis for market mechanisms to work and to assure the best distribution and use of resources. The invention of money has further facilitated the exchange of property. Only a functioning market can ensure that IPRs' benefits, first and foremost technological progress, can unfold (May 2010: 27-32; May/Sell 2006: 20-23).

Besides these theoretical and more general justifications, there are several empirical reasons that explain and vindicate IPRs. These refer directly to the philosophical narratives. I focus on four causes related to biotechnological patents that partly apply to other IPRs as well.

First, a rise in biotechnological inventions has created subjects of patentable worth. Technological advances were necessary in order for biotechnological products to fulfill the patent criteria of invention and industrial applicability (Rosendal 2006: 431). At the same time, the new biotechnological products have generated high returns that made their patents profitable. The revenues generated by biotechnological industry were estimated at \$54.6 billion in 2004 (Richerzhagen 2010: 35). Not without reason, plant genetic resources were termed "green gold" (Kloppenburg 2004: 338) or "genetic petroleum" (Safrin 2004: 672).

Second, IPRs should support technological progress that has become key to sustain international competitiveness in many branches. Technology-intensive sectors have become more lucrative as their increasing share in international trade proves, but they have demanded growing investment in R&D. Biotechnological R&D has undergone a growing privatization since the 1970s (Correa 2000: 3; Rosendal 2006: 431). Concurrently, technological progress have made it easier and cheaper to imitate innovative commodities (Sell 2003: 37-38). In order for R&D expenditures to pay off and to increase their profit margins, companies have been concerned to protect their knowledge and products by means of stronger IPRs.

These trends – the novelty and worth of created biotechnological goods and their demand for investment in R&D – have made IP protection in the biotechnological sector crucial. In accordance with the Lockean justification, the development of biotechnological goods has progressed to such an extent that they are clearly distinguishable from naturally existing things. The entitlement to ownership of biotechnological goods is understood as reward for the efforts put into their development and an incentive to further advance them.

Third, not only individual businesses but the entire society is expected to profit from the technological progress incentivized by IPRs. This belief can also be found in TRIPS as the currently most important IP agreement. Article 7 states that IPRs "should contribute to [...] social and economic welfare" (WTO 1994d). IP supporters have attempted to show in

empirical studies that a strong IP regime is a precondition for a country's economic development because it attracts foreign direct investment (FDI) and the settling of new industries. IPRs are not a sufficient but necessary condition for economic prosperity (Gervais 2007: 80-82). In particular in developing countries, a comprehensive IP regime as provided by TRIPS is said to stimulate investment and technology transfer. In addition to the improvement of a country's competitive economic situation, the technological progress that accompanies biotechnological patents is assumed to solve essential socio-economic problems in areas ranging from agriculture over health care to energy. For instance, genetically modified crops can assist in securing food security in hunger-afflicted regions (Yuan et al. 2011). Advancement in the medical sector can make the diagnosis and treatment of diseases more efficient and effective. The Biotechnology Industry Organization (BIO) heralds stem cell research, gene therapy, implantable sensors to monitor health conditions, and DNA vaccines as major technologies that will revolutionize health care.¹⁶¹

Fourth, advances in communication and transportation created a global marketplace that was eventually opened up by trade liberalization. Multinational companies have been eager to open up the market in developing countries and hence have pressured for the reduction of trade barriers (Correa 2000: 4). To ensure an efficient international market of knowledge, legal IP protection had to go global as well.

All in all, IPRs have presented a means for the Western-dominated private sector to internalize externalities, minimize commercial risks, and save revenues. This resulted in a growth of both IP standards and patented subjects. In order to exploit IPRs' economic benefits internationally, it has been essential to strengthen and harmonize existing IP regulations. The TRIPS agreement fulfills these requests so that most IP supporters consider the agreement as suitable policy instrument to optimize innovation.

Generally speaking, IP supporters are industrialized *countries* with a vibrant technology sector. This applies especially to the USA, Germany, France, Japan, Switzerland, and South Korea.¹⁶² These are among the highest ranking countries in terms of applications filed and received. This relates to both patents in general and biotechnological ones in particular. With regard to biotechnological patents in the period between 2006 and 2010, U.S. residents filed the by far largest number of patent applications followed by residents from Japan, Germany, China, South Korea, France, the U.K., and Switzerland (WIPO 2012: 73).¹⁶³ In accordance with these ranking, the USA, Germany, France, Italy, and Switzerland

¹⁶¹ Available at: <http://www.bio.org/articles/10-watch-hot-biotech-prospects> (Accessed 2 July 2013).

¹⁶² The aggregated value of U.S. owned patent rights for 1988 was higher than that of all other countries taken together (McCalman 2005: 586).

¹⁶³ 'Biotechnology' refers to the classification according to the IPC-technology concordance table, available at: http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/pdf/wipo_ipc_technology.pdf (Accessed 2 July 2013). According to the IPC fields of technology, pharmaceuticals are separated from biotechnology. This is not problematic insofar that the ranking of the top countries is similar for pharmaceutical and biotechnological patents (WIPO 2012: 73). The picture remains similar if one considers all patents (WIPO 2012: 47).

are estimated to be the largest beneficiaries of TRIPS in terms of short-run net transfers (McCalman 2005: 589). Although high-income countries predominantly issue patent applications, their share of patent applications worldwide declined from 85.8% in 2001 to 67% in 2011. Instead, the proportion of upper-middle income countries grew from 11.7% to 29.8% in the same period (WIPO 2012: 51). This trend was considerably driven by China which patent applications increased by 41.3% between 2010 and 2011 (WIPO 2012: 55).

Given this economic situation, it is not surprising that the driving force behind international IP law has been the *USA*. The USA rapidly changed their IP policy in the mid-1980s in an attempt to defend its declining leadership in manufacturing and technology. Having faced growing competition from Japan and newly industrialized Asian countries, the U.S. industry considered the fight against overseas counterfeit as one major countermeasure (Correa 2000: 4-5; Sell 2003: 12-13). The U.S. private sector, specifically a group of 12 U.S. based multinational companies, has exercised great influence via the U.S. Intellectual Property Committee (IPC) and U.S. Advisory Committee for Trade Negotiations. During the TRIPS negotiations, the USA rejected a narrow anti-counterfeiting code and successfully supported a comprehensive IP agreement along with other developed countries like France, the U.K., Japan, and Switzerland against the will of developing countries (Gervais 2007: 51-52; Sell 2003: 42, 47).

Concerning *IOs*, UPOV, WIPO, and the WTO have supported a strong and comprehensive IP regime. Among *NGOs*, mostly business actors are IP supporters. Most of the companies with the highest number of patent applications relating to plant genetic resources are located in the USA. This includes Incyte, Curagen Corporation, BASF, Monsanto, Agensys, and DuPont (WIPO Patentscope Database).¹⁶⁴

6.3.1.2 IP Skeptics

Critical voices against IPRs have become louder with an increasing awareness of the consequences that come with a strong IP regime. IP skeptics have often not rejected IPRs altogether but have opposed an unrestricted IP expansion (Choer Moraes/Brandelli 2009: 33-42). There are five main empirical reasons that disenchant the ideological hopes of IP supporters as described above.

First, a one-size-fits-all approach of IPRs has been criticized for not taking into consideration the needs and circumstances of non-industrialized countries. TRIPS has demanded from many developing countries and LDCs to build up a national system of IP protection from scratch in a very short period of time. They have to set up and modify national administration and often also to restructure their tariff law and judiciary (Correa 2000: 10). These requirements stand in stark contrast to the gradual evolvement of IP regimes in developed countries where they were accompanied by a continuous

¹⁶⁴ Available at: <http://patentscope.wipo.int/search/en/search.jsf> (Accessed 15 February 2013).

consolidation of the national economy. Studies affirm that IPRs can only unfold their welfare benefits if a certain economic threshold has already been reached (Basso/Beas Rodrigues 2007: 190-191). Since the negotiations of TRIPS, Southern countries have demanded greater flexibilities and longer transitional periods to implement TRIPS in order to be able to establish a viable and sound technological base beforehand. These demands have been opposed by industrialized countries – predominantly the USA, Canada, EU, Japan, and Switzerland – which only consented to limited transition periods in terms of duration and scope. In a latest attempt in November 2012, a group of LDCs called for an infinite extension of the transition period as long as a country holds the LDC status. This request eventually failed in June 2013 in which a compromise for the prolongation of the transition period for further eight years until July 2021 was reached.¹⁶⁵ As the renewals indicate, the original transition periods to implement TRIPS proved to be insufficient for developing countries and LDCs. These difficulties were further aggravated by TRIPS-Plus agreements (Lindstrom 2010). It is important to note that reverse engineering had been an important means to catch up economically in the past. The USA profited from copying British patents in the 19th century and East Asian countries – like China, Japan, and South Korea – from copying Western patents in the 20th century (UNDP 2005: 135).

Second, IP skeptics have criticized the prioritization of economic profit over social goals. Strict IP regulations do not sufficiently balance IPRs with human rights, public health, and environmental protection. With regard to biotechnology, IP skeptics have criticized that holders of genetic resources on which patents are based have not been sufficiently compensated, TK has been exploited and capitalized, and patents have restricted the access to fundamental goods such as seeds and vital pharmaceuticals. A more detailed elaboration of these arguments follows in the next subsections. On a more theoretical ground, critical theories on IPRs have highlighted that the ever-expanding commodification of knowledge is not a natural and inexorable course of development but the result of certain political-legal power structures (May 2010). The preference and protection of economic demands should therefore not be considered as inevitable means to protect the general welfare but as the representation of vested interests.

Third, the argument that IPRs lead to social welfare has no empirical support. Studies have shown that IP protection does not automatically lead to increased innovation, technology transfer, and FDI (Ohnesorge 2003: 103). Overly strict IP protection has created strong monopolies and high market prices of patented goods that have impeded the distribution of knowledge and further research (Gervais 2007: 60).

Instead, IPRs have been accused of being beneficial for only a limited number of Northern countries in which the greatest share of IPRs are concentrated. More than 95% of patented goods are developed in Northern countries while most of the other 5% created in the South are produced by Northern companies (Crookshanks/Phillips 2012: 69). In the

¹⁶⁵ Available at: http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (Accessed 7 February 2014).

mid-2000s, companies from developed countries cashed 96% of all patent royalties (UNDP 2005: 135). In 2011, China, India, and Russia were the only middle-income countries in the top 20 of patent applications by origin (WIPO 2012: 56). Against this background, Carlos M. Correa describes TRIPS as a means of “technological protectionism” that has created a division of labor. A few Northern countries with technological-intensive companies produce IP products while Southern countries serve as outlet (Correa 2000: 5). Although IPRs have sparked private investment in the R&D of agricultural biotechnology, most Southern countries did not profit from it. Since many farmers in developing countries are poor and produce on a small-scale, companies have concentrated on the needs of higher-income countries where markets are larger and more profitable (de Jonge/Korthals 2006: 154; FAO 2004: 104-105). Likewise in the health sector, pharmaceutical companies have been accused of neglecting the investment of R&D in diseases that in particular affect the South, such as tuberculosis and Malaria, due to its limited purchasing power. At the TRIPS Council, developing countries have frequently complained that measures on the transfer of technology are lacking or not sufficient. All in all, TRIPS has consolidated the competitive edge of developing countries.

Fifth, ethical concerns to patent living organisms have been raised. It has been hotly debated if and under what conditions genetic material can be patented. If one accepts that IPRs can be extended to life forms, the central point of discussion is the differentiation between discovery and invention. Is an isolated gene patentable because it involved an inventory step or is it still comparable with material as it naturally occurs? The U.S. Supreme Court ruled in the landmark case *Diamond vs. Chakrabarty* (1980) and later in *Ex parte Allen* (1985) that in principle any living organism – both plants and living animals – can be patented as long as it involves discovery (Bugos/Kevles 1992: 75). TRIPS reserves some flexibility in this respect and permits that members

“may exclude from patentability [...] plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes” (WTO 1994d: Art. 27(3b)).

Although this issue is far from being settled, patent offices have already granted numerous patents in this respect. The USPTO has handled it most liberally. It had already issued over 6,000 patents on isolated genes from living organisms by 2005 of which over sixth referred to human genes (Safrin 2004: 641).¹⁶⁶ The patenting of such fundamental knowledge can create ‘patent thickets’ that impede downstream research on drugs and other essential public goods (Oldham et al. 2013: 2).

The group of IP skeptics is more diverse than that of IP supporters. They have diverse interests and points of criticism. In general, developing *countries* are critical of IPRs. India is the by far largest loser of TRIPS in terms of estimated short-run net transfers with a loss of

¹⁶⁶ Most of the largest patent offices – the European Patent Office (EPO), USPTO, and Japan Patent Office (JPO) – recognize a (partial) genetic sequence as patentable even if the material’s structure can also be found in nature (OECD 2002: 2).

\$1.1 billion followed by Brazil (\$438 million) and Canada (\$317 million) (McCalman 2005: 589).¹⁶⁷ Other IP skeptics among developing countries vary with the issue area. Rather IP-skeptical *IOs* are the CBD, FAO, and WHO that are part of this project's sample, but also the UN Human Rights Council (UNHRC), UN Development Program (UNDP) and UN Conference on Trade and Development (UNCTAD). Among IP-skeptical *NGOs* are especially environmental, social welfare, indigenous, and development groups. Important *NGOs* encompass the Center for International Environmental Law (CIEL), Action Group on Erosion, Technology and Concentration (ETC; formerly RAFI), Friends of the Earth (FoE), Genetic Resources Action International (GRAIN), Greenpeace, IUCN, Practical Action (formerly ITDG), and the Third World Network (TWN) (Matthews 2006: 9).

In the following, the different positions are further specified for the areas (1) ABS, (2) TK, (3) IP protection of plant varieties, and (4) public health and IP. Each section provides the lines of conflicts, mostly affected actors, and relevant fora. I want to make three clarifying notes in advance. First, these topics are partly interrelated so that an overlap cannot be completely avoided. Furthermore, countries' positions have to be abridged and generalized. They not only changed occasionally in the course of negotiations but sometimes diverged depending on the national agencies that represent a country in the different fora. Last but not least, the number of mostly affected actors differs from issue area to issue area.

6.3.2 Access and Benefit-Sharing – Ownership of Genetic Resources versus Ownership of Patent Rights

In the light of biotechnological progress, plant genetic resources have gained enormous economic value.¹⁶⁸ New inventions in the fields of agribusiness and pharmaceutical industry often depend on the collection and exploration of new genetic material and information, so-called bioprospecting (Richerzhagen 2010: 2). The worldwide gains from products derived from genetic resources are estimated to be between \$500 and \$800 billion (Oberthür/Rosendal 2014: 3 citing ten Kate/Laird 1999).

The geography of the occurrence of genetic resources and their economic exploitation does mostly not overlap. Biodiversity-rich centers are tropical forests in Southern countries, so called *provider* or *supplier countries*. The industry that uses genetic resources is located in Northern industrialized countries. These *user countries* own the technological skills to process genetic resources and the legal expertise and financial means to patent the resulting

¹⁶⁷ It might come at surprise that Canada is one of the biggest losers, but Canada is the largest trading partner of the USA. Among foreigners, Canadian citizens applied for most patents in the USA (McCalman 2005: 589-590).

¹⁶⁸ 'Plant genetic resources' and 'genetic resources' are used interchangeably if not mentioned otherwise. In the debate, it has often been distinguished between three types of plant genetic resources: in situ, ex situ, and worked plant genetic resources. In situ plant genetic resources refer to those occurring in their natural environment and ex situ plant genetic resources to those being kept in gene banks. Worked genetic resources were modified through human innovation in contrast to raw material. Some would also include isolated plant genes in the latter category depending on where one draws the boundaries of invention (Helfer/Austin 2011: 379). Since I can only provide a brief overview on ABS here, I do not refer specifically to each category.

products. Also user countries can exhibit high rates of biodiversity. Decisive is their technological capacity to develop genetic resources into marketable products (Richerzhagen 2010: 26). The biotechnology sector could originally freely access genetic resources without compensating the countries from which the material originated. These genetic resources have been used by Northern companies to develop products that have not been accessible by actors from the source country because their IP protection has often led to unaffordable prices. With an expanding IP scope, even genetic resources' isolated genes and genetic sequences have already been patented. This constellation has offered great potential for conflicts and brought ABS as mode of regulating the acquisition and use of genetic resources on the international agenda in the 1990s (Oberthür/Pozarowska 2013: 106). *ABS* refers to a market-type contract between the provider and user of a resource. It regulates the resource's entry conditions and use as well as the share of benefits arising out of the utilization of the accessed resource. The legal and transparent recognition of reciprocal rights intends to help both parties to profit from a resource's commercialization.

By the same token, ABS has been considered as important means for the sustainable use and conservation of biodiversity (CBD 2002h: Art. 48). The "loss of biodiversity is estimated to proceed at 100 to 1000 times the natural rate" (Oberthür/Rosendal 2014: 1). The protection of biodiversity is more difficult to justify in economic terms. Since genetic resources are non-rival and non-excludable (de Jonge 2011: 130), everybody profits from their environmental services, but nobody wants to join in the cost-sharing. According to estimates of the 2005 UN Millennium Ecosystem Assessment report, the biodiversity loss has led to an annual human deprivation of \$250 billion in term of ecosystem services that are lost or impaired (Oberthür/Rosendal 2014: 5). Developing countries have born the bulk of costs to conserve biodiversity. By putting a price tag on genetic resources, the costs of conservation can be internalized. The commercialization of genetic resources under an ABS regime can create incentives for developing countries to continue with the conservation of genetic diversity in order to accrue their share from genetic resources' economic potential. The remuneration that is paid for access can be used for conservation efforts (Jungcurt 2008: 203).¹⁶⁹

Provider countries support a strong ABS regime with effective compliance mechanisms since they harbor most of the world's genetic diversity. In line with the CBD Convention, they assert sovereignty over the genetic material within their territory and the complete control of its transfer across borders. Access to genetic resources should depend on the provider country's prior informed consent and mutually agreed terms that respect the provider country's national and local laws. An agreement needs to guarantee the provider country a share of the benefits that are yielded from the resources' processing. Benefit-sharing refers to financial remuneration and non-market strategies such as the access to technology that

¹⁶⁹ Stefan Jungcurt argues that it is the legal insecurity caused by the incompatible rules of the different IOs dealing with ABS that prevents investments in conservation (Jungcurt 2008: 208).

was developed by means of the biological material. Technology transfer should take place irrespective if IPRs were obtained for a product (CBD 1992: Art. 15, 16(3)). In order to facilitate the adherence with these ABS standards and create legal liability, the disclosure of biological material's origin needs to be a compulsory requirement of patent applications. Linking ABS with IPRs represents an effective means to enforce ABS standards because patent regimes are vested with strong monitoring and sanction mechanisms. Provider countries have therefore unsuccessfully proposed to amend TRIPS to add ABS standards as mandatory preconditions for granting a patent.

The responsibility to observe the abidance with ABS rules should not only rest with provider countries. Also user countries should control the import and use of genetic resources within their jurisdiction, for example at patent and custom offices, and hold their nationals accountable if ABS principles are not met. With regard to the scope of an ABS regime, some developing countries pressed for the inclusion of genetic resources' products and derivatives¹⁷⁰ in the Nagoya Protocol. Since most revenues result from the processing of the genetic material – the DNA and RNA – and not of the physical raw material itself, it would also be the most lucrative component for benefit-sharing (Aubertin/Filoché 2011: 55-58).

Non-compliance with ABS can hardly be proven and penalized under the current international and national regulations. The ABS obligations of the CBD Convention have to be transformed into national legislation before complaints pertaining to ABS can be lodged with national authorities. Reliable international monitoring and sanction mechanisms do not exist. The acceptance of mandatory dispute settlement under the CBD is only voluntary (CBD 1992: Art. 27, Annex II). In order to establish harmonious and credible ABS rules, biodiversity-rich countries have supported an international legally binding and comprehensive ABS regime. It would provide stringent and precise ABS principles with an effective sanction mechanism. Several proposals to legally institutionalize ABS were made including the amendment of TRIPS or WIPO's PLT and SPLT.

Most of the provider-countries, like Brazil and India, have already installed national ABS regimes.¹⁷¹ Their arrangements vary considerably (Nijar 2010: 466). ABS systems can also be of regional scope. For example, the Andean Community, which covers a very biodiversity-rich area, enacted a Common Regime on Access to Genetic Resources in 1996.¹⁷² The Andean and Brazilian ABS regimes apply to internationals and nationals (Safrin 2004: 649-652).

Mostly affected IP skeptics are in particular biodiversity-rich *countries*. Twelve of them joined forces as the Group of Like-Minded Megadiverse Countries (LMMC) in Cancun in 2002.

¹⁷⁰ The Nagoya Protocol defines derivatives as “naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity” (CBD 2010g: Art. 2(e)).

¹⁷¹ The first state to adopt an ABS regime was the Philippines with the Executive Order 247 in May 1995 (Evanson Chege et al. 2010: 246).

¹⁷² Available at: <http://www.comunidadandina.org/ingles/normativa/d391e.htm> (Accessed 3 January 2014).

The founding members are Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa, and Venezuela (CBD 2002e). They were later joined by Bolivia, the Democratic Republic of Congo, Madagascar, Malaysia, and the Philippines. These 17 members are estimated to harbor 60 to 70% of the terrestrial species diversity (Wallbott et al. 2014: 43). Their high richness in biodiversity is affirmed by data from the 2002 UNEP World Atlas of Biodiversity (Groombridge/Jenkins 2002: 295-305).¹⁷³ Defining IP skeptics as the members of the LMMC also has the advantage that this group has frequently acted as a united actor in deliberations. The LMMC has coordinated their efforts to strengthen their bargaining power in the negotiations on an international legally binding ABS regime. Its demands have been supported by the African Group, the Group of Like-Minded Asia Pacific Countries (LMAPC), and most members of the Group of Latin American and Caribbean Countries (GRULAC) (Jungcurt 2008: 219-220; Oberthür/Pozarowska 2013: 111). Guatemala joined the LLMC in 2011. Since this occurred after the end of my research period, the country was not included in the group of mostly affected IP skeptics.

The divide neither between provider and supplier countries nor between the North and South are clear-cut. Some biodiversity-rich countries in the South – such as Brazil, China, India, Malaysia, and Mexico – have also developed a growing biotechnology sector. Therefore, they are not only interested in protecting their rights as providers but also as users of genetic resources. This partly explains why the LMMC's cohesion within the CBD crumbled as China and Mexico started to prefer a non-binding ABS agreement with limited scope. As a consequence the African Group took over the leadership for provider countries. By contrast, the solidarity of provider countries – irrespective of their biotechnological sector – stood firm at the TRIPS Council in which in particular Brazil and India raised their voice for supplier countries.¹⁷⁴

NGO groups that lobby for affected actors on the supply-side are mainly from the development and environmental sector. These encompass, for example, the CBD Alliance, CIEL, FoE, Global Forest Coalition, GRAIN, Greenpeace and the World Wide Fund for Nature (WWF).

User countries generally oppose the restriction of access to genetic resources. First, genetic resources are considered to be part of a common heritage of humankind and should therefore be treated as openly accessible resources. This approach of a global genetic commons was widely accepted and formally recognized in FAO's International Undertaking on Plant Genetic Resources (FAO 1983: Art. 1). The seed industry has argued that it is valid to distinguish between raw germplasm that is part of a global common heritage and researched germplasm that can be subject to private ownership. The value of

¹⁷³ The only megadiverse countries missing in this group are Australia and the USA. The dominance of business interests in these two countries caused the governments to mainly represent the interests of users of genetic resources.

¹⁷⁴ Jungcurt 2008: 220; Sell 2003: 144-145; Wallbott et al. 2014: 43 citing Ernst & Young 2011.

raw germplasm is inferior because it requires scientific analysis to explore if and what genes of a germplasm can be utilized for the development of new products (Kloppenborg/Lee Kleinman 1987: 27-28). The CBD turned away from FAO's understanding by recognizing countries' sovereign ownership over their genetic resources. This followed pressures by developing countries as the scope of IPRs increasingly expanded to cover also seeds and isolated genes (Safrin 2004: 644-649; Victor et al. 1998).

Second, a rigid ABS system is argued to impede innovation. The costs that come with ABS make R&D of new products based on genetic resources no longer profitable. It is estimated that the development of a new drug costs about \$500 million and it takes about 15 years for the drug to enter the market. At the same time, the chance that a component found in a genetic resource can be further developed into a commercial drug is below 0.001% (Richerzhagen 2010: 27). High payments for the usage of certain genetic resources prior to knowing their research potential make investments for companies very risky. A restrictive access regime with consent and benefit-sharing requirements can create a "tragedy of the anticommons" in which actors can block the entry to a given resource and "in so doing waste the resource by its underconsumption compared with a social optimum" (Safrin 2004: 652-654).

Against this background, provider countries have been accused of having unrealistic expectation of what can be gained from genetic resources since it requires considerable investment in R&D to add the decisive commercial value to genetic resources (Rosendal 2006: 438-439). By the same token, the biotechnological industry asserts that the importance of genetic resources have diminished in the light of new technologies to develop products (Richerzhagen 2010: 36).

Fourth, ABS application and implementation creates several technical difficulties. Often the country of origin cannot be determined unambiguously. A famous case is the flower Rosy Periwinkle that has successfully been used as cancer-fighting medicine (Hodgkin's disease and leukaemia). The plant is native to Madagascar but can also be found in Jamaica (Rosendal 2006: 431). Therefore, most developed countries have objected a mandatory disclosure of the source or country of origin and prior informed consent as part of patent applications (Oberthür/Pozarowska 2013: 111). The inclusion of such requirements in a patent application can also open the doors for developing countries to block patents in order to impede the research with or manufacturing of otherwise patented goods within their borders (Safrin 2004: 667-668). By the same token, the cross-border movement of plant genetic resources cannot be effectively controlled. This would require the monitoring of every plant that is brought abroad (Safrin 2004: 665).

With regard to the scope of an ABS regime, user countries rejected the inclusion of products and derivatives of genetic resources in the CBD framework. Instead they considered them to fall under responsibility of the WTO. The term 'derivative' entered the Nagoya Protocol, but its meaning and implications remain vague (Aubertin/Filoché 2011: 55, 59; Oberthür/Rosendal 2014: 7).

As to ABS's institutional architecture, most Northern countries believe that existing international and national instruments are sufficient. In accordance with Article 15(1) of the CBD, the regulation of access to genetic resources is under the authority of sovereign states so that the implementation of ABS standards should be left to states' discretion. Adequate national ABS regimes are already in place according to IP supporters (Aubertin/Filoché 2011: 54-55; Jungcurt 2008: 221). The introduction of ABS standards into the international patent system has been rejected as violation of the legitimate exemptions to patents as provided in Article 27 of TRIPS and the patent procedures as required according to Article 62 of TRIPS. Among IP supporters, the USA, Japan, and South Korea have strongly opposed TRIPS amendments. At the CBD, Japan and South Korea supported by Australia, Canada, the EU, and New Zealand delayed negotiations on the ABS protocol (Jungcurt 2008: 220-221) and considered patent requirements to be exclusively inside WIPO's and the WTO's remit (Oberthür/Pozarowska 2013: 111).

Mostly affected IP supporters are in particular *countries* with research- and development-intensive industries. To limit this group, I use data on the PCT applications for biotechnological products as provided by the OECD iLibrary.¹⁷⁵ The countries are ranked in accordance with applicant(s)'s country(ies) of residence and priority date based on their average ranking between 1990 and 2010. I include all countries with an at least 3% proportion of biotechnological patent applications worldwide as this represents a cutting point in the data. Most PCT applications for biotechnological products were issued by residents from France, Germany, Japan, South Korea, U.K., and the USA. In 2010, 39.6% of biotechnological PCT patent applications were filed by U.S., 26.1% by EU, 12.1% by Japanese, and 4.3% by South Korean citizens. Within the EU, Germany (6.3%) ranks highest, followed by France (4.8%) and the U.K. (3.5%).

The USA is the by far mostly affected user country. U.S. companies are estimated to hold a share of 78% of global revenues in the biotechnology market. At the same time, ten companies are believed to make up 80% of the biotechnological market (Richerzhagen 2010: 35). Most of them are located in the USA.

The EU has a rather ambivalent position on ABS. On the one hand, it generally supports ABS. It also acted as arbitrator in the negotiations of the Nagoya Protocol and proposed a compromise reconciling claims for an international and national solution (Aubertin/Filoché 2011: 54). On the other hand, it has often remained ambiguous concerning an ABS regime's scope and nature. One cause is the divergence of positions on ABS within the EU. While small EU countries have already ABS legislation in place, members with a large biotechnology sector – like Germany, France, and the U.K. – are still in the process of positioning themselves (Jungcurt 2008: 220-221).

¹⁷⁵ Available at: <http://www.oecd-ilibrary.org/> (Accessed 25 February 2012).

Affected *NSAs* are especially lobby groups that represent biotechnological companies.¹⁷⁶ These include, for example, the American Seed Trade Association (ASTA), the Biotechnology Industry Organization (BIO), and the International Chamber of Commerce (ICC).

The cross-border transfer of genetic resources requires international coordination. Most relevant for the discussion of ABS are the CBD, FAO, ITPGR, WIPO, and WTO – while the ITPGR was excluded from the analysis. In the area of genetic resources, Stefan Jungcurt differentiates between institutions that are rather supply-oriented and user-oriented. *Supply-oriented* are the CBD, FAO, and the ITPGR. They are concerned that suppliers of genetic resources get their share of the economic exploitation of genetic resources. *User-oriented* are UPOV, WIPO, and the WTO. They aim for strengthening the rights and protecting the benefits of users by promoting effective patent protection.¹⁷⁷ Therefore, great tension can be observed between the CBD and WTO. The conflict between the biodiversity and IP regime was anticipated and legally reinforced with Article 16(5) of the CBD Convention explicitly stating that IP-related law should “not run counter to its objectives”. Interestingly, the explicit reference to IPRs was eschewed in the Nagoya Protocol (CBD 2010g: Art. 4). FAO has originally been the main forum to debate issues relating to plant genetic resources. It lost its importance after the successful conclusion of the ITPGR that created a new platform for negotiations. Concomitantly, the WTO has become more relevant with IP skeptics shifting ABS issues to this forum. Indigenous communities are in general critical of ABS as it will be discussed in the following.

6.3.3 Traditional Knowledge – A Western Mode of Protection for a Non-Commercial Property?

Closely related to the debate on ABS is the protection of TK. There is no consensus on the meaning of TK. Even accords that mention the term carefully avoid a definition.¹⁷⁸ WIPO suggested that TK may be considered as

- “knowledge, know how, skills, innovations or practices;
- that are passed between generations;
- in a traditional context; and
- that form part of the traditional lifestyle of indigenous and local communities who act as their guardian or custodian.”¹⁷⁹

¹⁷⁶ The most successful biotechnological companies are Novo Nordisk, Amgen, and Gilead Sciences according to a ranking based on companies’ market capitalization at the end of the second quarter in 2012. In the top 25 are 15 U.S. and 8 European companies. Available at: <http://www.genengnews.com/insight-and-intelligence/top-25-biotech-companies/77899671/> (Accessed 3 January 2014).

¹⁷⁷ Jungcurt 2011: 171-172; Jungcurt 2008: 107-108; Oberthür/Pozarowska 2013: 108.

¹⁷⁸ See for example the Nagoya Protocol and UNDRIP.

¹⁷⁹ Available at: <http://www.wipo.int/tk/en/resources/faqs.html#a2> (Accessed 15 February 2014).

TK can be passed down both in codified and oral form (CBD 2009b: 10). In brief, Gurdial S. Nijar defines TK as a “system of self-management governing resource use which is embedded in the social and cultural practices of the community” (Nijar 2010: 462).

In particular the pharmaceutical industry heavily relies on TK to exploit plants’ economic potential (Oldham et al. 2013: 5-6). TK’s use to identify promising material is said to increase the “efficiency of screening plants for medicinal properties” that can be transformed into commercial products by more than 400% and the chance for successful drug development at the lead discovery stage by 50%. “The current value of the world market for medicinal plants derived from such leads is estimated at US \$43 billion” (Nijar 2010: 458-459).

While the industry considers the search and exploitation of genetic resources as legitimate means to develop new products, TK holders often feel betrayed and robbed of their cultural heritage. What the industry regards as bioprospecting, is experienced as biopiracy in the eyes of indigenous and local communities. *Biopiracy* refers to the misappropriation of biological resources and information by unauthorized parties in order to use them for the development of commercial products that are eventually brought under IP ownership. Others bluntly call it “a con-temporary version of Third-World plundering” (Aubertin/Filoché 2011: 52). There are prominent instances in which patents were granted without or little modification. One notorious example is the turmeric case. After the USPTO granted two U.S. researchers of the University of Mississippi Medical Centre a patent for the use of turmeric in wound healing, the India’s Council of Scientific and Industrial Research successfully filed a suit against the patent on the grounds that the patented information has been commonly known TK for generations in India (Verma 2004: 129). In the wake of such cases, a debate has been sparked on TK’s position within the ABS system and its legal protection.

TK holders demand that the general ABS principles should be applied to TK’s access and use. First, the acquisition and usage of TK should depend on the prior informed consent of the relevant indigenous and local communities. Although TK is often part of public knowledge, “it is not simply an open-access resource” (Munzer/Raustiala 2009: 54). Where national ABS laws are already in place, they typically require the involvement and/or approval of indigenous and local communities to obtain access to genetic resources on the territory they inhabit. Some countries demand the prior informed consent of indigenous and locals that cannot be vetoed by the state (for example Costa Rica, Pakistan, and South Africa). In other countries, the final decision rests with the state although indigenous and local communities have to be consulted (for example Guyana and India) or give their explicit consent (for example Bhutan and Brazil) (Nijar 2010: 465-466, 471). In any case, the ownership rights of genetic resources usually remain with the state as indigenous communities often lack land rights.

Second, rules that regulate TK holders' remuneration and share of the benefits, which result from the products that are developed on the basis of their TK, have to be established in advance. Indigenous and local communities contribute with their traditional practices and knowledge to the conservation and sustainable use of the ecosystem. Without indigenous peoples' awareness of the sustaining functions of an ecosystem's individual components and their respect therefor, many genetic resources would no longer be available today (CBD 2010h). It is no incident that regions of high biodiversity and large number of indigenous peoples significantly overlap. It is not only the mere existence of genetic resources for which indigenous groups should be rewarded. Also their knowledge of genetic resources is of continuing importance to the industry to detect relevant research material. Although scientific and technological methods of analysis have been considerably advanced, science still depends on natural material for drug discovery. The industry has been re-engineering old products and obtained new patents for more or less modified versions of naturally occurring matters. Frequently, these well-tried substances have been (in)directly related to TK (Dutfield 2012: 96-100). An UNDP study estimates that developing countries are annually deprived of over \$5 billion of unpaid royalties for medicinal plants based on a 2% royalty for material and knowledge transfer (Crookshanks/Phillips 2012: 89). In many countries, indigenous and local communities are entitled to benefit-sharing of their genetic resources and associated TK (Nijar 2010: 466).¹⁸⁰

In order to strengthen the application of ABS principles to TK, it should be enforced within an international legal framework. The Nagoya Protocol leaves this "subject to national legislation". This is in tradition with Article 8(j) of the CBD Convention (Aubertin/Filoche 2011: 61). A few authors suggest that prior informed consent for access to TK associated with genetic resources is already part of an emerging customary IL. Nijar observes evidence of *opinio juris* in the CBD and UN Declaration on the Rights of Indigenous Peoples (UNDRIP) and refers to the widespread state practice of establishing national ABS regimes with requirements to involve indigenous groups in the process of approving access to genetic resources (Nijar 2010: 460-461).¹⁸¹ Even if this case can be made, central monitoring and sanction mechanism to enforce these rights are missing. In the end, not all indigenous groups are interested in monetary benefits but merely want to protect their cultural heritage.

There is no consensus among TK holders on how TK has to be protected. Some consider the IP system as an appropriate means to ensure the rights of indigenous and local communities because the IP system is vested with strong enforcement mechanisms. Certain revisions and additions to the patenting process would assist in preventing erroneous patents.

¹⁸⁰ These include, for instance, Australia, Bangladesh, Bolivia, Brazil, Ethiopia, India, Pakistan, the Philippines, Sabah, South Africa, Uganda, and Vanuatu (Nijar 2010: 466).

¹⁸¹ Also Agenda 21 (1993) recommends that governments "[a]dopt or strengthen appropriate policies and/or legal instruments that will protect indigenous intellectual and cultural property and the right to preserve customary and administrative systems and practice" (Art. 26(4b)).

First, TK's disclosure of origin as well as indigenous groups' prior informed consent should become mandatory requirements of patent applications if TK is used for the development of a product (Andana 2012: 554).

Second, the establishment of national and international TK databases would help patent offices to include TK in their search for prior art in patent applications. In this respect, a role model represents India's Traditional Knowledge Digital Library. It encompasses 34 million pages in five languages. These can be accessed by six major patent offices, like EPO and USPTO, which concluded access- and non-disclosure agreements to prevent the misuse of knowledge that was obtained through the database. WIPO considers internationalizing this project. Other examples are the Traditional Chinese Medicine Patent Database and the Venezuelan Biozula Database on crops and medicinal plants (Andana 2012: 553).¹⁸² One limitation of such databases is that often only the database itself but not its content is legally protected. This is, for example, the case within the EU (Andana 2012: 553).

Third, capacity building has to be offered to indigenous groups. As most of them belong to the world's poorest, they usually lack the financial means and legal expertise to go through the application process (Hamilton 2006).

Others call for a *sui generis* TK protection by emphasizing TK's distinctiveness and rejecting IPRs' economic and ideological mindset. For many indigenous and local communities TK and IP protection are irreconcilable concepts. While IPRs have originated from economic considerations, TK has grown in a cultural and non-profit context (Koopman 2005: 531). Traditional communities reject the commodification of life (Hamilton 2006: 173; Sarma/Barpujari 2012: 2). The conventional IP principle that information can be owned by one individual stands in stark contrast to the collective ownership of TK. TK's collective character also makes it difficult to identify an individual patentee (Andana 2012: 549-550). In consideration of the refusal to accept these Western capitalist standards, some indigenous groups discard ABS altogether because it imposes an economic framing on their knowledge (IPCB 2004).

A *sui generis* system can protect indigenous rights independent from traditional IPRs. The WIPO's IGC has already presented draft provisions in this regard. A foundation for such an instrument can also build UNDRIP, which was adopted by the General Assembly in 2007 (Andana 2012: 551-552). Article 31 stipulates that indigenous peoples have "the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions" (UN 2007).¹⁸³ States

¹⁸² In Venezuela, however, indigenous groups criticized that the state did not obtain their prior informed consent before gathering their TK.

¹⁸³ Further, Article 11(2) calls states to "provide redress through effective mechanisms [...] developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs" (UN 2007).

like Peru, the Philippines, and Thailand have already implemented national sui generis systems for indigenous peoples (Sarma/Barpujari 2012: 2).

In any event, TK should be protected by an international legally binding system. So far, there exists no international legal obligation to protect TK and respect the rights of traditional communities over their genetic resources. UNDRIP is non-binding and also WIPO's draft provisions are currently rather recommendatory in nature. The system should be of international scope since IP activities that affect TK usually operate transnationally. The enforcement of indigenous rights also requires credible monitoring and sanction mechanisms.

Mostly affected IP skeptics are obviously countries with large *indigenous communities*. There are around 300 million indigenous peoples according to World Bank estimates.¹⁸⁴ More than a third of them are believed to live each in China (106 million) and South Asia (95 million), around 10% in Southeast Asia, and 7% in Africa (World Bank 2010: 2). In the absence of a widely accepted definition of indigenous peoples, there exists no comparable quantitative data on the country level.¹⁸⁵ I confine the mostly affected indigenous-rich countries according to the figures of the IWGIA's¹⁸⁶ Indigenous World Report of 2013 (IWGIA 2013). The numbers are based on various sources, usually nationally censuses. In some countries, indigenous groups doubted the credibility of the numbers and usually estimated them to be higher. I consider the ten countries with the highest absolute numbers of indigenous peoples and the five countries with the largest relative proportion of indigenous population. I combine the two forms as they both are relevant for affectedness. As democratic representation ultimately refers to the individual, the absolute numbers are crucial. But since state borders are still important to define the responsible authority to represent indigenous concerns, also the relative proportion of indigenous people within a country cannot be neglected. I select ten and five countries respectively as they mark cutting points: above 1 million in absolute terms and above 40% in relative terms. Due to some overlaps in both rankings, 12 countries are considered for the analysis. The mostly affected indigenous-rich countries are Algeria, Bolivia, China, Guatemala, India, Indonesia, Malaysia, Mexico, Morocco, Nepal, the Philippines, and Vietnam. According to the IWGIA's Indigenous World Report of 2013, the most indigenous-rich countries in absolute terms are China (113.8 million), India (84.3 million), Indonesia (50-70 million), Malaysia (28.6 million), Mexico (15.7 million), Morocco (14.9 million), the Philippines (14.0 million), Vietnam (13 million), Nepal (12.9 million), and Algeria (11

¹⁸⁴ The International Fund for Agricultural Development (IFAD) estimates that there are more than 370 million of self-identified indigenous peoples. Similar to the World Bank, 70% of indigenous peoples are believed to live in Asia and the Pacific (IFAD 2010: 1)

¹⁸⁵ The World Bank only provides estimates for regions (World Bank 2010).

¹⁸⁶ IWGIA=International Work Group for Indigenous Affairs.

million). In relative terms, highest rank Bolivia (62%), Guatemala (60%), Morocco (28-70%), Nepal (42.9%), Algeria (33.3%), and Indonesia (23-32%) (IWGIA 2013).¹⁸⁷

Important *associations* representing indigenous peoples include the Aboriginal and Torres Strait Islander Commission (ATSIC), Amazon Conservation Team, Asia Indigenous Peoples Pact, Assembly of First Nations, Congress of Aboriginal Peoples, Coordinator of Indigenous Organizations of the Amazon River Basin (COICA), CIEL, Global Forest Coalition, Indigenous Peoples' Biodiversity Network (IPBN), Indigenous Peoples of Africa Co-ordinating Committee, International Fund for Agricultural Development (IFAD), International Indian Treaty Council, International Indigenous Forum on Biodiversity (IIFB), International Work Group for Indigenous Affairs (IWGIA), Foundation for Aboriginal and Islander Research Action (FAIRA), Russian Association of Indigenous People of the North (RAIPON), Saami Council, and the Working Group of Indigenous Minorities in Southern Africa (WIMSA).¹⁸⁸

TK users have pointed to the difficulties of applying ABS to TK. First, TK's relevance for a final product and therefore its economic worth are disputed. It is argued that TK only relates to components of an invention and cannot be commercialized and patented without companies' technological expertise and great financial investments (Koopman 2005: 527-528). Similar to the case of genetic resources, TK's potential is also more difficult to assess a priori than for tangible resources (Koopman 2005: 530).

Second, the original author often cannot be determined. Problems of identification arise from TK's long history and the transboundary nature of many traditional communities. A prominent example is Hoodia that was patented as weight loss drug. Hoodia's occurrence as well as the location of the indigenous San communities, which identified Hoodia's use as food and water substitute, cross the borders of Botswana, Namibia, and South Africa (Nijar 2010: 468-469). Which is the competent local or national authority that companies would have to address to obtain prior informed consent in this case? What would be the country of origin that has to be inserted in a patent application?

Third, it can be very challenging to extent conventional IP protection to TK (Munzer/Raustiala 2009). TK is frequently not publicly documented or officially registered. TK must be known so that indigenous peoples can assert IPRs and prevent the erroneous patenting of TK knowledge by the industry. In the absence of a central international TK database, patent offices are often not able to take into account TK when examining patent applications for prior art. Therefore, one cannot accuse patent offices of piracy in a strict

¹⁸⁷ Although these numbers serve as an appropriate yardstick, one has to act with caution concerning their exactness as they are mostly estimates and their issuing institutions had an interest to under- or overstate them.

¹⁸⁸ For more information see:

http://www.ruralpovertyportal.org/topic/indigenous_peoples_organizations/tags/indigenous_peoples (Accessed 5 January 2014).

sense since they do not consciously infringe on indigenous rights (Koopman 2005: 527, 529).

Furthermore, the patent criteria of novelty cannot be applied to TK. In contrast to industry's secret and competitive usage of information, TK has usually been publicly available as it has been handed down through many generations. Hence, it can be considered state of the art (Janewa 2011: 164-165). TK and its applications are "mostly not considered patentable inventions but unpatentable discoveries" (Koopman 2005: 527-528).

Fourth, TK's introduction into the patent system would run counter to the purpose and criteria of the traditional IP regime. Patent holders possess exclusive rights for their patents and therefore have no obligation to share benefits (Koopman 2005: 533). Likewise, a mandatory TK disclosure requirement in patent applications would place a disproportional burden on patentees. Instead of actively protecting TK via IPRs, safeguards outside the patent system should prevent the misappropriation of TK by IP holders or applicants (Brody 2010: 241-242; Curci 2009: 131-274). As to the legal form, TK users have supported voluntary guidelines to ensure sufficient flexibility. Especially the USA has been a great foot-dragger in the discussion of international TK protection at WIPO and the WTO (Janewa 2011: 173).

Mostly affected IP supporters are countries with a large pharmaceutical *industry* because of its great use of TK.¹⁸⁹ The stakes for this branch are high as they invest the highest proportion of their profits in R&D among all innovative sectors (Richerzhagen 2010: 25-28). Therefore, pharmaceutical industries are particularly interested in both open access to genetic resources and associated TK and the right to patent them. According to Pharma Exec's Industry Outlook 2011, the largest pharmaceutical companies by global sale of prescription drugs are Pfizer, Novartis, Sanofi-Aventis, Merck, Roche, GlaxoSmithKline, AstraZeneca, Johnson & Johnson, Eli Lilly, and Abbott. This top 10 accounts for \$352.5 in sales which is 59.4% of the total revenues of the top 50. Within the top 50, 17 companies are located in the USA, 10 in Japan, 4 in Germany and Switzerland each, and 3 in the U.K.. For IPRs, it is not only important where the products are manufactured but also where they are sold. In 2010, the largest market share of pharmaceuticals was in the USA with a portion of 42.3%, followed by Europe with 29.2%, and Japan with 10.8% (Cacciotti/Clinton 2011: 41-42). The mostly affected *states* among IP supporters are determined based on the average proportion of PCT applications for pharmaceutical products worldwide between 1990 and 2010 (OECD iLibrary).¹⁹⁰ Like for ABS, the data is ranked in accordance with applicant(s)'s country(ies) of residence and priority date. IP supporters encompass the six highest ranking countries as this number marks a cutting point. Most PCT applications for pharmaceutical patents were issued by residents from France, Germany, Japan, Switzerland, U.K., and the USA. Between 1999 and 2010, on average 42.3% of all patent applications filed under the PCT were issued by U.S. residents,

¹⁸⁹ It exists no general data on companies that make use of TK

¹⁹⁰ Available at: <http://www.oecd-ilibrary.org/> (Accessed 25 February 2012).

28.0% by European, 10% by Japanese, and 4.2% by Swiss citizens. Within the EU, the forerunners are Germany with 7.3%, the U.K. with 5% and France with 3.7%.

Important business *federations* are the International Pharmaceutical Federation (FIP), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and Pharmaceutical Research and Manufacturers of America (PhRMA).

Relevant *fora* with respect to the IP protection of TK are the CBD, FAO, WIPO, and WTO. Initially, the CBD was the main addressee of TK holders who had great hopes to enforce their demands in the negotiations of the ABS Protocol. In the late 1990s, TK holders shifted the debate to WIPO and the WTO in order to link the CBD obligations with the international IP regime.

6.3.4 IP Protection of Plant Varieties – Breeders’ versus Farmers’ Rights

Seeds have been described as the Earth’s fourth fundamental resource after soil, air, and water (Kloppenburg/Lee Kleinman 1987: 9). Their crucial value for feeding the world is undeniable and also their economic worth has increased in the last half of the century. The value of the global commercial seed market has constantly grown since the 1970s and was estimated at \$45 billion in 2012 by the International Seed Federation (ISF).¹⁹¹ The market value of agrochemicals was estimated at \$32.7 million in 2004. This market has experienced some turbulence with declining margins in the late 1990s after a period of stagnation before its value increased again in 2004 (UNCTAD 2006: 3).

Countries that depend on a viable agricultural sector are usually not the same countries that host the major seed industries. This led to a situation of diverging economic interests. In the light of the large benefits that can be reaped in the seed market, life science groups and their supporting industrialized countries have asserted strict and comprehensive IP ownership over new varieties of plants. On the contrary, agricultural developing countries have demanded flexibility in the protection of plant varieties to secure the livelihood of their peoples. Since then, the debate has centered on the appropriate form of plant protection and the rights that should be granted to farmers to use patented seeds.

TRIPS leaves it to the discretion of member states to protect plant varieties by a traditional patent regime, an “effective *sui generis* system”, or dual protection (WTO 1994d: Art. 27(3b)). Neither ‘plant variety’ nor ‘effective’ are defined by TRIPS. These general parameters leave room for contradictory interpretations. Conflicts have been reinforced by the contradictory regulations of TRIPS, UPOV, FAO, and the ITPGR. Patent holders consider the stringent UPOV model as the only effective *sui generis* system while farmers insist on their right to choose alternative forms.

¹⁹¹ Available at: http://www.worldseed.org/isf/seed_statistics.html and http://www.worldseed.org/cms/medias/file/ResourceCenter/SeedStatistics/Domestic_Market_Value_2012.pdf (Accessed 15 January 2014).

IP skeptics put forward manifold arguments against UPOV. First, the access to seeds is vital for food security. UPOV's strict rules endanger farmers' subsistence by curtailing the saving, reuse, and exchange of seeds. This destroys the traditional exchange of propagating material between farmers. Not only farmers but large parts of a country can depend on the informal seed sector and farmers' right to sell seeds. In India, farmers supply 85% of the country's annual need of seeds. If their work would be taken over by large life science corporations, many farmers could not afford the commercial seeds. The subsequent implications for food availability and prices could be disastrous with the potential to threaten the country's national security (Sahai 2002: 216-217). It is, therefore, no coincidence that the agricultural sector plays a minor role in most economies of UPOV members. Among its early members, most had a less than 5% employment rate in agriculture. Developed countries in which agriculture makes up an important share of the economy, like Canada and New Zealand, are still members to the 1979 UPOV Act that is more farmer-friendly (Basso/Beas Rodrigues 2007: 203). In addition to that, major U.S. seed companies have circumvented the already confined farmer's privilege under UPOV by so-called bag-tag or seed-wrap licenses that require farmers to buy new seeds on an annual basis (Basso/Beas Rodrigues 2007: 202). This measure has often been buttressed by the so-called 'genetic use restriction technology' (GURT) or 'terminator technology'. GURT develops 'suicide seeds' that prevent farmers to save seeds from the harvest to sow the next crop.

By contrast, the strengthening of plant breeders' rights has not led to a general increase in R&D in new plant varieties. Private and public investment is concentrated on commercial crops. Even in cases in which public research centers worked on public-oriented plant breeding, the institutions faced difficulties to make effective use of IPRs. Since they lacked economic and legal expertise, they could not guarantee that their results can be freely accessed and distributed (Basso/Beas Rodrigues 2007: 205-206). Also the higher productivity of new genetically modified crop varieties could not fight domestic hunger. Brazil increased its productivity of basic crop varieties at a rate of 20% from 1970 to 1985. While this led to a growth of export-sown crops between 119% and 1,112%, over 50 million Brazilians are still undernourished (Basso/Beas Rodrigues 2007: 206).

Second, negative environmental effects can be expected from UPOV. Examples are the loss of genetic diversity and GMOs' noxious effects (Basso/Beas Rodrigues 2007: 171). The replacement of genetic diversity with monocultures creates imbalances in the ecosystem and usually requires a greater use of chemicals. In South East Asia, only a dozen of formerly over 30,000 varieties of rice are still cultivated. In the USA, 96% of peas are produced by only two varieties (Basso/Beas Rodrigues 2007: 207). The largest part of the world's population depends on just ten staple food crops for their food security: maize, rice, wheat, potato, soybeans, cassava, sweet potato, sorghum, yams, and plantain (Oldham et al. 2013: 8). The Green Revolution also illustrates the environmental damages that come

with monocropping. Its high reliance on chemical fertilizers and pesticides led to an enormous pollution of ground and tap water (Sreedharan 2011: 127).

Third, IPRs create incentives for businesses to act in a way that is detrimental to a competitive market system. 76% of patents in plant-based biotechnology are granted to the private sector in the USA (Atkinson et al. 2003: 174) while three quarters of the privately held patents belong to only five companies that are Pharmacia, DuPont, Syngenta, Dow, and Bayer (Kloppenburger 2004: 328-329). The patent system was one cause for extreme merges and acquisitions in the agriculture sector. For example, a direct relationship between the first wave of merges (1978-1980) and the strengthening of the U.S. Plant Variety Protection Act was observed (Cullet et al. 2006: 147). Several reasons explain IPRs' restructuring effects of the seed market. Life science groups have bought other firms to obtain their patents in order to pace down or block other competitors. With an increasingly diverse repertoire of patents, companies also expand their technological know-how and legal rights to use it for further research and product development. Besides patents' substance, the sheer quantity of patents can be helpful. It increases a company's leverage if it infringes – incidentally or deliberately – on other IPRs as the probability is high that also the other party made unauthorized use of a patent that is, in turn, held by the accused firm (Cullet et al. 2006: 149-151). These contractual practices have reduced competition in the seed market to the detriment of public interest.

Fourth, farmers' traditional work should not be restricted by excessive breeders' rights. Instead farmers' contribution to agro-biodiversity and the development of new breeders has to be acknowledged. The famous plant breeder Norman Simmonds concludes that

“probably, the total genetic change achieved by farmers over the millennia was far greater than that achieved by the last hundred or two years of more systematic science-based effort” (Kloppenburger/Lee Kleinman 1987: 28).

Therefore, farmers' rights, which go beyond the exemptions of breeders' rights, have to be recognized. The concept of farmers' rights was developed by Pat Mooney of RAFL. It was introduced in the FAO negotiations during the seed wars of the 1980s and was eventually recognized in FAO's International Undertaking on Plant Genetic Resources. It was later incorporated into the CBD Convention and the ITPGR (Sell 2003: 144; Singh/Manchikanti 2011: 109). The ITPGR, for instance, stipulates that farmers – either individual or collectively – should be entitled to benefit-sharing if their seeds were used as the foundation to breed new varieties (FAO 2001: Art. 9(3ii)).

Eventually, some opponents of UPOV consider the patentability of plants as a first step to accept the patentability of life in general.

Consequently, sui generis systems are more suitable for developing countries in which a great share of population depends on agriculture. These countries require a protection system that balances the interests of all stakeholders, is tailored to their local needs, and allows for different levels of protection. So should fundamental food crops not be subject to strong IP protection to ensure national food security. More commercial crops, especially

those that are predominantly produced for export, require stronger breeders' rights and the limitation of the farmer's privilege (Basso/Beas Rodrigues 2007: 207-208). One example for a balanced *sui generis* system is the 2001 Indian Protection of Plant Varieties and Farmers Rights Act that recognizes both commercial breeders' and farmers' rights. It allows the latter to save, sow and sell – even protected – seeds (Kochupillai 2011: 89). Also most members of the Association of South East Asian Nations (ASEAN) adopted *sui generis* systems for plant protection in which they incorporated elements of farmers' rights and ABS (Kanniah/Antons 2012: 5-6; Kochupillai 2011: 114). With a view to UPOV's possible harmful effects on human development, the UNDP advised developing countries to make full use of TRIPS flexibilities and adopt a balanced *sui generis* system (Kanniah/Antons 2012: 2). However, the majority of developing countries has not made full use of flexibilities allowed under Article 27(3) of TRIPS. Only 3% (2 countries) prohibit the patentability for all flora and fauna as existing in nature, 24% (16 countries) provide specific exclusion for all plants and animals, and 44% (29 countries) for the specific exclusion of plant and animal varieties (Thorpe 2002: 18). The reason can frequently be found in TRIPS-Plus agreements.

Mostly affected countries among *IP skeptics* are those that highly depend on agriculture. These are notably African countries and to a lower extent the regions of Southeast and South Asia. *IP skeptics* are identified by means of World Bank data on countries' percentage of employment in agriculture.¹⁹² An average is built for the period from 1990 to 2010. Agricultural states encompass all countries in which more than two-thirds of the population are employed in agriculture. These are Burundi (92.2%), Burkina Faso (86.2%), Cambodia (73.4%), Chad (83%), Ethiopia (83.6%), Guinea (76%), Laos (85.4%), Madagascar (79.2%), Myanmar (67.1%), Mozambique (80.5%), Nepal (74.3%), Papua New Guinea (72.3%), Rwanda (78.8%), Sierra Leone (67.9%), Tanzania (80.9%), and Uganda (67.8%). *NGOs* include, for example, the Association for Plant Breeding for the Benefit of Society (APBREBES), ETC/RAFI, GeneCampaign, TWN, Via Campesina, and various national farmers' unions.

IP supporters advocate UPOV as the only effective IP protection of plants. UPOV is essential to secure continuing investment in the improvement of plant varieties. Otherwise such ventures would not be profitable because free-riding on advanced seeds is easy feasible due their self-replicating nature (Helfer/Austin 2011: 380-381). Evidence for this assumption is provided by Deepthi E. Kolady and William Lesser who examined the effect of the U.S. plant variety protection on crop productivity by analyzing wheat varieties in Washington State. It is shown that the introduction of plant variety protection sparked private investment in open pollinated crops that led to higher yielding varieties from both

¹⁹² Available at: <http://data.worldbank.org/indicator/AG.LND.AGRI.ZS/countries?display=default> (Accessed 25 February 2012).

the private and public sector (Kolady/Lesser 2009: 148).¹⁹³ Also an UPOV study based on individual country reports draws the conclusion that the implementation of UPOV leads to the development of new and improved plant varieties (Jördens/Button 2011:82-83). Therefore, a strict IP protection of plants is not a danger to food security but its remedy. In contrast to conventional breeding, genetic engineering of plants can increase production rates and create crops that are less susceptible to diseases, pests, and abiotic stresses such as drought.

Second, a strong protection of breeders' rights is beneficial for international trade and countries' access to improved varieties. Only if breeders consider their invention to be appropriately protected in a foreign country, they are willing to transfer it abroad. The free flow of germplasm is beneficial for domestic farmers who can make use of a greater variety of plants. It also spurs agricultural progress because the access to foreign-bred varieties broadens the basis on which plant varieties can be advanced (Jördens/Button 2011: 79). By harmonizing plant protection, UPOV creates an international market that stimulates competition between companies to improve breeds (Jördens/Button 2011: 83).

The *mostly affected IP supporters* of a strict patent regime on plants are countries with large agrochemical and seed industries. Both are dominated by the same few multinational companies. Since the mid-1970s, large U.S. agrochemical and pharmaceutical companies have transformed into life science groups and expanded their activities to the seed business and plant biotechnology to overcome declining returns in the agrochemical sale (UNCTAD 2006: 7). The consolidation of the agribusiness was supported by extensive company merges and acquisitions as well as collusive practices (UNCTAD 2006: iv). In the agrochemical industry, two-thirds of the market share was held by only six companies in 2004. These were Bayer (19%), Syngenta (18%), BASF (13%), Dow (10%), Monsanto (10%), and DuPont (7%) (UNCTAD 2006: 3). In the same year, the four largest seed companies – DuPont/Pioneer, Monsanto, Syngenta, and Limagrain – held an almost 30% share of the global market (UNCTAD 2006: 8-9).

States that act as IP supporters are localized by seed patent applications filed under the UPOV system (UPOV 2011b). The data is ranked according to applicant(s)'s country(ies) of residence for the year 2010. In order to include the host countries of the main large life science groups, I consider all countries in which the residents make up of at least 3% of all applicants who filed seed titles with UPOV. These are China, Germany, France, Japan, Korea, Netherlands, Russia, Switzerland, Ukraine, and the USA. Most applications were filed by EU residents with a total number of 5,528 accounting for 42.6% of the total amount in 2010. Among EU countries, most applications were filed by Dutch (11.1%), followed by Germans (4.4%) and French (3.1%). Internationally, second ranks the USA (13.5%), followed by China (8.5%), Japan (7.3%), Russia (4.1%), and South Korea (4.0%) (UPOV 2011b). The rankings for applications filed and titles issued are similar.

¹⁹³ For a detailed overview of the U.S. IP system of plant protection, see Strachan 2011.

Lobby groups encompass, for example, the Association of European Horticultural Breeders (AHOE), ASTA, European Seed Association (ESA), International Association of Plant Breeders for the Protection of Plants Varieties (ASSINSEL), International Association for the Protection of Industrial Property (AIPPI), International Community of Breeders of Asexually Reproduced Ornamental Varieties (CIOPORA), ISF, and Croplife International. The latter represents seven of the most influential companies: BASF, BayerCropScience, Dow AgroScience, DuPont, FMC¹⁹⁴, Monsanto, Sumitomo, and Syngenta.¹⁹⁵

The protection of plant varieties has been mainly regulated in the *fora* of FAO, ITPGR (excluded here), UPOV, and WTO. While FAO was originally used as the main forum for this issue area, IP supporters gradually expanded the debate to UPOV and the WTO both of which are favorable to business interests.

6.3.5 Public Health and IP – Economic versus Public Interests

The right to health has become a fundamental right. The International Covenant on Economic, Social and Cultural Rights recognizes the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health” (UN 1966: Art. 12(1)). Essential medicine, as defined by the WHO Action Programme on Essential Drugs, has to be accessible to everyone in sufficient quantity and good quality as later specified by the Committee on Economic, Social and Cultural Rights (CESCR) (Micara 2012: 86). In this framework, economic interests do not justify to withhold lifesaving drugs from ill individuals. On the other hand, high-quality drugs are the result of long and cost-intensive research. Companies, in return, demand the monopoly to commercially exploit their medicinal inventions through patent protection to recoup their research costs. This constellation has caused an ostensible trade-off between medical innovation and access to medicine, in particular in most developing countries that cannot afford patented drugs.

The debate was intensified with the upsurge of HIV/AIDS epidemics in Southern countries such as Brazil, Thailand, and South Africa since the late 1990s (Muzaka 2009: 1344). These countries have licensed the production of generics to enable their population access to affordable medicine at the expense of restricting patent owners’ rights and economic benefits.¹⁹⁶

¹⁹⁴ Formerly: Food Machinery and Chemical Corporation.

¹⁹⁵ Available at: http://www.croplife.org/our_members (Accessed 15 January 2014).

¹⁹⁶ Public attention gained momentum in the late 1990s. A group of 39 global pharmaceutical companies filed a lawsuit against the South African government on the South African Medicines Act before the country’s high court in 1997. The Medicines Act allows the minister of health to grant compulsory licensing if she considers public health to be at stake (Matthews 2006: 20-21). As a response to growing public scrutiny, the USA halted its protests against the South African Medicines Act and removed South Africa from the USTR 301 watch list in 1999. Also the lawsuit against the South African government was dropped in 2001. In the same year, the USA also withdrew its claim against Brazil on compulsory licensing before the WTO (Morin/Gold 2010: 572; Sell/Prakash 2004: 166).

I focus on access to HIV/AIDS medicine in the further empirical analysis of public health and IP. This issue suggests itself for the discussion in several respects. First, HIV/AIDS is of global reach and therefore affects – although to different extents – almost every country on this planet. 35.3 million people were estimated to live with HIV worldwide by the end of 2012. Second, there are medicines, so-called antiretroviral drugs, which can considerably block the replication of HIV. In low- and middle-income countries, 61% of all persons that are eligible for HIV treatment under the 2010 WHO guidelines had received antiretroviral therapy in 2012. Under the revised 2013 WHO guidelines it was only a proportion of 34%. Third, most of these drugs have been under patent protection and pharmaceutical companies have sought their consequent enforcement (Helfer/Austin 2011: 91; UNAIDS 2013: 4, 46).

IP skeptics promote that public health should take priority over IPRs in cases of conflict. First of all, they accuse patents of skyrocketing drug prices. Since patent holders are granted exclusive rights of commercial exploitation, they can determine the price as they please. The pharmaceutical market is even described as a “form of price-fixing cartel” (Adusei 2011: 4). For example, the HIV drug Fluconazole cost \$703 pro 150 milligrams in Indonesia and \$817 in the Philippines in 2001, where it is patented, in comparison to only \$55 of the generic equivalent in India (ECOSOC 2001: 14). As a matter of fact, pharmaceutical companies bear the risks and costs involved in R&D. Nevertheless, they represented the most profitable industry sector in the USA from 1995 to 2002 (WHO 2006a: 18). To counter this trend, WHO’s CEWG recommended delinking the funding of R&D from the pricing of the end products so that drugs can be sold at marginal cost of production (Agitha 2013b: 591).

Second, WTO members frequently cannot make effective and full use of TRIPS flexibilities. This concerns first and foremost compulsory licensing and parallel imports. Public health advocates consider compulsory licensing as an indispensable means to supply countries that face health emergencies with life-saving drugs. Crucial medicine, such as antiretroviral HIV medication, is out of reach for large parts of affected groups. States should have the right to secure public health by authorizing the production of generic versions of patented goods if the patent holder is not willing to negotiate an affordable price. The scope of diseases for which compulsory licensing is eligible should not be limited. Most developing countries and LDCs also highly depend on the import of generics. It is estimated that about 60 developing countries have no manufacturing capacities at all and many others can only produce drugs with ready-made active pharmaceutical components (Muzaka 2009: 1346). Countries with sufficient domestic manufacturing capacity are in a better position to negotiate with pharmaceutical companies because they can credibly threaten to implement compulsory licensing. For instance, Brazil could successfully reduce drug prices in some instances. In 2007, however, the country issued a compulsory license for Efavirenz, a patented drug by Merck, as the company

refused to sell the drug for a price in a similar range as offered to other countries with the Brazilian income level. Brazil's action mitigated the spread of HIV/AIDS (Zolotaryova 2008: 1110-1112). Brazil's handling of compulsory licensing was not willingly accepted by developed countries. The USA initiated a complaint with the WTO in 2000. The case USA vs. Brazil 'Measures Affecting Patent Production' (DS 199) was resolved by a mutually agreed solution in 2001 (Matthews 2006: 20-21).

Although the use of compulsory licensing is under confined circumstances formally recognized by the TRIPS Council, most affected countries have refrained from making use of these flexibilities. The procedure for compulsory licensing as stipulated by the TRIPS Council's 2003 waiver and 2005 amendment has been criticized for being too burdensome and complex. The first official notification under this new regime provides evidence. It was not before 2007 that Rwanda as the first country notified the WTO of its intent to import compulsory-licensed drugs from Canada. The procedure took almost 15 months before Rwanda received the first Canadian shipments. This is a very long period given that Rwanda faced a case of health emergency. Previously, the Médecins Sans Frontier (MSF) failed to use the mechanism to obtain HIV/AIDS medications from a Canadian company in 2004. Most developing countries have yet to ratify Article 31bis¹⁹⁷, but they have been concerned that they could violate TRIPS-Plus agreements or face other consequences. For example, the U.S. FTAs with Singapore, Australia, and Morocco clearly prohibit parallel imports.¹⁹⁸ Most developed countries would have preferred an authoritative interpretation of Article 30 of TRIPS that would have provided them with great leeway to export generics. This demand failed due to strong U.S. resistance (Muzaka 2009: 1347-1349). Most developed countries built in provisions on compulsory licenses in their IP regimes, but they have been hesitant to use them for pharmaceuticals. A notable exception is Canada which granted 613 licenses for the production or importation of drugs between 1969 and 1992 (Dutfield 2008: 111-112). The country, however, changed its approach to compulsory licensing as a condition of joining the North American Free Trade Agreement (NAFTA) (Love 2002: 75).¹⁹⁹

Similarly, Article 39(3) of TRIPS allows members to disclose secret test data on pharmaceuticals. Nevertheless, developing countries have been pressured to guarantee data exclusivity to pharmaceutical companies. If clinical data trials are not accessible for generic companies that seek market approval for bio-equivalents of the patented drug, the

¹⁹⁷ As described in the section on the WTO regulation, Article 31bis formally allows a country that lacks manufacturing capacity to grant a compulsory license to import drugs and vice versa, a country to export drugs to a country that issued a compulsory license.

¹⁹⁸ Abbott/Reichman 2007: 921; Anderson 2010: 174-175; Lalitha 2008: 411-412; Muzaka 2009: 1355-1357.

¹⁹⁹ Before, Canada was a forerunner in using TRIPS flexibilities to produce generics. With reference to Article 30 of TRIPS, Canadian IP law permitted companies to use patented pharmaceuticals for research and testing in order to develop generics and obtain marketing approval as well as to stockpile generics before the patent expiration in order to enable a speedy marketing of generics after the end of the patent's protection period. The case was brought before the WTO Dispute Settlement Body (DSB). In 2000, the DSB decided that only the regulatory review is consistent with TRIPS but outlawed stockpiling (Helfer/Austin 2011: 122). The WTO decision has been criticized for being narrow and advantaging private interests (Agitha 2013a: 188).

regulatory approval for generics is unnecessarily delayed as tests have to be repeated. This indirectly extends the duration of the patent holders' monopoly rights which prevents competition and keeps drugs' prices high (Agitha 2013a: 187).

Another barrier to access generics represent external transit controls. Shipments containing generics in transit to developing countries were seized by developed countries, most notably by the EU, on suspicion of transporting counterfeit products. The legal grounds for this form of external transit control have been contentious. In one case, the Dutch custom authorities stopped 17 shipments with the generic medicine Abacavir, which was funded by the international drug purchase facility UNITAID, although the drug's quality was pre-qualified by WHO. Such measures have jeopardized the sufficient supply with essential medicine (Micara 2012: 73, 87). Therefore, Brazil and India formally started WTO dispute settlement procedures against the EU in 2010. The parties reached a mutually agreed solution in 2011 (Mercurio 2012).

Considering that all transition periods for pharmaceuticals end in 2016, the access to affordable medicine might even aggravate (Agitha 2013a: 187). But the pressure on Southern countries to establish IP protection for pharmaceuticals has been enormous from the beginning. Most African LDCs provided for IP protection within the original transition period (1.1.2006) despite the latter's prolongation of additional ten years (Thorpe 2002: 11-13).

Third, IPRs have diverted R&D to diseases that mainly concern industrialized countries. As MSF describes the situation in their Access Campaign:

“While wealthy nations pursue drugs to treat baldness and obesity, depression in dogs, and erectile dysfunction, elsewhere millions are sick or dying from preventable or treatable infectious and parasitic diseases.”²⁰⁰

The cause is the 10/90 gap: Only 10% of worldwide R&D in the health sector address diseases that affect 90% of the worldwide population (MSF 2001: 10). So called type II and III diseases, which are incident in either substantial proportions or exclusively in poor and developing countries, are not sufficiently addressed by R&D.²⁰¹ India's case shows that the strengthening of the patent regime has not led to technology transfer, good quality FDI, and investment in R&D on the development of type-II and -III drugs. New FDI in India's pharmaceutical sector was to a large extent directed to expedite mergers, acquisitions, and takeovers of Indian firms in order to increase the parent company's control over the local market. Likewise, FDI focused on integrating Indian expertise and facilities into the parent company's infrastructure instead of developing drugs that address local needs. Even in-house R&D of pharmaceutical companies had a stronger focus on the Western than the domestic market (Abrol et al. 2011: 341-342, 353).

²⁰⁰ Available at: <http://www.msf.org/article/fighting-1090-gap> (Accessed 3 February 2014).

²⁰¹ The classification is set up by WHO. Type I diseases occur more or less equally both in poor and rich countries.

A related problem is patent evergreening in the pharmaceutical sector. Instead of engaging in cutting-edge drug innovation, pharmaceutical companies have focused on improving existing products. Frequently, only minor changes have been conducted. Critically speaking, one could also say that only cosmetic changes have been made in order to be able to renew a drug's patent. This fundamentally violates the logic of IPRs as the monopoly of exclusive rights is only granted and protected by the state in exchange of making the invention publicly available after the protection duration ended. If the patent criterion of novelty is not entirely met, IP protection becomes illegitimate.²⁰² This trend fundamentally contradicts the assertion that patents incentivize innovation.

The *affectedness* of IP *skeptics* that prioritize health over IP can be measured by their countries' HIV/AIDS prevalence. I identify the mostly affected IP skeptics based on the prevalence of HIV/AIDS among adults aged 15 to 49 as provided by the WHO Global Health Observatory Data. The data is ranked in accordance with the average percentage for the time period between 2001 and 2006. I include all countries with an HIV/AIDS prevalence of more than 10%. These include Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, and Zimbabwe. Mainly sub-Saharan African countries are affected. Over 20% of the population between 15 and 49 years in Botswana, Swaziland, and Lesotho were estimated to be infected by HIV/AIDS. In South Africa, Zimbabwe, Namibia, Zambia, Mozambique, and Malawi, around 10% to 17% were infected.²⁰³ Affected are also the producers of generics. I add India to this group due its key role as generics producer. The country has commonly been called the 'pharmacy' of the developing world. Its capacity was so strong that also all major drug procurement agencies like UNICEF, IDA²⁰⁴ and MSF, purchased their generics from India. The introduction of the Indian patent regime of pharmaceuticals in 2005 had therefore also implications beyond the country's borders (Agitha 2013a: 187; Anderson 2010: 171).

NGOs started to call attention to IP's health implications in the mid-1990s. These have been mainly development, social welfare, and human rights NGOs. As one of the first, the MSF started their Access to Medicines Campaign in 1999 – the year it was awarded the Nobel Peace Prize. The organization was supported by the UNDP, WHO, and World Bank. Oxfam's launched its 'Cut the Cost' campaign in 2001 (Matthews 2006: 8; Sell 2003: 149). Other prominent NGOs in this respect are Health Action International (HAI), Knowledge Ecological International (KEI; formerly: Consumer Project on Technology (CPTech), and the TWN (Matthews 2006: 7).

IP supporters and hence proponents of a strict pharmaceutical patent regime emphasize that patents incentivize and secure continuing R&D in the development and improvement of

²⁰² Agitha 2013a: 187; Chamas et al. 2011: 64; Lalitha 2008: 410.

²⁰³ Other countries that have often been mentioned in this respect are Brazil and Thailand. In comparison to others, AIDS/HIV prevalence in these two countries is quite low with 0.3% and 1.2% of the population infected.

²⁰⁴ IDA=World Bank's International Development Associations.

drugs. If states leave this fundamental research to the private sector, they have to grant monopoly rights to companies so that they can regain their investment costs. After the patent protection ends, other manufacturers are allowed to produce generics to the benefit of even larger parts of society. Only if companies can make full use of their IPRs in developing countries, they have incentives to invest in the R&D of diseases that mainly affect developing countries (Gervais 2007: 57).

Restrictions of patentees' rights have to be limited and well-constrained. Unequal IP protection can produce a collective action problem in which countries with a weaker IP regime profit from technological progress but impose the R&D costs on countries with stricter IP rules. Therefore, exceptions to a strict IP regulation undermine the rationale of IPRs and eventually endanger the global IP system (Gervais 2007: 57). Legitimate IP exemptions can be health emergencies that should be clearly predefined by a list with a limited number of diseases. These include illnesses of epidemic scope like HIV/AIDS, tuberculosis, and malaria (Muzaka 2009: 1350-1351).

If exceptions to patents are granted, they need to include several safeguards for patentees. The patent holder should give its consent and has to be adequately compensated. The procedure has to be transparent so that compliance with the patent regulations can be monitored. The amount of drugs that are produced under compulsory licensing must not exceed the required quantity. Goods in external transit should be controlled if there are reasons to believe that they transport counterfeited goods. The latter diminish the economic return for pharmaceutical companies if they enter non-authorized markets and entail health risks as they can be of poor quality. In order to avoid an overly slack handling of compulsory licensing, developed countries led by the USA supported a moratorium on breaches of Article 31(f) instead of a TRIPS amendment (Muzaka 2009: 1348). The EU sought for implementing safeguards similar to the EU market to prevent trade diversion and the re-importation of drugs produced under compulsory licensing. It rejected the doctrine of international exhaustion and instead lobbied for stronger enforcement mechanisms of patent holders' rights (Muzaka 2009: 1350). Business groups, like PHRMA and IFPMA, considered it as crucial to restrict the list of countries that are eligible to import medicine under compulsory licensing. In order to reach a compromise, 47 developed and high-income developing countries formally affirmed that they would not make use of compulsory licensing as importers and take measures to prevent trade diversion (Muzaka 2009: 1352-1353).

Pharmaceutical companies have also rejected the argument that high drug prices are the main cause of health emergencies. Compulsory licensing might reduce the patent costs but not the production costs and infrastructural problems of national health sectors (Gervais 2007: 56). A stringent IP protection of pharmaceuticals might even be the solution since it attracts FDI and foreign R&D for the benefit of the national health sector.

According to IP holders, TRIPS already provides for a good balance between the protection of IPRs and public health. Generous built-in flexibilities contain the scope of

patentable subject matters (WTO 1994d: Art. 27), exceptions to patent matters (WTO 1994d: Art. 30), provisions for compulsory licensing and parallel imports (WTO 1994d: Art. 6, 31), and protection of test data (WTO 1994d: Art. 39(3)). These offer developing countries sufficient policy options to limit possible negative side-effectives of a strong IP system and to reap IPRs' benefits at the same time (Gopalakrishnan 2008: 397).

Mostly affected IP supporters are pharmaceutical companies and countries that host them. These were already listed in the subsection on TK.

Relevant *fora* in this debate are WHO and the WTO. WHO and the WTO have almost acted as antagonists. WHO has supported the protection of public health while the WTO has insisted on the maintenance of a strong and consistent IP regime.

6.3.6 Summary – Diametrical Interests of the Mostly Affected Actors

As the discussion showed, the application of IPRs to genetic resources and pharmaceuticals has been fraught with irreconcilable differences in terms of economic-political views and empirical facts. The mostly affected actors in these issue areas are diverse and usually vested with asymmetrical power resources. The debates in all four issue areas are highly politicized. They deal with the distribution of great economic benefits. They also touch on fairness between the North and South. Northern countries might not always be legally liable but have been argued to possess a moral obligation to compensate and assist Southern countries. Most fundamentally, the debates in these areas are concerned with the conception and worth of life itself and the significance of economic interests in comparison to social, environmental, and human rights in international relations. It is this constellation that makes democratic participation crucial in these areas. Affectedness changes with the topic at hand. I use quantitative indicators as proxies to measure affectedness in each issue area as presented above. The following table summarizes the mostly affected actors who are grouped in IP skeptics and IP supporters.

Table 7: Mostly Affected Actors: IP Skeptics and IP Supporters

	IP skeptics	IP supporters
Strong ABS regime <u>Fora:</u> CBD, FAO, WIPO, WTO	<u>LLMC:</u> Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Mexico, Malaysia, Peru, Philippines, Venezuela, South Africa	<u>Biotechnological patent applications:</u> France, Germany, Japan, South Korea, U.K., USA
Protection of TK <u>Fora:</u> CBD, FAO, WIPO, WTO	<u>Indigenous-rich countries:</u> Algeria, Bolivia, China, Guatemala, India, Indonesia, Malaysia, Mexico, Morocco, Nepal, Philippines, Vietnam	<u>Pharmaceutical patent applications:</u> France, Germany, Japan, Switzerland, U.K., USA
IP protection of plant varieties <u>Fora:</u> FAO, UPOV, WTO	<u>Agricultural countries:</u> Burundi, Burkina Faso, Cambodia, Chad, Ethiopia, Guinea, Lesotho, Madagascar, Myanmar, Mozambique, Nepal, Papua New Guinea, Rwanda, Sierra Leone, Tanzania, Uganda	<u>Seed titles applications:</u> China, Germany, France, Japan, South Korea, Netherlands, Russia, Switzerland, Ukraine, USA
Public health and IP <u>Fora:</u> WHO, WTO	<u>HIV/AIDS prevalence:</u> Botswana, Laos, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, Zimbabwe & India as main <u>producer of generics</u>	<u>Pharmaceutical patent applications:</u> Germany, Japan, Switzerland, U.K., USA

Chapter 7

Empirical Analysis of Legalization across International Institutions – Selective Expansion with the Handbrake On

The area of biotechnology-related IPRs is excellent to explore international legalization's effects because institutions that vary on legalization's different dimensions operate in this field. The three legalization dimensions 'legality', 'formalization' and 'delegation' are systematically evaluated according to the operationalization presented in chapter 2. The degree of legalization is assessed by means of institutional acts including the founding accords, RoPs, treaties, and decisions. The evaluation shows that

- (1) there is variation of legalization across the institutions even though to a different extent and
- (2) certain (combinations of) institutional design features are very common

The presentation of each dimension proceeds from the lowest to the highest ranking institution. I do not differentiate between the four issue areas in the discussion.

7.1 Legality – Small Fortresses of Legal Force Surrounded by Vast Arrays of Purposive Acts

Legality's two main criteria are competence and intention. In order to create legal bindingness, an international institution must be vested with the formal capacity to adopt legal instruments and its members must express their intention to use this formal capacity in order to adopt a legally binding document. While the former criterion refers to an institution's formal powers, the latter informs about the de facto state behavior and policies. The normative force to take political action can furthermore be strengthened or weakened by policies' precision. As already laid down in the theoretical discussion in chapter 2, softening devices can influence policy's legal depth but are not an integral element to determine legality.

Legality is evaluated on the basis of a survey of the institutions' founding treaties and decisions concerning the four issue areas of biotechnology-related IPRs between 1990 and 2010.²⁰⁵ Only competent decision-making bodies are considered. Decisions of other (sub)bodies with no formal rulemaking power are per definitionem non-legally binding and would distort the results. Given the broad scope of some institutions, it is important to note that the legality of institutions' policies might be differently assessed for other issue areas. Legality is not clear-cut in many cases and therefore often subject to legal

²⁰⁵ In order to be included, a decision has to refer to intellectual property (rights) (including patents, protection of knowledge/invention/innovation, right over, (un)lawful appropriation of ...) and at least one of the four issue areas ABS, TK, protection of plant varieties, and public health and IP. The name 'World Intellectual Property Organization' (WIPO) alone is not sufficient for the decision to be considered. Also excluded are agreements that only deal with the cooperation between institutions.

interpretation. In order to do justice to what might be considered a bold endeavor to lawyers, I evaluate legality by means of the formal powers that are explicitly granted to the institutions and the policies' language.

All institutions were founded by legally binding instruments. In other words, the constituent documents were negotiated and adopted by state representatives with full powers. The founding members showed their consent to be bound by signature or exchange of instruments. Members were required to ratify the treaty or to accede to it.²⁰⁶ All of the founding treaties – with the exception of FAO's – were registered with the UN secretariat.²⁰⁷ Although all institutions are based on hard law treaties, the legal character of their policies varies considerably. All institutions conclude by far more legally non-binding than legally binding regulations. This comes as no surprise since treaties require several rounds of negotiations and the bulk of an institution's work is of administrative nature. Therefore, it is necessary to focus on the legal status of the key documents. For this reason, administrative, so-called household matters are excluded from the analysis of legality.

WHO, which was often said to be concerned with rather technical activities, represents a typical case of a *soft law* institution. This development was not predetermined by its Constitution as it explicitly permits hard law policies. The WHO Constitution lists as one of its function the proposal and adoption of conventions, agreements, regulations, and recommendations (WHO 1947: Art. 2(k), 23). In five areas, which are outlined in Article 21, the World Health Assembly (WHA) possesses even law-making power in accordance with Article 22. The regulations become binding on all members unless one notifies a rejection or reservation (WHO 1947). Only one of the issues under Article 21 is relevant for biotechnological IPRs. These are “standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce” (Art. 21(d)).²⁰⁸ But this option has not been used with regard to this subject matter so far. Granting the authority to adopt legally binding rules was one of the most controversially discussed topics among the founding fathers because some countries were eager to protect their state sovereignty (Lee 2009: 18). It is maybe owed to these concerns that Article 22 allows states to make a rejection or reservations to regulations within the scope of Article 21.

Despite the – even if limited – formal powers to adopt legally binding agreements, all of WHO's relevant policies concerning the four issue areas of biotechnological IPRs are

²⁰⁶ CBD 1992: Art. 33-36; FAO 1945a: Art. 21; UPOV 1991: Art. 37; WHO 1947: Art. 78-80; WIPO 1967: Art. 14-15; WTO 1994c: Art. 14.

²⁰⁷ CBD 1992: Art. 41; UPOV 1991: Art. 42; WHO 1947: Art. 81; WIPO 1967: Art. 20(4); WTO 1994c: Art. 16(6).

²⁰⁸ The other four issues are: “(a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; [...]; (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce” (WHO 1947: Art. 21).

legally non-binding. These include, for example, the Revised Drug Strategies of 1996 and 1999 (WHO 1999b; WHO 1996) and other resolutions like the “WHO medicines strategy” (WHO 2001e), “Scaling up the responses to HIV/AIDS” (WHO 2001d), “Strengthening Health Systems in Developing Countries” (WHO 2001c), “Ensuring Accessibility of Essential Medicines” (WHO 2002c), “Intellectual property rights, innovation and public health” (WHO 2003c), “Public health, innovation, essential health research and intellectual property rights” (WHO 2007e; WHO 2006d), “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property” (GSPA-PHI) (WHO 2008b), and “WHO’s role and responsibility in health research” (WHO 2010b).²⁰⁹

All in all, biotechnological IP-related policies center on data collection, guidelines, recommendations, evaluation, and the monitoring of one’s own and other institutions’ policies. The language remains hortatory and vague. As a general trend, members are not required but simply “urged” to act. As prominent examples, both the 1996 and 1999 Revised Drug Strategy “urge” members to “ensure equitable access to essential drugs” without mentioning any concrete measures or goals (WHO 1999b: para. 1(1); WHO 1996: para. 1(1)). By the same token, the GSPA-PHI already clarifies in advance that any reference to governments only indicates that members are “urged to take action” although it provides a timeframe with specific action to be taken (WHO 2008b: explanatory note). Symptomatic for the overall advisory and aspirational tone, the 1999 Revised Drug Strategy calls members to “explore and review their options [...] to safeguard access to essential drugs” and to “to encourage the pharmaceutical industry and the health community to establish an ethical code” (WHO 1999b: para. 1(3, 5)). Similarly, resolution WHA54.13 on “Strengthening health systems in developing countries” urges members “to make any effort to ensure that countries are not hindered in their efforts to utilize the options available to them under international agreements [...] in order to protect and advance the access to life-saving and essential medicine” (WHO 2001c: para. 3(5)). The international community and other multilateral institutions should consider IPRs’ public-health dimension but only “where appropriate” (WHO 2001c: para. 5(2)).

These policies do not insist on precise action or change of behavior but rely on members’ good will. At the same time, WHA resolutions’ scope is confined by emphasizing the need to abide by existing IL. It indirectly hints at TRIPS that apparently should be respected in case of conflict or doubt. This is characteristic for many other resolutions in which the WTO or TRIPS are addressed without directly naming them. Instead, it is referred to “international trade agreements” (WHO 2003c: para. 2(3); WHO 2001e: para. 2(4)) or only “international agreements” and “international law” (for example: WHO 2001e: para. 1(2)). In decision WHA64(10), the newly-established working group on

²⁰⁹ Others resolutions are WHA63.18 (WHO 2010a), WHA62.13 (WHO 2009a), WHA62.16 (WHO 2009c), WHA60.28 (WHO 2007c), WHA60.20 (WHO 2007a), WHA60.18 (WHO 2007d), WHA60.28 (WHO 2007c), WHA60.30 (WHO 2007e), WHA59.19 (WHO 2006b), WHA57.14 (WHO 2004a), WHA56.31 (WHO 2003a), WHA51.24 (WHO 1998a), and WHA50.20 (WHO 1997b).

“substandard/spurious/false-labelled/falsified/counterfeit medical products” is even explicitly requested to exclude “trade and intellectual property considerations” (WHO 2010d: para. 3). After the 2001 WTO Doha Declaration, WHA resolutions became slightly more precise. They make more often direct reference to TRIPS and specific action that is required to protect public health.²¹⁰ But concrete political steps are not demanded and action remains voluntary. This is indicated by formulations such as “to take into account” TRIPS flexibilities when new agreements are adopted (WHO 2004a: para. 2(6)). Although the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) did not have the mandate to negotiate a legally binding instrument, its normative force was further weakened by only calling WHO members to “consider the recommendations” of the CIPRH’s report (WHO 2006d: para. 2(2)). The IP area stands for a general soft law trend at WHO. In the few instances in which its members adopted legally binding policies, like for example the revised 2005 International Health Regulations or the Framework Convention on Tobacco Control, provisions remained vague (van de Pas/van Schaik 2014: 197). The ongoing negotiations on an R&D Treaty can potentially bring back some legal force to WHO, but the negotiations’ outcome has to be awaited.

Also the CBD is classified as a *soft law* institution although its institutional set-up was originally intended to embark on a hard law route (Harrop/Pritchard 2011; Helfer 2004: 32). The institution is based on a framework convention. It is legally binding but does not contain substantive commitments, policy targets, and timeframes. Action is frequently only called upon “as far as possible and as appropriate” (CBD 1992: Art. 5-12, 14) or in accordance with a country’s “particular conditions and capabilities” (CBD 1992: Art. 6). The only substantive obligation for members is the submission of national reports on the status of the CBD Convention’s implementation (CBD 1992: Art. 26; Harrop/Pritchard 2011: 476). Similar to WHO, the CBD regulations’ legal validity is constrained by highlighting members’ obligation to comply with existing international agreements (CBD 1992: Art. 16(3, 5), 22). The only exemptions are cases in which adherence to other IL “would cause a serious damage or threat to biological diversity” (CBD 1992: Art. 22(1)). A yardstick to identify when a state of sufficient ‘seriousness’ is reached is lacking so that this provision is of little practical relevance. The Nagoya Protocol, which again takes up this formulation, also clarifies that it does not “create a hierarchy between this Protocol and other international instruments” (CBD 2010g: Art. 4(1)).²¹¹ IPRs are stated to only “may” interfere with the CBD’s implementation.²¹² The implementation of the CBD and other international agreements relating to IPRs should be exercised in a mutually supportive way.

²¹⁰ WHO 2006d; WHO 2004a: para. 2(6); WHO 2003c: para. 1(2-3); WHO 2002c.

²¹¹ At the same time, the Nagoya Protocol lacked in clarity by stating that “nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements [...] provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol” (CBD 2010g: Art. 4(2)).

²¹² CBD 2000d: preamble; CBD 1998c: preamble; CBD 1996d: preamble.

But principles to regulate conflicts are not established.²¹³ Stuart R. Harrop and Diana J. Pritchard arrive at the conclusion that the CBD Convention's accomplishment is "little more than to allow nations to accept merely that there is an environmental concern that requires a global response" (Harrop/Pritchard 2011: 476).

The CBD's COP as the plenary body of all member states is authorized to formulate and adopt protocols as well as amendments and annexes to the CBD Convention and protocols (CBD 1992: Art. 23(4), 28, 29). Protocols are legally binding and typically specify the framework's regulations. Two protocols have been negotiated to date whereas only the 2010 Nagoya Protocol on Access and Benefit-Sharing is relevant for this study.²¹⁴ The Nagoya Protocol is coined as a "masterpiece of ambiguity" by the International Centre for Trade and Sustainable Development (ICTSD) (Crookshanks/Phillips 2012: 75).

Irrespective of COP decisions' formal legal significance²¹⁵, their language is very tentative and stresses their non-legally binding nature. The titles of the most relevant and well-known policies already advert to their voluntariness. These include the 2002 Bonn *Guidelines* on Access and Benefit Sharing (CBD 2002h), the 2004 Akwé: Kon *Guidelines* (CBD 2004c), and the 2010 Tkarihwaïé:ri *Code* (CBD 2010h). Their provisions further underline their legal non-bindingness.²¹⁶ Taking the example of the Bonn Guidelines, parties are "invite[d] [...] to use the Guidelines" (CBD 2002a: preamble). They "may serve as inputs" and are explicitly "voluntary" (CBD 2002a: Annex: I.A.1, 7). The introductory comments by the then Executive Secretary Hamdallah Zedan repeat that the Bonn Guidelines are not legally binding but at the same time tries to qualify their lack of legal weight:

"the fact that the Guidelines were adopted unanimously by some 180 countries gives them a clear and indisputable authority and provides welcome evidence of an international will to tackle difficult issues."²¹⁷

But "will" and the goal to address "difficult issues" do not set up specific policy targets the pursuit of which could compensate for legality. Similarly, the Akwé Guidelines' purpose is to provide "general advice" and "should be adapted to suit the appropriate circumstances of each development" (CBD 2004c: para. 2, 4). Also the Tkarihwaïé:ri Code is "intended to provide guidance" (CBD 2010h: para. 3) whereas most provisions add that certain action "should" be implemented. These outcomes are only consequential given the mandate of

²¹³ See for example: CBD 2010g: Art. 4(4); CBD 2002c: para. 1; CBD 1998b: para. 9; CBD 1996d: preamble.

²¹⁴ The Cartagena Protocol on Biosafety is less important for IPRs and therefore is not considered in the analysis.

²¹⁵ Brunnée characterizes of COPs' formal powers as a "grey zone" between legally binding and non-legally binding (Brunnée 2002: 32). COPs are described as "hybrids between issue-specific diplomatic conferences and the permanent plenary bodies of international organizations; they exercise their functions at the interface of the law of treaties and international institutional law" (Brunnée 2002: 16). This discussion is of minor importance here since the CBD COP decisions make very clear that they have usually not been adopted with the intention to create legal bindingness.

²¹⁶ Other legally non-binding decisions with relevance for biotechnological patents are: CBD 2010b; CBD 2010a; CBD 2008c; CBD 2006a; CBD 2006h; CBD 2006j; CBD 2006f; CBD 2004a; CBD 2002j; CBD 2002i; CBD 1998a; CBD 1996f.

²¹⁷ Available at: <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> (Accessed 3 February 2013).

the working groups that drafted these proposals. Their work was often explicitly of terminological, exploratory, and information-gathering nature and was intended as input for future negotiations on policies.²¹⁸ In general, “recommend”, “invite”, “encourage”, “may consider” are typical verbs chosen in numerous COP decisions.²¹⁹ In many instances debilitating qualifiers are used (Evanson Chege et al. 2010: 262). It is, for example, frequently stated that each party shall only take measures “as appropriate”.²²⁰

All in all, the CBD policies have yielded no significant legal obligations for its members despite its hard-law framework. The institution’s action pertinent to biotechnological patents have typically focused on information-gathering and sharing of best-practice – either by commissioning in-house studies and background documents on IPRs’ effect on ABS and TK²²¹ or “encouraging” and “inviting” governments and NSAs to submit case studies and other information on IPRs’ impact on the achievement of the CBD’s objectives²²². In addition to that, much effort has been spent on observing relevant activities in other IOs and coordinating the CBD’s work with these. These include, for example, FAO²²³, UPOV²²⁴, WIPO²²⁵, and the WTO²²⁶.

FAO’s legality is more ambivalent, but it has a greater tendency toward a *soft law* institution. On the one hand, its Constitution emphasizes its policies’ non-binding nature. It stipulates that FAO shall “recommend national and international action” (FAO 1945a: Art. 1(2)). The FAO Conference as plenary body may “make recommendations” by a two-thirds majority to members and associates “for consideration by them with a view to implementation by national action” (FAO 1945a: Art. 4(3)) or “make recommendations to any international organization regarding any matter pertaining to the purpose of the Organization” (FAO 1945a: Art. 4(4)). On the other hand, the FAO Constitution vests the Conference and the Council with the formal powers to approve conventions and agreements and submit them to its members. This also requires a two-thirds majority of

²¹⁸ This applies, for example, to the Panel of Experts on Access and Benefit-Sharing (CBD 1998a: para. 3) and the Ad Hoc Open-Ended Working Group on Access and Benefits-Sharing (CBD 2002a: para. 8; CBD 2000c: para. 11).

²¹⁹ For a few examples see: CBD 2008h: para. 13; CBD 1996e: para. 11; CBD 1994c: para. 5(4.1).

²²⁰ One typical example is the Nagoya Protocol. See Articles 5(2, 5), 6(2), 7, 11, 12(3), 14(3), 15(3), 16(1, 3), 17(1), 18(3), 19(1), 20(1), 21 (CBD 2010g).

²²¹ See for example: CBD 2010e: para. 6, 8; CBD 2008a: para. A.11; CBD 1996b: para. 10(a); CBD 1995d: para. 1.

²²² See for example: CBD 2010e: para. 4; CBD 2008f: para. 9; CBD 2006i: para. 3; CBD 1998c: para. 10, 15; CBD 1996d: para.1

²²³ CBD 2010j: para. 5; CBD 2008h: para. 11; CBD 2006g: para. 9; CBD 2004b: para. 5; CBD 2002b: para. 23-24; CBD 2002c: para. 7; CBD 2000a: para. 11-12, 20-22; CBD 2000c: para. A.8; CBD 1996b: para. 4; CBD 1996c: para. 7; CBD 1994b.

²²⁴ CBD 2004b: para. 5; CBD 2002b: para. 24.

²²⁵ CBD 2010e: para 10, 12; CBD 2008a: para. C.2; CBD 2008h: para. 10; CBD 2004b: para. 5; CBD 2002b: para. 24; CBD 2002f: para. 26, 31, 48; CBD 2002c: para. 35-39; CBD 2002a: Annex to Appendix: C.3-4, 8-12; CBD 2000d: para. 14; CBD 1998c: para.14-17; CBD 1996b: para. 4; CBD 1996d: para. 3.

²²⁶ CBD 2006g: para. 13; CBD 2004e: para. 4; CBD 2002c: para. 25-30; CBD 2002a: Annex to Appendix: D; CBD 2000d: 14; CBD 2000c: para. B.2-4; CBD 1998b: para. 9; CBD 1996b: para. 4; CBD 1996c: para. 8; CBD 1996d: para. 4; CBD 1995d.

votes cast. The content of such accords is kept open as they should concern “questions relating to food and agriculture” (FAO 1945a: Art. 14(1-2)). For a long time, FAO’s policies in the area of biotechnology-related IPRs remained legally non-binding with the 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture together with its 1991 Annex and the 1993 revision being the most prominent ones (FAO 1983). A large share of the political discussion on biotechnological patents went on at the Commission on Genetic Resources for Food and Agriculture (CGRFA) that had no formal powers to generate legal bindingness. The discussions at the Conference and Council only led to few and at the same time legally non-binding decisions like the 2009 resolution on ABS (FAO 2009b). One notable exception is the International Treaty on Plant Genetic Resources (ITPGR). It is one of 18 instances in which FAO made use of its legal powers under Article 14 of its Constitution to adopt a treaty. The ITPGR’s legal direction is difficult to judge based on its few years of existence. The ITPGR is legally binding with precise rules and processes that have contributed to the reduction of legal uncertainty in the field of plant genetic resources for food and agriculture (Jungcurt 2011:183).

WIPO is a hybrid *between a hard and soft law* institution with respect to the issue areas at hand. To be precise, WIPO serves as an umbrella organization for legally separate organizations. One of WIPO’s main functions is “to encourage the conclusion of international agreements designed to promote the protection of intellectual property” (WIPO 1967: Art. 4(iv)). The legal nature of such agreements is not specified. The 1970 Patent Cooperation Treaty (PCT) and the 2000 Patent Law Treaty (PLT) are legally binding. Both require ratification and were deposited with WIPO’s Director General (WIPO 2000: Art. 20, 27; WIPO 1970: Art. 62, 68). With the aim to harmonize patent applications across borders, both treaties regulate in detail the technical aspects of the patent process. The PCT prescribes precisely and comprehensively the requirements and steps of an international application ranging from the request to the publication (WIPO 1970). On the basis of the PCT, the PLT further harmonizes and facilitates the application procedures by clarifying topics like formal patent requirements and time limits.

Not only has WIPO shied away of stepping out of the technical-procedural administration of patents. It also took a soft law turn in the last decade (Hrbatá 2010: 22). An important example for this study is the Development Agenda of 2007 (WIPO 2007a). WIPO’s general soft law turn has been explained by its failure to agree on the Substantive Patent Law Treaty (SPLT) and the fact that other treaties, such as the both internet treaties – the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty – have not entered into force yet (Kwakwa 2006: 149-152). Also the work of the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) on the “Provisions for the Protection of Traditional Cultural Expressions and Traditional Knowledge” has been underway since a decade without tangible results to date. Although WIPO’s hard law framework and the legally binding PCT and PLT have to be

recognized, its policy output pertinent to biotechnological patents has been scarce and not legally binding.

UPOV represents a *hard law* institution. Although the UPOV Convention remains silent on its organs' formal powers, the treaty itself lays out detailed obligations that its members have to nationally implement and enforce. It clearly defines breeders' rights including their scope, duration, limited exceptions, and exhaustion (UPOV 1991: Art. 14-18). The conditions of protection are comprehensively explained in separate articles (UPOV 1991: Art. 5-9). UPOV's exactness continues with the elaboration of the application process such as the filing, right of priority, and examination (UPOV 1991: Art. 10-12). Strong emphasis is also put on the requirement that candidates have to implement UPOV regulations in form of hard law in their national systems before they can join the organization. Contracting parties have to "provide for legal remedies for the effective enforcement of breeders' rights" (UPOV 1991: Art. 31(1i)). All national laws are published online.²²⁷ In order to facilitate a smooth implementation of the UPOV Convention, the UPOV Council has adopted a considerable number of explanatory notes, information documents, and technical guidelines. Examples for technical assistance are the "General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants" (UPOV 2002), "Arrangements for DUS Testing" (UPOV 2005a), "Constitution and Maintenance of Variety Collections" (UPOV 2008a), "Development of Test Guidelines" (UPOV 2010), "Examining Distinctness" (UPOV 2008b), and the "Guidance for New Types and Species" (UPOV 2009b).²²⁸ Explanatory deal, for example, with the definition of breeders (UPOV 2013b), enforcement of breeders' rights (UPOV 2009e), and right of priority (UPOV 2009a).²²⁹ In addition to that, the Technical Committee adopted test guidelines for 272 species that form the basis for obtaining a patent (upov.int/test_guidelines/en/list.jsp). The decisions of the UPOV Council are not intended to create legal obligation. They note that the "only binding obligations on members of the Union are those contained in the text of the UPOV Convention itself" and that these documents "must not be interpreted in a way that is inconsistent with the relevant Act for the member of the Union concerned" (for example UPOV 2002: para. 1(3)). But the breadth and depth of the technical and explanatory documents underline members' seriousness of enforcing the UPOV Convention's legal obligations.

Also the WTO is a clear case of a *hard law* institution. Its purpose is to serve as a "common institutional framework" to adopt, administer, and implement legal instruments for the conduct of trade relations (WTO 1994c: Art. 2(1), 3(1)). The founding treaty stresses that

²²⁷ Available at: <http://upov.int/upovlex/en/> (Accessed 8 June 2014).

²²⁸ An overview is available at: <http://www.upov.int/en/publications/tgp/> (Accessed 8 June 2014).

²²⁹ An overview is available at: http://www.upov.int/explanatory_notes/en/index.jsp (Accessed 8 June 2014).

the organization's policies should be predominantly "legal instruments" (WTO 1994c: Art. 2, 3) and that the Annexes to the Agreement establishing the WTO shall be "binding on all Members" (WTO 1994c: Art. 2(2)). In fact, the WTO's most essential rules are legally binding. First and foremost relevant for this study, TRIPS is not only legally binding but also lays out comprehensive and positive legal obligations for its members. With regard to patents, it clearly prescribes the criteria and scope of patentable subject matters (WTO 1994d: Art. 27), patent-holders' rights (WTO 1994d: Art. 28, 31), and duration of patent protection (WTO 1994d: Art. 33). The obligations' legal force is accentuated by the exact elaboration on the patentability's exceptions (WTO 1994d: Art. 27(3), 30) and the transitional periods for certain members (WTO 1994d: Art. 65-66).

Besides the TRIPS agreement, also the decisions of the Ministerial and General Conference are legally binding. This relates, for example, to the extensions of the transition period to implement TRIPS (WTO 2005c; WTO 2002f). The only exception is the legally non-binding "Declaration on the TRIPS Agreement and Public Health" of which an important component eventually led to a legally binding amendment of TRIPS (WTO 2013a).²³⁰

Comparing the six institutions, the differences with regard to legality are obvious. They range from hard law institutions (UPOV, WTO) over institutions with a more or less balanced output of legally non-binding and binding policies (WIPO) to soft law institutions (WHO, CBD, FAO). Despite this variety, the majority of institutions did not adopt hard law. This shows that legally binding rules are consciously chosen for selective purposes. Not all constituent treaties specify the institutions' formal powers. Where clear boundaries are laid down, they were respected. The table below locates each institution on a continuum between soft and hard law institution. The presentation of institutions' legality as continuum should not hide the fact that a single rule's legality is strictly binary. But since institutions adopt policies of both legal qualities, their aggregation can be located on a continuum.

Figure 4: Legality across Institutions

soft law			hard law		
WHO	FAO		WIPO	UPOV	WTO
CBD					

²³⁰ For more information on the role of soft law at the WTO see Footer 2010.

7.2 Formalization – Between Meticulousness and Fuzziness

Formalization describes the degree of procedural standardization by predefined written rules. It is therefore evaluated in terms of the precision to which institutional action is structured. Formalization is relevant with regard to

- (1) membership,
- (2) decision-making,
- (3) monitoring, and
- (4) dispute settlement.

Formalization is categorized as

- *absent* if no rule with regard to the respective indicator exists,
- *low* if the rules are ambiguous,
- *moderate* if the rules are partly vague/precise, and
- *high* if the rules are precise and comprehensive.

The basis of the evaluation constitutes the institutions' RoPs. It is important to note that formalization cannot be assessed by the sheer length of the respective paragraphs. If, for example, NGOs are not allowed to plenary meetings, it can be expressed very briefly and at the same time rigidly. By contrast, a lengthy elaboration can still lack clarity due to vague language.

None of the institutions is not or very lowly formalized.²³¹ This result is not surprising. International institutions with a broad membership such as the selected ones in this sample require a minimum of formalization to ensure a functioning administration and organization of meetings. Nonetheless, there are observable differences across the six institutions.

UPOV is rather lowly formalized and hence the least formalized institution in the sample. *Membership* is moderately formalized. The institution adopted clear rules governing full membership and observer status including the admission criteria and process (UPOV 2009d; UPOV 2005b; UPOV 1991: Art. 34). Important criteria that are missing for full membership and observer status are the criteria and voting modes by which the Consultative Committee and the Council take their decisions. This gives both bodies a significant leeway to reach an assessment.

Decision-making is highly formalized. UPOV's decision-making body is the UPOV Council. The UPOV Convention and RoP regulate tasks, frequency of meetings, and attendees.²³² By the same token, agenda-setting, points of orders, right to speak, limitation of the number and length of speeches, adjournment, suspension or closure of debate, discussion of proposals, amendments and revisions, and in particular the required

²³¹ No institution or network with a low degree of formalization is available in the field of biotechnological IPRs for the research period.

²³² UPOV 1991: Art. 26; UPOV 1982: Rules 1-4, 20.

majorities for decisions are highly elaborated.²³³ *Monitoring, sanctioning, and dispute settlement* are not regulated and therefore not formalized.

More distinct is formalization at WHO, and WIPO where formalization is overall moderate.

At WHO, *membership* is for most parts unambiguously regulated. Full and associate membership is clearly regulated by the WHO Constitution and RoP (WHO 2008d: para. 113-116; WHO 1947: Art. 3-5, 8). Also WHO's relationship with NGOs was highly standardized with resolution WHA40.25 (WHO 1987). Its detailed criteria for candidates, admission process, and NGOs' rights and responsibilities make it the most formalized NGO accreditation procedure among all six institutions. However, one important element is not specified. It is unclear according to which voting procedure the Executive Board decides on the admission of a new NGO. The IO admission process remains vague. It is only stated that IO admission requires a two-thirds WHA majority and that the relationship should be "effective" (WHO 1947: Art. 70-71).

Decision-making is highly formalized. The institution's main decision-making body is the WHA. The WHO Constitution and RoP regulate the WHA's functions and authority, frequency of regular and special WHA sessions, preparation and composition of the agenda, attendees allowed to the WHA and their credentials, maximum number of delegates and composition of delegations, introduction and deliberation of proposals and motions, points of orders, right to speak, right of reply, length of statements, order of speakers, the availability of documents, amendment of the WHO Constitution and RoP, and many other aspects of the debate's structure.²³⁴ The RoP also lays down in detail the composition and procedures of the Executive Board and WHAs' committees (WHO 2008d: Rules 29-40, 42-43). In particular the voting procedures, voting weight, and majority requirements are very clearly and comprehensively prescribed. The voting rules encompass, for example, the adoption of conventions, constitutional amendments, adoption of proposals and motions, voting in the WHA's committees and sub-committees, and the voting on voting procedures (WHO 2008d: Rules 59-84; WHO 1947: Art. 7, 59-60, 73).

In contrast to membership and decision-making, the other parts of the policy cycle are only very vaguely formalized. This is also holds true for *monitoring* whose formalization is practically absent. In general, members only have a broadly defined reporting obligation (WHO 1947: Art. 61-65). The unspecific procedure to control for adequate implementation is a consequence of the vague implementation process itself.²³⁵ *Sanctioning* is not formalized

²³³ UPOV 1991: Art. 26, 38; UPOV 1982: Rules 5, 10-19, 21-34, 38, Annex.

²³⁴ WHO 2008d: Rules 1-7, 11-13, 15, 19, 22-23, 44-50, 53-62, 117-120; WHO 1947: Art. 10, 12-13, 18-23.

²³⁵ The WHO Constitution does not mention implementation as it focuses on the organization's institutional setting and only contains general political principles. Also WHA resolutions addressing biotechnology-related IP policies leave the process of accomplishing the adopted policies at their members' discretion – not least because all of them are recommendations with no legal force to compel implementation. It is, for example, stated that members should "take effective measures" (WHO 2001e: para. 1(2)) or "necessary mechanisms"

since all of the relevant policies are not legally-binding so that deviation from them cannot be legally pursued. For the same reason also *dispute settlement* is hardly formalized. WHA resolutions do not address the handling of conflicts between members. Generally, the WHO Constitution only states that disputes concerning its provisions that cannot be settled by the WHA shall be referred to the ICJ “unless the parties concerned agree on another mode of settlement” (WHO 1947: Art. 75). This provision extremely restricts the issues that can be brought before the ICJ. They can only concern the WHO Constitution. Great leeway is also left for interpretation and speculations because it remains uncertain which majority is required to submit a case to the ICJ or how much time is granted to the parties concerned to find an alternative mode of settlement.

Equally moderately formalized is WIPO. *Membership* is overall moderately formalized. For full members the rules are clearly established (WIPO 1967: Art. 5, 14). All parties to the Paris Union can also become members to the PLT and PCT (WIPO 2000: Art. 20(1); WIPO 1970: Art. 62(1)). For observers, the regulations are vague and do not specify requirements pertinent to observers’ nature and the admission process (WIPO 1979: Rule 8; WIPO 1967: Art. 13).

Decision-making takes place at different bodies owed to WIPO’s structure. Since (almost) each of the 24 treaties under WIPO forms a relatively independent institution with its own assembly, WIPO’s legal framework is highly complex (Niemann 2008: 145-177). The legislative governing bodies encompass the General Assembly, Conference, and Assemblies of the respective treaties. The General Assembly as WIPO’s supreme organ consists of all states that are members to the WIPO Convention and one of the treaties administered by WIPO. It is, among others, responsible for approving the budget and measures relating to the administration of treaties on IP protection. By contrast, the Conference consists of member states to the WIPO Convention regardless of their membership in any other WIPO Union. It has originally served as a platform to discuss IP matters and the Unions’ competence and autonomy. In contrast to their formal institutional separation, the General Assembly and the Conference are very interrelated as they meet during the same period and discuss very similar items. In order to avoid duplication of work, WIPO’s constitutional reform is directed toward the abolishment of the Conference (WIPO 2004d: 7-8, 10). Relevant for biotechnology-related IPRs are also the Assemblies of the PCT and PLT. Decision-making in all four relevant WIPO bodies – the General Assembly, Conference, and PCT and PLT Assemblies – is highly formalized not least because they share a General RoP. Highly formulated elements of decision-making include the bodies’ functions, participants and composition of delegations, frequency of sessions, agenda,

(WHO 2002c: para. 1(2)), “make every effort” (WHO 2001d: para. 1(5, 9)) or just plainly that members should “implement the specific actions” (WHO 2008b: para. 2(1)). One of the few exceptions is the 2008 Global Strategy and Plan of Action that mentions at least the items to be monitored and the frequency of progress reports and evaluation (WHO 2008b: para. 43-44).

points of orders, speaking rights, adjournment, suspension or closure of debate and meeting, motions and proposals, amendments, and revisions.²³⁶ Like in the other institutions, voting majorities and procedures are particularly specified.²³⁷

Monitoring and *sanctioning* are not formalized at all. The WIPO Convention does not mention monitoring and sanction mechanisms as it constitutes an administrative umbrella for its Unions. But also the PCT and PLT remain silent on these subject matters. Sanctions clauses are also absent in the dispute settlement provisions.

Dispute settlement is overall moderately formalized. Dispute settlement regulations are absent in the WIPO Convention and PLT. The PCT states that disputes which cannot be settled by negotiation should be brought before the ICJ, but it provides no further details on the procedure (WIPO 1970: Art. 59). Besides the dispute settlement clauses in the WIPO treaties, the WIPO General Assembly established the WIPO Arbitration and Mediation Center (formerly the WIPO Arbitration Center) in 1993. It offers four forms of alternative dispute resolutions: mediation, arbitration, expedited arbitration, and expert determination.²³⁸ The rules were first adopted in 1994, reformed in 2002, and just recently updated.²³⁹ The latest version, which entered into force in June 2014, is not addressed here since my research period ranges between 1990 and 2010. The procedures of all four alternative dispute resolutions are highly formalized with regard to the intermediaries' selection, legal mandate, procedural rules, and standing.²⁴⁰

Formalization is more advanced at the CBD and FAO where it is still intermediate although on a high level.

At the CBD, *membership* is overall highly formalized. Admission requirements and process for full members and observers are clearly stipulated (CBD 1994a: Rule 7(1); CBD 1992: Art. 34-35).

The *decision-making* by COP is highly formalized. This includes the attendees allowed to COP meetings, delegations' composition and credentials, frequency and venues of meetings, COP's functions, agenda-setting, right and time to speak, and the discussion of and voting on points of orders, motions, proposals and amendments.²⁴¹ In particular precisely laid down are voting majorities and procedures (CBD 1994a: Rules 39-51).

Monitoring is lowly formalized. The CBD Convention does not mention frequency, content, or process of review, but leaves it to COP to decide on these matters. It is only

²³⁶ WIPO 2000: Art. 6, 16, 17; WIPO 1979: Rules 3, 5, 7-8, 14-24, 53(2), 56; WIPO 1970: Art. 53, 58, 60-61; WIPO 1967: Art. 6-7, 17.

²³⁷ WIPO 2000: Art. 17(3-5); WIPO 1979: Rules 25-39, Annex; WIPO 1970: Art. 3-6; WIPO 1967: Art. 6(3), 7(3).

²³⁸ In addition to that, WIPO provides for domain name dispute resolution services which are not relevant for biotechnology-related IPRs.

²³⁹ Available at: <http://www.wipo.int/amc/en/rules/newrules.html> (Accessed 8 September 2014).

²⁴⁰ Mediation: WIPO 2002f: Art. 1-17, 20; arbitration: WIPO 2002d: Art. 13-35, 37-58, 64b; expedited arbitration: WIPO 2002c: Art. 13-52, 57; expert determination: WIPO 2007d: Art. 5, 8, 13, 16.

²⁴¹ CBD 1994a: Rules 4-20, 31, 33-38; CBD 1992: Art. 29, 23.

stated that members have to present reports on their implementation (CBD 1992: Art. 23(4a), 26). COP adopted a new guideline for each round of national reports. By the end of 2010, four rounds of review with varying intervals, content, and criteria were completed.²⁴² These guidelines, as the title indicates, are of voluntary nature so that comprehensive and consistent adherence to the schemes is low. The guideline to the first national reports, for example, only requires states to report “in so far as possible” and “as the information [is] available in a country” (CBD 1995a: para. 3). Also the format changed in every round. Hence, standardization neither within each round nor across rounds was given. In the second round of national reports, the format for the “thematic report on transfer of technology and technology cooperation” explicitly stresses that “information provided by the Contracting Parties will not be used to rank performance between individual Contracting Parties” (CBD 2002d). The Nagoya Protocol establishes an Access and Benefit-Sharing Clearing-House through which states shall make information available on their implementation progress (CBD 2010g: Art. 14). Its process is not clarified and modalities of its operation are left to COP to decide. In addition to that, national checkpoints should enhance the monitoring of compliance with the Nagoya Protocol. Although members have considerable leeway to design these checkpoints, the Nagoya Protocol formulates minimum standards that have to be fulfilled (CBD 2010g: Art. 17). Nevertheless, the overall monitoring process remains ambiguous (CBD 2010g: Art. 29). *Sanctioning* rules are not mentioned in the CBD agreements and hence are not formalized.

Dispute settlement is moderately formalized. Under the CBD Convention, parties can consent to arbitration or dispute resolution under the ICJ. If they do not accept them, the conciliation rules apply for non-resolved conflicts (CBD 1992: Art. 27). The arbitration rules specify who has a standing, the arbitral tribunal’s composition, selection, legal mandate, and procedure. Conciliation is slightly less formalized because it includes no details about the procedure and does not clarify who has a standing (CBD 1992: Annex I). These regulations on the settlement of disputes are valid for all protocols if not stated otherwise (CBD 1992: Art. 27(5)). The Nagoya Protocol does not add adjudication provisions and leaves it to the users and providers of genetic resources to include them in their transfer agreements (CBD 2010g: Art. 18).

Also formalization at FAO is pronounced in many areas. Besides its Constitution, General and Financial Rules, FAO provides for detailed RoP of its Council and eight committees and several guidelines for its relationship with NSAs. Full *membership* is clearly determined by the FAO Constitution. It is also very specific about the distribution of competences between the IO and its members (FAO 1945a: Art. 2). The latter is exceptional in comparison to the other five institutions. Observer status is detailed in the General Rules (FAO 1945b: Rule 17) and specific policies for states (FAO 1957b), IOs (FAO 1959; FAO

²⁴² The deadline for submitting the fifth national reports was 31 March 2014. For an overview of the national reports see: <https://www.cbd.int/reports/national.shtml> (Accessed 9 September 2014).

1957a) and NGOs (FAO 1957c). The resolutions carve out several types of observers with different admission criteria, rights, and responsibilities and they elaborate on various methods of cooperation.

FAO's *decision-making* body is the Conference. Its procedures are very highly formalized by the FAO Constitution and the General Rules. This encompasses the Conference's and Commissions' functions and competences, attendees and their credentials, frequency of sessions, agenda, proposals, and amendments.²⁴³ Similar to other institutions, the required majorities to adopt decisions and voting procedures are meticulously determined (FAO 1945b: Rule 12).

Monitoring is moderately formalized. The FAO Constitution generally states that the review of members' programs and the Medium Term Plan is part of regular sessions' provisional agenda (FAO 1945b: Rule 2c). Greater formalization can be observed for some individual policies. The 1983 International Undertaking decides to establish an intergovernmental body to monitor agreements on the "exploration, collection, conservation, maintenance, evaluation, documentation, exchange and use of plant genetic resources" as referred to in Article 7 (FAO 1983: Art. 9). It also asks members for annual progress reports without further specification of the review process like report's format or reviewers (FAO 1983: Art. 11). Also the ITPGR envisages monitoring mechanisms that should be further specified and developed by its Governing Body (FAO 2001: Art. 21).

Sanctioning measures are absent in the FAO Constitution and its agreements including the 1983 Undertaking and the ITPGR.

Dispute settlement is overall lowly formalized. The FAO Constitution stipulates that disagreement on its interpretation that cannot be solved by the Conference shall be decided by the ICJ (FAO 1945a: Art. 17).²⁴⁴ For both pathways, no procedure or schedule is determined. The procedures shall be described by the Conference (FAO 1945a: Art. 17(3)). By contrast, the ITPGR's rules on the settlement of disputes are highly formalized and provide comprehensive arbitration and reconciliation regulations encompassing the selection of the arbitral tribunal's and conciliation commission's members, their mandate, and a detailed stipulation of the process including time schedules for the different stages (FAO 2001: Art. 22, Annex 2). Nevertheless, these rules primarily concern disputes arising out of the ITPGR which constituted a new IO separated from FAO.

The WTO exhibits the overall highest degree of formalization. But *membership* is only moderately formalized. Merely the preconditions for full membership are precise (WTO 1994c: Art. 12(1)). The admission procedure is lowly formalized as accession depends on "terms to be agreed" that have to approved by a two-thirds majority of all WTO members

²⁴³ FAO 2001: Art. 23; FAO 1945a: Art. 3-4, 10; FAO 1945b: Rules 1-3, 5, 11, 13-14.

²⁴⁴ Also the Committee on Constitutional and Legal Matters can serve as a forum to discuss legal matters pertaining to the FAO Constitution and other treaties (FAO 1945b: Rule 34(7)), but it is not an adjudication body.

at the Ministerial Conference (WTO 1994c: Art. 7, 12(2), 14). The observer rules are only moderately formalized for states and IOs. They lay out minimum criteria for obtaining observer status. The decision is taken on a “case-by-case basis” by the respective WTO body without clarifying the decision procedure (WTO 1996d: Annex 2-3). NGOs accreditation is standardized in so far as it was prohibited in 1996 (WTO 1996c). The ad hoc admission of NGO observers to the Ministerial Conference is less institutionalized and does not follow clearly defined rules.

Decision-making, as it is relevant for biotechnology-related IPRs, takes place at the Ministerial Conference, General Council, and TRIPS Council. In all three bodies, it is highly formalized whereas the TRIPS Council mostly adapts the General Council’s RoP (WTO 1996b). Among the precisely regulated matters are the required majority votes for different types of decisions, method of voting, amendment process, frequency of meetings, agenda’s preparation and composition, attendees allowed to the sessions and their credentials, right and time limit to speak, orders of speakers, discussion of proposals, and various aspects of the conduct of business.²⁴⁵

Monitoring is overall moderately formalized. As implementation is even listed as the WTO’s first function (WTO 1994c: Art. 3(1)), also monitoring takes a prominent role. Under the guidance of the General Council act three Councils of which each one oversees the functioning of one multilateral trade agreement. Monitoring is executed by the TRIPS Council and the Trade Policy Review Body. The monitoring procedure at the TRIPS Council is only partially specified. TRIPS only general notes that the TRIPS Council “shall monitor [...] Members’ compliance with their obligations” (WTO 1994d: Art. 68) and “review the implementation of this Agreement” every two years (WTO 1994d: Art. 71). More standardized is the process laid down by the Trade Policy Review Mechanism (TPRM). It regulates the review intervals and the reporting format (WTO 1994a).

Sanctioning and *dispute settlement* are highly formalized in the TRIPS agreement and the Understanding on Rules and Procedures Governing the Settlement of Understanding (DSU). TRIPS emphasizes that members have to provide for enforcement procedures under their national law including “remedies which constitute a deterrent to further infringements”. Procedures have to be expeditious, financially and timely reasonable, but first and foremost they need to be “fair and equitable”. This requires a proper judicial process to decide about disputes and indemnification or other remedies (WTO 1994d: Art. 41). TRIPS elaborates in detail on the procedural requirements of the civil judicial procedures including the rights of the defendant and plaintiff, evidence, injunctions, compensation and other remedies, possibility of criminal procedures, obligation to publish relevant national regulation and judicial decisions, and border measures (WTO 1994d: Art. 42-63).

²⁴⁵ WTO 1996f: Rules 3-11, 16-34; WTO 1996e: Rules 1-11, 16-29; WTO 1996d: Annex 2-3; WTO 1994c: Art. 9-10.

Also the DSU comprehensively formalizes the entire adjudication process including the composition of the Dispute Settlement Body (DSB) and panel, selection of adjudicators, legal mandate, standing, and the individual steps and possible turns of the process including detailed time-frames and sanctions (WTO 1994b).

All in all, formalization is the most distinct design feature across all six cases. At first glance, all international institutions might seem to be in one way or another equally structured by rules and predefined procedures. In fact, the comparison reveals similarities. Decision-making is highly formalized in all institutions while membership is at least moderately formalized. Remarkably, membership is least formalized at the WTO, UPOV and WIPO that are all hard law institutions. More evident are the differences in the enforcement dimensions. Dispute settlement provisions are absent at UPOV, only lowly formalized at FAO and WHO, moderately standardized at the CBD and WIPO, and very detailed at the WTO. Only three institutions (CBD, FAO, WTO) have monitoring clauses. Sanction provisions can only be found at the WTO. The results are summarized below.

Figure 5: Formalization across Institutions

low	moderate		high
UPOV	WHO	CBD	WTO
	WIPO	FAO	

7.3 Delegation – Reluctant Transfer of Authority

Relevant for legalization is delegation in the areas of

- (1) legal personality,
- (2) legal commitment,
- (3) monitoring,
- (4) adjudication, and
- (5) resources.

The values for delegation depend on the indicators. Among all six institutions, UPOV is lowest delegated. However, UPOV is the only institution in which its founding treaty expressively states that the “Union has legal personality” under domestic law” (UPOV 1991: Art. 24(1-2)). This amendment was added with the 1978 revision (Jördens 2005: 234). It is silent on the institution’s legal capacity outside the territories of its member states. The delegation of *legal commitment* is moderate. UPOV prohibits reservations (UPOV 1991: Art. 35(1)) but allows for the Convention’s denunciation. It takes effect “at the end of the calendar year following the year in which the notification was received from the Secretary-General” (UPOV 1991: Art. 39(3)).

Monitoring rules do not exist. UPOV completely relies on a police-patrol system assuming that parties who are affected by insufficient enforcement of breeders’ rights bring non-compliance to the Council’s attention.

Also *sanctioning* and *dispute settlement* are not delegated in the absence of formal rules. As parties are required to legally implement the UPOV Act in their national laws (UPOV 1991: Art. 30(1i)), actors' only chance of remedy is to bring cases directly before national courts.²⁴⁶

Resources are moderately delegated. UPOV's budget is composed of members' annual contributions. A member's contribution is computed based on the total estimated expenditures and the contribution units applicable to the member (UPOV 2013a; UPOV 1991: Art. 29).²⁴⁷ The budget for the financial period 2010-2011 was CHF 6,782,000. This revenue was comparatively low but sufficient to cover the expenditures (UPOV 2011a: 20).

UPOV does not elect its own administrative head. Its Secretary-General is WIPO's Director General (WIPO 2004d: 332). Although the WIPO-UPOV Agreement of 1982 clarifies that the Office of UPOV "shall exercise its functions in complete independence of WIPO" (WIPO/UPOV 1982: Art. 3), an institutional connection is manifest.²⁴⁸ UPOV adopts, if not stated otherwise, WIPO's staff and financial regulations. WIPO's controller is also responsible for the UPOV Council (WIPO/UPOV 1982: Art. 8(1,3)). No independent staff besides presidents and chairs of UPOV's organs is mentioned by UPOV.²⁴⁹

A higher degree of delegation can be observed at the CBD, FAO and WHO, which is overall still low.

At the CBD, *legal personality* is lowest. It is the only institution in the sample that makes no reference to its legal status. *Legal commitment* is overall moderate. No reservations are allowed to the CBD Convention and the Nagoya Protocol (CBD 2010g: Art. 34; CBD 1992: Art. 37). But parties can withdraw from both. However, members cannot leave the institution or the Protocol immediately. They can give notice two years from the date on which the document entered into force. It becomes valid one year after the withdrawal was received by the depositary (CBD 2010g: Art. 35; CBD 1992: Art. 38).

Monitoring is lowly delegated, nevertheless with an upward trend. The CBD relies on a vague self-reporting system (CBD 1992: Art. 26). Members' reports shall be reviewed by COP (CBD 1992: Art. 23(4)). The CBD Convention does neither clarify in which intervals the reports have to be submitted nor which yardstick is used to evaluate them. These elements are specified by National Report Guidelines adopted by COP. The Guidelines have hardly increased the degree of delegation as they have not led to systematic and independent data. The CBD depends on members' own information and performs no own investigations. Monitoring was also impaired content-wise. The first national report solely focused on implementation of Article 6 "General Measures for Conservation and

²⁴⁶ In 2013, the Council adopted an information document of alternative dispute settlement mechanisms and clarified that UPOV itself does not offer such services (UPOV 2012).

²⁴⁷ Members have to pay one, three, or five contribution units (Jördens 2005: 233).

²⁴⁸ UPOV's founding members explicitly refused to be integrated into the WIPO framework (Niemann 2008: 174).

²⁴⁹ Available at: <http://www.upov.int/about/en/officers.html> (Accessed 9 September 2014).

Sustainable Use” and called upon parties to report only “in so far as possible” and “as the information available in national country studies on biological diversity” (CBD 1995a: para. 3). By the same token, the first guideline suggested to report rather on strategies, plans and goals than on concrete planned or implemented policies (CBD 1995a: Annex). Although the harmonization, comprehensiveness and depth of the report formats has constantly increased with each round of review, the adherence to them remains voluntary. Last but not least, review has not been executed by a centralized mechanism (Jungcurt 2011: 185). The CBD’s clearing-house mechanism has no autonomous implementation and monitoring functions. It rather serves as a network to facilitate information exchange and technical cooperation. Therefore, implementation has mostly depended on parties’ willingness to adopt and enforce National Biodiversity Strategies and Action Plans (CBD 1992: Art. 6). The Nagoya Protocol also establishes a clearing-house mechanism (CBD 2010g: Art. 14). But the main responsibility of monitoring the adherence to the ABS standards is passed to parties. They are required to establish national checkpoints to collect information and control the users of genetic resources (CBD 2010g: Art. 17(1)). An internationally recognized certificate of compliance should serve as prove of adherence to rules (CBD 2010g: Art. 17(2)). Although members have to report on their implementation to COP, the treaty clearly states that “[e]ach Party shall monitor the implementation of its obligation” (CBD 2010g: Art. 29). Both implementation and monitoring were hampered by the fact that the CBD does not provide for clear policy goals and an operative implementation mechanism (Crookshanks/Phillips 2012: 74; Harrop/Pritchard 2011: 477-479; Helfer 2004: 31).

The delegation of *sanctioning* is non-existent in the CBD Convention in the absence of rules governing parties’ non-compliance. The Nagoya Protocol generally stipulates that parties “shall take appropriate, effective and proportionate measures to address situations of non-compliance” and “as far as possible and as appropriate, cooperate in cases of alleged violation”. Tangible consequences in the case of violating rules remain absent (CBD 2010g: Art. 15(2-3), 16(2-3)). The Nagoya Protocol stipulates that COP should consider institutional mechanisms to address non-compliance. But these seem to be more directed toward assistance rather than the imposition of penalties (CBD 2010g: Art. 30).

Dispute settlement is lowly delegated. First of all, the mandate is weak. States have to actively declare their interest to subject themselves to arbitration or ICJ dispute settlement (CBD 1992: Art. 27(3)). Nevertheless, if parties consent to arbitration, the tribunal’s award shall be binding on the parties (CBD 1992: Annex I: Part I, Art. 16). If parties have not accepted these terms, conciliation should be brought into bearing. But also this mechanism’s force is weak. Parties can agree not to make use of conciliation (CBD 1992: Art. 27(4)) and its ruling is only a “proposal for resolution of the dispute, which the parties shall consider in good faith” (CBD 1992: Annex I: Part II: Art. 5). Second, the independence of both adjudication and reconciliation is diminished because the great

majority of members of the arbitral tribunal and commission are direct representatives of the parties concerned. The parties select two out of three and four out of five members respectively (CBD 1992: Annex I: Part I, Art. 2; Part II, Art. 2). By the same token, they also do not need to be experts or lawyers. Third, there is no right of appeal unless the parties have agreed otherwise (CBD 1992: Annex I: Part I, Art. 16). Fourth, procedural obstructions are limited but exist. The composition of the arbitral tribunal and conciliation commission cannot be infinitely delayed. In the case of arbitration, parties have two months to appoint an arbitrator each. They, in turn, have again two month to designate a third one (CBD 1992: Annex I: Part I, Art. 3). The same time limits also apply to conciliation (CBD 1992: Annex I: Part II, Art. 3-4). The arbitral tribunal's final decision has to be rendered within five months after its establishment. The time limit can only be extended once for a maximum of five more months (CBD 1992: Annex I: Part I, Art. 14). No time period for the conciliation commission's proposal is stated. In both modes of dispute resolution, the final decision is taken by majority vote so that one party alone cannot prevent a verdict (CBD 1992: Annex I: Part I, Art. 12; Part II, Art. 5). Last but not least, only states have a standing and no sanction rules are laid down. The Nagoya Protocol does not add delegation to dispute settlement. Instead it hands down this responsibility to the users and providers of genetic resources. They are encouraged to include the acceptance of dispute resolution in their bilateral agreements (CBD 2010g: Art. 18).

Resources are very lowly delegated. Although the CBD Convention acknowledges that “substantial investments” are necessary to conserve biological diversity (CBD 1992: preamble), it remains very vague with regard to the organization of the newly established financial mechanism (CBD 1992: Art. 21). It only notes a special responsibility of developed countries to provide financial assistance to developing countries in order to implement the CBD (CBD 1992: Art. 20(2)). The financial mechanism's institutional structure was fleshed out with two decisions in 1996 and 2008 (CBD 2008b; CBD 1996a). They adopted a system of annual contributions. The total budget was \$10,505.8 million in 2009 and \$11,451.3 million in 2010 (CBD 2008d: 6). Around \$1 million was provided by the host country Canada and the Province of Quebec to the operation of the secretariat in Montreal (CBD 2008d: para. 1). The CBD is systematically underfinanced. For the 2007-08 biennium, the projected shortfall was \$800,000 (CBD 2008d: para. 2). Last but not least, the CBD is, considering its scope, also under-staffed with around 70 international and neutral civil servants.²⁵⁰

Also FAO possesses an only low degree of delegation. It has *legal personality* under domestic law (FAO 1945a: Art. 1). It is hinted at its international legal personality by stating that FAO “shall have the capacity of a legal person to perform any legal act appropriate to its purpose which is not beyond the powers granted to it by this Constitution” (FAO 1945a:

²⁵⁰ Available at: <http://www.cbd.int/secretariat/role.shtml> (Accessed 9 September 2014).

Art. 16). FAO is also vested with the right to request an advisory opinion from the ICJ (FAO 1945a: Art. 17).

Legal commitment is overall moderate. Reservations are neither explicitly granted nor denied in the FAO Constitution. The ITPGR does not allow for reservations (FAO 2001: Art. 30). Some members made reservations to the 1983 International Undertaking although this right was not explicitly granted in the agreement since it is non-legally binding and did not establish an autonomous institution. Members can leave FAO with a notice of one year in advance after the FAO Constitution has been in force for at least four years (FAO 1945a: Art. 19). The ITPGR can be exited one year after having given notice and two years after the treaty entered into force (FAO 2001: Art. 32).

Monitoring is lowly delegated. The purpose of FAO's Conference and Council is not to strictly control implementation but to make recommendations and provide assistance (FAO 1945a: Art. 4). In order to monitor the operation of the 1983 International Undertaking, FAO established the CGRFA which is open to all of FAO's members and associate members. Its work, as envisaged in the Undertaking, should address FAO's own work rather than individual members' implementation progress (FAO 1995: Rule 1; FAO 1983: Art. 9(2)). Besides that, the Undertaking asks members for annual reports on their measures to achieve the Undertaking's goals (FAO 1983: Art. 11). Also systematic *sanction* mechanisms are absent.

Dispute settlement is lowly delegated. Conflicts that cannot be settled by the Conference shall be brought before the ICJ "or to such other body as the Conference may determine" (FAO 1945a: Art. 17). Due to the great ambiguity of this procedure, there is neither an obligatory jurisdiction nor a clear legal mandate. Instead, FAO members are left with a large leeway to obstruct the dispute settlement. Even the higher legalized ITPGR lets its parties choose if they accept formal arbitration, conciliation or submission of disputes to the ICJ (FAO 2001: Art. 22(3)).

Resources are lowly delegated. With regard to the budget, members have to pay an annual contribution which is determined by the Conference every two years (FAO 1945a: Art. 18). These fixed appropriations account for less than the majority of the total budget. Of the total 2011-11 budget in the amount of \$2,211 million, only 43% were estimated to derive from fixed appropriations while the other 57% represented voluntary financial contributions (FAO 2009a: 27). Given FAO's broad mandate and great number of programs, the institution is underfunded. Also in the case of the International Undertaking members did not agree on financial mechanisms that would guarantee a stable and sufficient financial support (FAO 1983: Art. 8)

The filling of staff is independent. It is appointed by the Director-General and shall be selected "without regard to race, nationality, creed or sex" (FAO 1945a: Art. 8(1); FAO 1945b: Rule 40(1)). Members shall respect the international character of FAO's staff and

shall not attempt to influence it (FAO 1945a: Art. 8(2)). With a total of 3,334 individuals employed in 2007, FAO staffing situation is tight.²⁵¹

Similarly, WHO exhibits a low degree of delegation. The institution enjoys *legal personality* under domestic law (WHO 1947: Art. 66-68). International legal personality is not explicitly granted by the founding treaty. However, WHO is entitled to request the ICJ for an advisory opinion (WHO 1947: Art. 76). The *legal commitment* is intermediate. Although WHO has no exit clause, states can reject or make reservations against regulations adopted by the WHA under Article 21 (WHO 1947: Art. 22). A right of making reservations against provisions in the WHO Constitution is not mentioned. It might be owed to WHO's overall low degree of legalization that the founding fathers, unlike in the case of the other five institutions, did not consider it as necessary to include a withdrawal clause in its Constitution.

Low delegation continues with *monitoring*. Members have an annual reporting obligation with regard to “action taken and progress achieved in improving the health of its people” and “recommendations made to it by the Organization and with respect to conventions, agreements and regulations” (WHO 1947: Art. 61-62). WHA resolutions, if they mention monitoring at all, typically leave it to members to control their own progress.²⁵² Also the Director-General has frequently been asked to monitor performance. Interestingly, the resolutions generally do not speak of members' individual performance but only of general progress made in the implementation of policies. In some rare instances, a timeline for review is added (WHO 2008b: para. 4(10)) or the Director-General is asked to prepare recommendations to improve monitoring based on the experience from reviews (WHO 1999b: para. 2(9); WHO 1996: para. 2(11)). However, it remains unclear what means and resources the Director-General has at hand to conduct this tasks.

At first glance, independent and centralized monitoring should be easily feasible as WHO country offices are typically located within member states' ministries of health. However, the regional and national offices are not in place to grant centralized implementation and monitoring. Their task is confined to technical assistance, management, public relations, and advocacy (Lee 2009: 34). This corresponds with the commonly held view that WHO is and should focus on setting standards rather than enforcing them (Lee 2009: 18-19). From a legal perspective, members are free to decide if they want to enforce decisions at all since the policies are non-legally binding.

Given the very low delegation of monitoring, it is only consequential that *sanctioning* and *dispute settlement* are not delegated at all. There are no institutionalized sanction and adjudication mechanisms in place. Also procedures to settle conflicts and disputes are

²⁵¹ Available at: http://www.un.org/womenwatch/osagi/pdf/Nationalities/FAO_All_Staff.pdf (Accessed 6 April 2011).

²⁵² See for example: WHO 2004a: para. 2(2); WHO 2002c: para. 1(2, 5); WHO 2001c: para. 4(3); WHO 1999b: para. 1(1); WHO 1996: para. 1(4).

absent. The ICJ is only mentioned to settle questions concerning the interpretation and application of the Constitution. Even within this restricted scope, WHO possesses no obligatory jurisdiction because parties can agree on another mode of dispute settlement (WHO 1947: Art. 75).

Last but not least, the delegation of *resources* is overall moderate. WHO's budget is unstable and insufficient. The broadening of WHO's mandate has not been accompanied by an equal increase in budget. WHO receives payments by its members in two equal annual installments. The individual contributions are determined by the scale of assessments that are adopted by the WHA (WHO 2003g: Rules 5-6). They are calculated based on members' gross national product and population (Lee 2009: 38). But despite members' contributions, WHO heavily relies on voluntary allowances which it is allowed to accept in accordance with Article 57 of its Constitution. In 2010, only 33% of the total operating budget of \$2,323 million was made up of fixed member contributions. The rest stemmed from voluntary revenues of which only 32% originated from member states (WHO 2011a: 2-3). The remarkable amount of \$219,787,513 was contributed by the Bill & Melinda Gates Foundation (WHO 2011b: 8). It is WHO's second largest funder after the USA (van de Pas/van Schaik 2014: 197). Since 1988 extrabudgetary funds have exceeded the regular ones. Voluntary contributions have the advantage for donors that they can earmark them for specific projects. They offer donors who are overwhelmingly NSAs to directly influence WHO's priority-setting. The prevalence of extrabudgetary contributions does not only pose a threat to WHO's independence and flexibility. The financial unstable situation also prevents long-term planning (Cassels et al. 2014).

“WHO has been forced to choose between pursuing high-profile campaigns to attract continued donor funding, and fulfilling its unique mandate of carrying out the day-to-day tasks that form the building blocks of global health cooperation” (Lee/Pang 2014: 120).

The problem is aggravated by members' growing arrears and late payments. This relates in particular to the USA. This led to a situation in which the proper execution of WHO's programs is at risk (Lee 2009: 40-42). The unsatisfying financial situation is one main, maybe even the central part of a general reform endeavor within the institution (Lee/Pang 2014: 197). Since my analysis focuses on the period between 1990 and 2010, recent institutional changes are not discussed here.²⁵³

By its own account, WHO comprises about 8,000 permanent experts and support staff.²⁵⁴ This makes it the UN specialized agency with the largest bureaucracy. The secretariat and its staff should enjoy independence and “not seek or receive instructions from any government or from any authority external to the Organization” (WHO 1947: Art. 37). Staff should primarily be selected on the basis of “competence and integrity” (WHO 2009b: para. 410.1). The Director-General conducts the appointment process

²⁵³ For further information on the WHO reform consult the WHO website. Available at: http://www.who.int/about/who_reform/en/ (10 September 2014).

²⁵⁴ According to UN Women Watch, the total number of permanent staff was almost 4800 in 2007. Available at: http://www.un.org/womenwatch/osagi/pdf/Nationalities/WHO_All_Staff.pdf (Accessed 6 April 2011).

which should be protected from members' influence (WHO 2009b: para. 440.1-3). In practice, the WHO staff has been careful to not tread on any state's toe by

“analyzing but never auditing; advising but never directing; participating but never interfering; guiding but never governing; leading but never advocating; evaluating but never judging” (Hoffman/Röttingen 2014: 190).

More advanced is delegation at WIPO that displays a moderate level of delegation. WIPO enjoys *legal personality* within the territory of its member states (WIPO 1967: Art. 12). Reference to its international legal capacity is not made. *Legal commitment* is moderate. The WIPO Convention does not allow for reservations (WIPO 1967: Art. 16). By contrast, the PCT grants the right to make reservations to a list of its provisions such as the obligation to send disputes to the ICJ (WIPO 1970: Art. 64). The PLT only allows to declare that the requirements for a patent application under Article 6(1) “shall not apply to any requirement relating to unity of invention” under the PCT (WIPO 2000: Art. 23). Members can leave WIPO and the PCT already six months after they notified the Director General (WIPO 1970: Art. 66; WIPO 1967: Art. 18). Exit from the PLT is possible one year after notification (WIPO 2000: Art. 24).

Monitoring and *sanctioning* instruments are not explicitly stated in WIPO's treaties relevant for biotechnological IPRs. WIPO's approach of technical support emphasizes assistance rather than control. Although capacity-building, information dissemination, and education can enhance compliance, these tools do not represent independent enforcement mechanisms. Also WIPO's mediation and arbitration procedures do not contain sanction clauses. In this respect, the WIPO Handbook clarifies that although a state

“may grant patent rights, it does not automatically enforce them, and it is up to the owner of a patent to bring an action, usually under civil law, for any infringement of his patent rights. The patentee must therefore be his own “policeman” (WIPO 2004d: 17).

Also *dispute settlement* is lowly delegated. The WIPO Convention does not mention adjudication. Disputes on the PCT's interpretation and application can be brought before the ICJ, but can also be solved by “some other method of settlement” (WIPO 1970: Art. 59). By the same token, a state can make a reservation that it considers itself not to be bound to submit cases to the ICJ (WIPO 1970: Art. 64(5)). Most member states availed themselves of this right (Woodward 2012: 142-143). Negotiations on a mandatory dispute settlement procedure similar to the WTO failed at the beginning of the 1990s. Besides formal litigation, disputes can be voluntarily submitted to the WIPO Arbitration and Mediation Center. The legal force of these alternative dispute resolutions is already limited by the fact that affected parties can freely choose if they want to submit a case to these ad hoc bodies. Two of WIPO's four alternative dispute resolutions are more closely examined in the following.

Mediation is lowly delegated. Political independence is moderate. Parties are consulted before a “neutral, impartial and independent” mediator is appointed by the Center (WIPO 2002f: Art. 6-7). No requirements as to the mediator's expertise and legal education are set

up. The legal mandate is low as the mediation's output is not legally binding. By the same token, the mediator has only a weak decision-making authority. She possesses neither obligatory jurisdiction nor the power to impose a settlement (WIPO 2002f: Art. 18). Only the disputing parties have a legal standing (WIPO 2002f: Art. 8).

Arbitration is moderately delegated. If there is a sole arbitrator, she is appointed jointly by the parties (WIPO 2002d: Art. 16(a)). In the case of three arbitrators, one is announced by each party. These two arbitrators appoint together a third one (WIPO 2002d: Art. 17).²⁵⁵ The arbitrators shall be "impartial and independent" (WIPO 2002d: Art. 22(a)), but they need not to be lawyers or experts in the field. The legal mandate is high. The award is binding on the parties as the result of a binding procedure (WIPO 2002d: Art. 64(b)). The procedural obstacles are moderate. If arbitrators are not announced within a specific period of time, they are appointed by a default procedure (WIPO 2002d: Art. 16(b), 17(d), 19). Nevertheless, there is great leeway to challenge or replace arbitrators (WIPO 2002d: Art. 24-32) which can delay the procedure. Arbitration is not stopped if the defendant fails to submit its statement of defense "without showing good cause" (WIPO 2002d: Art. 56). The tribunal can only terminate arbitration without an award if no party objects (WIPO 2002d: Art. 65(c)). Like in the case of mediation, only the parties concerned have a legal standing. Due to its similar rules, also expedited arbitration is moderately delegated (WIPO 2002c).

Resources are highly delegated. As to finances, WIPO changed to a unitary contribution system in 1993. A party to any of WIPO's treaties makes only a single payment irrespective of the number of treaties it has membership to (WIPO 2004d: 9). The budget for 2010-11 was CHF 618,637,000 (WIPO 2009e: 7). Notably, it is the only institution in the sample that is mostly self-financing by its international registration services (Kwakwa 2002: 181). Due to its financial independence from member contributions, it is at least partly immunized from political pressure (May 2007: 37). Also, its secretariat is well-staffed with around 2,000 permanent employees.²⁵⁶

At the WTO, the highest degree of delegation can be observed. It is overall located at the upper intermediate end. The WTO enjoys *legal personality* under domestic law (WTO 1994c: Art. 8). As to *legal commitment*, the founding treaty does not allow for reservations (WTO 1994c: Art. 16(5)). "In exceptional circumstances", the Ministerial Conference can waive a legal obligation with a three-fourth majority (WTO 1994c: Art. 9(3)). Reservations to TRIPS are practically not permissible as they require the consent of all members (WTO 1994d: Art. 72). Exit is possible with a six months' notice (WTO 1994c: Art. 15).

²⁵⁵ If three arbitrators in the case of multiple claimants or respondents are appointed, the procedure becomes more complex in accordance with Article 18 (WIPO 2002d).

²⁵⁶ Available at: http://www.un.org/womenwatch/osagi/pdf/Nationalities/WIPO_All_Staff.pdf (Accessed 6 April 2011).

Monitoring's degree of delegation is medium. The frequency of the TPRB's reviews depends on a member's share in world trade. The review is based on two reports. One is drawn up by the reviewed country. The other is prepared by the secretariat on the basis of its own information on the concerned member. The independence of data is increased by the secretariat's report although it is uncertain how comprehensive its data pool is. If it has to rely in large parts on members' information, its report becomes a duplication of the self-report. The scrutiny of the information is strengthened by the fact that both reports are published after review, but before they are forwarded to the Ministerial Conference. In-between the reviews, members have to report to the TPRB based on an agreed format and in the case of considerable changes in their trade policies (WTO 1994a). This systematic and comprehensive data additionally advances the degree of delegation. Stringent monitoring is further ensured by the TRIPS Council's routinely reviews of national implementation (Helfer 2004: 23). Monitoring is shared with WIPO in so far that member states do not have to communicate new IP law, rulings and interpretation to the TRIPS Council if they have already done so with WIPO's International Bureau (WTO/WIPO 1995: Art. 2(3); WTO 1994d: Art. 63(2)). Nevertheless, monitoring remains a "peer review mechanism" that relies on the reports' critical examination by WTO fellow members (Bohne 2010: 55).

Sanctioning is moderately delegated. The decision to grant a claimant compensation in return for a defendant's non-compliance as well as its amount is determined by the DSB (WTO 1994b: Art. 22). If a party does not implement the DSB's panel report, the DSB can mandate sanctions, but it has to be executed by the affected state(s) (WTO 1994b: Art. 22). Furthermore, sanctioning is restricted because information obtained in the trade policy review is prohibited to be used in the WTO's dispute settlement procedures (WTO 1994a: A.i).

Dispute settlement is highest delegated at the WTO. The old GATT model was completely reformed with the establishment of the WTO.²⁵⁷ The procedural rules for the panels were judicialized and an Appellate Body to review the initial decisions was established. The reformed DSB is hailed as the "crown jewels of the WTO system" (Esserman/Howse 2003: 131). The DSB's independence is high. The Appellate Body is a permanent body consisting of seven independent persons "of recognized authority, with demonstrated expertise in law" (WTO 1994b: Art. 17(3)). They are elected for a four-year term with the option of one reappointment. Three of them serve on one case (WTO 1994b: Art. 17). Second, the mandate is strong. The Appellate Body's decisions are legally binding and follow a binding procedure. Veto and blockade opportunities are de facto abolished. The establishment of a panel and the adoption of panels' and Appellate Body's reports can only be prevented by the DSB's consensus (WTO 1994b: Art. 14). Strict deadlines prevent

²⁵⁷ The powers of the dispute settlement procedure are restricted in so far as the "exclusive authority to adopt interpretation" of the Marrakesh Agreement and of the multilateral trade agreements lies with the Ministerial Conference and General Council (WTO 1994c: Art. 9).

delays in the procedure. The period between submission of a claim and adoption of an Appellate Body report takes regularly not more than 12 months (WTO 1994b: Art. 20) and is one year and three months at the maximum (Helmedach 2009: 62). Only states have a full standing. In its 1998 US-Shrimp case's report, the Appellate Body decided that panels do not have to, but can accept *amicus curiae* briefs from NGOs. In most disputes, the panels have not accepted such friend-of-the-court briefs in which actors who are not party to a dispute can submit additional information on a case (van den Bossche 2008: 739-740).

The WTO's *resources* are moderately delegated. It is financed by members' annual appropriations according to a scale of contributions which depends on the WTO expenses (WTO 1994c: Art. 7(4)). The budget for 2010 summed up to CHF 193,989,500. Since the annual contribution depends on the actual expenses and payment behavior has been good, the institution has been less at risk of being underfinanced.

Also the WTO emphasizes the autonomous character of its secretariat by stating that it "shall not seek or accept instructions from any government or any other authority external to the WTO" (WTO 1994c: Art. 6(4)). The WTO recruits staff on the basis of "merit, qualifications and expertise". In practice, staffing had a geographical bias. In 2000, 23 out of 26 WTO division directors came from developed countries (Steinberg 2002: 356). With regard to the Director-General's home country, the geographical distribution improved from GATT to the WTO. While all four of GATT's Director-Generals were Europeans, only three out of so far six WTO Director-General have been Europeans. The others came from New Zealand (Mike Moore: 1999-2001), Thailand (Supachai Panitchpakdi: 2002-2005), and Brazil (Roberto Azevêdo: 2013-today). The WTO secretariat had 621 staff on the regular budget in 2010 (WTO 2010a: 140-141). Given its remit, the WTO secretariat is not well-funded and small in comparison to other economic institutions like the IMF and World Bank (Jackson 2006: 116-117). The Uruguay Round demands about 400 meetings a year, 175 matters have to be regularly notified by members, and around 81 million pages of documentation must be processed annually (Dunkley 2000: 279).

In comparison to the other dimensions, delegation is the least pronounced one. No institution is highly delegated. This is not surprising as IL's enforcement mainly remains in the hands of states. All institutions with the exception of the CBD are explicitly granted legal personality. Legal commitment is moderate in all six institutions. Monitoring mechanisms are absent at UPOV and WIPO, only lowly delegated at CBD, FAO and WHO, and moderately delegated at the WTO. Sanction mechanisms only exist at the WTO. Dispute settlement is absent at UPOV, highly delegated at the WTO, and only lowly delegated at the CBD, FAO, WHO, and WIPO. Resources are tight at the CBD, FAO, and WHO, better at UPOV while WIPO and the WTO are best-equipped.

Figure 6: Delegation across Institutions

	low		moderate		high
		CBD			
UPOV		FAO	WIPO		WTO
		WHO			

The systematic evaluation of legalization shows that legalization is advanced to different extents at the six institutions. Most common are least legalized institutions that are characterized by soft law, moderate formalization, and low delegation (CBD, FAO, WHO). The most legalized institution is the WTO with its hard law character, high formalization, and moderate delegation. There are also combinations of the legalization dimensions that might be unexpected. For example, UPOV is a hard law organization with only a low degree of formalization and delegation. The results also affirm that it is crucial to consider legalization's individual dimensions and indicators. The picture that results from this analysis is complex but necessary if one intends to distill the elements within legalization that have an effect on a certain variable. An aggregated concept of legalization would throw together too many diverse indicators to deliver any meaningful results on legalization's operation and effects. The implications of legalization's dimensions for democratic participation are discussed in chapter 9.

Chapter 8

Empirical Analysis of Democratic Participation in International Institutions – Undemocratic Trends to Different Extents

Most international institutions consider themselves as democratic. The CBD Convention was the first international treaty to explicitly use the term ‘democracy’ in the context of inter-state relations (Pinto 1996a: 259). Article 21 demands in relation to the financial mechanism that it “shall operate within a democratic and transparent system”. Also the WTO defends itself against the claim that it is undemocratic in its booklet “10 Common Misunderstandings about the WTO”. Consensual decision-making is the most democratic rule, it is argued, because it prevents the discrimination against a country. Negotiating in the mode of a single-undertaking is said to reduce the influence of special interest groups because governments have to find a package that is acceptable to all countries (WTO 2008d: 9-10).

In contrast to institutions’ self-description and own standards, the empirical data presented in this chapter illustrates that all six analyzed international institutions struggle to live up to the principles of democratic participation. Although democracy might be an unattainable ideal, some institutions perform better than others. All in all, the CBD is among the highest ranking institutions while the WTO brings up the rear in almost all dimensions.

As described in chapter 3, democratic participation requires *congruence* between rules’ authors and addressees and *contestation* in international decision-making. Congruence and contestation have to be fulfilled with regard to *access* (who) and *involvement* (how) in decision-making. All dimensions have to be satisfied *de jure* and *de facto*. The *de jure* dimension refers to the regulations as of 2010 if not mentioned otherwise. For the *de facto* dimension, I make use of original data on actors’ attendance rate, delegation size, and statements in plenary bodies between 1990 and 2010. The evaluation primarily refers to plenary sessions but also mentions other points of access and involvement if appropriate and illustrative. Following the structure of democratic participation, I start with access and then discuss involvement of states and NSAs. For each dimension, the *de jure* provisions are presented before the *de facto* participatory situation is analyzed.

8.1 De Jure Access – Apparent Democracy on Paper

De jure access is assessed by means of the de jure accreditation rules and other constituent and secondary legal instruments. The formal regulations serve as a first step to assess potential institutional obstacles to or stimuli of democratic participation. It is differentiated between full-fledged members and NSA observers.

8.1.1 States as Primary Full-Fledged Members

With the exception of the WTO, all institutions have de jure democratic membership rules both with regard to congruence and contestation. In all institutions, full membership is primarily provided for states. WIPO adds that a state has to be either a member of a WIPO Union, the UN, any of the UN specialized agencies, the International Atomic Energy Agency (IAEA), the ICJ or be invited by the WIPO General Assembly. Some institutions also admit other actors than states as full members. This encompasses regional economic integration organizations (CBD, FAO), separate customs territories (WTO), and IOs (UPOV).²⁵⁸ The requirements for IOs, however, are high. They are only eligible if the majority of their members are also parties to the respective IO (FAO), possess the authority to make binding decisions for their members (FAO, UPOV), have full autonomy in the conduct of relations relevant for the treaties (WTO) or are competent to grant patents for its members (WIPO-PLT). In practice, this could only be fulfilled by the EU in most cases. FAO and WHO also grant associate membership to any territory or group of territories that is not responsible for the conduct of its international relations (FAO 1945a: Art. 11; WHO 1947: Art. 8).

As to the membership procedure, the CBD only demands accession to the founding treaty. In order to become a party to WIPO, a state that is only member to the Paris or Berne Convention has to concurrently ratify or accede to the Stockholm Act (1967) of the Paris Convention or the Paris Act (1971) of the Berne Convention in its entirety with only one possible limitation (WIPO 2004d: 9; WIPO 1967: Art. 14(2)).

WHO only demands a simple WHA majority (WHO 1947: Art. 6). This also explains why it was the first UN body to which the Palestine Liberation Organization (PLO) applied – even if unsuccessfully – for membership (Lee 2009: 23-24). At FAO and the WTO, one-third of the present parties at plenary bodies can object the admission of a new member (FAO 1945a: Art. 2(2-3); WTO 1994c: Art. 12(2)). More detailed requirements are held by the WTO and UPOV. Both demand compliance with their regulation ahead of full membership. Their membership's higher degree of formalization is indicative for the greater depth of adaption that is demanded from candidates.

Concerning the WTO, the Marrakesh Agreement stipulates that accession to the WTO depends “on terms to be agreed” (WTO 1994c: Art. 7). A 1995 note by the secretariat

²⁵⁸ CBD 1992: Art. 32(1); FAO 1945a: Rules 1-4; FAO 2001: Art. 27; UPOV 1991: Art. 34; WHO 2003e: Rule 13; WIPO 1967: Art. 2(vii), 5; WTO 1994c: Art. 12.

provides further specification and has become the default procedure. The acceding country submits a communication to the Director-General. After the application was circulated to all members, the General Council establishes a working party. This body, which is open to all members, examines the request and submits recommendations that may include a draft Protocol of Accession to the General Council or the Ministerial Conference. In a next step, the applicant is required to prepare a Memorandum on its Foreign Trade Regime. This provides detailed information about the country's trade regulations and statistics relevant to the WTO including GATT, GATS²⁵⁹, and TRIPS. The secretariat or other members can support the candidate's preparation process with technical assistance. The circulation of the Memorandum is followed by one or several Q&A round(s) in which the candidate has to answer questions of clarification and provide further information. If a sufficient fact-finding status has been reached, the working parties launch meetings to enable a further in-depth discussion of outstanding issues and terms of accession. Concurrently, bilateral market access negotiations are held. Interested members submit requests to the applicant who tenders initial offers including a draft Schedule of Concessions and Commitments on goods and a Schedule of Specific Commitments on services. The term and conditions also encompass commitments, disciplines upon accession, and transitional periods for institutional and legislative reforms. After the bilateral negotiations have come to a mutual agreement, the Schedules are consolidated in a multilateral review process and annexed to the draft Protocol of Accession. The latter together with a summary report of the discussion and a draft decision are submitted by the working party to the General Council or the Ministerial Conference that can approve the draft decision with a two-thirds majority (WTO 1995: para. 1-3). The Protocol of Accession enters into force 30 days after the applicant accepted the accession package. Despite these instructions, the WTO accession procedure is not completely predetermined by rules. This applies in particular to the entry costs. These vary significantly in accordance with the interests of existing members and candidates' leverage in the negotiations. The guidelines just refer to the expectation that "the Applicant will ensure that its proposed bindings are at commercially viable levels and reflect the general benefits the Applicant will enjoy upon membership" (WTO 1995: para. 3). This formulation leaves the burden entirely on the candidate to spur the negotiations with its offers while no limit is put to the depth of concessions that can be demanded. Interestingly, bilateral negotiations were not common before the end of GATT (Pelc 2011: 644).

UPOV provides for greater certainty concerning membership price as described in its "Guidance on How to Become a Member of UPOV" (UPOV 2009d). The UPOV Convention as revised of 1991 demands candidates to bring their national law in conformity with UPOV provisions and ensure effective implementation. In contrast to the WTO, the required compliance criteria are more predicable due to UPOV's comprehensive and specific set of IP protection rules for plants. No additional concessions are negotiated

²⁵⁹ GATS=General Agreement on Trade in Services.

bilaterally with existing members. Nevertheless, the procedure is not free of ambiguity: Accession to UPOV is only allowed after the Council's positive examination. In order to get the Council's 'advice', a candidate has to undergo a review of several rounds. It starts with the applicant's request for the Council to study the conformity of its (draft) law with the UPOV Convention. The Council assisted by the Office of the Union prepares an 'analysis document' of the national law. The analysis document together with the national law is published on the website where it can be commented by members and observers. Before the Council reaches its final decision, the Consultative Committee, which is responsible for the preparation of the Council's sessions, scrutinizes the law. The Consultative Committee consists of all full-fledged UPOV members and usually meets prior to the Council's sessions. Upon the Consultative Committee's recommendation, the Council adopts either a positive advice that may include a few modifications of the law or a negative decision that requires re-submitting the law for examination after having satisfied the Council's requests for modification. In addition to the annual membership contribution, a new member has to make a one-time payment of CHF 8,333 multiplied by its assigned number of contribution units to the Working Capital Fund (UPOV 1991: Art. 30, 34). One contribution unit was CHF 53,641 in 2011. The number of contribution units ranges between 0.2 and 5 contribution units (UPOV 2011c). 5 units are paid by the EU, France, Germany, Italy, and the USA.

States can also attend meetings as observers. At the CBD, any state that is not party to the CBD Convention may attend upon the invitation of the President any meeting unless at least one third of the parties present at the meeting object (CBD 1994a: Rule 6; CBD 1992: Art. 23(5)). Any member to the CBD Convention is also permitted to all meetings in relation to protocols regardless if it is a party to that protocol (CBD 1992: Art. 32(2)).

The WHO Director-General may invite candidates for full or associate membership as observers to the WHA (WHO 2003e: Rule 3).

At FAO, parties and associate members that are not members of the Council may attend as observers any Council sessions. This includes also private sessions unless the Council decides otherwise (FAO 1957b: para. A.2). Committees consisting of a limited number of members are generally not open to other parties or associate members unless decided otherwise by the Conference, the commissioners or the Council (FAO 1957b: para. A.4). In addition to that, Conference and Council sessions can be attended upon invitation by members of the UN, any of the UN specialized agencies or the IAEA (FAO 1957b: para. B.1). Such non-members may also attend regional and technical meetings on request and with the Council's approval (FAO 1957b: para. B.2). Former members that exited the institution leaving arrears of contribution are prohibited to send an observer to any meeting of the institution until they have paid up all arrears or the Conference or Council decides otherwise (FAO 1957b: para. B.4).

At UPOV, non-member states may be granted observer status to Council meetings if they have "officially expressed an interest in becoming a member to UPOV and in

participating in the sessions of the Council” (UPOV 2005b: Rule 2(a.i)). As a general rule, observer status is granted for an unspecified duration (UPOV 2005b: Rule 3). Observer status for the Council is the precondition for attending meetings of other UPOV bodies as observers (UPOV 2005b: Rules 2(c.i, d.i, e.i)).

At WIPO, the respective assembly decides on the observer status of non-member states (WIPO 1970: Art. 53(2ix); WIPO 1967: Art. 6(2ix)).

Last but not least, also the WTO grants states observer status to the General Council and its bodies so that they can acquaint themselves with the WTO. Applicants have to express their intent to initiate negotiations for accession within a maximum of five years together with an overview of their current economic and trade policies and future plans of reforms. The General Council decides on a case-by-case basis if observer status is granted. The duration of observership is initially five years and can be extended after a renewed examination by the General Council. Observers have to keep the WTO up-dated on their economic and trade policies. This information may be scrutinized by the General Council. Governments with observer status in the General Council and its bodies shall also be invited to the Ministerial Conference. Also the Ministerial Conference can decide on a case-by-case basis to accord observer status to states. If a request for observer status to the Ministerial Conference is granted, it is not automatically valid for the Councils (WTO 1996d: Annex 2).

Although the institutions’ admission procedures vary, *de jure* congruence and contestation of state access is fulfilled at the CBD, FAO, UPOV, WHO, and WIPO. No state that is potentially affected or critical and wishes for participation is *de jure* explicitly excluded. As already discussed in chapter 3, it is justifiable from a democratic perspective that the status of full membership is predominantly granted to states. Nor is it *per se* democratically problematic that candidates are required to adapt to the institution’s regulations as long as membership is voluntarily.

Nevertheless, the principle of equal treatment is violated at the WTO. Access is not granted on equal terms in a transparent and systematic procedure for every candidate but depends on multi- and even bi-lateral negotiations. The fact that new members have to commit themselves to additional concessions in contrast to original members has created a second class of WTO citizens (Charnovitz 2008). In the other institutions, the veto possibilities of existing members are within reasonable boundaries so that small fractions cannot block the admission of new members. An overview of the *de jure* access of full-fledged members is provided in the table below.

Table 8: De Jure Access of Full-Fledged Members

	Full-fledged members		Procedural criteria
	States	NSAs	
CBD	yes (no restriction)	regional economic integration organizations	accession
FAO	yes (no restriction)	regional economic integration organizations with legal capacity	approval by ² / ₃ of present parties at FAO Conference
UPOV	yes (no restriction)	IOs with legal capacity	‘advice’ by Council on conformity with UPOV law; accession
WHO	yes (no restriction)	no	simple majority of WHA
WIPO	<ul style="list-style-type: none"> • members of the Berne or Paris Union, UN or its specialized agencies, IAEA, or ICJ or • upon invitation 	no	<ul style="list-style-type: none"> • accession • Union members have to accept Berne/Paris Convention in its entirety
WTO	yes (no restriction)	separate customs territory	<ul style="list-style-type: none"> • approval of ²/₃ of present parties at Ministerial Conference • “terms to be agreed”; bi- and multilateral negotiations

8.1.2 NSAs as Observers

The results for NSAs’ de jure access in terms of congruence and contestation are more mixed. While the CBD, FAO and UPOV possess formal democratic access, it is undemocratic at WHO, WIPO and the WTO. I start with the presentation of the formal access rules for IOs followed by those for NSAs.

All institutions allow states, the UN, its agencies, and other IOs to attend meetings as observers. The greatest number of selection criteria for IOs can be found at FAO. FAO requires an observer IO to be in conformity with the general principles of the UN Charter and FAO Constitution, at least partial engagement in food and agriculture policies, an organizational structure that makes effective cooperation with FAO possible, and membership of its members in at least one UN body or agency. Last but not least, FAO scrutinizes the nature of an IO’s relations with other IOs (FAO 1959: para. B.1). In general, the options of informal cooperation should be exhausted before entering formal agreements with IOs (FAO 1959: para. B.2(c.iii)). FAO differentiates between liaison and close cooperation with IOs. The former encompasses reciprocal reporting of activities, representation at meetings, and exchange of information. Close cooperation goes beyond liaison by also including consultation on programs of mutual interest and joint action (FAO 1959: para. C).

The WTO demands observer IOs to be competent in trade policy matters. Other criteria include nature of work, nature of membership, number of WTO members in the IO, and reciprocity of access to meetings and information (WTO 1996d: Annex 3(2-3)).

The CBD and UPOV do formally not differentiate between governmental and non-governmental organizations. At the CBD, NSAs have to be qualified in the fields relating to conservation and sustainable use of biological diversity. At the request of representation, IOs and NSAs are allowed to participate in meetings unless at least one third of the present parties object (CBD 1994a: Rule 7(1); CBD 1992: Art. 23(5)). UPOV requires IOs and NGOs to be of “direct relevance” to UPOV matters (UPOV 2005b: Rule 2). The head of the organization has to send a letter of membership request to UPOV’s Secretary-General containing a brief description of the organization’s objectives, activities, structure and membership. IOs have to add a copy of their constituent treaty and NGOs a copy of their statutes (UPOV 2005b: Rule 3).

WHO regulations do not stipulate specific criteria that are required to enter into a formal relationship with an IO. Consultation and cooperation with NSAs should be “effective” and “suitable” (WHO 1947: Art. 70-71).

All institutions – with the notable exception of the WTO – also allow NGOs to attend meetings as observers. FAO and WHO lay down the most detailed requirements which are to a large extent similar. Comparable to the standards for IOs, FAO requires NGOs – irrespective of their status – to be qualified, be in conformity with FAO’s principles, be substantially engaged in FAO’s field of activity, possess an international organizational structure and a permanent body with representation mechanisms, and have a “recognized standing” (FAO 1957c: Rule 6). Generally, FAO prefers larger organizations and encourages organizations which work in the same field to form associations at meetings (FAO 1957c: Rules: 11(b), 14). In accordance with the UN model, FAO differentiates between NSAs that are granted general consultative status, special consultative status, and roster status (FAO 1957c).

At WHO, eligible NGOs need to be in conformity with the values and goals of the WHO Constitution, possess expertise in health or health-related fields that is also relevant for the implementation of WHO’s health-for-all-strategies, and “present a substantial proportion of the persons globally organized for the purpose of participating in the particular field of interest”. Internal requirements include an international structure with headquarters, representative governing bodies, and voting rights for their members on the organizations’ policies. Like FAO, WHO also encourages NGOs with similar interests to join forces (WHO 1987: Rule 3).

At the CBD, NGO observers only have to be qualified in the field (CBD 1994a: Rule 7(1)). The CBD emphasizes in a draft policy in the course of efforts to reform NGO accreditation that

“[t]he term “qualified” must be interpreted broadly given the nature of the Convention and the range of its stakeholders. In effect, “qualified” should not be interpreted in the classical

scientific sense since there are many community-based organizations (CBOs) as well as indigenous and local community organizations implementing practical conservation and sustainable use measures at the local level but which might not necessarily be “qualified” in that sense” (CBD 2006b: 2).

No criteria with regards to NGO’s nature are specified at WIPO (WIPO 1979: Rule 8).

Being most exclusive, the WTO does not allow for meaningful NGO access to meetings of the Ministerial Conference and completely bars their access to the Councils. While the Marrakesh Agreement does not prohibit but calls for “appropriate arrangements for consultation and cooperation” with NGOs (WTO 1994c: Art. 5(2)), NGO access is restricted by the 1996 “Guidelines for Arrangements on Relations with NGOs”. It rules out direct NGO participation at WTO bodies and encourages informal arrangements and consultation at the national level. Direct contact with NGOs should only be conducted via the WTO Secretariat. Having apparently been aware of its restrictive handling of NGO participation, the WTO pledges in the same breath to improve transparency by a publicly accessible database of WTO documents (WTO 1996c). The Sutherland Report confirms the WTO’s intergovernmental nature and stresses that “the primary responsibility for engaging civil society in trade policy matters rests with the Members themselves” (Sutherland et al. 2004: para. 212). NGOs are only allowed on an ad hoc basis to the formal part of the plenary sessions of the Ministerial Conference. This is not explicitly mentioned in the 1996 Guidelines, but legally possible on the basis of the Marrakesh Agreement (van den Bossche 2008: 726-727; Woodward 2010: 306-307). Also in vociferous protest of these regulations, NGOs have famously called attention to the WTO’s undemocratic procedures outside the Ministerial meetings like in Seattle in 1999. Since May 2008, local NGOs can be granted accreditation to access WTO buildings for specific events and meetings without previous registration (van den Bossche 2008: 728). The accreditation badges are valid for one year. 52 NGOs were accredited by mid-2014.²⁶⁰

The accreditation of new observers is left to various bodies. This is decided by the plenary body at the CBD and WIPO (CBD 1994a: Rules 6-7; WIPO 1967: Art. 6(2ix)). For establishing formal relationships with NSAs, WIPO demands the Coordination Committee’s approval and in the case of national NGOs the consent of the respective government (WIPO 1967: Art. 13(1)). The access of national NGOs has only been possible since 2002 when members agreed on additional principles of granting observer status (Kwakwa 2006: 146; WIPO 2002e: para. 316). WIPO’s subsidiary bodies are allowed to override the General RoP with their own provisions. Most subsidiary bodies have done so in the case of NGOs that can participate on an ad hoc basis even if they have no permanent observer status to WIPO (Woodward 2012: 46).

At FAO, the entering of formal agreements with IOs and the granting of associate membership and consultative NGO status has to be approved by the Conference. The Director-General admits NGOs with specialized consultative and liaison status (FAO

²⁶⁰ Available at: http://www.wto.org/english/forums_e/ngo_e/ngo_e.htm (Accessed 3 April 2014).

1945a: Art. 8; FAO 1957c: Rules 10, 12, 15). At UPOV, the Consultative Committee, which usually holds closed sessions, decides on observer status according to not specialized rules (UPOV 2005b: Rule 2(a.ii)). UPOV's observer status is valid for an unlimited period if not mentioned otherwise (UPOV 2005b: Rule 4). At the WTO, an IO has to request for observer status by the respective body which decides on a case-by-case basis. Observer status to one WTO body cannot be automatically transferred to others. By the same token, IOs may be invited by a WTO body on an ad hoc basis. Also formal arrangements between the WTO and IOs can regulate access conditions (WTO 1996d: Annex 3)

The most intricate accreditation process for NGOs takes place at WHO. The procedure starts with informal contacts in which joint working programs are identified and specified. Successful working relations of at least two years can lead to a formal application for observer status that has to be approved by the Executive Board upon the recommendation of its Standing Committee on Nongovernmental Organizations which is composed of five members (WHO 1987: para. 2-4). If the Board rejects an application, a re-application is only possible after two years since the Board's decision on the original application (WHO 1987: para. 4(3)). National NGOs are only granted admission in "exceptional cases" and "in consultation with and subject to the recommendations of the respective WHO Regional Director and the Member state involved" (WHO 1987: para. 3(5)).

Concerning the veto possibilities of observer status, one-third of parties present at the plenary meeting can object the accreditation of a new IO or NGO observer at the CBD (CBD 1994a: Rules 6(2), 7) and the formal agreement with an IO at WHO (WHO 1947: Rule 70). UPOV, WHO, and WIPO remain silent on the decision-procedure according to which the respective body reaches its decision on the admission of NSAs.

At FAO and the WTO, relationships with observer organizations which did not attend a meeting for two years are likely to be terminated (FAO 1957c: Rule 28; WTO 1996d: Rule 10).

The institutions also differ in respect of meetings to which NSAs are allowed. The CBD is most inclusive stating that NSAs may upon the invitation of the President attend "any meeting in matters of direct concern" (CBD 1994a: Rule 7(2)). At FAO, NSAs with consultative status may attend plenary sessions and meetings of any commission (FAO 1945b: Art. 17(3)). The FAO Guidelines concerning the cooperation with NGOs specify that NGOs with consultative status are entitled to attend sessions of the Conference and Council and may be invited by the Director-General to other relevant FAO meetings (FAO 1957c: Rule 19(a-b)). NGOs with specialized consultative status can send an observer to "appropriate technical meetings" with the approval of the Director-General or may be invited by the Director-General to participate in expert meetings, technical conferences or seminars (FAO 1957c: Rule 21(a)). The Director-General may also invite NGOs with liaison status to specialized meetings if "he is satisfied that such participation may make a significant contribution to the meeting concerned" (FAO 1957c: Rule 24) or to the

Conference and Council sessions if “there are concrete reasons” (FAO 1957c: Rule 25). At WHO, IOs and NGOs with formal cooperation arrangements may attend the WHA’s plenary sessions and the main meetings of the committees (WHO 2008d: Rule 47). WIPO remains vague on this matter.

Evaluating the variety of observer rules, it is positive in democratic terms that almost all institutions require NSA to be qualified in the respective field. In addition to that, FAO and WHO have access requirement relating to an NGO’s internal structure to ensure its accountability to its members.

On the contrary, WHO, WIPO, and the WTO stand out negatively from a democratic perspective. All of them violate the equality standard of congruence and contestation. In the case of WIPO, the principle of equal access is violated since national NGOs face an additional obstacle. The requirement to obtain the consent of their respective government is also democratically questionable in so far as it can impede access of critical NGOs. In fact, indigenous representatives from the Foundation for Aboriginal and Islander Research Action (FAIRA) reported at WIPO’s Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) that some governments are “hostile” toward indigenous groups within their territory (WIPO 2004c: para. 50). Therefore, they most likely encounter problems to obtain their governments’ consent.

The WTO categorically denies NGOs access to Council meetings and leaves it to states to engage with them at the national level. As previously discussed, NGOs can assume important democracy-enhancing functions such as giving marginalized groups a voice. The ad hoc basis on which observers at WTO are invited impedes reasonable and stable relationships with NSAs. For example, many NGOs can no longer afford airplane tickets to the meetings if they are informed on a short notice. The claim that NGOs should predominantly lobby on the national level neglects the necessity for international institutions to improve their democratic quality.

Last but not least, WHO self-critically describes its own process of obtaining observer status as onerous, being dependent on individual contacts, administratively overloaded, and longsome taking up to four years (WHO 2003d: para. 13). This discriminates against understaffed NGOs that often belong to already marginalized groups among affected actors. It also deters NGOs that urgently desire to address a current issue. In addition to that, WHO, like WIPO, requires in the case of national NGOs the consent of the respective member state. An overview of de jure access regulations for observers to plenary bodies is provided in the table below.

Table 9: Overview of NSA Observers' De Jure Access to Plenary Bodies

	NSA Observers	Requirements	Procedural criteria
CBD	<u>IOs/NGOs</u> : any meeting of direct concern	<u>IOs/NGOs</u> : Q	(silent) approval by 2/3 of present parties at COP
FAO	<ul style="list-style-type: none"> • <u>IOs/ consultative NGOs</u>: plenary sessions, Committee meetings • <u>special consultative/liaison NGOs</u>: technical/specialized meetings upon invitation/approval of Director-General 	<ul style="list-style-type: none"> • <u>IOs</u>: C, IR, NIO, Q, UN • <u>NGOs (all statuses)</u>: C, IR, IS, Q, RS 	<ul style="list-style-type: none"> • <u>IOs</u>: approval by Conference • <u>consultative NGOs</u>: approval by Conference • <u>special consultative/liaison NGOs</u>: approval by Director-General
UPOV	<u>IOs/NGOs</u> : yes	<u>IOs/NGOs</u> : IR, Q	<u>IOs/NGOs</u> : decision by Consultative Committee
WHO	<u>IOs/NGOs</u> : WHA's plenary sessions and main committee meetings	<u>IOs</u> : not specified <u>NGOs</u> : C, IR, IS, Q, RS	<u>IOs</u> : approval by 2/3 WHA majority <u>NGOs</u> : approval by Executive Board; working relationship with WHO
WIPO	<u>IOs/NGOs</u> : not specified	<u>IOs/NGOs</u> : not specified	<u>IOs/NGOs</u> : <ul style="list-style-type: none"> • formal relationship: approval by Coordination Committee • national NGOs: consent of 'their' government • access to meetings: approval by respective Assembly or subsidiary body
WTO	<ul style="list-style-type: none"> • <u>IOs</u>: Ministerial Conference, Councils • <u>NGOs</u>: Ministerial Conference (not mentioned in RoP) 	<u>IOs</u> : Q, number of WTO members, reciprocity, past membership with GATT <u>NGOs</u> : Q	<ul style="list-style-type: none"> • <u>IOs</u>: case-by-case basis of respective WTO body (upon invitation, formal agreement) • <u>NGOs</u>: ad hoc system for Ministerial Conference

[Legend: C=in conformity with institution's general principles; IR=internal requirements; IS=international structure; NIO=nature of relations with other IOs; Q=qualified in field; RS=recognized standing; UN=membership in at least one UN body or agency.]

8.2 De Facto Access – Dominance of IP Supporters

In order to assess de facto access, meeting documents of the institutions' plenary bodies are analyzed. The investigated time period differs across institutions since the CBD and WTO were established only after 1990 and not all documents for UPOV and WIPO are made available. An overview of the analyzed documents is presented below.

Table 10: Analyzed Documents for De Facto Access

	Meeting	Time period	Number of meetings
CBD	COP 1-10	1994-2010	10
FAO	FAO Conference 26-36	1991-2009	11
UPOV	UPOV Council 33-44	1999-2010	12
WHO	WHA 43-63	1990-2010	21
WIPO	WIPO Assemblies 22-26, 28-48 ²⁶¹	1991-2010	26
WTO	Ministerial Conference 1-7	1996-2009	7

I focus in the analysis of states on the *mostly affected actors* in the fields of (1) ABS, (2) TK, (3) protection of plant varieties, and (4) public health as presented in chapter 5. To simplify matters, I refer to states that are predominantly negatively affected by a strict and comprehensive IP regime à la TRIPS as IP skeptics and those that are positively affected as IP supporters. It is assumed that the representation of IP supporters and IP skeptics needs to be balanced in order to allow for contestation between mostly affected actors.

The discussion of state access encompasses (1) de facto membership and the absolute number of actors who have de facto access, (2) attendance rate, and (3) delegation size. If not stated otherwise, only full-fledged state members are included in the analysis because observer states and associate members do not observe the same participatory rights. Their attendance rate and delegation size are counted as zero although it is noteworthy that their exclusion would not significantly change the results.

8.2.1 De Facto State Access – Undemocratic Trends at UPOV and WTO

8.2.1.1 State Membership – Congruence and Contestation I

Concerning the institutions' absolute number of state parties (EU excluded) in 2010, WHO (193), CBD (192), FAO (190), and WIPO Convention (184) were the most global ones, the WTO (152) ranks on a medium level, and UPOV (67) had the lowest number of members. WIPO's membership appears in a less democratic light if one considers the individual treaties that it administers. Two treaties are in particular relevant for biotechnological patents. While the PCT counted 142 state members in 2010, there were only 26 parties to the PLT.²⁶² Not all of the full-fledged members are sovereign states in the sense that they

²⁶¹ If not specified otherwise, the results refer to the participants of all Assemblies. The main reason is that the lists of participants do not differentiate between the Assemblies for some years.

²⁶² In January 2015: CBD (194), FAO (196), WHO (194), WIPO Convention (188), WIPO-PCT (148), WIPO-PLT (36), WTO (160).

are at the same time UN members. This explains also the high number of states at WHO. With 193 member states, it had more parties than the UN with 192 member states in 2010. Among them are the Cook Islands and Niue which are also full members to the CBD and FAO. In exceptional cases, few international institutions have accepted dependent territories as full members. For example, FAO had already admitted on the recommendation of the UN General Assembly Namibia as full member in 1977 before the country became officially independent in 1990 (Schermers/Blokker 2011: 67). Other exceptions are Hong Kong and Macau which become members to the WTO in 1995 before they become Special Administrative Regions of China in 1997 and 1999 respectively. Associate members are Tokelau and Puerto Rico at WHO and Faroe Islands and Puerto Rico at FAO.

As indicated by the absolute membership numbers, most of the mostly affected states concerning biotechnological patents remain outside UPOV and the WTO. Not only congruence is impaired in these institutions but also contestation because most of the mostly affected actors who were either excluded or coerced into membership are IP skeptics.

All of the mostly affected states are members to FAO and the WIPO Convention. Most of them are members to the CBD and WIPO's PCT and PLT. At the CBD, the USA is the only among the mostly affected actors who is not a full member – but of its own choice. President Clinton signed the CBD Convention in 1993 after George W. Bush refused to do so one year earlier. However, it has not been ratified by the U.S. Senate. One reason for its refusal was the concern that the demand for the transfer of technology could infringe on IPRs (Bang 2011: 73). By January 2015, the USA together with Andorra and the Holy See were the only states that were not a party to the CBD. Although the USA has been a member to the WIPO Convention and PCT since 1970 and 1978 respectively, it only joined the PLT in December 2013. Also Mozambique, which is a mostly affected IP skeptic in the debate on public health, only became a member of the WIPO Convention in 1996 and the PCT in 2000. But this country is an exception to WIPO's generally broad membership.

At UPOV, all of the mostly affected IP skeptics, which are predominantly African countries, had no membership. Also India as an IP skeptic has not joined UPOV so far. China, being within the group of countries with most applications for seed titles, only became a UPOV member in 1999. IP skeptics' absence is owed to these countries' concerns against a strict and comprehensive protection of breeders' rights.

At the WTO, especially in the area of TK and protection of plant varieties, mostly affected IP skeptics only became members in recent years. This includes, for example, Cambodia (2004), China (2001), Laos (2013), Nepal (2004), Ukraine (2008), and Vietnam (2007). Russia as one state with the most applications for seed titles, only acted as observer government in the WTO during the analyzed time period and became a full member in August 2012. Also Algeria and Ethiopia have only been granted observer status.

The lowest numbers of members at UPOV and WTO indicate democratic access problems of two different kinds. First, the WTO accession procedure leads to unequal conditions under which candidates are allowed to enter the institution. Depending on existing members' interests and demands in the bi- and multilateral negotiations of the working party, the accession packages differ with regard to candidates' commitments. The WTO explicitly emphasizes on its website:

“Because each accession Working Party takes decisions by consensus, all interested WTO Members must be in agreement that their individual concerns have been met.”²⁶³

WTO members' capability to enforce concessions is highest at the institution's gateposts where every existing member holds veto power to reject candidates. Having got 'inside' the institution, new members have not only reached their goal of entry but are also protected by the most-favored-nation principle (Pelc 2011: 641). Sudip Ranjan Barcu and his colleagues arrive at the conclusion that lower middle-income countries had to make the deepest commitments. The two countries with the greatest commitments are mostly affected actors with regard to biotechnology-related patents: China and Viet Nam (Basu et al. 2009: 14).²⁶⁴ An illustrative case for the WTO's burdensome procedure is Saudi Arabia. It had to endure ten years of negotiations in which it replied to 3,500 questions, provided 7,600 pages of documentation, and demonstrated its compliance with 28 Royal Orders and 42 laws and regulations (Evenett 2006). Also Russia applied for WTO membership in 1993 but did not receive full membership before December 2011.

The reasons why candidates, including IP skeptics, accept these conditions are manifold. First, developing countries can profit from market access in developed countries in fields of comparative advantage. Second, the WTO's external demand for economic adaption can help policy-makers to enforce structural reforms. Third, WTO membership can help to build up credibility with business actors. This can create new business relationships and attract investment. Fourth, the WTO agreements also promise technical assistance and measures of capacity-building for developing countries and LDCs. Fifth, members can use the dispute settlement procedure in the case of illegal trade restrictions. Sixth, the participation as a full member in the WTO is a precondition to influence the development of the trading regime in the future. These hopes, however, have been widely disappointed (Basu et al. 2009: 1-3; Pelc 2011: 648-649).

Secondly, democratic standards demand that accession is an act of candidates' own volition. This is very questionable in the case of UPOV. While developing and transition countries usually aspire to become WTO members in order to reap economic benefits by the integration into the international trading system, they are more reluctant to join UPOV. Especially agricultural developing countries have raised concerns that UPOV one-sidedly

²⁶³ Available at: http://www.wto.org/english/thewto_e/acc_e/acces_e.htm (Accessed 8 May 2013).

²⁶⁴ Similarly, Krzysztof J. Pelc argues in his statistical analysis that in particular middle-income countries have to commit to the deepest liberalization concessions since they are vested with a lower bargaining capacity than the wealthiest countries, but they have a more valuable market access to offer than developing or least-developed countries. In fact, the latter had to make the relative smallest adjustments (Pelc 2011: 641-642).

protects breeders' rights that destroy the traditional system of saving and freely exchanging seeds on which national farmers heavily depend (Lindstrom 2010: 958). As a reaction to this widespread reluctance, economically powerful countries and most prominently the USA forced countries into UPOV by either making UPOV membership a precondition to WTO accession or part of TRIPS-Plus agreements. With regard to WTO accession, the USA attempted to make UPOV membership a precondition in Nepal's accession talks to ensure compliance with Article 27(3b) of TRIPS (Rajkarnikar 2005: 425-427). As part of TRIPS-Plus, UPOV accession is, just to name a few examples, a clause in the U.S. FTAs with Laos, Singapore and Vietnam²⁶⁵, the Japanese FTA with Indonesia, and the EU's FTAs with Egypt, Mexico, South Africa, and Turkey (Basso/Beas Rodrigues 2007: 193-196; Lindstrom 2010: 930-933). "Accession to or compliance with the UPOV Convention is perhaps the most common TRIP-plus provision found across PTAs [Preferential trade arrangements] in the Asia Pacific region" (Lindstrom 2010: 958). The UPOV accession procedure has also run into national opposition. In spring 2013, fervent protests accompanied Tanzania's attempt to modify its Rights Act for Mainland Tanzania in order to conform to UPOV's latest 1991 Act. Protestors criticized farmers' exclusion in the preparation of the new law (Saez 2013). One step further went Colombia's Constitutional Court in December 2012. It declared the Act 1518, which approves UPOV's 1991 version, unconstitutional because it was passed without the consultation of indigenous and local people in the beginning of 2012. The accession to UPOV's latest Act was made a precondition by the U.S. for signing the Free Trade Agreement with the country.²⁶⁶ Also in Costa Rica the ratification of the U.S.-Central American Free Trade Agreement (CAFTA) met harsh criticism due to its requirement to join UPOV, but it was eventually approved by a referendum (Aistara 2012).

UPOV and the WTO share a similar outcome: candidates are pressured into strict conformity with the institutions' rules before they can enter. The requirement of an a priori structural adaption of one's national system can potentially nip contestation in the bud.

Among IOs, only the EU could live up to the demanding criteria for NSAs to become a full-fledged member. It is a full member to the CBD (1993), FAO (1991), UPOV (2005), and WTO (1995). FAO is an exception to the general UN rule that the EU cannot become full member to the UN and its specialized agencies. An amendment to the FAO Constitution made it possible to accept the EU in form of a regional economic organization as full member. In order to ensure a division of competences, FAO has to be provided with a list that explicates the areas in which the EU possesses full powers. In practice, EU powers and the distribution of voting rights have to be determined for each agenda item prior to each FAO session. Otherwise, member states' competences are

²⁶⁵ The bilateral trade agreement between Vietnam and USA is the "most comprehensive bilateral agreement that Vietnam has ever signed with another country" (Kuanpoth 2007: 207). It was signed in 2000 and entered into force in 2001.

²⁶⁶ Available at: <http://sullivanlaw.net/colombian-court-strikes-law-approving-1991-plant-variety-protection-convention/> (Accessed 2 February 2014).

presumed. The EU has no competences for financial and organizational matters and therefore is not eligible for election and designation to sub-bodies with restricted membership. The WTO, by contrast, does not differentiate between the EU and other member states (Frid 1993; Wessel 2011: 628-629). With regard to the evaluation of democratic participation, the EU membership renders no significant influence. It has neither a particularly positive nor negative influence on democratic participation as long as its members' overall voting weight is not diminished or amplified. The advanced state of EU integration justifies that the organization acts on behalf of its members in areas of common policies.

8.2.1.2 State Attendance Rate – Congruence and Contestation II

State members' attendance rate in the plenary sessions serves as an indicator of both states' capacity and willingness to engage in meetings. The results show three main trends.

First, there is a general high attendance rate. The overall attendance rate of state members was particularly high at the WTO (93.2%) and WHO (91.6%), moderate at FAO (83.3%) and the CBD (80.1%) and lowest at WIPO (69.8%) and UPOV (54.1%). If one considers full state members only, the ranking stays the same but on a higher level of attendance rate: WTO (99.5%), WHO (94.6%), FAO (88.1%), CBD (83.8%), WIPO (79.1%), and UPOV (74.8%). UPOV and WIPO also stand out when comparing the frequency of states' individual attendance rates. While the great majority of full state members participated in at least 90% of all meetings at the CBD (56.6%), FAO (67%), WHO (77.2%), and the WTO (80.3%), it was only 38.3% at WIPO and 30% at UPOV. UPOV also displays the highest frequency of low attendance rates. 26% of all states participated in less than 20% of all meetings.

Second, congruence with regard to attendance rate of full-fledged members was fulfilled in all institutions with the exception of UPOV and the WTO. There, the mostly affected actors exhibit lower attendance rates than the average delegation. As a yardstick, I consider the ratio of mostly affected actors' attendance rate to the average one. It meets the standard of congruence if it is at least 1.0. At UPOV, the ratio is only 0.5. The reason for this low ratio is the fact that none of the mostly affected IP skeptics attended a meeting. If one only includes IP supporters, the ratio increases to 1.2. At the WTO, the ratio is only 0.8 with regard to the protection of plant varieties and 0.9 with regard to TK. Besides the WTO, there are also ratios of 1.0 at WHO and FAO with regard to plant varieties. These are not optimal but still acceptable in terms of congruence due to the overall high attendance rates that make variation more demanding.

Third, contestation with regard to attendance rate was fulfilled in four of the institutions (CBD, FAO, WHO, and WIPO). As a benchmark, I choose the interval of [0.9; 1.1] to represent a balanced ratio between IP supporters and IP skeptics. IP supporters have clearly higher attendance rates at UPOV (0.5) and the WTO (1.3) concerning TK. Again, one main cause for the lack of meaningful differences between the institutions is the low

variance of attendance rates. The results for full-fledged members are summarized in the table below.

Table 11: Democratic State Access and Attendance Rate

Issue area	Indicators	CBD	FAO	UPOV	WHO	WIPO	WTO
All actors	Average (in %)	83.8	88.1	74.8	94.6	79.1	99.5
ABS	MAA (in %)	92.2	98.8	–	–	93.1	96.6
	Ratio: MAA/AV	1.1	1.1	–	–	1.2	1.0
	Ratio: IP sp./ IP sk.	0.9	1.0	–	–	1.1	1.0
TK	MAA (in %)	90.0	100	–	–	91.9	84.1
	Ratio: MAA/AV	1.1	1.1	–	–	1.2	0.9
	Ratio: IP sp./ IP sk.	0.9	1.0	–	–	1.1	1.3
Plant varieties	MAA (in %)	–	88.8	34.6	–	–	77.5
	Ratio: MAA/AV	–	1.0	0.5	–	–	0.8
	Ratio: IP sp./ IP sk.	–	1.0	<i>IP sp. only</i>	–	–	1.0
Public health	M MAA (in %)	–	–	–	98.8	–	100
	Ratio: MAA/AV	–	–	–	1.0	–	1.0
	Ratio: IP sp./ IP sk.	–	–	–	1.0	–	1.0

[Legend: AV=average; MAA=mostly affected actors; sk.=skeptics; sp.=supporters.]

8.2.1.3 State Delegation Size – Congruence and Contestation III

Delegation size serves as another indicator for assessing state access. The data on the CBD needs to be considered cautiously as the institution only provides detailed lists of participants in four out of ten meeting documents so that generalizability cannot be ensured. For the WTO Ministerial Conference, five out of seven meetings include information on delegation size. Three main findings can be derived from the data.

First, the delegation size of full-fledged state members varies considerably across the institutions. States made a significant effort to attend with large delegations at the WTO where on average almost 14 individuals per state attended the Ministerial Conference. It is followed by WHO (7.1), the CBD (6.2), FAO (5.4), WIPO (2.9), and UPOV (1.7). If one considers all state members including observers, the ranking does not change and only the delegation size slightly increases. Concerning states' individual delegation size, one can generally observe great variance across all institutions. For almost all delegation sizes the standard deviation is at least one-third if not one-half of states' average delegation size. Therefore, one can draw the conclusion that states' delegation size also depends on other context factors such as issues at stake or meeting place. An analysis of the countries with the largest delegation sizes demonstrates that the venue affects delegation size. Italy ranks among the three largest delegations in 10 out of 11 meetings of the FAO Conference that always takes place in Rome. A similar effect can be observed for the host countries of the CBD COPs and WTO Ministerial Conference. Taking the example of CBD, the Bahamas participated with a delegation size of 42 at the first COP meeting taking place in its capital

Nassau. It was only a delegation of 4 representatives the year afterwards and even no delegate in 2010. Similarly, Brazil was represented with 417 individuals at COP 8 in Curitiba. In the following year, there were only 98 delegates and only 11 and 13 delegates at the first two COP meetings.

Second, congruence with regard to delegation size was fulfilled in all institutions except for UPOV. Mostly affected actors attended with larger delegations than the average delegation. Only at UPOV, the absence of IP skeptics considerably decreases the ratio to only 0.5. IP supporters participated with a 1.3 larger delegations size than the average delegation size. The results are presented in the table below.

Table 12: State Congruence and Delegation Size

Issue area	Indicators	CBD	FAO	UPOV	WHO	WIPO	WTO
All actors	Average DS	6.2	5.4	1.7	7.1	2.9	15.7
ABS	MAA DS	22.3	8.9	–	–	5.2	34.9
	Ratio: MAA/AV	3.6	1.6	–	–	1.8	2.2
TK	MAA DS	18.4	9.9	–	–	5.3	33.9
	Ratio	3.0	1.8	–	–	1.8	2.2
IP plant varieties	MAA DS	–	7.1	0.9	–	–	21.0
	Ratio	–	1.3	0.5	–	–	1.3
Public health	MAA DS	–	–	–	12.0	–	34.6
	Ratio	–	–	–	1.7	–	2.2

[Legend: AV=average; DS=delegation size; MAA=mostly affected actors.]

Third, contestation with regard to delegation size was best fulfilled at the CBD, FAO, and WIPO and worst at UPOV, WHO, and the WTO. I compare the average normalized delegation sizes of IP skeptics and IP supporters and calculate the ratio of IP supporters to IP skeptics. One general result is that the mostly affected IP supporters always attended with larger delegation sizes than the mostly affected IP skeptics. Other trends can be drawn from the individual issue areas.

ABS. The comparison of the delegation size between the group of the LMMC and the countries with the six highest numbers of biotechnological patent applications illustrates that IP supporters exhibit higher delegation sizes in all institutions although to a varying degree. Their representation was by far highest at the WTO where bio-tech countries had 3.3 times higher delegation sizes than the LMMC. Japan always attended with the highest largest delegation ranging from 87 representatives in 1998 to 235 in 2010. At the WTO, one can also observe a growing increase of IP supporters. IP supporters' dominance was lowest at the CBD where their average delegation size was only 1.6 times higher, slightly followed by FAO with a ratio of 1.9. In the case of the CBD, it is reasonable to consider also the ratio without the Bonn COP meeting in 2008 because the enormously and unusually large German delegation of 403 individuals considerably distorts the results.²⁶⁷

²⁶⁷ The German delegation consisted of only 13 representatives in 1994, 38 in 1995, and 36 in 2006.

The exclusion of this year reduces the ratio to only 1.1. At FAO, the delegation size of both groups considerably increased in 2001 at the meeting in which the ITPGR was adopted, but the ratio between the groups stayed the same. In-between lays WIPO with a ratio of 2.1 while the millennium marked a turn toward better representation of the LMMC.

TK. In the field of TK protection, IP skeptics are indigenous-rich countries and IP supporters countries with most pharmaceutical patent applications. IP supporters were most predominant at the WTO where they attended with delegation sizes that were on average 3.9 times higher than those of IP skeptics. The balance between IP supporters and IP skeptics was greatest at FAO with a ratio of 1.6. WIPO and the CBD lay in the middle with ratios of 2.0 and 3.2 respectively. At WIPO, the delegation size of indigenous-rich countries had more or less continuously increased since 2003. Without the 9th COP of 2008, the ratio at the CBD is only 2.1

Plant varieties. As to the IP protection of plant varieties, I compare agricultural states with countries of which the residents file most seed title applications. At UPOV, none of the mostly affected IP skeptics participated to counterbalance the interests of the mostly affected IP supporters. The ratio is also high at the WTO with 7.4 and lowest at FAO with 2.7.

Public health. To analyze the balance for public health, I compare the countries that are mostly affected by HIV/AIDS with the countries of which the residents file most pharmaceutical patent applications. The dominance of IP supporters was highest at WHO and the WTO with a ratio of 4.5 and 4.4 respectively. At WHO, IP supporters' delegation size increased since 2004. This coincides with the establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). The average ratio for the period between 1990 and 2003 is only 4.1.

The table below presents a summary of contestation in terms of affectedness and delegation size. If the democratic principle of contestation is taken seriously, all institutions are fairly undemocratic since IP supporters were overrepresented. The representation of both sides was most balanced at the CBD and FAO and most imbalanced at UPOV and the WTO.

Table 13: State Contestation and Delegation Size (Normalized Data)

Issue area	Average delegation size	CBD ²⁶⁸	FAO	UPOV	WHO ²⁶⁹	WIPO ²⁷⁰	WTO
ABS	IP skeptics	5.9 (6.5)	1.5	–	–	1.4 (1.2)	2.2
	IP supporters	9.4 (6.0)	2.8	–	–	3.0 (3.0)	7.2
	Ratio: IP skeptics/ IP supporters	1.6 (1.1)	1.9	–	–	2.1 (2.5)	3.5
TK	IP skeptics	2.8 (2.8)	1.7	–	–	1.4 (1.3)	1.7
	IP supporters	9.1 (5.8)	2.7	–	–	2.8 (2.9)	6.8
	Ratio	3.2 (2.1)	1.6			2.0 (2.3)	3.9
Plant varieties	IP skeptics	–	0.9	none	–	–	0.6
	IP supporters	–	2.4	1.6	–	–	4.5
	Ratio	–	2.7	<i>only IP supporters</i>	–	–	7.4
Public health	IP skeptics	–	–	–	1.3 (1.3)	–	1.5
	IP supporters	–	–	–	5.8 (5.1)	–	6.8
	Ratio	–	–	–	4.5 (4.1)	–	4.4

The dominance of economic power can also be illustrated by GDP's influence on delegation size. The Spearman Test confirms a highly statistically significant positive correlation between GDP and delegation size in all institutions. The relationship is strongest at the WTO (.820/.000), closely followed by WHO (.789/.000), FAO (.725/.000), WIPO (.682/.000), and the CBD (.584/.000).

All results taken together, yield similar results. UPOV and the WTO consistently displayed the least democratic state access. As to membership, states were pressured to join UPOV while the WTO admitted members on unequal terms. Also with regard to attendance rate and delegation size, UPOV could not live up to the standards of congruence and contestation whereas the WTO was only democratic in terms of congruence and delegation size. In both institutions, IP supporters were most dominant. WHO did not fulfill contestation with regard to delegation size. The CBD, FAO, and WIPO did not violate the standards of congruence and contestation with regard to state access.

²⁶⁸ ()=without 2008.

²⁶⁹ ()=period 1990-2003.

²⁷⁰ ()=period 1991-2000.

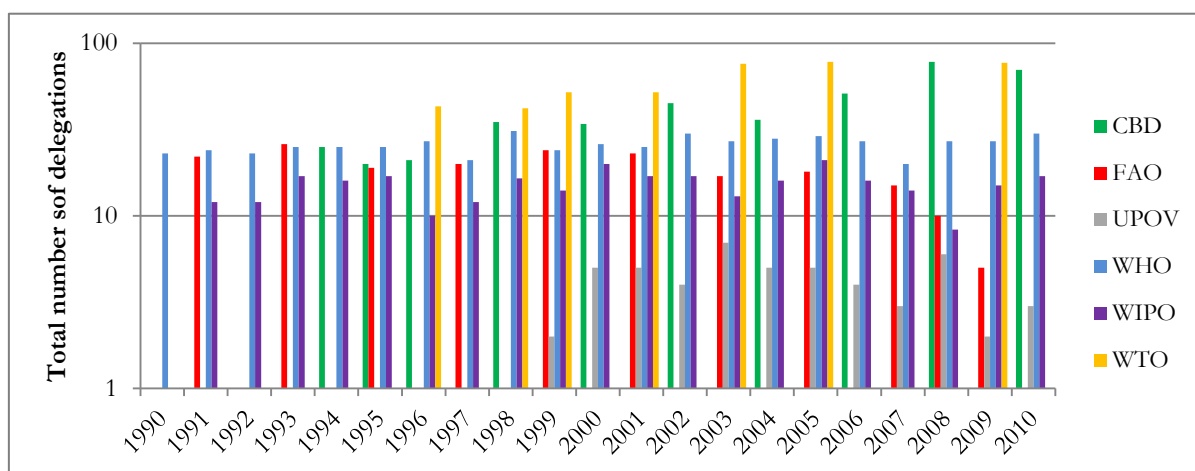
8.2.2 De Facto NSA Access – Unequal Attendance of a Heterogeneous Group

The measurement of affectedness is more complicated for NSAs than states. The quantitative proxies that are used for states cannot be applied since they are bound to territorial borders which NSAs are famously known to cross. In order to still differentiate between the various organizations in this heterogeneous group, I present information on NSAs' relative and absolute numbers, NSAs' nature, IOs' scope of membership, and NGOs' headquarters.²⁷¹ It is presumed that there needs to be a balance in terms of NSAs' interests and origin to enable contestation. The analysis shows striking differences across the institutions. I consider IOs and NGOs separately in order to do justice to both groups' different de facto access possibilities.

8.2.2.1 Relative and Absolute Numbers of NSA Attendance – NSA Congruence

The average proportion of *UN and other IO bodies* among all delegations was comparatively constant ranging from 7.2% (UPOV) to 9.7% (WTO). In absolute numbers, the picture becomes more diverse. While the WTO still spearheads with an average of 60.0 IOs at the Ministerial Conference, it is followed by the CBD (37.7), WHO (25.9), FAO (18.1), WIPO (14.2), and UPOV (4.5). A comparison of IOs' de facto access from 1990 to 2010 across the institutions shows fluctuation in most cases (see figure below). Only at the CBD and the WTO the absolute numbers of IO attendance increased constantly. The number rose from 20 IOs in 1995 to 70 IOs in 2010 at the CBD and from 43 IOs in 1996 to 76 IOs in 2003 where it remained on a steady level at the WTO. The highest variation can be observed at FAO where the number of attending IOs ranged between 5 and 26, followed by WIPO [8; 20]. More constant was IO attendance at WHO [21; 31] and most stable but also lowest at UPOV [2; 7]. The following figure summarizes IOs' de facto access to plenary sessions between 1990 and 2010.

Figure 7: IOs' De Facto Access to Plenary Meetings, 1990-2010 (Log Scale)



²⁷¹ A project by Marcel Hanegraaff and his colleagues also presents information on NGOs' nature and region (Hanegraaff et al. 2011).

The WTO figures for the Ministerial Conference can be misleading. If one takes into consideration IOs' attendance at the Council bodies, which meet more regularly, WTO's de facto IO attendance is far more restrictive. By September 2014, the Councils granted 6 to 10 IOs permanent observer status. The TRIPS Council allowed for 9 permanent observers and 4 ad hoc observers.²⁷²

The average attendance rate of IOs, like for states, was highest at the WTO and WHO. On average, an IO attended 75.7% of all meetings at the WTO (5.3/7) and 59.1% at WHO (12.4/21). The other institutions' ranking of IO attendance does not commensurate with those for states. IOs attended on average 44.2% of all meetings at UPOV (5.3/12), 30.9% at FAO (3.4/11), 30.7% at the CBD (3.1/10), and 25.7% at WIPO (6.7/26). The high attendance rates for WHO and the WTO are not surprising. The WHO accreditation procedure, as it has already been described, is longsome. One would expect only those IOs to undergo this procedure which are sincerely interested in a meaningful and long-term relationship with WHO. In the case of the WTO, high-profile issues with an impact on the work of other organizations have attracted NSA attendance. Therefore, many financial and regional IOs attended the Ministerial sessions.²⁷³

With regard to IOs' delegation size, the CBD and WTO rank highest with an average value of 4.8 and 4.0, closely followed by WHO with 3.6 and FAO with 3.2. Bringing up the rear, WIPO had an average delegation size of 2.2 IOs and UPOV only of 1.5 IOs. The ranking for IOs is similar to that of states' delegation size.

Relatively speaking, by far most NGOs attended the WTO Ministerial Conference. The absolute number of NGO delegations ranked between 107 NGOs in 1996 to 883 in 2003.²⁷⁴ On average 59.6% of all delegations were NGOs. The main selection criteria were relevant activities and the non-profit character of the NGO. However, NGOs could only attend the formal plenary meeting where state representatives mostly read prepared statements (van den Bossche 2008: 727, 746). Beyond this number, one should also not forget that no NGO has been allowed to the WTO Council meetings. In principle, the TRIPS Council has one legal loop hole at its disposal that would make it formally possible to also invite NGO representatives. Article 69 of TRIPS notes that in "carrying out its

²⁷² For an overview see: http://www.wto.org/english/thewto_e/igo_obs_e.htm#trips (Accessed 26 September 2014).

²⁷³ This includes, for example, the Andean Community (CAN), African Union, Latin American Integration Association (ALADI), Arab Monetary Fund (AMF), Arab Organization for Agricultural Development (AOAD), ASEAN, Asian Development Bank, CARICOM, Common Market for Eastern and Southern Africa (COMESA), European Bank for Reconstruction and Development (EBRD), Economic Community of West African States (ECOWAS), Cooperation Council for the Arab States of the Gulf (GCC), Islamic Development Bank, Organization of the Petroleum Exporting Countries (OPEC), South Asian Association for Regional Cooperation (SAARC), and Southern African Development Community (SADC).

²⁷⁴ My data on NGO delegations lies systematically below the official WTO data as available at http://www.wto.org/english/news_e/news03_e/ngo_minconf_6oct03_e.htm (Accessed 2 July 2014). It is only a difference of one delegation for 1996 and three NGO delegations for 1998 and 1999. But the discrepancy is larger in the following years with 40 delegations in 2001 and 88 delegations in 2003. One reason is that I pool together NGOs of one organization if it was represented by various national groups.

functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate.” This provision has not been used yet.

The WTO has been trying to compensate for the lack of formal contact with NGOs with numerous outreach activities. These include seminars and public symposiums (WTO Public Forum, formerly: Public Symposium)²⁷⁵, circulation of NGO position papers and NGO studies, regular Secretariat briefings, participation of the WTO organs’ chairpersons in NGO discussions, and a special website-section for NGOs²⁷⁶. In 2003, the then WTO Director-General Supachai Panitchpakdi established the Informal NGO Advisory Board and Informal Business Advisory Board in 2003. The NGO Advisory Board consisted of 10 high level NGO representatives who could communicate their position on WTO matters to the Secretariat. They met with the Director-General three times a year for a joint lunch prior to important WTO events. The work of both Advisory Bodies ended with Panitchpakdi’s term of office. Also the effects of the other measures have been limited. So have only a low number of officials and diplomats participated in the public symposia.²⁷⁷

Second ranks the CBD with an average proportion of 59.0% NGO delegations and over 650 NGO delegations at the COPs in 2006 and 2010. It is followed by WHO with an average proportion of 28.2% and an absolute number of 79.6 NGO delegations. In this context, it is worth noting that by the institution’s own account its formal contacts with NGOs made up for only 45% of its total relationships with NGOs (WHO 2003d: para. 8). The FAO Conference was on average attended by 29.4 NGO delegations making up 13.9% of all delegations. At WIPO, NGOs comprised on average 10.5% of all delegations. The bottom is represented by UPOV with only 6.6% NGO delegations.

If the “opening up of international institutions to TNAs [transnational actors] is one of the most profound changes in global governance over the past quarter of a century” (Tallberg 2010: 60), one would expect an increasingly inclusive NGO access to international institutions (Charnovitz 1997; Tallberg 2008). NGOs’ growing influence in international rulemaking has usually been proven with reference to the formal access that is granted to NGOs in almost all international institutions nowadays.²⁷⁸ Indeed, the number of NGOs with consultative status at ECOSOC grew from 41 in 1946 to 3,536 by the end of 2011 (ECOSOC 2011).²⁷⁹ However, if one evaluates the absolute number of NGO delegations in the six cases, as illustrated in the figure below, a general trend of increased NGO access to international institutions cannot be discovered de facto.

²⁷⁵ Available at: http://www.wto.org/english/forums_e/public_forum_e/public_forum_e.htm (Accessed 3 July 2014).

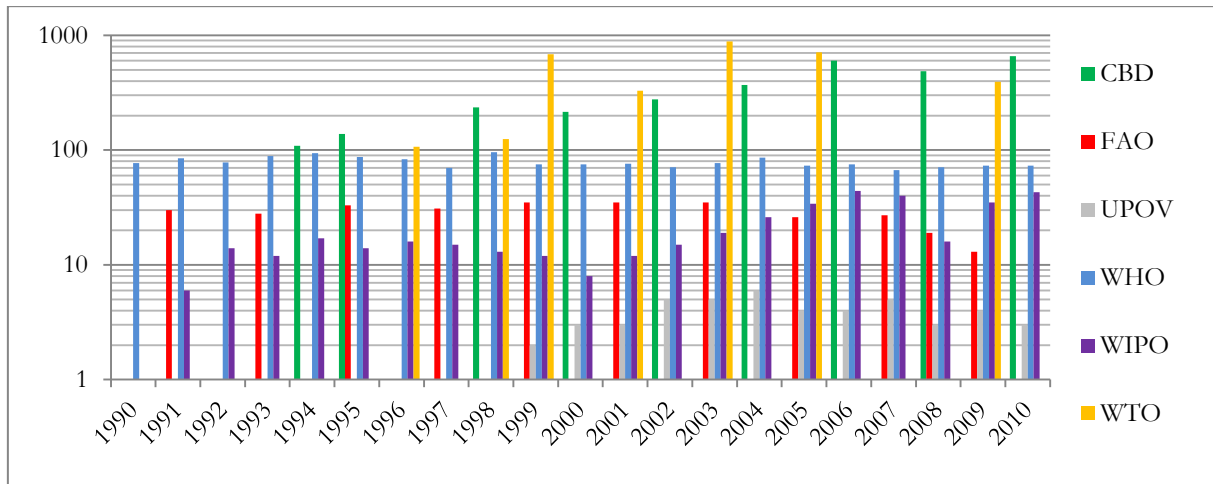
²⁷⁶ Available at: http://wto.org/english/forums_e/ngo_e/ngo_e.htm (Accessed 3 July 2014).

²⁷⁷ Steffek/Ehring 2008: 109; van den Bossche 2008: 728-735; Williams 2011: 116-117; WTO 2001h.

²⁷⁸ Charnovitz 1997; Tallberg et al. 2014; Tallberg et al. 2013.

²⁷⁹ This apparently “clear trend towards increasing NGO participation” (Oberthür et al. 2002: 210) and “dramatic growth in TNA access to IOs over recent decades” (Tallberg et al. 2014: 742) was even euphorically labeled as “participatory revolution” (Raustiala 1997a: 537).

Figure 8: NGOs' De Facto Access to Plenary Meetings (Total Number of Delegations in Log Scale)



Given these figures, the emergence of a universal norm of democratic participation that includes NGO participation has to be questioned. It demonstrates that de jure provisions do not necessarily have to materialize in de facto participatory rights. Absolutely speaking, the number of NGOs only steadily increased at the CBD from 109 delegations in 1994 to 658 delegations in 2010 and at a much lower level at WIPO in the 2010s from 8 in 2000 to 43 in 2010. Most irregular was the total number of delegations at FAO and the WTO.

As to the consistency of NGO attendance, the CBD ranks lowest. An NGO attended on average only 1.5 out of eleven, or in other words 13.4% of all COP meetings. Closely ahead is WIPO where NGOs were present at 15.4% (4/26) of all meetings. Higher ranks the WTO with an attendance rate of 27.1% (1.9/7), FAO with 31.8% (3.5/11), and UPOV with 35.8% (4.3/12). The highest attendance rate exhibits WHO. NGOs attended on average 8 out of 21 meetings (38.1%). In its own review, WHO summarizes that 40.4% of the 189 NGOs that were in official relationships with WHO between 1998 and 2002 attended WHA meetings (WHO 2003d: para. 7; WHO 2002b: 3). Similar to IOs, also NGOs that made the effort to endure the accreditation procedure showed a serious interest to consistently attend meetings. The importance that NGO attribute to an official relationship with WHO is also illustrated by the fact that many advertise their WHO accreditation on their website.²⁸⁰ By comparison, IOs' attendance rate was generally higher than those of NGOs with the exception of FAO at which NGOs attended with slightly more consistency.

NGOs' delegation size was by far highest at WHO with 4.9, medium at FAO (1.8), UPOV (1.7) and WIPO (1.6), and lowest at the CBD with on average only one delegate for each NGO. According to WTO data, the average delegation size was 1.2 at the Ministerial Conference's meetings between 1996 and 2003.²⁸¹ No data on delegation size is provided in

²⁸⁰ See for example: http://www.haiweb.org/01_about_c.htm (Accessed at 3 March 2013).

²⁸¹ The data are available at: www.wto.org/english/news_e/news03_e/ngo_minconf_6oct03_e.htm (Accessed 4 April 2014).

the WTO's lists of participants. As in the case of attendance rate, IOs' delegation size was on average larger than those of NGOs with the exception of WHO.

Taking the proportion of NGOs and IOs together, the CBD was with an average share of 67% NSA delegations the by far most open institution toward NSA access followed by WHO with 37.2% whereas UPOV was most exclusive with a proportion of 13.7% NSA delegations. Although the WTO had a share of 69.3% NSA delegations, it has to be assessed as very exclusive as no NGO has been permitted to the Councils' meetings. An overview of delegations' composition at the plenary sessions is provided below.

Table 14: Delegations' Composition at Plenary Meetings (Number of Delegations in %)

	CBD	FAO	UPOV	WHO	WIPO	WTO <i>(Ministerial Conference, not Councils)</i>
State parties (excl. EU)	29.6	76.1	69.8	62.3	80.8	24.5
State observers	3.4	2.0	16.5	0.9	0.1	6.1
UN & IO bodies	8.0	8.5	7.2	9.0	8.6	9.7
NGOs	59.0	13.4	6.5	28.2	10.5	59.6

Based on the comparison of the indicators across the institutions, I evaluate UPOV's, WIPO's, and the WTO's NSA access as exclusive. WIPO's classification is not unequivocal if one only considers delegations' composition. But FAO, which has a similar NSA proportion, performs better for all other indicators including IOs' and NGOs' attendance rate and delegation size.

From a democratic point of view, inclusive NSA participation is generally positive. However, the magnitude of NGO participation at the sessions of the CBD COP and WTO Ministerial Conference has at least to be carefully scrutinized. Therefore, their composition is specified in the analysis of NGOs' nature. Before I discuss NGO contestation with regard to access, I address IOs.

8.2.2.2 IOs' Membership Scope and Nature – IO Contestation

With regard to IO contestation, I present information on IOs' membership scope and nature. For each category, I present the average proportion calculated in dependence of the number of delegations (one delegation as one actor) and delegates (absolute number of individual delegates irrespective of their membership to an IO). Four findings are noteworthy, two for membership scope and nature each.

First, IOs with international membership represented the majority with regard to the average proportion of delegations and delegates in all institutions with the exception of WIPO. The average number of delegates from IOs with international membership ranged from 29.8% at WIPO to 78.5% at the CBD. Latin American IOs were the least represented IOs among all regional IOs while European IOs attended with the largest proportion of

delegates with the exception of WHO. The low percentages for the category ‘USA and Canada’ are due to the fact that the group only consists of two countries.

Second, UPOV and the WTO did not ensure contestation with regard to IO access. Leaving IOs with international membership aside, the geographical regions were best balanced at the CBD and WHO and worst at UPOV, WIPO and partly the WTO with regard to the proportion of both delegations and delegates. In particular at WHO, the balance between African (8.9%), Asian (8.8%), and European IO delegates (6.9%) is striking. At UPOV, an average of 41.2% IO delegates came from European IOs in contrast to only 4% from African and Asian IOs. The average proportion of European IO delegates had more or less constantly increased at UPOV since 2000 while the average proportion of delegates from IOs with international membership scope decreased. At WIPO, the average percentage of European IO delegates was even 1.1 times higher than those of ‘international’ ones. Similarly at the WTO, the number of European IO delegates was 2.5 times higher than that of African IOs which represent the second largest number of delegates. Remarkably, African IOs had the largest proportion of non-international delegations at the WTO with 16.1%. By the same token, Latin American IOs with an average proportion of 13.3% delegations were best represented at the WTO in comparison to the other five institutions. The results for IOs’ membership scope are provided in the following table. Decimal numbers are the result of cross-regional IOs. IOs with members from more than three regions are classified as international.

Table 15: IOs’ Membership Scope (in %)

Region	CBD		FAO		UPOV		WHO		WIPO		WTO	
	DG	DI	DG	DI	DG	DI	DG	DI	DG	DI	DG	DI
International	76.0	78.5	48.1	50.9	72.2	55.0	80.2	75.4	38.2	29.8	51.3	40.4
Africa	5.2	1.2	21.8	11.4	1.2	2.0	6.1	8.9	24.8	23.2	16.1	12.5
Asia	4.3	1.4	12.1	7.0	1.4	1.9	9.5	8.8	10.6	10.4	9.4	6.2
Europe	8.9	12.4	9.2	27.5	25.2	41.2	4.1	6.9	23.0	33.6	6.6	31.8
Latin America	4.6	3.7	7.3	2.6	0	0	0	0	1.6	1.6	13.3	6.2
Oceania	0.2	0.1	0	0	0	0	0.1	0.1	1.1	1.4	1.8	1.9
USA & Canada	0.9	2.8	1.5	0.7	0	0	0	0	0	0	1.0	0.4
unknown	0	0	0	0	0	0	0	0	1.3	1.1	0	0

[Legend: DG=delegation (delegation as one actor); DI=delegates (absolute number of individual delegates).]

Third, also IOs’ nature varied considerably across the institutions. This fact suggests itself given the institutions’ different functions. As expected,

- environmental IO delegations were best represented at the CBD (36.0%),
- social welfare and human rights IO delegations at WHO (53.3%) and FAO (36.8%), and
- economic IO delegations at the WTO (44.9%), WIPO (42.4), and UPOV (39.1%).

The same trend can be observed for individual delegates.

Fourth, the balance in terms of nature was most pronounced at the CBD and WHO and most impaired at UPOV and WIPO if one accounts for the institution's main focus such as environmental IOs in the case of the CBD. The WTO's failure to meet contestation becomes obvious if one takes into consideration the TRIPS Council. It only permitted UN agencies and IP-friendly IOs encompassing FAO, IMF, UPOV, OECD, UN, UNCTAD, World Bank, WCO²⁸², and WIPO. Regional non-Western-IP IOs (ARIPO and OAPI) and rather IP-skeptical organizations (WHO and UNAIDS) were only accepted on an ad hoc basis or completely barred.²⁸³ Most significantly, the WTO has not accredited the CBD as observer although the CBD has actively tried to be awarded observer status and the TRIPS Council's discussions touched on topics such as ABS and TK which are key to the CBD. Even when members raised concerns of potential tensions between the CBD and TRIPS and proposed to include elements of the CBD Convention into TRIPS, the CBD was not invited. On the causes and driving forces for this conduct, which fundamentally violates the principles of contestation, is further elaborated in the next chapter. The fact that the CBD could attend some meetings of the Ministerial Conference and special sessions of the Committee on Trade and Environment and the Negotiating Group on Trade Facilitation demonstrates the greater importance attributed to the Councils' meetings.

Especially with a view to affectedness, it is troublesome, that the main indigenous IO, the UN Permanent Forum on Indigenous Issues (UNPFII), only participated at the CBD although TK has also been discussed in other institutions as well. The distribution of IOs' nature is summarized in the table below.

Table 16: IOs' Nature in Plenary Sessions (in %)

Nature	CBD		FAO		UPOV		WHO		WIPO		WTO	
	DG	DI	DG	DI	DG	DI	DG	DI	DG	DI	DG	DI
Comprehensive scope	13.5	13.9	22.1	34.1	38.6	51.4	20.3	30.7	28.8	36.6	17.3	41.6
Economic	11.6	7.4	21.9	8.3	39.1	31.8	9.6	6.5	42.4	41.1	44.9	27.3
Environment	36.0	23.8	5.2	3.3	1.6	1.7	2.8	2.2	2.6	1.3	2.4	1.1
Social welfare & human rights	20.2	31.4	36.8	47.8	17.3	11.5	53.3	48.7	14.5	11.4	20.5	21.4
Science	13.1	20.4	8.7	3.6	3.3	3.6	5.6	7.9	5.5	4.2	6.9	6.2
Indigenous	0.7	0.4	0	0	0	0	0	0	0	0	0	0
Other/unknown	4.9	2.8	5.4	3.0	0	0	8.4	4.0	6.4	5.3	8.0	2.4

[Legend: DG=delegation (delegation as one actor); DI=delegates (absolute number of individual delegates).]

To sum up, IO contestation was not fulfilled at UPOV, WIPO, and the WTO both with regard to IOs' membership scope and nature.

²⁸² WCO=World Customs Organization.

²⁸³ ARIPO=African Regional Intellectual Property Organization; OAPI=African Intellectual Property Organization/Organisation Africaine de la Propriété Intellectuelle; UNAIDS=Joint United Nations Programme on HIV/AIDS.

8.2.2.3 NGOs' Geographical Origin and Nature – NGO Contestation

NGOs' contestation with regard to access encompasses the indicators geographical origin and nature.

The geographical origin can be an indicator of which interests and values are promoted by a NGO. A well-balanced distribution of NGOs' origin can be considered as democratically desirable to avoid one-sided interest representation. Although the results show interesting trends, they have some limitations that have to be taken into consideration in the evaluation of NSAs' de facto access. First, the analysis is restricted to NGOs' headquarters and therefore neglects local and national branches. Second, it cannot be assumed that NGOs only represent interests of actors within the country of their headquarters. It should not be disregarded that organizations usually act transnationally. The data yields four main insights.

First, the major proportion of NGOs had their headquarters in Europe and North America in all institutions. Both areas taken together were best represented at UPOV where on average 89% of all present NGO delegations originated from Western countries. It is followed by WHO (88.4%), WIPO (88.4%), FAO (70.3%), WTO (66.4%), and the CBD (45.4%).²⁸⁴ The Western dominance at WHO is probably most surprising. One would expect more non-Western organizations to attend the WHA given that developing countries are usually most vulnerable to widespread diseases and require greater assistance to build up and consolidate their national health systems. But health crises affects countries worldwide as the outbreaks of communicable diseases have shown in the last years.

At WIPO and the WTO, the number of European NGO delegations decreased while those of North American ones increased. At WIPO, the share of European NGOs decreased from 100% in 1991 and 1992 to 59.3% in 2010. To a lower extent, the proportion of European NGOs declined from 44.4% in 1996 to 29.6% in 2005 at the WTO. The same trend applies to WHO if one considers the number of delegates. At the CBD, the share of North American NGOs even continuously decreased in terms of all NGO delegates from 36.3% in 1994 to 8.8% in 2008 but increased again to 19.2% in 2010.

The lack of basic means of communication and funding has been identified as a general cause for the underrepresentation of Southern NGOs (Matthews 2006: 22-23). Among the few influential Southern NGO is the TWN. It participated regularly in the plenary sessions at the CBD and FAO and less frequently at the meetings of the WIPO Assemblies and WTO Ministerial Conference. Another important Southern NGO is Via Campesina that participated at the CBD, FAO, and WTO.

²⁸⁴ One reason for the bias can be owned to the fact that the U.K. and the U.S. are said to have an advantageous charity law for societal associations (Martens 2002: 275). In fact, over a third of all NGOs had their headquarters in one of these countries at WIPO (38.7%), UPOV (38.5%), and WHO (37.8%). But the proportion was lower at the WTO (31.2%), FAO (20.9%), and the CBD (9.7%). Also in consideration of the great variance across institutions, the national regulation for societal groups seems to have no general explanatory power.

Second, most balanced was the geographical distribution at the CBD and worst at UPOV and WIPO. The CBD exhibits the second highest proportion of African NGO delegations (7.4%) and highest share of Asian NGO delegations (19.7%) and Latin American NGO delegations (16.3%). UPOV's and WIPO's geographical imbalance is caused by the dominance of European NGOs.

An overview of NGOs' geographical distribution at the institutions' plenary sessions is provided below. Decimal numbers can result from the fact that NGOs can be attributed with more than one characteristic. For example, if two NGOs form an alliance, they can span two regions. In such cases, each region counts as 0.5.

Table 17: NGOs' Geographical Distribution (in %)

Region	CBD		FAO		UPOV		WHO		WIPO		WTO
	DG	DI	DG	DI	DG	DI	DG	DI	DG	DI	DG
Africa	7.4	3.5	9.5	7.1	0	0	1.3	0.7	0.7	0.5	6
Asia	19.7	15.2	7	6.1	0	0	6.1	3.6	6.1	6.4	17.2
Europe	27.3	38.5	60.3	59.1	89	93.2	62.5	67.3	74.9	75	34.2
Latin America	16.3	19	1.2	2.7	11	6.8	1.1	0.4	2	1.9	6.3
Oceania	2.0	0.9	0.8	0.5	0	0	0.8	0.3	0.2	0.2	2.2
USA & Canada	18.1	19.2	10	12.3	0	0	25.9	25.7	13.5	12.7	32.2
Miscell./ unknown	9.2	3.8	11.1	12.2	0	0	2.3	1.9	2.7	3.3	2

[Legend: DG=delegation (delegation as one actor); DI=delegates (absolute number of individual delegates).]

Third, also NGOs' nature varied considerably across the institutions. As anticipated by the institutions' focus of work,

- environmental NGOs were best represented at the CBD (29.4%),²⁸⁵
- social welfare and human rights organizations at WHO (55.3%) and FAO (40.7%),
- business organizations at UPOV (100%), WIPO (64.9%), and the WTO (46.7%), and
- scientific actors at WHO (30.6%) and the CBD (26.2%).

The previous results do not necessarily imply that NGOs from other areas were excluded. In the case of WIPO, for example, non-business NGOs' interest in the institution's activities grew at the beginning of this century (Woodward 2012: 45-47). Before, even the few development NGOs that were accredited, like ActionAid, did not attend WIPO meetings regularly (Matthews 2006: 29). Some NGOs also rejected offers of formal relationship. This happened, for instance, as the WTO Director-General invited Friends of the Earth and Oxfam International to be part of the NGO Advisory Board (van den Bossche 2005: 154). But in other circumstances, institutions tried to minimize the influence

²⁸⁵ As the CBD displays a high fluctuation of NGOs, I tested if the results alter if one excludes all NGOs that attended only once. The percentages did not change considerably.

of certain actors. FAO, for example, has been resistant to collaborate with the private sector that is mirrored in the low presence of business actors at the Conference meetings (FAO 2007: 239-241; Liese 2010: 101).

Fourth, contestation in terms of nature was only clearly violated at UPOV and the WTO. The WTO has not permitted NGOs to attend Council meetings in the first place. At the Ministerial Conference, the number of business NGOs increased from 43.9% in 1996 to 52.4% in 2005. At UPOV, only associations representing breeders' interests were represented despite the fact that other NGOs sought admission (APBREBES 2009). In 2010, UPOV granted observer status to the first civil society organizations, the Association for Plant Breeding for the Benefit of Society (APBREBES) and European Coordination Via Campesina after their first applications for observer status were rejected in 2009 (APBREBES 2010).²⁸⁶

By contrast, most balanced was NGOs' nature at the CBD and FAO assessed on the basis of the ratio of the overall distribution of NGO groups. At the CBD, however, the share of environmental NGOs decreased from 36.9% in 1994 to 23.8% in 2010 while that of business NGOs increased from 10.3% to 16.6% in the same period. Also the presence of indigenous representatives increased in the new millennium.

With regard to WHO, it is notable that the data does not confirm the ostensible increase of private industry at WHO. The proportion of business NGO delegations only increased slightly with several fluctuations from 7.1% in 1990 to 10.1% in 2010. More significantly, the attendance of the scientific community decreased from 41% in 1990 to 21.8% in 2009. At the same time, the share of social welfare and human rights increased from 44.2% to 61.7% at WHO.

Indigenous groups were overall least represented. In particular, indigenous and local groups often depend on external funding in order to be able to participate. Within WIPO, the most open and at the same time most actively used forum by NGOs has been the IGC and the Provisional Committee on the Development Agenda. At the IGC, every NGO application for accreditation has been approved so far. The Director-General decides about applications based on the recommendation of the Advisory Board. The latter encompasses the Chair of the Committee *ex officio*, five WIPO state members that participate in the IGC and reflect a geographical balance, and three members from accredited indigenous and local observers (WIPO 2010c). The number of NGO observers rose from 15 to 47 in the first two sessions and then fluctuated between 69 at the twelfth meeting in 2008 and 38 at the third meeting in 2002.²⁸⁷ By the same token, the IGC made an effort to reach and

²⁸⁶ Available at:

http://www.upov.int/export/sites/upov/members/en/pdf/list_of_observers_in_upov_bodies.pdf and <http://www.apbrebes.org/about> (Accessed 6 October 2014).

²⁸⁷ The number of NGOs for the other meetings are: 15 (WIPO 2001a), 47 (WIPO 2001b), 38 (WIPO 2002a), 55 (WIPO 2002b), 52 (WIPO 2003b), 60 (WIPO 2004a), 50 (WIPO 2004c), 50 (WIPO 2005a), 59 (WIPO 2006b), 53 (WIPO 2006c), 55 (WIPO 2007c), 69 (WIPO 2008a), 55 (WIPO 2008b), 54 (WIPO 2009d), 52 (WIPO 2009c), 45 (WIPO 2010f), and 46 (WIPO 2010e).

include local and indigenous communities by undertaking on-site visits and setting up a Voluntary Fund for Accredited Indigenous and Local Communities in 2005 to facilitate and encourage the participation of indigenous and local communities. However, the Fund is only financed by voluntary contributions and restricted to the IGC's work. Despite these activities, no indigenous organization was represented at one of the WIPO Assemblies' meetings. By the same token, some NSAs withdrew their engagement in the IGC due to the forum's incapacity to produce presentable policy results (Matthews 2006: 23, 29-30; WIPO 2005c). A summary on NGOs' nature is presented below.

Table 18: NGOs' Nature in Plenary Sessions (in %)

Nature	CBD		FAO		UPOV		WHO		WIPO		WTO
	DG	DI	DG	DI	DG	DI	DG	DI	DG	DI	DG
Environment	29.4	37.6	8.2	11.3	0	0	0.1	0.0	3.9	5	7.7
Social welfare & human rights	12.2	10.7	40.7	39.6	0	0	55.3	65.9	7.3	8.1	23
Indigenous	14.1	8.4	0	0	0	0	0	0.0	0	0	0.4
Business	12.7	9.4	12.3	15	100	100	6.9	9.2	64.9	63	46.7
Trade union	0.5	0.3	6.6	6.7	0	0	3.2	2.3	18.5	18.9	8.7
Science	26.2	26	18.4	14.2	0	0	30.6	18.4	2	2.1	8.1
Miscellaneous	12.2	7.6	13.8	13.2	0	0	3.8	4.2	3.3	2.9	5.4

[Legend: DG=delegation (delegation as one actor); DI=delegates (absolute number of individual delegates).]

The table shows that despite institutions' policy focus, some institutions allowed for a greater balance of interest groups than others. Most balanced was NGOs' nature at the CBD and FAO and by far least balanced at UPOV where exclusively business organizations attended the plenary sessions. The percentages in the other institutions – although differently distributed across the various groups – are rather similar.

To sum up, IOs' and NGOs' de facto access was most inclusive at the CBD and WHO, moderate at FAO and WIPO, and most exclusive at UPOV and the WTO. Contestation of NSA access was best fulfilled at the CBD and FAO and most impaired at UPOV, WIPO, and the WTO. Only with regard to NGO's geographical distribution, the WTO did not exhibit unbalanced representation. WHO fulfilled all contestation requirements with the exception of NGOs' geographical distribution due to the great dominance of Western NGOs. Its NSA access with regard to contestation is therefore assessed as partly (un)democratic.

The comparison with the de jure access regulations illustrates that formally inclusive NSA regulation do not automatically lead to inclusive de facto access and vice versa. The most striking example for the latter is WHO. Although the institution's formal NGO access is burdensome, the de facto NSA access was overall democratic.

8.3 De Jure Involvement – No Formal Discrimination

Having discussed actors' access possibilities, it remains to clarify what actors can make out of their attendance. Can they meaningfully participate in discussions and negotiations or is their presence rather symbolic? The analysis starts again with the formal provisions followed by the de facto observed participatory possibilities. De jure involvement refers to the rules pertaining to the plenary bodies as of 2010. It is distinguished between involvement of state members and NSA observers.

8.3.1 De Jure State Involvement – Formal Equality

Concerning congruence, all full-fledged members are de jure granted the same means of involvement and voting rights in all institutions. Therefore, no affected actor is formally disadvantaged.

For the discussion on contestation, I address voting weight and procedure and possibilities to express one's opinion. With regard to voting weight, all institutions follow the rule 'one state, one vote'.²⁸⁸ At FAO, a member who is in arrears in the payment of its financial contributions in or above the amount of the contributions due for the two preceding calendar years loses its vote if the failure to pay was in its control (FAO 1945a: Rule 4). Also the WHA possesses the right to suspend voting rights if a member is in arrears or in "other exceptional circumstances" (WHO 1947: Art. 7).

More variety can be found considering the institutions' voting procedures. At the CBD, WIPO's PLT, and the WTO, it is required to seek consensus before resorting to majority voting (CBD 1994a: Rule 40(1); CBD 1992: Art. 29(3); WIPO 2000: Art. 17(4a); WTO 1994c: Art. 9(1)). If consensus cannot be reached, the CBD demands a two-thirds majority for all matters of substance (CBD 1994a: Rule 40(1); CBD 1992: Art. 29(3)). For procedural matters, only a simple majority is generally necessary (CBD 1994a: Rule 40(2)). At the Ministerial Conference and General Council, WTO members can formally make use of majority voting if attempts to reach consensus have failed. A decision on the interpretation of WTO treaties requires a three-fourths majority and amendments two-thirds of the votes (WTO 1994c: Art. 9(2), 10(1)). The TRIPS Council applies *mutatis mutandis* the General Council's RoP with a few exceptions. One of these affects decision-making because the TRIPS Council only decides by consensus. If members cannot arrive at consensus, the matter shall be referred to the General Council for decisions (WTO 1996d: Rule 33).

The WIPO Convention demands a nine-tenths majority for approving agreements with the UN, three-fourths of the votes for administering IP agreements, and a simple majority for other matters (WIPO 1979: Rule 35; WIPO 1967: Art. 6(3d-g)). The PCT demands two-thirds majorities if not stated otherwise (WIPO 1970: Art. 6(a)). Three-fourth

²⁸⁸ CBD 1994a: Rule 39; FAO 1945a: Rule 4; FAO 1945b: Rule 3(6); UPOV 1991: Art. 26(6); WHO 2008d: Rule 69; WIPO 2000: Art. 16(4bi); WIPO 1970: Art. 53(4); WIPO 1967: Art. 6(3a); WTO 1994c: Art. 9.

majorities are required for amendments of regulation, unanimity for regulations pertinent to time limits and amendments of certain essential treaty provisions such as the competency of its main bodies and finances (WIPO 1970: Art. 47(2b), 58(2b), 61(2b)). Also the PLT generally requires two-thirds of the votes casts, three-fourths for the adoption of PCT changes in the PLT and amendments of the PLT Assembly's tasks and sessions, and a three-fourths of votes for amendments (WIPO 2000: Art. 14(2-3), 16(1), 17(5)).

Similarly, WHO requires a two-third majority for “important questions” such as the adoption of accords, formal agreements with other IOs, amendments to the WHO Constitution or amount of budget, and a simple majority for other matters (WHO 2008d: Rules 70-21; WHO 1947: Art. 19).

FAO in general requires an absolute majority (FAO 1945b: Rule 7(3a)).

A simple majority is generally sufficient for decisions at UPOV (UPOV 1991: Art. 26(7)). The revision of the UPOV Convention requires a three-quarters majority (UPOV 1991: Art. 38(2)).

Opportunities to express one's opinion are determined by several factors. Concerning the right to speak, speakers need to obtain permission of the chairman to speak in all institutions.²⁸⁹ At FAO and WIPO, the chairman's power is underlined by emphasizing that the person “shall have complete control” over the proceedings. This includes decisions on the points of orders, proposals of speakers' time limitations, and suspension, adjournment or closure of the debate on an item under discussion (FAO 1945b: Rule 9; WIPO 1979: Rule 13).

Likewise time limits can be imposed on speakers in all institutions. Most democratic is this issue handled at the CBD. Not only is the time limit valid for each speaker on a topic. But before the decision is taken, two representatives supporting and opposing the time limit have to be heard (CBD 1994a: Rule 32). Also the UPOV Council and the WIPO Assemblies can decide to limit the length of speeches and also the numbers of speakers on a topic (UPOV 1982: Rule 12(1); WIPO 1979: Rule 16(1)). At FAO, WHO, WIPO, and the WTO, the plenary body can limit the time allowed to each speaker on a topic without precisely clarifying the procedure.²⁹⁰ With regard to a limited number of topics, the chairman of the FAO Conference and WIPO Assemblies can also limit the time allowed to one speaker. This applies only to proposals on the suspension or adjournment of the meeting at FAO and also to the closure of the debate or the reconsideration of a proposal at WIPO (FAO 1945b: Rule 12(22); WIPO 1979: Rule 16(2)). The WTO General Council additionally specifies that oral statements should be kept brief and circulated in writing if a position needs further elaboration. By the same token, the repetition of full debates at each meeting should be avoided (WTO 1996d: Rules 23, 27).

²⁸⁹ CBD 1994a: Rule 31; UPOV 1982: Rules 11(1, 4); WHO 2003e: Rules 25, 53; WIPO 1979: Rules 13(1), 15(1); WTO 1996d: Rule 17.

²⁹⁰ FAO 1945b: Rule 12(19); WHO 2003e: Rule 55; WTO 1996d: Rule 22.

All institutions require a debate before decisions on certain topics are taken. For example, the CBD requires that the proposer, an additional speaker in favor of and two against the motion can speak before the motion is put to vote (CBD 1994a: Rule 36). Similar procedures are applied at the FAO Conference, WHA, WIPO Assemblies, and the WTO Ministerial Conference. The subject matters encompass the request of separate voting on parts of proposals, adjournment or closure of the debate on a certain issue, and the reconsideration of a motion. The number of commentators ranges from two to five.²⁹¹

Based on these formal rules, no institution violates the principles of congruence and contestation with regard to voting weight, voting procedure, and speakers' rights. Small groups of states cannot block decisions. The involvement rights do formally not prevent democratic participation as it is not discriminated against certain actors. From a democratic point of view, it is positive that all institutions require a debate before decisions are taken.

8.3.2 De Jure NSA Involvement – Regulatory and Democratic Vagueness

Likewise, de jure NSA involvement shows no undemocratic rules with the exception of the WTO. As to congruence, no affected NSA is formally disadvantaged at the CBD, UPOV, WHO, and WIPO. The WTO Councils, as it was already mentioned above, only permit the inclusion of IOs, not NGOs. The realization of contestation can hardly be judged on the basis of the formal regulations since they mostly remain vague.

The CBD, UPOV, and WIPO do not differentiate among observers. All three of them also remain vague concerning observers' participatory rules and only stipulate that observers can participate at the invitation of the chairman.²⁹²

The other institutions distinguish between different 'classes' of observers. Most participatory rights are usually granted to state observers or if applicable associate members, less to IOs, and least to NGOs. The UN agencies are a good case in point. WHO allows associate members to "participate equally with Members" with the exceptions of holding an office and the right to vote (WHO 2008d: Rule 44). From non-member states over IOs to NGOs, the involvement rights become increasingly vague. IOs are generally allowed to participate in WHA meetings and its main committees and have access to non-confidential documents. NGOs can participate in meetings as determined by the arrangements with WHO (WHO 2008d: Rules 45-47).

FAO grants UN bodies and IOs the right to speak, participate, and to circulate papers to the Conference while IOs require the chairperson's approval to participate (FAO 1945b: Art. 17(1-2)). NGOs with consultative status are allowed to circulate written opinions to the Conference and under certain circumstances to the Council. They also can speak before the Conference's technical committees. They are only allowed to participate in discussions of the technical committees if requested by the chairman and can only speak before the

²⁹¹ FAO 1945b: Rules 12(19), 23-24, 26; UPOV 1982: Rules 14, 18; WHO 2003e: Rules 60-61, 64, 68; WIPO 1979: Rules 18, 23; WTO 1996d: Rules 19-20.

²⁹² CBD 1994a: Rule 7; UPOV 1982: Rule 20; WIPO 1979: Rule 24.

Conference with the consent of the Conference's General Committee. In preparation of the meetings, they receive non-confidential documents on policies and technical matters. The Director-General may also invite these NGOs to participate in or submit written opinions to other FAO meetings (FAO 1957c: Rule 19; FAO 1945b: Art. 17(3)). NGOs with specialized consultative status may submit memoranda on technical aspects to FAO, participate in or submit written statements to expert and technical meetings, and submit short written statements to the Council (FAO 1957c: Rule 21). In exchange for participatory rights, FAO requires NGOs with consultative and specialized consultative status, among others, to "cooperate fully with FAO" and invite a representative of the Director-General to the meetings of its governing bodies, general assemblies, and other relevant organs (FAO 1957c: Rules 20, 22). The participatory rights of NGOs with liaison status have to be determined beforehand by the Director-General, but they shall not exceed those of NGOs with specialized consultative status (FAO 1957c: Rules 23-24). It was recently specified that cooperation with IOs should primarily serve the exchange of information and joint action. Moreover, IO participation should be mainly restricted to technical meetings or meetings in which technical policies are discussed (FAO 2011).

All institutions explicitly deny observers – both states and NSAs – the right to vote.²⁹³ Beyond that, UPOV, WIPO and the WTO explicitly prohibit observers to submit proposals, amendments, and motions.²⁹⁴ At the WTO Council meetings, only IOs are allowed to participate. NGOs' rights at the Ministerial Conference are not formally laid down. IOs can be invited to speak and receive copies of the main WTO document series and additional documents as specified by the terms of formal arrangements (WTO 1996d: Annex 2).

All in all, no institution exhibits formally undemocratic NSA participatory rights with the exception of the WTO. This comes as no surprise since it can be expected that no institution evidently discriminates against NSAs. Therefore, a bias toward inclusive participation has to be assumed. But as no formal hindrance for democratic NSA involvement could be found, I evaluate the dimension of de jure NSA involvement as democratic for all institutions with the exception of the WTO. The de facto dimension sheds light on the question if the lack of formalized participatory rights turns out to be a drawback for NSAs.

²⁹³ CBD 1994a: Rules: 6-7; FAO 1945a: Art. 3(5); FAO 1945b: Art. 17; WIPO 1979: Rule 39; WHO 2008d: Rules 44, 46-47.

²⁹⁴ UPOV 1982: Rule 20; WIPO 1979: Rules 24, 39; WTO 1996d: Annex 3.8.

Table 19: Overview of NSAs' De Jure Participatory Rights in Plenary Bodies

Institution	Rights	Prohibition
CBD	not specified (participation “upon invitation of the President”)	voting
FAO	<ul style="list-style-type: none"> • <u>UN bodies/IOs</u>: speak and participate in discussions • <u>NGOs with consultative status</u>: oral and written statements to sessions, access to non-confidential documents, participation in discussion only at Assembly’s technical committees • <u>NGOs with specialized consultative status</u>: submit memoranda to IO, written statements to expert and technical meetings, written statements to Council • <u>NGOs with liaison status</u>: determined on case-by-case 	voting
UPOV	not specified (“may take part in debates at the invitation of the chairman”)	<ul style="list-style-type: none"> • voting • submission of proposals, amendments or motions
WHO	<ul style="list-style-type: none"> • <u>UN/IOs</u>: participation in discussion, access to non-confidential documents • <u>NGOs</u>: participation according to arrangements 	voting
WIPO	not specified (“take part in debates at the invitation of the Chairman”)	<ul style="list-style-type: none"> • voting • submission of proposals, amendments or motions
WTO	<u>IOs</u> : following of discussions, oral statements, access to documents	<ul style="list-style-type: none"> • voting • submission of proposals, circulation of papers

8.4 De Facto Involvement – Overall Dominance of IP Supporters

For the analysis of de facto involvement, speaking rights are vital. Voting rights are not mentioned in the de facto dimension because they were not put into practice. In order to gain systematic data on de facto involvement, I code statements in plenary sessions for the CBD, WHO, and the WTO. For the WTO, the minutes of the TRIPS Council are used because they deal more specifically with biotechnological patents than any other WTO body. A statement refers to one argument or position in a speech. Therefore, more than one statement is possible for each speech. An overview of the coded material is provided below. More information on the documents can be found in chapter 5.

Table 20: Analyzed Documents for De Facto Involvement

	Meeting	Time period	Number of meetings
CBD	COP 1-10: Final reports	1994-2010	10
WHO	WHA 43-63: Verbatim records of WHA plenary sessions and committee sessions	1990-2010	21
WTO	TRIPS Council 1-64: minutes	1995-2010	64

My database contains information on the frequency of speakers, the topics mentioned, and for the most part the positions taking with regard to a certain issue. The latter was only partially feasible in the case of the CBD since its reports do often not specify the statements' content.

State congruence is analyzed on the basis if (1) all mostly affected states are able to make a statement and (2) mostly affected states make more statements than non-affected ones in a given issue area. NSA congruence is assessed by comparing NSAs' statement rates with those of states in order to evaluate the institutions' openness toward NSA involvement.

Contestation for states and NSAs is assessed by comparing (1) the statement rate of IP supporters with IP skeptics and (2) the positions uttered in the debate.

8.4.1 De Facto State Involvement

8.4.1.1 State Statement Rate – Congruence

State congruence is measured by two indicators. First, the great majority of the mostly affected actors made a statement at the CBD and WHO. At the CBD, the proportion of non-speakers among mostly affected actors ranged between 0% with regard to ABS and 1.8% with regard to TK. At WHO, 11.8% of the mostly affected actors did not speak on IP and public health. By far highest was the outage at the WTO with 19% non-speakers among mostly affected actors with regard to ABS.

Second, mostly affected actors made on average more statements than non-mostly affected actors in all three institutions. By comparison, mostly affected actors had the highest proportion of non-speakers in all issue areas at the WTO. All non-speakers among mostly affected actors were IP skeptics. This fact becomes relevant for the evaluation of contestation. To conclude, congruence with regard to de facto state involvement was fulfilled by the CBD and WHO, but not the WTO. The results for mostly affected actors' statement rates with regard to congruence are summarized in the table below.

Table 21: State Congruence and Mostly Affected Actors' Statement Rate

Issue area ²⁹⁵	Indicator	CBD	WHO	WTO
ABS	Abs. statement number	470	–	951
	Abs. number of speakers	102	–	51
	% of MAA non-speakers	0	–	19
TK	Abs. statement number	408	–	313
	Abs. number of speakers	89	–	46
	% of MAA non-speakers	5.3		31.3
Public health	Abs. statement number	–	551	1132
	Abs. number of speakers	–	88	71
	% of MAA non-speakers		11.8	28.6

[Legend: MAA=mostly affected actors.]

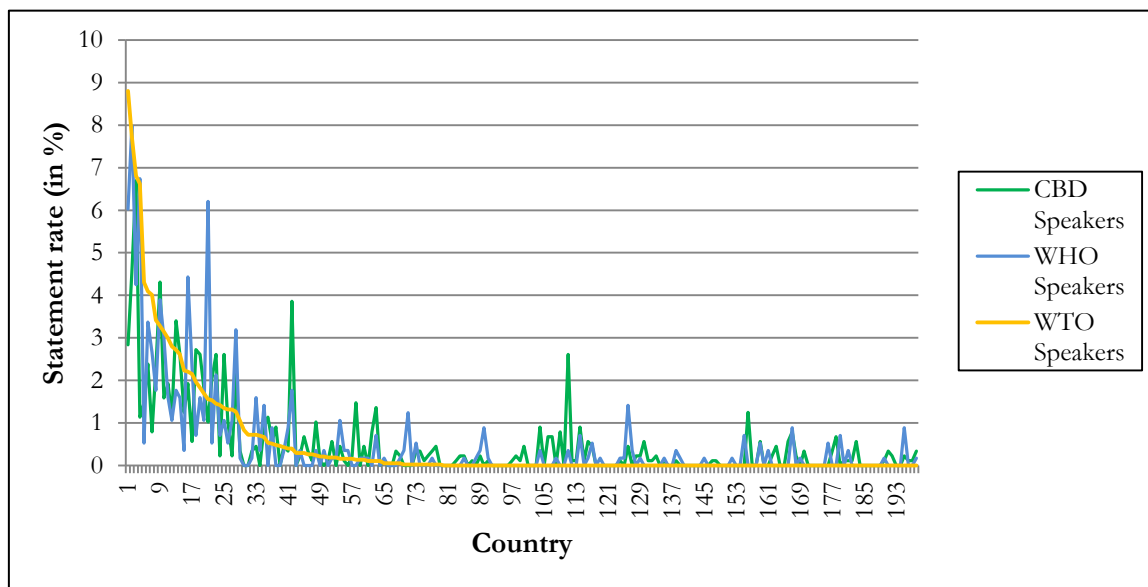
²⁹⁵ I exclude the issue area 'protection of plant varieties' since the WTO results could not have been compared with another institution.

8.4.1.2 State Statement Rate – Contestation I

On a general note, the analysis of biotechnological-related IP matters has good potential to be representative for involvement in the three institutions. There is a high correlation between actors' statement rates on all topics and those of biotechnological patent-related ones only. As the Spearman test proves, the correlation is highest at the WTO with .873 (.00) and the CBD with .858 (.000) and lowest at WHO with .509 (.000). Topics referring to biotechnological patents were least debated at WHO that also explains why one finds the highest number of state members who remained silent on biotechnological-related IP matters at this institution. There, the number of non-speakers was 19.5%. It was lowest at the WTO with 3.2% while the CBD ranges with 9.3% in the middle.

The figure below shows how the frequency of statements on biotechnological IP issues is distributed. The countries are sorted according to the ranking of statement rates at the WTO. The graph illustrates that there is a common trend among the highest statement rates – even on different levels.²⁹⁶

Figure 9: Distribution of Speakers Related to Biotechnological Patents (in %)



Consequently, some states are preponderant across all institutions. Nevertheless, there are important differences as the share of percentages and outliers in comparison to the WTO line demonstrate. There were, for instance, three states within the first 30 countries that displayed considerably higher statement rates at WHO than at the WTO. These were Venezuela (4.4%; country 16), Thailand (6.2%; country 21), and Bolivia (3.2%; country 28). All of them are countries that are highly affected by IP-related biotechnological policies.

²⁹⁶ The frequency of statements concerning biotechnological patents is positively correlated between the institutions. Statistically, the relationship is greatest between WHO and the WTO (.585/.000), but closely spaced by the correlation between the CBD and the WTO (.555/.000), and the CBD and WHO (.528/.000) according to the Spearman test. If one considers statements made on all issues, there is also a positive relationship between all institutions but the order changes. The correlation is highest between the CBD and WTO (.523/.000), followed by the CBD and WHO (.463/.000) and WHO and the WTO (.370/.000).

Venezuela and Bolivia are members of the LMMC and Thailand suffered from severe HIV/AIDS epidemics. By contrast, economically powerful IP supporters, such as Japan (1.8%; country 8) and South Korea (0.4%; country 15), had a considerable lower statement rate at WHO in comparison to the WTO.

The distribution of statement rates between IP skeptics and IP supporters yields two main findings. First, none of the three institutions exhibited balanced statement rates between IP skeptics and IP supporters. Even within one issue area, no institution stands out as being more balanced. Second, the statement rate of mostly affected actors is highly issue-dependent. Within the WTO, the ratio of IP supporters' statement rate to the one of IP skeptics ranges from 0.4 in the debate on ABS to 1.8 in the debate on public health. An overview of the results is provided below.

Table 22: State Contestation and Statement Rate of Mostly Affected Actors (in %)

Issue area ²⁹⁷	Mostly Affected Actors	CBD	WHO	WTO ²⁹⁸
ABS	Abs. number of MAA statements	217	–	627
	IP skeptics: LLMC (in %)	67.7	–	73.2
	IP supporters: biotechnological patents (in %)	32.3	–	26.8
	Ratio: Biotech. patents/ LLMC	0.5	–	0.4
TK	Abs. number of MAA statements	126	–	124
	IP skeptics: indigenous-rich countries (in %)	57.9	–	44.4
	IP supporters: pharmaceutical patents (in %)	42.1	–	55.7
	Ratio: Pharmaceutical patents/ indigenous-rich countries	0.7	–	1.3
Public Health	Abs. number of MAA statements	–	164	350
	IP skeptics: HIV/AIDS prevalence (in %)	–	40.2	35.1
	IP supporters: pharmaceutical patents (in %)	–	59.8	64.9
	Ratio: Pharmaceutical patents/ HIV/AIDS prevalence	–	1.5	1.8

[Legend: MAA=mostly affected actors.]

Given the lack of meaningful differences between the institutions, contestation with regard to statements' content becomes more decisive for the evaluation.

²⁹⁷ I exclude the issue area 'protection of plant varieties' because the WTO results could not have been compared with another institution.

²⁹⁸ Meetings for one year are calculated together.

8.4.2 De Facto NSA Involvement – Limited Participatory Possibilities

8.4.2.1 NSA Statement Rate – Congruence

A comparison of the absolute number of statements made by states, IOs and NGOs illustrates that the by far greatest share of statements were uttered by states. Nevertheless, there are clear differences concerning NSAs' possibilities to speak. While 10.1% of all speeches on all issues were made by NSAs at the CBD COPs and 4.6% at the WHAs, it was only 1.6% at the TRIPS Council meetings.

This trend is even stronger for statements made only with regard to biotechnological patents. The CBD has a proportion of 18.8% NSA statements, WHO is situated at a medium level with 5.3%, and the WTO brings up the rear with only 1.1% NSA statements. If one considers speeches on biotechnological-related IP issues, the NSA share remains at a steady level at the CBD and WTO with 15.9% and 0.7% respectively, but WHO's NSA speech proportion rises to 34.6%. All in all, the CBD and WHO display the highest NSA statement rates and the WTO lowest rate. The results are summarized in the both tables below.

Table 23: Speech Rates across All Actors on All Topics

	CBD	WHO	WTO (TRIPS Council)
Absolute number	8809	18315	5071
States (incl. EU)	90.0% (P: 737; SB: 7,186)	95.5% (P: 2555; SB: 15,220)	98.4% (4,988)
IOs	4.1% (P: 92; SB: 265)	2.2% (P: 65; SB: 340)	1.6% (83)
NGOs	6.0% (P: 64; SB: 465)	2.4% (P: 0; SB: 441)	0% (0)

[Legend: P=plenary body; SB=sub-bodies.]

Table 24: Biotechnological Patent-Related Speeches and Statement Rates across All Actors

	CBD		WHO		WTO (TRIPS Council)	
	Speeches	Statements	Speeches	Statements	Speeches	Statements
Absolute number	1020	1085	179	1281	4603	3758
States (incl. EU)	84.1% (P: 41; SB: 817)	81.2% (P: 63; SB: 819)	65.4% (P: 96; C: 21)	94.7% (P: 690; C: 523)	99.3% (4569)	98.9% (3715)
IOs	4.9% (P: 19; SB: 31)	5.0% (P: 23; SB: 31)	22.3% (P: 37; C: 3)	3.1% (P: 37; C: 3)	0.7% (34)	1.1% (43)
NGOs	11.0% (P: 20; SB: 92)	13.8% (P: 57; SB: 93)	12.3% (C: 22) ²⁹⁹	2.2% (C: 28)	0% (0)	0% (0)
Ratio: NSAs/states	0.2	0.2	0.5	0.1	0.0	0.0

[Legend: C=Committees; P=plenary body; SB=sub-bodies.]

8.4.2.2 NSA Statement Rate – Contestation I

The number of *IO* statement-makers for biotechnological patent-related issues illustrates great variation across the three institutions. Only three statements were made at WHO, 36 at the WTO, and 53 at the CBD. Most balanced were the statement rate at the CBD – both in terms of the *IO* speakers' membership scope and nature. Almost all *IO* speakers (98.1%) were members of *IOs* with international membership so that no regional *IO* could dominate. The *IO* speakers also presented different issue areas including statements by economic (32.1%), environmental (11.3%), social welfare and human rights (26.4%), scientific (15.1%), and even indigenous (5.7%) *IOs*. At the WTO, by contrast, a quarter of *IO* statements were made by Asian *IOs* while no statement was made by an environmental, scientific or indigenous *IO*. WHO's results are difficult to interpret due to only three *IO* statements. An overview of the distribution of *IO* statements made on biotechnological patent-related issues is provided in the two subsequent tables.

Table 25: Geographical Distribution of IO Speakers on Biotechnological Patent-Related Issues (in %)

Geographical origin	CBD	WHO	WTO
International	98.1	33.3	75.0
Africa	1.9	0	0
Asia	0	0	25.0
Latin America	0	66.7	0
TOTAL (absolute numbers)	53	3	36

²⁹⁹ WHO states that on average 16 NGO delegations made statements in each WHA between 1998 and 2002 (WHO 2003d: para. 7; WHO 2002b: 5). My results for the years 1990-2010 yield that it were on average even 21.

Table 26: Nature of IO Speakers on Biotechnological Patent-Related Issues (in %)

Nature	CBD	WHO	WTO
Comprehensive scope	9.4	0	20.9
Economic	32.1	100	38.4
Environment	11.3	0	0
Social welfare & human rights	26.4	0	40.7
Science	15.1	0	0
Indigenous	5.7	0	0
TOTAL (absolute numbers)	53	3	36

As to NGOs, the number of statement-makers was highest at the CBD with 55 NGOs, followed by 11 NGOs at WHO. Since the WTO does not permit NGO participants in the TRIPS Council, there were obviously no NGOs among the statement-makers. Also at the Ministerial Conference, NGOs were not allowed to make any oral or written statements (van den Bossche 2008: 727). I again differentiate between NGOs' geographical origin and nature. The CBD was far more balanced with regard to both categories than WHO. In both institutions, most statements were made by NGOs from Latin America (29.1%) and Europe together with North America (29.2%). By contrast, only NGOs with headquarters in Europe and North America made statements at WHO although on average 12.7% NGOs from other regions participated in the WHA. Concerning NGOs' nature, more diversity can be observed at the CBD. This also mirrors the results for NGO access that showed a balanced representation of NGOs of various natures. Indigenous groups were the best represented group with a speech proportion of 46.4% at the CBD. This is remarkable given that they only made up on average 11.7% of all NGOs. At WHO, on the contrary, only business and social welfare and human rights organizations made statements. The proportion of business actors was comparatively low at both institutions although it was almost twice as high at WHO. Taking into consideration the number of present NGO delegates, it follows that the attendance of business actors translates much stronger in the capacity to speak at WHO than at the CBD. On average, only 5.5% of all NGOs that were present at WHO were business actors in contrast to 11.7% at the CBD. The following two tables summarize the results.

Table 27: Geographical Distribution of NGO Speakers on Biotechnological Patent-Related Issues (in %)

Geographical origin	CBD	WHO
Africa	3.6	0
Asia	14.6	0
Europe	16.4	90.9
Latin America	29.1	0
Oceania	5.5	0
USA & Canada	14.6	9.1
Alternating/ none/ unknown	16.4	0
TOTAL (absolute numbers)	55	11

Table 28: Nature of NGO Speakers on Biotechnological Patent-Related Issues (in %)

Nature	CBD	WHO
Business	7.3	13.6
Environment	17.3	0
Indigenous	46.4	0
Science	10.9	0
Social welfare & human rights	10.9	86.4
Unknown	7.3	0
TOTAL (absolute numbers)	55	11

All in all, the CBD performed best. In this institution, the number of NSA statement-makers was highest and most diverse in comparison to the other two institutions. The diversity in terms of NSAs' nature promotes the comprehensive representation of affected actors' opinions. The situation is at least moderately democratic at WHO where most IO statements could be observed.

8.4.3 Positions in the Debate and Contestation II – Dominance of IP Skeptics

As I have already discussed in chapter 3, a balanced presentation of different opinions forms the foundation of contestation. I focus on formal sessions to measure contestation. Although negotiations always have informal stages, the importance of formal debates is nevertheless high. Being captured in form of minutes and therefore being often public available, formal sessions serve not only as a condensed presentation of states' views and interests but also as a message to their constituency to inform them about their activities. It can therefore be assumed that formal discussions mirror well actors' positions although in an admittedly diplomatic manner. In informal meetings, by contrast, the diplomatic tone is mostly lowered. This does not necessarily lead to more contested discussions since informal consultations sometimes take place between rather like-minded groups to gain an upper hand in the subsequent course of negotiations.

In order to evaluate contestation, the different positions taken with regard to biotechnological-related topics are compared. It is differentiated if a topic item is supported or opposed. The 'vague/other'-category is excluded as it is not justifiable from a democratic point of view that an ambiguous position should be represented in the same way as support and opposition.³⁰⁰ Vague positions are per se democratically legitimate but not vital for contestation. Contestation is conceptualized as a continuum on which +1 stands for complete support, -1 for complete opposition and 0 for an absolute balance. It is calculated by the following formula:

$$Z_{Contestation} = \frac{x_{pro} - x_{con}}{x_{pro} + x_{con}}$$

³⁰⁰ Another calculation that included the vague/other-category yielded similar results.

The indicator does not measure the intensity of contestation. While contestation was far from being balanced in all institutions, it was considerably highest at the WTO, followed by WHO while the CBD ranks last.

Table 29: Contestation across Actors and Issue Areas

Issue Area	Actor	CBD	WHO	WTO
Strong ABS	States	1.0	–	0.75
	IOs	0.67	–	1.0
	NGOs	0.83	–	–
	All	0.89	–	0.76
Strong protection of TK	States	1.0	–	0.86
	IOs	–	–	1.0
	NGOs	1.0	–	–
	All	1.0	–	0.86
Public health prioritizes IP protection	States	–	0.51	0.27
	IOs	–	1.0	0.56
	NGOs	–	–	0
	All	–	0.51	0.28

The WTO displays the highest contestation rates for all aggregated topics. With regard to a strong system of ABS, the contestation factor for all actors is 0.76 at the WTO in contrast to 0.89 at the CBD. As to strong TK protection, the contestation factor is 0.86 at the WTO and 1.0 at the CBD. The CBD's factor of 1.0 does not mean that all statements approved strong protection of TK, but that no actor directly opposed them since the 'vague/other'-category is neglected. In the debate if public health should prioritize IPRs, the contestation factor is 0.28 at the WTO and 0.51 at WHO. The lower level of contestation at WHO in comparison the WTO can also be seen at the discussion's meta-level. While the word 'solidarity' was used 967 times in 21 WHA's plenary sessions, it was only used 4 times in 64 TRIPS Council meetings. Besides this accumulated result, three other findings are worth presenting.

First, the positive signs show that IP-skeptical positions were dominant in all issue areas across all institutions. This distribution of opinions is unexpected given that the statement rate of IP supporters was higher than those of IP skeptics in almost all cases. The apparent cause is that IP supporters did not openly express their views but remained vague in their statements. The numbers for the vague/other-category were on average above 50% for all institutions. Taking the case of ABS, for example, the question if the existing system is sufficient to fight biopiracy was answered with 'no' by 50% of all statements, with 'yes' by 3.9% while 53.9% remained vague at the WTO. Another explanation is that IP supporters promoted the status quo of IP regulations while IP skeptics demanded critical changes and amendments. Given that decisions are mostly made by consensus, IP skeptics had to make a greater effort to achieve their objectives while IP supporters could easily veto any reform. Legalization's influence in this respect is discussed in the next chapter.

Second, IP supporters raised their voice considerably more often when it came to key proposals to change the existing IP regime and meta-topics that touched on IP's fundamentals. With regard to ABS, most opposing views were directed toward the controversy on the legal form of ABS policies at the WTO. While 55.1% supported an international legal ABS regime, 36.7% preferred an international non-binding or national solution.

Concerning public health, there was consensus among actors in the WHA and TRIPS debates that IPRs do not directly cause health problems. Also a high percentage of opposition received the question if further TRIPS flexibilities are needed to protect public health. This is valid for both WHO and the WTO with a share of 66.7% and 91.7% respectively. On the contrary, actors agreed at the WTO that it is allowed to produce generics under certain circumstances and that existing flexibilities should be used. But there was no agreement on what constitutes legitimate flexibilities within the TRIPS framework.

IP supporters' eagerness to sustain the ideology of IP's positive influence on social welfare also can be demonstrated by another dimension coded in the analysis: IP vs. public interests. This category refers to IP's impact on a country's general development, technological development, environment, and food security. WHO displays a slightly higher contestation rate with -0.12 than the WTO with -0.20. Both institutions were dominated by the view that IPRs spur technological development. This conviction was brought forward in 75% of all statements on IP's effect on technological development at WHO and 78.4% at the WTO. At the WTO, more than 40% of IP supporters' comments were made by the USA and Japan. Also when it came to monitoring and enforcement, only a few states dominated the TRIPS sessions. While many states reported on their countries' status of TRIPS implementation, mainly four IP-supportive states commented on these reports and posed critical questions: the EU and USA accounted for almost 25% each, and Japan and Switzerland for almost 14% each of all comments and questions.

Third, NSAs had no significant influence on the overall opinion in the plenary debates. The aggregated contestation factor was clearly driven by states' opinions. This is evident given the very high proportion of state statements in all institutions.

Taking together the results for contestation's different indicators, state contestation was best fulfilled at the WTO and worst at the CBD while WHO ranges in the middle. By contrast, NSA contestation was best met at the CBD and worst at the WTO while WHO ranges again in the middle.

8.5 Summary of Results on Democratic Participation

The individual results illustrate that no institution fully met the principles of democratic participation. Nevertheless, there are considerable differences among the institutions.

- (1) With regard to *de jure state participation*, all institutions with the exception of the WTO formally allowed for democratic participation both with regard to access and involvement. The WTO violated the democratic principle of access on equal term.
- (2) By contrast, *de jure NSA* participation was less democratically regulated. *De jure NSA access* was undemocratic in half of the analyzed institutions (WHO, WIPO, WTO). The *de jure NSA involvement* was often only vaguely regulated, but it was not formally discriminated against NSAs with the exception of the WTO.
- (3) The *de facto* dimensions of democratic participation differ considerably from their *de jure* counterparts in all institutions. This demonstrates that formal participatory rights do not lead to empowerment without proper enforcement. On the other hand, the WHO case demonstrates that *de facto* NSA participation can be more democratic than the *de jure* provisions would suggest. This finding is crucial for research because most studies on NGOs have focused on the formal dimensions so far.³⁰¹
- (4) In general, non-democratic trends concerning *de facto* state participation were mostly caused by IP supporters' dominance in all institutions. Consequently, congruence was overall better satisfied than contestation.
- (5) As to *de facto state access, congruence* was fulfilled at the CBD, FAO, WHO, and WIPO but violated by UPOV and the WTO. The imbalance resulted from IP supporters' better representation. With regard to *de facto state involvement*, congruence was fulfilled by the CBD and WHO, but not the WTO.
- (6) *State contestation* was overall rather low. With regard to *de facto state access*, contestation could only be realized at the CBD, FAO and WIPO, only partly at WHO, and was imbalanced at UPOV and the WTO. As to *de facto state involvement*, by contrast, contestation was highest at the WTO, moderate at WHO, and lowest at the CBD. Contestation with regard to statements' content was mainly driven by IP-skeptical states. Interestingly, the prevalence of IP skeptics' opinion does not correlate with statement rate. At WHO and the WTO, statements' content was in favor of IP skeptics despite IP supporters' higher statement rate.
- (7) Concerning *NSAs' de facto congruence*, most open were overall the CBD, FAO, and WHO in contrast to UPOV, WIPO, and the WTO both with regard to access and if applicable involvement. *De facto NSA contestation* was most balanced at the CBD and FAO, intermediate at WHO, and most imbalanced at UPOV, WIPO, and the WTO.

All in all, the CBD came closest to the ideal of democratic participation although it did not fully comply with it. By contrast, the WTO was furthest away from it. Remarkably, the

³⁰¹ Only few studies have dealt with *de facto* NGO participation in a comprehensive manner (Betsill/Corell 2008a; Brühl 2003; Oberthür et al. 2002).

WTO had the highest rate of contestation and the CBD the lowest one. For a brief overview, the empirical results on democratic participation are summarized below. As some dimensions were measured by several indicators, their results had to be aggregated. This explains the value of ‘partly (un)democratic’ (D/U).

Table 30: Overview of Empirical Results for Democratic Participation in International Institutions

	Access						Involvement									
	DJ state		DJ NSA		DF state		DF NSA		DJ state		DJ NSA		DF state		DF NSA	
	CG/CT	CG/CT	CG	CT	CG	CT	CG/CT	CG/CT	CG	CT	CG	CT	CG	CT	CG	CT
CBD	D	D	D	D	D	D	D	D	D	D	U	D	D	D	D	D
FAO	D	D	D	D	D	D	D	D	D	-	-	-	-	-	-	-
UPOV	D	D	U	U	U	U	D	D	D	D	-	-	-	-	-	-
WHO	D	U	D	D/U	D	D/U	D	D	D	D	D/U	D	D/U	D	D/U	D/U
WIPO	D	U	D	D	U	U	D	D	D	D	-	-	-	-	-	-
WTO	U	U	U	U	U	U	D	U	U	U	D	U	U	U	U	U

[Legend: CG=congruence; CT=contestation; DF=de facto; DJ=de jure; D=democratic; U=undemocratic.]

The large number of ‘democratic’ values in the table should not be misinterpreted. It only indicates that most formal rules are not explicitly undemocratic. The numerous indicators of democratic participation mirror the complexity of measuring normative concepts. Decisions in the evaluation often cannot be lightly made. This implementation of democratic participation’s operationalization is therefore understood as a starting point to spark a greater discussion and research on the connection between empirical and normative research. An explanation of these results by means of the institutions’ different degree of legalization follows in the next chapter.

Chapter 9

Legalization's (Un)Democratic Forces at Work

Having empirically assessed the institutions' degree of legalization (chapter 7) and democratic participation (chapter 8), I bring both variables together in this last empirical chapter. My goal is to connect the dots between legalization and democratic participation and show that it is something within legalization that has direct important implications for democratic participation.

First, I describe the patterns that can be observed between a certain degree of legalization and democratic participation. Legalization has overall democracy-impeding effects but also limited democracy-enhancing ones. Second, legalization's structure-inherent effects are presented. The costs for actors vary in accordance with an institution's legality and delegation. Participatory rights leave room for (un)democratic leeway depending on their degree of formalization. On this basis, I demonstrate how legalization's structure-inherent effects influence actors' preferences for a certain participation constellation. I further explore how actors attempt to achieve the participation constellation that is favorable to them. The results show that legalization can be both an incentive and means that affect participation. Since my concern rests with *democratic* participation, the focus is on mostly affected actors as presented in chapter 6. By the same token, I focus on democratic participation's de facto dimension as the decisive one. In order to avoid duplication, FAO is neglected in this section because it shares all values of legalization and democratic participation with the CBD. While it is beyond this project's scope to show causality by means of process-tracing, I present empirical illustrations for the connection between legalization and democratic participation for selected cases only. The generalizability of the results derived from this study also depends on other variables that are reviewed in the fourth subsection.

9.1 Patterns between Legalization and Democratic Participation

Three main patterns between a certain degree of legalization's dimensions and democratic participation can be observed:

- (1) Soft law organizations (CBD, FAO, WHO) tend to have a more democratic de facto access for states and NSAs than hard law organizations (UPOV, WTO), in particular with regard to congruence. The same trend can also be found with regard to congruence in the case of de facto involvement.
- (2) By contrast, state contestation concerning involvement is higher at hard law organizations (WTO) than soft law organizations (CBD, WHO) while NSA contestation is higher at soft law organizations than hard law organizations.

- (3) Formalization has no apparent effect at an aggregated level but with regard to membership. A lack of formalization concerning state membership can decrease democratic access (UPOV, WTO).

Among all legalization dimensions, legality appears to be the most decisive one while formalization and delegation are of minor importance. The results for institutions' degree of legalization and democratic participation are brought together in the table below.

Table 31: Summary of Empirical Results on Legalization and Democratic Participation

		CBD	FAO	UPOV	WHO	WIPO	WTO	
Legality		soft	soft	hard	soft	soft/hard	hard	
Formalization		M	M	L	M	M	H	
<i>Formalization of membership</i>		H	H	M	M	M	M	
Delegation		L	L	L	L	M	M	
Access	CG/ CT	DJ state	D	D	D	D	D	U
		DJ NSA	D	D	D	U	U	U
	CG	DF state	D	D	U	D	D	U
		DF NSA	D	D	U	D	U	U
	CT	DF state	D	D	U	D/U	D	U
		DF NSA	D	D	U	D/U	U	U
Involvement	CG/ CT	DJ state	D	D	D	D	D	D
		DJ NSA	D	D	D	D	D	U
	CG	DF state/NSA	D	–	–	D	–	U
	CT	DF state	U	–	–	D/U	–	D
		DF NSA	D	–	–	D/U	–	U

[Legend: CG=congruence; CT=contestation; DF=de facto; DJ]=de jure; H=high; L=low; M=moderate; D=democratic; D/U=partly (un)democratic; U=undemocratic.]

9.2 Legalization's Structure-Inherent Effects on Democratic Participation

9.2.1 The Costs of Commitment in Practice

Legalization causes costs in three main respects: sovereignty costs, costs of non-compliance, and costs of legal capacity. These costs are mainly caused by legality and delegation. The institutional rules are not comprehensively repeated here as chapters 6 and 7 already elaborated on them, even if from a different angle.

9.2.1.1 WTO and UPOV – Hard Law, High Costs

The hard law character of the WTO and UPOV makes these both institutions the most costly ones in the sample. The high delegation of adjudication at the WTO amplifies these costs.

The WTO's *sovereignty costs* are enormous and considerably higher than in the old GATT regime. The WTO system added new sectors and issue matters including IPRs, sanitary measures, and international services. In accordance with the principle of a single undertaking, every member must become a party to all sectoral agreements. The WTO regulations reduce members' domestic policy space. This affects not only trade as a vital policy field that originally was completely under national control but also environmental and social standards. The principles of national treatment and most favored nation further reduce a state's flexibility in its foreign affairs with other countries.³⁰² In contrast to GATT, the WTO vests foreign and national economic actors with "an entitlement to substantive rights in domestic law" (Charnovitz 2001: 99). The WTO's sovereignty costs can further grow if stalemates in the current Doha Round are resolved.

In the case of UPOV, the policy scope is smaller as the institution only deals with the protection of plant varieties. Nevertheless, UPOV regulations touch on the core of state survival: the feeding of its population. UPOV does not only encompass ornamental plants but also crops. By becoming a party to UPOV, a state substantially constraints its control over the staple foods that are legally allowed to be cultivated on the fields within its territory. UPOV's regulatory remit is smaller than that of WTO policies but the institution's rules are more detailed. This leaves its parties with almost no policy space to implement the Convention and curtails the possibilities to take account of countries' special circumstances and needs. Relinquishing the authority of such a sensible policy area creates high sovereignty costs.

At the WTO, the *costs of non-compliance* are high. By the end of 2010, 419 cases had been submitted to the DSB.³⁰³ In the same period, the ICJ received only 123 contentious

³⁰² Hoekman/Mavroidis 2007: 14-20; Jackson 2006; von Bogdandy 2001: 621-622.

³⁰³ The number rose to 488 cases by the end of December 2014. For an updated overview see: http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm (Accessed 15 January 2015).

cases.³⁰⁴ Economically powerful actors are particularly in the spotlight. In 97 cases, the USA acted as complainant, as respondent in 110 cases. The EU acted 82 times as complainant and 70 times as respondent. 50 disputes were between the EU and the USA. The frequent participation of powerful actors in the legal proceedings serves as an indication of their high stakes in the WTO's highly legalized framework.

In contrast to the WTO, enforcement at UPOV exclusively takes place nationally. Therefore, there are no reliable data on the total sum of UPOV cases worldwide. But the national enforcement has proved to be not less effective as the frequent reports on UPOV-related cases before national courts demonstrate.³⁰⁵ National adjudication typically has the advantage of being embedded in the more advanced domestic judicialized systems in contrast to international dispute settlement which has to operate under more insecure conditions. The case of UPOV illustrates legality's central role in the creation of costs. Although delegation of adjudication to supranational bodies is beneficial in several respects, decisive is hard law's effective enforcement – be it nationally or internationally.

Legal capacity is a precondition to meaningfully participate in the WTO ranging from negotiations over implementation to adjudication. The WTO law is complex due to its broad coverage but also its intersection with international rules of other trade regimes and with issue areas like environment, health, labor, and human rights. Therefore, an entire law industry is engaged at the WTO. Law firms have specialized in providing legal assistance with the WTO's legal matters ranging from lobbying over implementation, accession to dispute settlement.³⁰⁶ Legal expertise is also a prerequisite to understand and keep up with the WTO's technically complex regulation in order to avoid unconscious non-compliance. A 2001 Commonwealth study shows that 36 developing countries that are members or candidates to the WTO did not even have a permanent representation in Geneva (Commission on Intellectual Property Rights 2002: 164).³⁰⁷ This represents a great impediment to obtain up-to-date information on current legal developments on-site. Also with regard to the use of the DSB, wealthier countries have an edge. According to a study by WTO officer Henrik Horn and his colleagues, there is a clear tendency of countries with higher GNP per capita at market prices to file complaints (Horn et al. 1999: 15-16; likewise: Kim 2008).³⁰⁸ Legal capacity's dependency on financial resources is also shown

³⁰⁴ Available at: <http://www.icj-cij.org/docket/index.php?p1=3&p2=3> (Accessed 16 September 2014).

³⁰⁵ See for example: UPOV 2009c: Annex I para. 1(2); Annex III para.1(3); UPOV 2003: Annex I para. 1(2).

³⁰⁶ See for example: <http://www.kslaw.com/offices/geneva>; <http://www.sidley.com/wto/>; <http://www.chambersandpartners.com/80/455/editorial/2/1>; <http://www.stewartlaw.com/PracticeAreas/WTOPractice> (Accessed 17 September 2014).

³⁰⁷ The data is based on the number of delegates listed in the WTO phone directory that can be found in Michalopoulos 1999: 33-36.

³⁰⁸ Joseph Francois and his colleagues challenge these results. In their analysis, they use a model encompassing the composition of trade, volume of trade, income levels, aid levels, and legal capacity as explanatory variables. They conclude that low income developing countries “have launched more complaints than they should have, based on these characteristics” (Francois et al. 2008: vii). They, however, exclude LDCs from the group of low income developing countries and admit the problem of missing values in their statistical data.

by a 1996 UNCTAD study. It finds that developing countries have to spend a great amount of financial and administrative resources to implement TRIPS. For example, Egypt is estimated to spend additional annual costs of around \$1 million for training. In Bangladesh the annual implementation costs are estimated to be \$1.1 million. Subsequent studies indicate that the actual costs turned out to be even higher (Commission on Intellectual Property Rights 2002: 145).

Also the UPOV Convention is legally and technically very intricate. Legal expertise is required to comprehend the Convention and keep up-to-date with the periodically published explanatory notes and information documents. Legal knowledge has to be paired with specialized biotechnological know-how on scientific matters like DNA-profiling, botanic taxonomic classifications, and biochemical and molecular techniques. This considerably confines the scope of competent experts.

9.2.1.2 WIPO – In-Between Soft and Hard Law, Moderate Costs

WIPO's *sovereignty costs* are moderate. The PCT and PLT are hard law treaties but allow for more flexibility than TRIPS. In contrast to TRIPS's substantive rules on patents, these agreements are regulatory by standardizing the patent application procedure. The discretion to grant patents rests with national or regional patent offices. Hence, the objective is to facilitate the patent process and not to confine state sovereignty.

The *costs of non-compliance* are low. Dispute settlement regulations are absent in the WIPO Convention and the PLT. The PCT states that disputes that cannot be settled by negotiation should be brought before the ICJ (WIPO 1970: Art. 59). But most states used their right to make reservations to this enforcement provision (WIPO 1970: Art. 64; Woodward 2012: 142-143). The WIPO Arbitration and Mediation Center is only a voluntary option to lodge complaints. In addition to that, WIPO's soft law policies like the Development Agenda encompass mostly general political aims with no concrete demand for action. Consequently, non-compliance can hardly be determined. Even if deviation from rules can be identified, no legal remedies are possible.

The costs of *legal capacity* are rather high. The subject matters in WIPO's treaties are of a highly legal and technical nature. IP protection including the patent application process is the domain of lawyers. Political actors depend on specialized legal experts who are acquainted with IPRs' (inter)national state of the art and their implications for a country. This knowledge forms the foundation to analyze what IP policies are beneficial for a state and what legal possibilities exist to change current IP rules to one's advantage. In contrast to the PCT's and PLT's legally binding rules, WIPO's soft law policies require less legal capacity as they only represent vague political goals that cannot be legally enforced.

9.2.1.3 CBD and WHO – Soft Law, Low Costs

Sovereignty costs are low at WHO and the CBD. At WHO, most policies are not legally binding. Therefore, they neither oblige changes in domestic regulations nor significantly restrict states' policy space in the realm of public health. Examples are the Revised Drug Strategies of 1996 and 1999. Also the efforts of the working groups on public health, R&D and IPRs – the CIPIH, IGWG, CEWG, and EWG – have not resulted in hard law so far. Instead their policies, like the 2008 GSPA-PHI, are of a purposive nature. However, WHO possesses under Article 22 of its Constitution the formal powers to adopt legally binding instruments. This option has not been used for topics pertinent to biotechnology patents so far. However, this could change with the ongoing discussion on an R&D treaty on neglected diseases.

Also the CBD's policies entail low sovereignty costs. The 2000 Bonn Guidelines, the 2004 Akwé Guidelines, and the 2010 Tkarikwaí:ri Code represent soft law. The only exception with regard to biotechnological patents represents the Nagoya Protocol. It is legally binding but suffers from considerable deficiencies. For instance, contentious issues such as retroactivity, were not clarified and its language is often noncommittal (“encourage”, “consider”, “as appropriate”, “where applicable”, “as far as possible”) (Evanson Chege et al. 2010: 162).

Due to their soft law character, the *costs of non-compliance* are very low at the WHO and the CBD. The costs are further decreased by the absence of effective monitoring and sanction mechanisms. Even in the Nagoya Protocol, implementation and consequences of non-compliance are not precisely regulated (CBD 2010g: Art. 15(2-3), 16(2-3)).

Also the members of WHO and the CBD require less *legal capacity*. The low relevance of legal expertise at WHO is mirrored in the distribution of its staff's occupational groups. In 2012, half of all posts in the professional and higher categories were held by medical specialists (43.4%), 34.5% were administrative staff, and only 1.4% were lawyers (WHO 2013: 45). Likewise, national delegations at the CBD COPs have exhibited a high proportion of environmental and scientific experts. The lower demand of legal capacity should not neglect the fact that members still require expertise of the issue-specific field like environmental and medical knowledge respectively in these institutions.

9.2.2 (In)Flexibility of Membership Rules

Another structure-inherent effect of legalization is formalization. Particularly relevant for this study is the formalization of participatory rules in terms of membership and decision-making. Regulatory impreciseness can be used as a means to impede democratic participation. Decision-making is highly formalized in all institutions. Greater variance can be observed with regard to membership rules. In this sample, a lack of formalization is often accompanied by more veto possibilities.

9.2.2.1 CBD – High Formalization, Few Veto Possibilities

Membership is highly formalized at the CBD. This leaves no veto possibilities for small fractions. The CBD only demands accession to its Convention to obtain full membership. CBD observers require the consent of two-thirds of the plenary body. These clear rules reduce the leeway to politically negotiate membership and subject its approval to differential treatment.

9.2.2.2 WHO and WIPO – Moderate Formalization of Observer Access, Moderate Veto Possibilities

At WHO, membership is highly formalized with one notable exception. For full state membership, only a simple WHA majority is required. IOs need the consent of two-thirds of the plenary body so that only few veto possibilities exist. However, it is unclear according to which decision procedure the Executive Board admits NGOs. Therefore, the NGO accreditation procedure possesses an important loophole despite its overall high formalization.

At WIPO, the formalization of membership is moderate. In order to become a party to the WIPO Convention, countries have to be member of the Paris or Berne Union, UN or one of its specialized agencies, IAEA, or the ICJ (WIPO 1967: Art. 5, 14). All parties to the Paris Union can also become members of the PLT and PCT, and parties to the WIPO Convention also to the PLT (WIPO 2000: Art. 20(1); WIPO 1970: Art. 62(1)). These unambiguous regulations leave existing members with almost no means to impede the access of unpleasant states. For observers, the regulations are vague and do not specify the requirements in relation to observers' nature and the admission process (WIPO 1979: Rule 8; WIPO 1967: Art. 13). Most subsidiary bodies have made use of their right to supplement or replace WIPO's General RoP to allow for NGO observers on an ad hoc basis if they have no permanent observer status to WIPO (Woodward 2012: 46).

9.2.2.3 UPOV and WTO – Moderate Formalization, Great Veto Possibilities

At UPOV and the WTO, membership is moderately formalized. At UPOV, the requirements to gain full membership or observer status are outlined but the criteria and voting modes by which the Consultative Committee and Council make their final decision are missing. This leaves ample wiggle room for political maneuver to admit or reject candidates. WTO membership rules lack even more formalization. The admission of full members requires not only the implementation of WTO regulations but also concessions that have to be negotiated bilaterally, regionally, and internationally. State and IO observer status is only granted on a "case-by-case basis" (WTO 1996d: Annex 2-3). Likewise, NGOs can only attend the Ministerial Conference on a vague ad hoc basis.

9.3 Legalization's Actor-Dependent Effects on Democratic Participation

The cases yield three main insights on legalization's influence on democratic participation.

First, legalization impairs mainly affected actors' democratic access and involvement. To be precise, it concerns congruence in all dimensions and contestation with regard to involvement. This restricting effect hits especially IP-skeptical states and NSAs. The cause lies in legalization's costs that influence the mode of bargaining. Participation preferences in the debates on biotechnological patents are evident. Both IP supporters and IP skeptics favor to be supported by like-minded parties in the relevant fora. But actors' cost calculations associated with legalization and their degree of affectedness determine the strength of their participation preferences and their willingness to achieve them. In the case of hard bargaining in highly legalized institutions, IP supporters as generally more powerful actors exhaust all available means to exert their prevalence with harmful effects on democratic participation. By contrast, lowly legalized institutions are conducive to reach concessions by IP supporters with regard to IP-skeptical policies and the inclusion of IP-skeptical actors.

In addition to IP supporters' consciously democracy-impairing behavior, the costs of legal capacity associated with hard law institutions represent a direct burden for less affluent participants who are in general IP skeptics.

Second, formalization has a tendency to guard democratic participation. IP supporters took advantage of the paucity of formalized membership rules to accept new members on undemocratic conditions or to bar IP-skeptical actors.

In contrast to legalization's democracy-damaging effect on congruence, third, one can observe greater contestation – by those actors who successfully made it to the debate – in higher legalized fora. The reason also lies in the hard-bargaining character of highly legalized institutions. Due to the higher costs involved, participants have a strong interest to make their positions and proposals heard. This applies in particular to those actors who intent to bring about policy change. The current IP regime, epitomized by TRIPS, has operated exclusively in favor of IP supporters. Therefore, every modification tends to degrade rather to further strengthen IP supporters' situation. Since it is always easier to maintain the ad hoc status than to bargain a new compromise between conflicting interests, IP supporters could lean back in the debate and let IP skeptics bring forward their arguments. It was also wise from IP supporters to hold back their views because their economic and profit-oriented thinking could have caused further public outrage. In the end, the consensual decision-making mode provided them with a veto power.

The empirical evidence requires a prior note. As legalization's impact on democratic participation is most of the times only a side-product of negotiations, one rarely finds statements in which actors set these two variables in direct relation with each other. Likewise, the examples used here serve as illustrations for legalization's structure-inherent

and actor-dependent effects on democratic participation. Not all of an institution's bodies and meetings can be considered. Instead, systematic theory-testing must be left to future qualitative studies. For each section, I proceed institution-wise starting with legalization's negative effects. I do not differentiate between the four issue areas – ABS, TK, plant varieties, and public health – in the discussion.

9.3.1 Legalization as Restriction of Democratic State Participation

9.3.1.1 WTO – 'Like-Minded Welcome – Others Assimilate Yours Law!'

The WTO depicts three facets of legalization's impairing influence on democratic state participation. First, legalization's costs served as rationale for IP supporters to restrict democratic participation in this hard law organization. Second, the paucity and circumvention of formalization was used as an opportunity by IP supporters to achieve their preferred participation constellation and eventually their policy goals. Third, legalization's costs were a direct burden for IP skeptics to be democratically represented as mostly affected actors at the WTO.

First, the WTO environment demands from its members costly commitments. These costs were consciously brought about by highly affected IP supporters who shifted the IP debate from WIPO to the WTO in order to negotiate an IP regime to their advantage. The rules were mainly dictated by U.S. economic interests and bolstered with more effective enforcement mechanisms than available at WIPO (Drahos 2002: 166; Helfer 2004: 20-21).³⁰⁹

IP supporters as the driving forces behind this trade regime have been keen on accepting either new members that are also devoted to the elevation of strict IP rules or those that have – even reluctantly – adapted their national trade systems to IP supporters' satisfaction. Candidates do not only have to comply with existing WTO rules. They also have to accept further concessions at the bilateral, regional and international level in order to gain existing members' approval (Basu et al. 2009; Pelc 2011). For example, Cambodia as an LDC and highly affected IP skeptic had to agree to implement TRIPS already by 2007 and guarantee five years of data exclusivity. All these measures were not required by TRIPS but demanded by the USA (MSF 2003: 2). The Cambodian government, which negotiated with WTO members at utmost secrecy and without the consultation of its National Assembly, appeared to be unaware of the full implications of its WTO membership (Chea/Sok 2005: 120, 124). The access commitments made during the accession process are in fact enforced within the WTO framework. In 2006, the first law suit on the violation of an accession protocol was brought before the WTO DSB (Charnovitz 2008: 856). Canada, the EU, and the USA charged China with having established illegitimate measures on the export of automobile parts from the three

³⁰⁹ "Lobbying understates the actual process of what occurred. It was in reality a form of private governance" (Drahos 2004: 270).

countries (DS342).³¹⁰ The differential requirements that are required before entering the WTO harm the participation of affected and at the same time critical actors. Both congruence and contestation have been violated. IP supporters created *fait accompli* because IP skeptics already had to change their national systems under the terms of IP supporters before discussion on certain policies could even take place.

Not only the entrance was controlled and guarded by IP supporters. They also ensured that the continuing trade negotiations developed in accordance with their interests to avert economic losses in the profitable IP field. To this end, IP supporters exerted their legal strength. They participated with large delegations including a large entourage of lawyers to be effectively informed and represented in the negotiations. The success of their strategy is mirrored in IP supporters' great dominance of statements made at the TRIPS Council. The USA, as relentless and successful driver of IP expansion could rely on the IP expertise of the U.S. Advisory Committee on Trade Policy and its subcommittees to provide technical advice and assist in drafting work (Draho 2004: 270-271). Given this legal advantage, it is only consequential that most successful drafts were tabled by the USA or the EU (Steinberg 2002: 355).

Second, IP supporters did not adhere to formal procedures when informal and at the same time more exclusive avenues were more promising. With respect to the accession process, WTO members do not even have to circumvent legal procedures as their differential treatment of applicants is legally secured by the institution's rules. Informal consultation is explicitly envisaged in the operation of the working parties (WTO 1995: para. 8, 11). The use of informal mechanisms in negotiations is neither new nor uncommon in multilateral organizations, but the conditions of and frequency with which they have been used at the WTO have been harshly criticized (Albin 2008: 762, 767; Khor 1999). Most infamous have become the so called 'green room' meetings named after the Director-General's conference room. Green room sessions with a very much reduced number of (core) members, usually encompassing 20 to 40 heads of delegations, impede congruence. Participants are not chosen in accordance with their affectedness but their power position in negotiations. This is in particular troubling because these small and opaque meetings take typically place at critical stages in the negotiation process. They are used to reach consensus or bargain drafts that give an essential direction for the further course of the negotiation process. The WTO makes no secret that informality is important in its procedures. Informal consultations are portrayed as "vital" and the only practical resort to reach consensus among its members on the WTO's website.³¹¹ The USA frequently called for informal consultations to settle conflicts when debates did not take a preferred course and often related their arguments to decisions and documents of

³¹⁰ The original documents are available at: http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds342_e.htm (1 October 2014).

³¹¹ Available at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm (Accessed 2 October 2014).

informal consultations.³¹² Brazil supported by India openly criticized the TRIPS Council's "disregard of procedures". Informal debates on the review of Article 27(3b) were described as "selective and partial" and were accused of excluding affected actors. Non-official documents discussed in these informal meetings were later addressed in the negotiations without the other parties sometimes being acquainted with them (WTO 2005e: 195-196, 205-208, 212). In the light of the democratic drawbacks that come with informal meetings, NGOs called for a formalization of the procedures to ensure more transparent and inclusive meetings (Bohne 2010: 169,192-194).

If negotiations were dragged on for too long or did not develop as wished, IP supporters opted for legal means external to the WTO to enforce higher levels of IP protection by wrenching additional concessions from their trading parties (Basso/Beas Rodrigues 2007: 173). Bilateral agreements give the economically more powerful actor a competitive edge in the negotiations because it deprives the weaker one of the possibility to forge alliances with similar-minded actors. Under these conditions, the latter often chooses the short-term interest of market access in exchange for stricter IPRs the costs of which are often underestimated (El-Said/El-Said 2007: 447-452; Muzaka 2009: 1357).

Best known have become the U.S. and EU's Economic Partnership Agreements (ACP) and FTAs. These, for example, further limit patentability's exemptions as specified in Article 27(2-3) of TRIPS, narrow the understanding of IP exhaustion under Article 30 of TRIPS, and demand a stricter protection of undisclosed test data as provided in Article 39(3) by establishing fixed periods of non-reliance. The IP protection required by their trading parties sometimes even exceeds IP supporters' own level of IP protection like in the case of the USA with regard to the use of compulsory licensing.³¹³ The then EU Trade Commissioner Pascal Lamy candidly told in an interview: "We always use bilateral free trade agreements to move things beyond WTO standards. By definition, a bilateral trade agreement is 'WTO plus'" (Choudry 2005: 9).

The USA has exerted additional pressures by using its Special 301 process as 'stick' and the Generalized System of Preferences (GSP) as a 'carrot' (Woodward 2012: 43). The Special 301 process was introduced by the US Trade Act of 1974 under which the Office of the United States Trade Representatives (USTR) annually reviews trading partners to identify countries with inadequate and ineffective IP protection or unfair market access for U.S. IP holders. Based on their categorization, countries can be included in a watch list or even priority watch list. As the USA applies higher standards than demanded by TRIPS in its examination, countries can become subject of Special 301 investigations although they comply with TRIPS. The GSP, which was already adopted under GATT, enables developing countries to obtain non-reciprocal preferential treatment by developed countries with regard to tariffs on their products which is in particular important for their

³¹² For example: WTO 2009a: para. 134; WTO 2002d: para. 279; WTO 2000b: para. 136, 229; WTO 2000a: para. 101; WTO 1999b: para. 71; WTO 1999a: para. 66; WTO 1997c: para. 5; WTO 1996h: para. 13.

³¹³ Basso/Beas Rodrigues 2007: 174; Drahos 2004: 268-269; Scott/Harman 2013.

agricultural and textile sectors. The 1984 U.S. Trade Act determined that the approval of preferential treatment under GSP has to strongly consider a country's IP protection of foreign inventions (Drahos 2002: 169-173). Key IP skeptics, such as Brazil as regional leader in South America and India with its great technical expertise on par with Western know-how, were pressured by the unilateral U.S. threats under the Special 301 process to approve TRIPS. Since 1988, countries that are not "making significant progress in bilateral or multilateral negotiations" on effective IP protection can become subject to 301 investigations (Drahos 2002: 170-171). TRIPS establishes minimum standards for IP protection and does not protect developing countries from TRIPS-Plus treaties. Nevertheless, illegitimate under TRIPS has been considered the U.S. demand for the retroactive application of TRIPS patent protection under Section 301, the so called 'pipeline solution'. For instance, during the Argentinian legislation of a new patent law in 1995, the USA constantly threatened Argentina with unilateral trade retaliations for not ensuring the retroactive protection of pharmaceutical patents. After the parliamentary approval of the law, the USA sanctioned Argentina's alleged failure to comply with "international standards" and partially withdrew its benefits under the GSP in 1997 (Correa 2000: 10-12).

If IP-constraining policies were not preventable, IP supporters chose soft law as a means of compromise. Soft law is less costly since its implementation is not obligatory. Therefore, it has often been considered to be inconsequential. The Doha Declaration is a case in point. A group of eighty countries headed by Brazil, India, and the African Group demanded a legally binding agreement but could not overcome the U.S. resistance to a hard law document (Sell 2003: 161). Also in the subsequent negotiations on the legal approach to implement the Doha Declaration, the USA categorically rejected the Article 30 approach as it would have vested members with comparatively great discretion to export generics (Muzaka 2009: 1348-1349). Brazil criticized the U.S. attempt to undermine the legal quality of the 2003 General Council's decision "Implementation of Paragraph 6 of the Doha Declaration" by calling it only an "agreement" or "solution" (WTO 2005e: 195). The Doha Declaration was hailed as a major success of developing countries and NGOs. But together with the 2005 TRIPS amendment, it had little practical influence (Morin/Gold 2010: 564-565; Oxfam 2002). In particular "pharma-emerging" countries – like Brazil, China, India, and Thailand – with large domestic markets and the manufacturing capacities to produce generics have continued to be under the radar of strong IP supporters such as the USA and EU. Since 2000, every U.S. FTA has included TRIPS-Plus requirements, especially concerning pharmaceutical data exclusivity and patent extensions. Also major pharmaceutical companies fought back. Novartis unsuccessfully filed several law suits against the Indian government from 2006 onwards after its patent application for Glivec, a key cancer drug, was rejected (Muzaka 2009: 1356-1357). From IP supporters' point of view, the Doha Declaration served as symbolic policy

to prove that TRIPS does not epitomize sheer cold-blooded liberalism in which only the fittest survive but is reconcilable with developing countries' needs (Morin/Gold 2010: 578).

Third, legalization's costs created participatory barriers for IP skeptics. IP skeptics of who most are developing countries have joined the WTO to integrate themselves into the international trading system. They hope to reap the promised benefits of trade liberalization and to influence as full member the future development of the WTO regime (Basu et al. 2009: 2-3; Chea/Sok 2005: 121). This view proved to be perilous. Persisting in the WTO's highly legalized and therefore costly environment requires large legal, administrative, and human resources that differ in amount and character from the capabilities demanded in traditional diplomatic proceedings (Esserman/Howse 2003: 131). Most developing countries neither have been prepared to comply with existing rules nor to influence negotiations. Attempts to mitigate their participation constraints have been less successful. For example, when Bolivia noted that its small delegation could not participate in an informal meeting of "great interest" to its country because of several other parallel meetings, its request for a factual summary of the respective session was denied by the USA and Canada (WTO 2000b: para. 207-210). But also larger delegations, like Brazil and Egypt, faced participation problems when TRIPS Council meetings were scheduled simultaneously to WIPO meetings (WTO 2004d: para. 291; WTO 2003a: para. 189). Countries with a small staff number, sometimes only consisting of one responsible expert as in the cases of Saint Kitts and Nevis, Saint Vincent and the Grenadines, could not adequately prepare for review procedures and answer questions in time (WTO 2001e: para. 42; WTO 2001g: para. 34). States also faced similar problems in bilateral TRIPS-Plus negotiations in which they were confronted with far better resourced and trained delegations like the USA and EU (Choudry 2005: 11).

Furthermore, developing countries and LDCs have frequently criticized that they are lacking the legal training and resources to effectively engage in the WTO's legal proceedings. For example, the African Group complained that their rare use of the DSB is owed to its costly and legally intricate procedures (WTO 2002e). Studies found that the lack of legal capacity is developing countries' main restraint to make use of the WTO's dispute settlement (Busch et al. 2009; Guzman/Simmons 2005). Also TRIPS itself was possible because developing countries' lack of legal IP expertise prevented them from completely understanding the technical details of TRIPS and foreseeing its consequences. They were sidelined and blindsided during the negotiations and fobbed off with only few concessions (Gervais 2007: 51-54; Sell 2003: 30; UNDP 1999: 74).

In order to alleviate this problem, the Advisory Centre on WTO Law (ACWL) was founded in 2001. The independent Geneva-based organization provides legal advice and training to developing countries and LDCs free of charge up to a maximum number of hours. It recognized that

“[f]or countries with inadequate human and financial resources, that [legal] knowledge is difficult to acquire. WTO law consists of a complex web of over 20 agreements, which – together with the attached Member-specific schedules of concessions and commitments – cover more than 20,000 pages. [...] To take full advantage of the opportunities offered by the WTO, therefore, a country must make a significant investment in knowledge.”³¹⁴

The effectiveness of the ACWL’s work has been questioned on the basis of the organization’s limited number of employed lawyers and their professional level (Esserman/Howse 2003: 138). Others have noted that legal capacity already represents a precondition for countries to effectively avail themselves of the ACWL (Busch et al. 2009: 574).

Being aware of their participatory constraints, a large group of developing countries conditioned the launch of a new negotiation round on procedural reforms (Steinberg 2002: 368). The WTO pledged to improve “effective participation” in the Ministerial Declaration of Doha (WTO 2001d), but the road to this goal seems to be long and rocky.

9.3.1.2 UPOV – Coerced Membership into Hard Law

UPOV is a remarkable case in this study. Legalization’s costly commitments have also been the driving rationale to determine participation in this institution. But in contrast to the WTO, states were not excluded but pressured into UPOV even if they had no intent of becoming parties. The reason is UPOV’s hard law nature to which IP supporters wanted IP skeptics to see committed. In the beginning, UPOV was a purely Western endeavor by six European countries (Jördens 2005: 233). Its structure has therefore often said to be tailor-made to Western needs and was successively adapted with UPOV’s revisions due to the continuing Western dominance in the institution (Ravishankar/Archak 1999: 3661). Today, the seed market, which is worth of over \$45 billion, is dominated by a few U.S. and European multinational life science groups as already described in chapter 6.3.4. Developing countries with their typically large agricultural sectors are lucrative outlets for the seed industry. Consequently, it is in IP supporters’ interests that also these developing countries, which are mostly IP skeptics, are legally bound by UPOV.

IP supporters used several means to lure IP-skeptical states to accede to UPOV. First, the WTO’s and UPOV’s hard law nature exercised joint pressure on IP skeptics. 1999 marked a decisive year in this respect. Until April 1999 countries had the opportunity to join the less restrictive 1978 UPOV Act. In the same year, Article 27(3) of TRIPS on the exemption of patentability of plants and animals including the *sui generis* option to enact plant variety protection was scheduled for review at the TRIPS Council. IP skeptics felt that they ultimately had to accept some form of UPOV-conform plant protection and could only choose between the least of evils. These concerns were not without cause as

³¹⁴ Available at: http://www.acwl.ch/e/about/the_ACWL%27s_mission.html (Accessed 17 September 2014).

the USA favored the abolishment of all patent exemptions on plants and animals (GRAIN 1998b). At the same time, IP supporters including the USA, EU, Japan, South Korea and Switzerland prevented a substantial review of Article 27(3) that could have challenged the patenting of life forms in general. Instead, they insisted on a limited review on the implementation of Article 27(3).³¹⁵

Second, it was reported that the WTO, WIPO and UPOV secretariats promoted UPOV as the best – sometimes even the only viable – option to fulfill Article 27(3) of TRIPS. GRAIN criticized that these secretariats did not provide developing countries with unbiased information. Under the guise of technical assistance, the officials persuaded developing countries to become parties to UPOV in workshops and seminars around the world (GRAIN 1999b). These workshops did in fact not mention alternatives to UPOV (for example: UPOV 2000 and WIPO 2002g). This represented one main reason that these events were accompanied by widespread protests like in Thailand in 1999 (Raghavan 1999).

Third, the recent example of the African Regional Intellectual Property Office (ARIPO) shows another way to bypass national opposition to UPOV. Only two African countries, Kenya (1999) and South Africa (1977), have joined UPOV to date. These only acceded to the less restrictive 1978 Act.³¹⁶ On 10 July 2014, ARIPO as an IO became a party to UPOV. With the successful entry into force of ARIPO's draft protocol, ARIPO members can upon adoption of the protocol accede to the 1991 UPOV Act. In his legal opinion, Thomas Cottier of the World Trade Institute reaches the conclusion that ARIPO does not meet UPOV's membership requirements and an accession of ARIPO's members by only adopting the ARIPO's draft protocol bypasses UPOV's accession rules (APBEBES 2014a).³¹⁷ Thus, ARIPO's accession to UPOV violates UPOV law. Civil society actors have criticized the opaque and exclusive mode of developing the draft law and accused ARIPO of circumventing national laws and parliaments' approval (APBEBES 2014b).

Fourth, the USA and the EU included UPOV membership in several of their FTAs. The accession to UPOV was, for example, a requirement in the U.S. FTAs with Bahrain (2004), Chile (2003), Jordan (2000), Morocco, Singapore (2003), Viet Nam (2000), the

³¹⁵ WTO 2000b: para. 150, 176; WTO 2000a: para. 130, 162-164; WTO 2000c: para. 126, 128, 131, 139; WTO 1999b: para. 72; WTO 1999d: para. 94, 99, 105.

³¹⁶ Available at: <http://upov.int/export/sites/upov/members/en/pdf/pub423.pdf> (Accessed 8 October 2014).

³¹⁷ First, ARIPO's draft protocol is not "binding on all its members" as required by Article 34(1bii) (UPOV 1991) but only on those members who ratify the protocol. Therefore, ARIPO's draft protocol does not apply to the organization's entire territory as it is necessary in accordance with Article 1(viii). Second, there is no evidence that ARIPO "has been duly authorized, in accordance with its internal procedures to accede" to UPOV (UPOV 1991: Art. 34(1biii)). Third, ARIPO is not "in a position, under its laws, to give effect to the provisions of this Convention" (UPOV 1991: Art. 30(2)). This would require national legislation or vesting the UPOV Convention with direct effects on national laws. At the same time, the decision that ARIPO's members can become parties to UPOV by acceding to ARIPO's draft protocol bypasses Article 34(3). It stipulates that a candidate country should request the "Council to advise it in respect of the conformity of its laws with the provisions" of UPOV (APBEBES 2014a).

U.S.-Dominican Republic-Central American Free Trade Agreement (2004), NAFTA (1994), the U.S.-Cambodia IPR Agreement (1996), the U.S.-Laos Trade Relations Agreement (2003) as well as in the EU FTAs with Chile (2003) and Mexico (2000) and the EU Mediterranean Agreements with Algeria (2005), Egypt (2004), Jordan (2002), Lebanon (2006), and Tunisia (1998) (Aistara 2012: 127; Basso/Beas Rodrigues 2007: 193-196).³¹⁸

All of the four presented approaches illustrate that the extension of UPOV's hard law to IP-skeptical countries had negative implications for democratic participation. Therefore, plans by developing countries to accede to UPOV have evoked over and over again irate protests by citizens and civil society actors. This includes, for example, Colombia, Ghana, and Thailand (Porteus Viana 2014).

9.3.1.3 WIPO – Tension between Legal-Political and Democratic Prevalence

From WIPO's case, two lessons can be learnt for the legalization-democracy relationship. First, IP supporters shifted IP-skeptical issues from hard law to less costly soft law fora in which greater democratic participation was possible at the expense of the diminished democratic participation in the respective hard law forum. Second, IP supporters allowed for more inclusive participation in soft law institutions as long as there was no threat of legal commitments. Also WIPO's legalization-democracy relationship is inextricably linked with the WTO. Therefore, the WTO has to be mentioned in this subsection, too.

First, IP supporters undermined the discussion of ABS and TK at the WTO by denying WTO's mandate and competence to address these issues. Almost only developed countries sought to transfer the discussion on ABS and TK to WIPO. These included IP supporters like Japan, South Korea, Switzerland, and the USA. According to the official justification, a duplication of work with WIPO should be avoided and WIPO possesses the greatest technical knowledge to establish a TK protection regime (Hrbatá 2010: 26; WTO 2006a: 6-7). This reasoning is remarkable given that the USA previously shifted IPRs from WIPO as specialized IP agency to the WTO. Underneath the formal argumentation rather hides developing countries'

“fear of a system being developed as part of the WTO package, with all the latter's strength – including the ‘bite’ and burden of enforcement and dispute settlement – which, in this field of intellectual property would exceptionally be borne mainly by the industrialized nations” (Hrbatá 2010: 26-27).

For example, an ABS amendment of the PCT instead of TRIPS, as it was proposed by the EU and Switzerland, would allow IP supporters to cherry-pick the scope and depth of domestically implementing ABS requirements in the absence of central PCT enforcement provisions (Jungcurt 2008: 221).

By contrast, affected IP skeptics – such as the African Group, Brazil, India, Venezuela, and Zimbabwe – argued that TK has also to be addressed by the WTO.

³¹⁸ For a current overview of the EU trade agreements see: <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/> (Accessed 9 October 2014).

According to these countries, the WTO has not only the mandate under the Doha Declaration to deal with TK but also the expertise. TRIPS would be directly affected by TK regulations and therefore should directly engage with this topic to guarantee consistency with WTO regulations. By the same token, WIPO's negotiations on TK proceeded only slowly and cumbersome despite the urgency to address biopiracy (WTO 2006a: 7-9). But most importantly, IP skeptics emphasized the legal dimension. The outcome of WIPO's TK policy would not automatically be binding for WTO members (WTO 2003e: para. 5). It was questionable if it would be legally binding at all. Therefore, the African Group supported by LLMC members – like Brazil, India, Peru, and Venezuela – advocated the integration of ABS and TK into the WTO's framework of “compulsory obligations” so that they are “enforceable in accordance with the DSU” (WTO 2003e: 5; WTO 2003d: para. 78). This ensures that the violation of TK protection can be sanctioned within the WTO framework. Likewise, the Peruvian delegation reasoned that the “binding nature of the WTO mandates make this the ideal forum for incorporating requirements concerning disclosure of origin” (WTO 2005b: 13) and that the WTO is “the appropriate forum to discuss this issue, because of the legally-binding nature of its agreements” (WTO 2005f: para. 23). Brazil supported that a “mandatory requirement of disclosure of origin of genetic resources in patent applications” has to be included in TRIPS as the WTO is “the single most important and comprehensive international treaty on intellectual property rights” (WTO 2010b: para. 48). Eventually, IP skeptics – such as Brazil, Pakistan, and Peru – accused IP supporters, in particular the USA, of forum-shopping.³¹⁹

But under the given circumstances, IP skeptics gave in to IP supporters' forum-shifting and thereby surrendered parts of their participatory rights at the WTO including the right to have a meaningful debate on an issue which is of great concern to a considerable amount of members. IP skeptics chose to discuss ABS and TK at WIPO instead of the WTO where no progress of development concerns in the Doha Round negotiations seemed to be into reach instead of risking that these topics would be addressed by no IO at all. Therefore, Argentina and Brazil tabled a proposal to reintroduce the development agenda at the WIPO General Assembly in 2004 (Hrbatá 2010: 10-11).³²⁰ They formed an alliance of 15 states, the Group of Friends of Development, which was later replaced by the Development Agenda Group (DAG).³²¹

In fact, greater congruence could be observed at WIPO than at the WTO. As already described in the last chapter, more mostly affected actors are members to WIPO. One

³¹⁹ See for example: Brazil (WTO 2010b: para. 47; WTO 2005f: para. 32, 86); Pakistan (WTO 2003a: para. 112); Peru (WTO 2005f: para. 16).

³²⁰ Available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=31737 (Accessed 1 October 2014).

³²¹ The alliance encompassed Brazil, Argentina, Bolivia, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania, Venezuela, and Uruguay. Informally, the development agenda was supported by India (Choer Moraes/Brandelli 2009: 44).

reason for this is that interested countries only have to accede to the WIPO Convention. In contrast to the WTO, membership of IP skeptics cannot be blocked by IP supporters. Also attendance in terms of delegation size was more than 1.5 times better balanced between IP supporters and IP skeptics at WIPO than at the WTO in the new millennium. The presence of indigenous- and biodiversity-rich countries has grown more or less constantly at WIPO since 2000.

Second, IP supporters tolerated more democratic participation at WIPO as long as legality was left out of the debate. A case in point is the establishment of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The IGC “rapidly developed into a very lively forum with the highest participation of any WIPO body, regularly exceeding the capacity of the main plenary hall” as a NGO representative of GRAIN observed (GRAIN 2004: 2). But IP supporters stressed from the IGC’s first session on that they would oppose a legally binding policy and instead preferred a “flexible”³²² or “voluntary”³²³ approach. They even insisted on their position after the IGC was charged with the mandate to draft a legally binding instrument.³²⁴ Furthermore, ABS standards and the TK have to be in conformity with existing IP law as for example South Korea noted.³²⁵ IP supporters also advocated the disentanglement of ABS and TK protection from IPRs. So recognized the EU the necessity of “legal certainty” but stipulated that “the legal consequences to the non-respect of the requirement should lie outside the ambit of patent law” (WIPO 2003b: para. 114). The USA refused to discuss the linkage of ABS with IPRs because it rejected, among others, the legally binding ITPGR “in favor of a system of voluntary contributions to the multilateral system” (WIPO 2001a: para. 105). Furthermore, existing legal means should be fully explored with a view that no further measures might be necessary as for example Canada brought forward.³²⁶ Defensive TK protection was portrayed as a more practical solution than positive TK protection via an international legal instrument. To this end, IP supporters like Japan supported the work on a TK database to prevent the granting of erroneous patents (WIPO 2008b: para. 34).³²⁷ But most strikingly, the USA argued that given TK’s diversity and practices, it

“expressed doubt about the development of a new intellectual property-type regime to protect traditional knowledge as it did not appear to be the best fit for holders of such

³²² See for example: Australia (WIPO 2001a: para. 61); EU (WIPO 2001a: para. 20); Japan (WIPO 2005a: para. 135); USA (WIPO 2005a: para. 147; WIPO 2004c: para. 72, 111).

³²³ For example: Japan (WIPO 2005a: para. 135); USA (WIPO 2001a: para. 105).

³²⁴ For example: EU (WIPO 2010f: para. 26, 77; WIPO 2009d: para. 18; WIPO 2006b: para. 15); Japan (WIPO 2008a: para. 30; WIPO 2004a: para. 31; WIPO 2002b: para. 137); New Zealand (WIPO 2003b: para. 147); South Korea (WIPO 2009d: para. 20); Switzerland (WIPO 2005a: para. 142); USA (WIPO 2004a: para. 35; WIPO 2002b: para. 136; WIPO 2002a: para. 71, 223; WIPO 2001a: para. 49).

³²⁵ WIPO 2008b: para. 22; WIPO 2001a: para. 48.

³²⁶ WIPO 2002a: para. 235; WIPO 2001a: para. 46.

³²⁷ Some IP skeptics have been critical of the TK database because it facilitates TK’s illicit exploitation in their view.

knowledge. [...] Indeed a “one size fits all” approach could be interpreted as demonstrating a lack of respect for local customs and traditions” (WIPO 2001a: para. 49).³²⁸

The same critique of an one-fits-all approach was raised against TRIPS by IP skeptics as highlighted by an Indian delegate (WIPO 2004c: para. 106). Although the USA had previously successfully diverted the TK discussion from the TRIPS Council to WIPO, it subsequently questioned WIPO's mandate to address TK protection with regulatory policies. It argued that WIPO's competence encompasses “the provision of technical and legal assistance” so that it could help “holders of commercially valuable traditional knowledge” to use existing IP means to “exploit” TK (WIPO 2001a: para. 49). Likewise, the USA, Japan and Switzerland opposed to discuss patents on biotechnological inventions at the IGC and rather preferred WIPO's IP-friendlier Standing Committee on the Law of Patents (WIPO 2001a: para. 105, 113-114).

In general, IP supporters exerted a delaying strategy to adjourn the discussion on legally binding and therefore costly commitments. Before substantive and text-based negotiations on ABS and TK measures could start, conceptual work should lay the foundation as the main IP supporters – like South Korea, Switzerland and the USA – argued in the beginning.³²⁹ Later on, they emphasized that a richer empirical understanding of facts and the drafting of objectives and principles needed to precede discussions on the legal format of the IGC's work.³³⁰

By contrast, mostly affected indigenous-rich countries – such as Algeria, India, Indonesia, Kenya, and South Africa – supported an international legal instrument from the onset.³³¹ The African Union urged

“to make firm decisions and precise recommendations to the General Assembly for the need to create a legal instrument”

and criticized that

“discussions had thus not been sufficiently focused and expeditious with regards to a legally-binding international instrument and had continually been used as an excuse to exclude or delay work in other fora” (WIPO 2003b: para. 123).

Brazil and Pakistan were concerned that too much time of discussion was devoted to concepts and definitions. Conceptual work, according to them, should not be used as impediment for a discussion on legal instruments (WIPO 2001a: para. 27, 47).

³²⁸ The argument was also repeated in later discussions (WIPO 2005a: para. 147).

³²⁹ See for example: South Korea (WIPO 2001a: para. 48); Switzerland (WIPO 2002a: para. 224; WIPO 2001a: 113); USA (WIPO 2001a: para. 49, 105).

³³⁰ See for example: USA (WIPO 2009c: para. 125; WIPO 2008a: para. 37; WIPO 2006c: para. 148).

³³¹ For example: African Group (WIPO 2008b: para. 45; WIPO 2008a: para. 14; WIPO 2006b: para. 17; WIPO 2001a: para. 25); Algeria (WIPO 2001a: para. 44); Brazil (WIPO 2009d: para. 26; WIPO 2006b: para. 29; WIPO 2003b: para. 136); Colombia (WIPO 2009d: para. 24); Ecuador (WIPO 2008b: para. 32); Egypt (WIPO 2008a: para. 28); India (WIPO 2009d: para. 42; WIPO 2006c: para. 24; WIPO 2006b: para. 32; WIPO 2005a: para. 153; WIPO 2004a: para. 48, 81; WIPO 2003b: para. 100, 166; WIPO 2002a: para. 35, 47); Indonesia (WIPO 2009d: para. 25; WIPO 2008b: para. 19; WIPO 2008a: para. 29; WIPO 2001a: para. 29); Iran (WIPO 2002a: para. 185); Kenya (WIPO 2008b: para. 41; WIPO 2005a: para. 156; WIPO 2003b: para. 137; WIPO 2001a: para. 65); LMMC (WIPO 2002a: para. 120-121); Peru (WIPO 2005a: para. 139); South Africa (WIPO 2009d: para. 27; WIPO 2008b: para. 23; WIPO 2008a: para. 22; WIPO 2001a: para. 52); Thailand (WIPO 2006c: para. 17).

The struggle for legality intensified in the debates on the IGC's mandate. In 2003, the IGC did not reach an agreement with regard to the Committee's mandate for 2004-2005 "despite extensive informal consultations". One main reason was that states could not find a compromise if the IGC should be vested with the mandate to draft a legally binding instrument (WIPO 2003b: para. 175-176). Therefore, the legal quality of the IGC's outcome remained open in its mandate by the General Assembly (WIPO 2003a: para 93). In the next two rounds, the IGC only agreed that its mandate should be extended without referring to legality (WIPO 2007c: para. 542; WIPO 2005a: para. 206). In 2009, the IGC was eventually accorded with the mandate to draft a hard law instrument in order to protect TK and genetic resources due to increasing pressure by IP skeptics who have been strongly affected by the illicit use of these resources. This did not prevent the USA from welcoming that the 2009 mandate had a "flexible outcome" (WIPO 2009b: 232). As soon as the development discussion at WIPO threatened to take a hard law turn, IP supporters' cooperation mode changed. Although WIPO has assured that the IGC is a "true negotiating body, framed by clear and tight schedules and sound working methods" (WIPO 2011: 4), no agreement has been reached by the end of 2014.

While the IGC's work illustrates that legality has prevented a tangible outcome to date, the converse is shown by WIPO's Development Agenda. The adoption of the non-legally binding recommendations was easier because they did not entail "burdensome obligations" like changes or amendments in TRIPS would have implicated (Hrbatá 2010: 22). The price of reaching a consensus on a policy that also reflects IP skeptics' concerns came at the expense of concrete and legally binding commitments. Due to the same logic, also hard law endeavors like the SPLT have not been successful at WIPO (Hrbatá 2010: 22).

Not only did IP supporters take care that no legality was created within WIPO but also that no IP-skeptical soft law entered WTO's hard law regulations. After the WIPO Development Agenda was formerly adopted in 2007, mainly affected IP skeptic Brazil tried to bring back the development discussion to the WTO. It proposed that the TRIPS Council should take into consideration the Agenda's Cluster A on technical assistance and capacity-building in its implementation of TRIPS Article 67 on technical cooperation (WTO 2008e). Brazil supported by other IP skeptics, such as Argentina, Ecuador and India, argued that the acknowledgement of these recommendations would assist in tailoring WTO's technical cooperation and capacity-building activities to the needs of developing countries and LDCs.³³² The USA joined by Australia, Canada, and Switzerland instantly rejected Brazil's proposal in order to insulate TRIPS's hard law from undesired

³³² WTO 2010c: para. 368; WTO 2010b: para. 130, 138, 155, 157, 160, 162; WTO 2010d: para. 119, 122-125, 127; WTO 2009a: para. 197, 199-200, 203, 209; WTO 2009c: para. 46, 73, 79-80, 82; WTO 2009b: para. 92-93, 95; WTO 2008c: para. 193, 196-198.

IP-skeptical influences.³³³ According to the USA, “many of the recommendations did not make sense outside WIPO as they expressly concerned its responsibilities, capabilities and resources” (WTO 2008c: para 195). These concerns were shared by Canada although admitting that the work of the two institutions with respect to technical assistance and cooperation were “complementary” (WTO 2010d: para. 128). Eventually, the Swiss delegation “believed that the two Organizations should work collaboratively, but each of them within its respective context and mandate” (WTO 2010d: para. 131).

These considerations are two-faced in the light of the long history of the WTO-WIPO collaboration on technical assistance. WIPO's technical assistance to WTO members was already affirmed by the 1995 WTO-WIPO Cooperation Agreement that entered into force in 1996 (WTO/WIPO 1995: Art. 4). Many scholars, politicians and activists observed an unequal distribution of labor between WIPO and the WTO in which the WTO sets the hard law that WIPO helps to implement (Helfer 2004: 25). For example, the WTO and WIPO launched a joint initiative in July 1998 to support developing WTO members to meet their TRIPS commitments by the 2000 deadline.³³⁴ In this context, WIPO has been accused of not being impartial in assisting developing countries with the implementation of TRIPS. For example, WIPO was said to have not comprehensively informed developing countries about their rights and flexibilities under TRIPS (GRAIN 2003). Therefore, WIPO has been described as a mere instrument and “handmaiden” of the WTO (GRAIN 1998a).

The examples illustrate WIPO's tensions-filled position between democratic participation and legal-political relevance. On the one hand, WIPO has often been portrayed as a forum in which developing countries have greater chances to represent their interests (Drahos 2002: 166). On the other hand, WIPO has not yielded any legally binding norms with regard to ABS and TK. Although IP skeptics were still better represented at WIPO in comparison to the WTO, an IP bias was also prevalent there. With IP supporters' growing quest to establish a comprehensive and stringent IP regime, a balanced representation of interests between industrialized and developing countries at WIPO in the 1970s shifted toward an advocacy of protectionist IP norms (Sell 2003: 20).

9.3.1.4 WHO – Moderate Democratic Access in the Realm between Legal Irreverence and Rearing Up

WHO provides three main insights on legalization's influence on democratic participation. First, as long as WHO restricted itself to soft law, IP supporters had no incentives to intentionally exclude other state parties from access. Second, as soon as the WHO debate on IP and public health became more specific and proposals for legal instruments gained

³³³ WTO 2010d: para. 126, 128, 131, 133; WTO 2009a: para. 201, 207; WTO 2009c: para. 81; WTO 2009b: para. 96-97; WTO 2008c: para. 195, 199.

³³⁴ Available at: http://www.wto.org/english/news_e/pres98_e/pr108_e.htm (Accessed 20 October 2014).

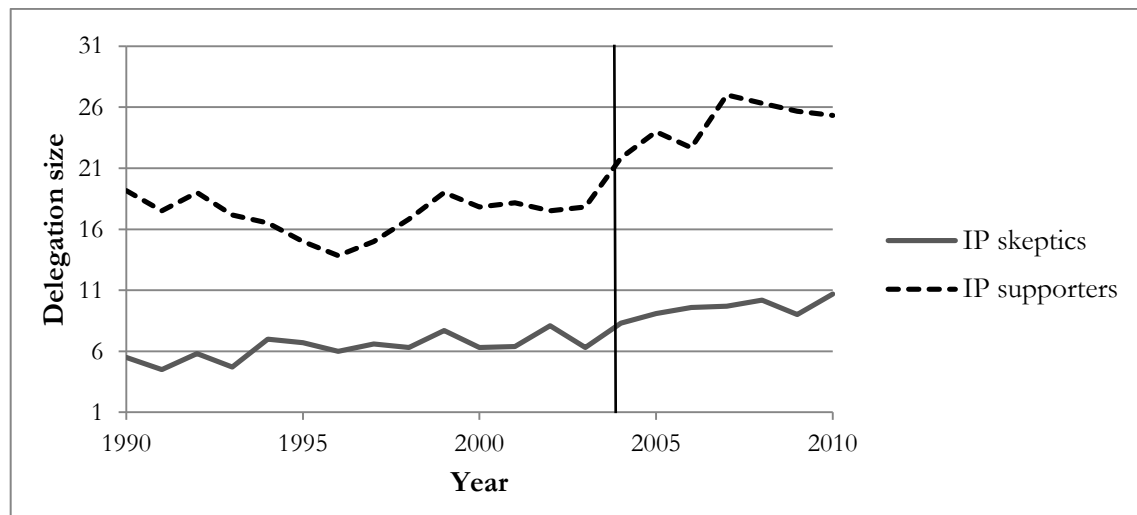
currency, democratic participation decreased. Third, the circumvention of formalization increased under the threat of legality.

First, WHO's disastrous administrative-political situation has often prevented the institution from being a platform of high-stake political relevance. In addition to that, over 26 UN bodies, 20 multilateral development funds, 90 global health initiatives, and 40 bilateral development agencies add to the fragmentation of current global health governance (Hoffman/Röttingen 2014: 190). Against this background, IP supporters have long not perceived the WHA as a political-legal intimidation. Already WHO's first working group on public health and IP – the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) – charged with the investigation of the interface between IPRs and public health did not pose the threat of a significant legal-political change. The CIPRH's mandate only was to “collect data and proposals from the different actors involved and produce an analysis” (WHO 2003c: para. 2(2)). In the light of its very confined remit, the CIPRH was characterized by inclusive participation. The Commission consisted of ten members with a North-South balance. The majority of Commission members worked in scientific institutions. From the business sector, only the Director-General of the Association of the British Pharmaceutical Industry (ABPI) participated.³³⁵ The CIPRH held regional and national meetings both in major IP-supportive and IP-skeptical countries to obtain a comprehensive view on the subject matter (Matthews 2006: 23; WHO 2006a: 199-200). Despite a few deadlocks on key points, the CIPRH report was also complimented by NGO representatives like the MSF and HAI (‘t Hoen/Arkininstall 2007). The CIPRH was from the onset meant to be a “time-limited body” (WHO 2003c: para. 2(2)). This clear time constraint facilitated the control of the CIPRH's development and outcome.

Second, IP supporters' dominance increased as WHO's action on IP and public health became more serious. This is clearly indicated by the development of IP supporters' delegation size at the WHA. It had increased since 2004 which coincides with the launch of the CIPRH's work and further grew during the operation of the CIPRH's successors: the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG; 2006-2008) and the Expert Working Group on Research and Development Financing (EWG; 2008-2010). The figure below illustrates this trend.

³³⁵ An overview of all members is available at: <http://www.who.int/intellectualproperty/background/members/en/> (Accessed 3 October 2014).

Figure 10: State Delegation Size at the World Health Assembly (WHA)



Was the CIPIH’s mission only to collect and review proposals, encompassed the IGWG’s mandate the development of a “medium-term framework based on the recommendations of the” CIPIH (WHO 2006d: para. 3(1)) by the 61st WHA in 2008. This demand for a concrete policy outcome increased the stakes so that the debate became more intense in the course of the IGWG negotiations. The legal threat of IP-skeptical policies was bolstered by growing concerns about WHO’s repercussions on TRIPS. Consequently, most of the IGWG negotiations took place behind closed doors (Mara 2008). Also IP supporters’ willingness to make concessions decreased. At the IGWG’s first meeting in 2006, IP supporters blocked an insertion that public health should take priority over IPRs. IPRs also remained a controversial topic at the second meeting in 2008. The element “management of intellectual property” was one of three items out of seven on which no agreement could be reached. A former WHO official described that IP supporters like the USA developed a “schizophrenic” stance according to which the IP word should at best be completely silenced. Since the USA represented the greatest veto power to an agreement, it was inserted “consensus pending USA” in the respective five paragraphs of the final draft that was adopted with resolution WHA61.21 (Velasquez 2014: 71-73). For instance, the U.S. did not support paragraph 15 that advocated WHO’s leadership in the debate on IP and public health and noted that

“WHO should play a strategic and pro-active role in contributing to pursue the agenda on “public health, innovation and intellectual property” [...]. To achieve this, WHO [...] shall strengthen institutional competencies and programmes” (WHO 2008c: para. 15).

The other provisions that could not find U.S. approval referred to the linkage between R&D costs and pharmaceuticals’ prices, transfer of technology and production of health products in developing countries, differential pricing, and monitoring of pricing (WHO 2008c: Annex 1 para. 4, 34(4.1b), 39(6.3d-e)).

As in the consecutive EWG calls for a legally binding instrument became louder, both IP as a subject matter and IP skeptics’ participation were marginalized. IPRs were gradually detached from the debate and hard bargaining intensified. Resolution

WHA61.21, which establishes the EWG, does no longer directly refer to IPRs (WHO 2008b). IP is neither inserted in the EWG's name nor mentioned in its mandate. Its purpose was confined to the examination of current R&D models and the development of proposals to stimulate R&D in particular for diseases that disproportionately affect developing countries (WHO 2008b: para. 4(7)). In comparison to the IGWG, the EWG's process was even more criticized for being nontransparent and sidelining its members (Mullard 2010; Shashikant 2010). Among the critics were many mostly affected IP skeptics like Bolivia, Ecuador, India, Kenya, and Thailand (Agitha 2013b: 592). A Columbian member of the EWG, Cecilia López Montaña, left the EWG discussion because of procedural critique of the EWG's mode of operation. She felt "utilized to legitimize a process in which neither I [López Montaña] nor the majority of the members of the group participated in a full manner". IP-related topics were avoided on the grounds of the EWG's mandate and the participation of critical members was restricted. She therefore urged the Executive Board not to endorse the report (López Montaña 2010). Likewise, the director of Thailand's International Health Policy, Viroj Tangcharoensathien, lamented that the "EWG lost all legitimacy and credibility" (Mullard 2010: 2133). The final report was excoriated for its vagueness, the neglect of IP-related matters, the delinking of R&D costs from the price of medical products, and its unclear yardstick to evaluate R&D proposals (Agitha 2013b: 592; Shashikant 2010).

The legal stakes further increased with the subsequent CEWG that eventually recommended in its findings "a binding agreement based on Article 19 of the WHO constitution" (WHO 2012a: 14). Concurrently, participatory constraints intensified. After the EWG had come under great procedural criticism, the CEWG was instructed to be more transparent with regard to its meetings, documentation used, and its members' potential conflicts of interests (Agitha 2013b: 592). The hopes of IP skeptics were quickly disappointed when Paul Herrling, the head of Novartis Institutes for Developing World Medical Research, was appointed upon U.S. insistence to the CEWG (Saez 2011).³³⁶ Herrling is a top-ranking employee of a very influential pharmaceutical company and authored a Novartis proposal that was submitted for consideration to the CEWG and suggested that WHO should fund the Novartis Fund for R&D in Neglected Diseases (FRIND) with several billions (Love 2011). WHO's short list of potential CEWG members also initially lacked a representative from India as one of the main IP-skeptical countries (Love 2011). The first CEWG meeting in November 2012 was only attended by 81 out of 194 WHO members (Gopakumar 2013). A coalition of NGOs disapproved the CEWG deliberations for its exclusive character in a joint letter to the WHO Executive Board:

"The report and the draft resolution were adopted after 2AM, when many lead negotiators had to fly back to their respective capitals and interpretation in the World Health

³³⁶ A list with all CEWG members is available at: http://www.who.int/phi/news/phi_cewg_members_2011_en.pdf?ua=1 (Accessed 10 November 2014).

Organization's official languages had long stopped. The number of Member States present at the time of finalizing the draft report was less than 25 out of a membership of 194" (KEI 2013).

Due to the absence of interpretation, an Argentinian delegate who was unsatisfied with many provisions in the draft resolution could no longer meaningfully participate in the last three hours of negotiations (Gopakumar 2013). Also the CEWG's recommendation of negotiating a legal instrument found no mentioning in the draft resolution. Likewise, NGOs opposed the draft report's recommendation to adopt "the resolution by the World Health Assembly without reopening it" (WHO 2012b: para. 6). This provision was contested during the negotiations. The draft resolution was not approved by the Executive Board in the end (Gopakumar 2013).

Third, IP supporters availed themselves of informal procedures if debates did not develop in accordance with their interests. For instance, informalization increased during the IGWA negotiations. At the end of the 61st WHA session in 2008, the president invited nine countries to a "lunch with 'the president's friends'". This benevolent sounding expression signified nothing less than WHO's first 'green room' meeting (Velasquez 2014: 73). Two more followed at the January Executive Board Meeting and the 62nd WHA in 2009 (Velasquez 2014: 72). By the same token, resolution WHA59.24, which requests the establishment of IGWIA, demands that the IGWA's final global strategy and plan of action should be submitted to the WHA through the Executive Board (WHO 2006d: para. 3(4)). However, several developed countries tried to prevent the report's transmission to the WHA through the Executive Board. Instead, they preferred it to be directly send to the WHA in order to be rubber-stamped without being thoroughly discussed by the Executive Board (Shashikant 2010).

The WHO experience demonstrates that legality has immediate ramifications on both democratic participation and policies' content. Considering with which topics the debate on IP and public health initially started at the CIPIH, IP supporters have successfully prevented IP-skeptical policies. When political action became more tangible in terms of precision and legality, IP supporters made sure to influence the outcome. Although several authors have seen some potential in the WHO debate to "fundamentally overhaul the way the pharmaceutical R&D process is funded and the IP system to which it lends itself", they admit that these new ideas are "highly unlikely" to "improve access to affordable medicines in developing countries now or in the immediate future" (Muzaka 2009: 1358).

9.3.1.5 CBD – Inclusion at the Price of Legalization

At the CBD, the institution's low degree of legalization promoted inclusive state participation. The CBD posed no legal threat to IP supporters as the debate on ABS shows.

The CBD faced for a long time obstacles to provide a framework in which effective negotiations could take place. The fourth COP, for instance, had to struggle with organizational problems and “identity problems” due to the CBD's broad mandate (ENB 1998e: 13). Deliberations in the working groups were described with the words “pandemonium” and “chaos” (ENB 1998d: 2). At the end of the sixth COP, the CBD still was awaited to make the “shift from words to action” (ENB 2002c: 16). Likewise, the eighth COP was occupied by procedural rather than substantive matters (ENB 2006b: 22). In addition to that, the CBD was not as well equipped as other fora like WIPO which dealt with similar issues (GRAIN 2004: 2).

The CBD's soft law character can be demonstrated by the mandate of its ABS bodies. The first working group, the Panel of Experts on Access and Benefit-sharing, only had the objective to develop

“a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements” (CBD 1998a: para. 3).

Similarly, its successor, the Ad Hoc Open-Ended Working Group on ABS had the “concrete” or in other words constrained instruction to “develop guidelines and other approaches to address ABS matters such as the “terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; [...] mechanisms for benefit-sharing”. The outcome of the working groups was not meant to materialize in concrete policy action but as “input” for future “[l]egislative, administrative or policy measures” on ABS. (CBD 2000c: para. 11). Also the mandate of the reconvened Working Group in 2002 remained limited to terminological, information-compiling, and policy-reviewing tasks (CBD 2002h: para. 8).

After the LMMC threatened to restrict access to genetic resources on their territory at the World Summit for Sustainable Development in 2003, IP supporters agreed to negotiate an international ABS regime under the auspices of the CBD (Evanson Chege et al. 2010: 249; WSSD 2002: para. 44(o)). In 2004, the Working Group was mandated to develop an “international regime” on ABS (CBD 2004b: para. D.1).

The legality of the instrument remained a constant and one of the most controversial issues during the deliberations of the Working Group on ABS.³³⁷ The interconnectedness between legality and policy's content is striking. IP skeptics – the LMMC, GRULAC, and the African Group – supported a legally binding instrument.³³⁸ IP supporters – the EU,

³³⁷ ENB 2009g: 3; ENB 2007b: 13; ENB 2005b: 4; ENB 2001a: 2.

³³⁸ See for example: African Group (CBD 2009a: para. 25; CBD 2006e: para. 14; CBD 2004d: para. 57; CBD 2002g: para. 340); Brazil (CBD 2009a: para. 40; CBD 2009c: para. 19); Costa Rica (CBD 2009a: para. 39);

Japan, and Switzerland – reacted reserved.³³⁹ The USA, even though having only been an observer at the CBD, attempted to prevent hard law from the beginning. Already at a working group of the fourth COP in 1998, the USA

“emphasized voluntary contractual agreements as the most effective vehicle for benefit sharing, and expressed opposition to a multilateral attempt to regulate benefit sharing arrangements. The US also stressed active involvement of the private sector and disagreed that the issue be a standing agenda item for the COP” (ENB 1998c).

IP supporters insisted that the agreement's content would determine its nature (CBD 2009a: para. 38), or in the words of the Japanese delegation:

“If the international regime were to be composed of provisions that were acceptable to Japan, then Japan would not exclude a legally-binding regime. The nature of the regime would be determined after having discussed the substance of each provision and at this time Japan was consequently not in a position to unconditionally accept a legally-binding international regime at this stage” (CBD 2009a: para. 28).

Also the Swiss delegation reacted skeptical to the possible hard law nature of an ABS regime. The Swiss delegation did in principle not impose a legally binding instrument but it

“should not be interpreted as implying any change in the rights and obligations of a Party under any existing international agreement. It also needed to be flexible in order to allow for the adoption and implementation of other more specialized international agreements that were in harmony with the Convention” (CBD 2009a: para. 31).

As a reaction to this argumentation, Brazil warned “to avoid the chicken-and-egg trap. The Convention on Biological Diversity needed a legally binding regime” (CBD 2009a: para. 40). The nature of the ABS instrument was left open until the very end of the negotiations.³⁴⁰ At the ninth COP in 2008, a Canadian delegate declared that it is still too early to decide if the “international regime might be best effected in a legally binding fashion” (CBD 2008g: para. 66). The term ‘draft protocol’ was first mentioned in the first part of the Working Group's last session at the end of March 2010.

Although legality was a major issue in the debate, IP supporters' interests were never seriously jeopardized but rather the negotiations at a constant brink of collapse. Similar to other deliberations on IP-skeptical policies, IP supporters also protracted proceedings at the CBD Working Group on ABS. The EU supported by South Korea, New Zealand, Norway, and Canada requested a gap analysis to evaluate to what extent ABS is already

GRULAC (CBD 2011: para. 33; CBD 2010i: para. 12; CBD 2009a: para. 26, 32; CBD 2009c: para. 125; CBD 2004d: para. 59); Indonesia (CBD 2010c: para. 43; CBD 2009a: para. 35); LMMC (CBD 2002g: para. 45).

Besides the mostly affected IP skeptics see also: Argentina (CBD 2009a: para. 37); Bangladesh (CBD 2009a: para. 36; CBD 2006d: para. 33); Central and Eastern European Group (CBD 2010i: para. 13, 33; CBD 2009a: para. 41); Cuba (CBD 2009a: para. 34), Egypt (CBD 2009c: para. 123; CBD 2006e: para. 48); El Salvador (CBD 2006d: para. 39); Jordan (CBD 2009a: para. 42); Liberia (CBD 2009a: para. 45); Malawi (CBD 2009a: para. 47); Senegal (CBD 2009a: para. 43); Thailand (CBD 2009a: para. 29); Yemen (CBD 2010c: para. 47).

³³⁹ See ENB 1996: 1. Also Canada, Australia, and New Zealand were skeptical of a legally binding ABS instrument, but they do not represent mainly affected IP supporters according to my definition. Instead they were concerned about the implications of ABS regulations on their sovereignty over genetic resources vis-à-vis their indigenous populations.

³⁴⁰ CBD 2008f: para. 8; Annex(4); CBD 2006i: Annex; CBD 2004b: Annex(b).

sufficiently addressed by current international instruments (ENB 2005a: 1). Therefore, the negotiations were described as “a race between hares and turtles” (ENB 2005b: 10). Serious negotiations were prevented by lengthy procedural debates.³⁴¹ In general, IP supporters tended to avoid the word ‘law’ and paid much attention to keeping the protocol’s scope limited. The USA, for example, argued that derivatives of genetic resources are beyond the CBD’s mandate (CBD 2003: para. 66). They also promoted the softening of compliance measures. At the seventh meeting of the Working Group on ABS, for instance, IP supporters called for replacing “securing” compliance with “supporting it” in the proposal (ENB 2009f: 4). At the end of this session, most paragraphs on compliance tools were bracketed that means that they needed further consideration (ENB 2009f: 8). IP supporters like Switzerland advocated that the protocol should only refer to compliance with respect to access, not the use of genetic resources (ENB 2010e: 7). Japan demanded to not insert provisions on compliance with respect to mutually agreed terms of access “noting that compliance with the protocol requires only that MAT have been established” (ENB 2010c: 10). South Korea successfully proposed to add qualifiers like “as appropriate” with respect to cooperation in cases of alleged violations of national legislation (CBD 2010g: Art. 15-16; ENB 2010c: 10). The EU seized a middle ground. It slowly started to get accustomed to a mandatory disclosure of origin (ENB 2005b: 11), but it only supported international minimum standards that left sufficient flexibility for national implementation (ENB 2007b: 14).

Not only the nature but also the decisions on many contentious issues were taken last minute.³⁴² In the end, the Nagoya Protocol did not significantly limit IP supporters’ rights and benefits. It picks up large parts of the CBD Convention and contains obligations that disadvantage neither IP skeptics nor IP supporters. More importantly, most controversial issues were decided in favor of IP supporters. All provisions pertinent to retroactivity, such as the applicability of the Protocol to genetic resources accessed pre-CBD or pre-Protocol, were abandoned. Likewise, the scope of the Protocol is limited and excludes biological resources as well as TK. The latter was preferred to be tackled by WIPO’s IGC. Also the proposal to establish checkpoints in order to enhance compliance was weakened. Eventually, a mandatory disclosure of origin in patent applications did not make it into the final protocol. This is even more astonishing as all of these matters were included in the draft protocol (ENB 2010c: 14-15; Evanson Chege et al. 2010: 253-256). All in all, IP supporters could accept a legally binding agreement because contentious issues were either successfully “deleted from the text or replaced by short and general provisions allowing flexible interpretation” or their implementation left great discretion to user states (ENB 2010b: 26).³⁴³

³⁴¹ ENB 2009g: 14; ENB 2009f: 12; ENB 1999b: 2; ENB 1999a: 2.

³⁴² ENB 2010c: 14; ENB 2009e: 2; Evanson Chege et al. 2010: 253.

³⁴³ The fact that the USA only holds observer status at the CBD was not the main cause for the adoption of the Protocol. The U.S. average delegation size (19.3) with which it attended the COPs and its statement rate

This environment of soft law and toothless hard law facilitated favorable conditions of inclusive state participation. The CBD provided for comprehensive democratic state access and congruence with regard to involvement. IP supporters' dominance was lower than in all other institutions with the exception of FAO. The CBD endeavored to address and involve all "relevant stakeholders".³⁴⁴ Even IP supporters attached importance to democratic proceedings the very same of which they impaired in other institutions. For example, Switzerland criticized the absence of interpretation at an informal meeting of the Working Group on ABS (CBD 2003: para. 26). The country also pointed to matters that were typically addressed by IP skeptics:

"priority should be given to resuming the work of the Working Group to engage into concrete negotiations rather than informal consultations with limited participation in order to ensure a clear, transparent and inclusive process and legitimacy. In addition, the resumed meeting of the Working Group should not be held in parallel with the meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety in order to allow full participation" (CBD 2010c: para. 157).

As the debate on ABS in the Working Group reached a critical stage, the deliberations were heavily concerned with procedural matters to make sure that no one "falls of the bus" as one delegate explained it (ENB 2009d: 2). Besides Switzerland, also the EU supported broader participation in the work on ABS (ENB 2000a: 2).

Also the CBD made use of smaller negotiations groups to forge compromises. This was mostly conducted in contact groups or the more smaller Friends-of-the-Chair groups (Strasser/Redl 2010: 85). But evidently, neither IP skeptics nor IP supporters opposed their work or complained about their exclusion. The fifth COP, for example, emphasized that "participation was open to representatives of other countries" (CBD 2000b: para. 124, 170, 304). Likewise, attention to the regional balance within the informal groups was paid.³⁴⁵ For instance, GRULAC "supported the idea of working in contact groups, participation in which should be limited in order to increase efficiency" (CBD 2009c: para. 15). The Earth Negotiations Bulletin (ENB) described the use of informal groups at the end of the intricate discussions of the Nagoya Protocol as "constructive small group discussions" to tackle highly complex legal and political matters (ENB 2010c: 15).

In conclusion, IP skeptics, like Brazil and India, negotiated hard for their interests to be represented in the outcome of the Nagoya Protocol (Aubertin/Filoché 2011: 53), but it ultimately depended on IP supporters to tolerate inclusive participation. Their concession was made possible by the lowly legalized setting and vague outcome.

(78) was far above average (6.2/38.2). The USA also attended all sessions of the Working Group on ABS and was even included in the contact groups (for example: CBD 2006c: para. 109).

³⁴⁴ For instance: CBD 2010g: para. 15; CBD 2008f: para. 15, 18; CBD 2006i: para. 3; CBD 2006j: para. 7; CBD 2004b: para. A.2-3, B.1, C.1-2, D.6-8; CBD 2000c: para. 14.

³⁴⁵ See for example: CBD 2009a: para. 116, 199; CBD 2006e: para. 76, 106, 108.

9.3.2 Legalization as Restriction of Balanced NSA Inclusion

9.3.2.1 WTO – Hard Law Forum Shielded from NSAs I

There is no doubt that the WTO put much effort in the improvement of its public image. It offers systematic access to WTO documentation and educational campaigns to explain the WTO structure and its proceedings. But with the emphasis on the WTO's special mandate of negotiating legally binding trade agreements and its intergovernmental nature, NSA participation has been handled restrictively (Loy 2001: 123; WTO 1996c).

Formal contact with IOs has been very limited and selective. In all instances in which an IO's admission was openly rejected at the TRIPS Council between 1990 and 2010, the USA acted as objector. Most debated was the CBD's application for observer status which has been unsuccessful to date.³⁴⁶ The USA self-reflectively admitted that it is "the only impediment to granting observer status to the CBD" (WTO 2002a: para. 514). The USA also upheld its opposition to granting at least ad hoc observer status to the CBD after the General Council urged the TRIPS Council to do so in October 2000 (WTO 2001g: 176). Even a presentation by the CBD at an informal TRIPS Council meeting was rejected by the USA (WTO 2010c: para. 421). The official justification was twofold. First, the General Council had not established guidelines for granting (ad hoc) observer status to IOs in its sub-bodies yet. Second, the overlap of interests between the CBD and TRIPS Council was not satisfactory.³⁴⁷

This official line of argumentation is not very credible as an Indian delegate convincingly countered. First, the USA approved the invitation of the CBD at WIPO in December 2009. Second, the CBD is not an IO specialized in IPRs but neither are FAO, IMF, OECD, World Bank, WHO, UNAIDS, and the WCO all of which have at least ad hoc observer status at the TRIPS Council. The Indian representative concluded that:

"[t]he continued opposition by a Member without providing credible reasons made his delegation believe that they had hit an ideological or possibly a political stone wall. Such stone walls, reminding him of some accession processes" (WTO 2010b: para. 344).

The reasoning behind the U.S. opposition to the CBD's admission was rather driven by costs calculations. The disclosure group gained ground in the debate and urged to include ABS requirements in the legally binding and highly delegated TRIPS framework. Some African countries even suggested that the CBD should take precedence over TRIPS. The CBD's participation would have further strengthened IP skeptics in their endeavor. This ran counter to the interests of the USA as a mostly affected IP supporter in the ABS

³⁴⁶ The USA rejected the admission of the CBD in twelve sessions (WTO 2010c: para. 60, 63, 419, 422; WTO 2010b: para. 355; WTO 2010d: para. 153; WTO 2009a: para. 240; WTO 2009c: para. 102; WTO 2009b: para. 116; WTO 2007c: para. 158; WTO 2005e: para. 342; WTO 2004a: para. 146; WTO 2003d: para. 200; WTO 2002a: para. 514; WTO 2000c: para. 9). The rejection of admitting the International Organisation of Vine and Wine (OIV) (WTO 1997c: para. 79) and the South Centre (WTO 2005e: para. 342) was only mentioned once each. WHO should only be admitted on an ad hoc basis (WTO 2000c: para. 7). In some instances, all pending requests by IOs for observer status were negated (WTO 2010c: para. 63; WTO 2001a: para. 227; WTO 2001g: para. 177; WTO 2002d: para. 319).

³⁴⁷ WTO 2004a: para. 146; WTO 2002d: 319; WTO 2000c: para. 9.

debate. The CBD's official exclusion underlined the U.S. position that the CBD is not only not in conflict with, but also not relevant for TRIPS. Hence, no CBD requirement should be incorporated into TRIPS.

The very defensive U.S. stance has been perceived as inconsistent with the strong U.S. engagement in the debate on the relationship between the CBD and TRIPS (WTO 2001g: para. 128). The USA only reluctantly agreed to grant WHO access to TRIPS but only on an ad hoc basis because, in its view, WHO did not completely fulfil the criteria for observer status in accordance with the General Council's RoP (WTO 2000c: para. 3, 7; WTO 2000d: para. 2). WHO's admission was more difficult for the USA to prevent. First, the debate on public health and IP had already gained international momentum. It was rhetorically almost impossible to argue against the importance of affordable access to medicine in general and compulsory licensing in particular without putting one's country's reputation and the WTO's legitimacy at risk (Morin/Gold 2010: 578). Second, the USA faced significant domestic pressure to change its position on compulsory licensing (Sell/Prakash 2004: 161-167). However, U.S. representatives and WTO officials treated WHO not as an equal and trustworthy partner in the debate on IP and public health (Morin/Gold 2010: 575; Sell 2004: 391-392).

On the contrary, the USA never raised doubts to allow UPOV as an observer to TRIPS despite the fact that UPOV's engagement with TRIPS is limited to Article 27(3) and many WTO members are not a party to UPOV. But since the UPOV Convention represents the U.S. favored model to protect plant varieties, UPOV's participation supported the USA in its efforts to delegitimize other protection forms of plant varieties. Hence, when Under Secretary of State for Global Affairs Frank Loy called for greater interaction between the WTO and IOs, his invitation was certainly limited to a specific group of IOs (Loy 2001: 122).

Legalization played not only a role in shaping U.S. participation preferences but was also a means to defend them. The alleged lack of formalization in the Councils' accreditation procedure for observers was frequently upheld as one U.S. justification not to deal with pending observer requests. It nevertheless leaves a hypocritical taste. First, the USA did not mind the participation of IP-friendly IOs. Second, also the WTO accession process for full members is not completely standardized but subject to ample room for negotiations. The shortage of formalization in this institution has not been an U.S. concern so far.

The EU felt less threatened by the CBD.³⁴⁸ One reason lies in its evaluation of the institution's degree of legalization. In a communication to the TRIPS Council, the EU claimed that the CBD and TRIPS Agreement do not only deal with different subject matters but "are of a different legal nature" (WTO 2001f: para. 5). While the CBD only

³⁴⁸ Even the EU "regretted the fact that, due to the opposition by only one member, it [the CBD] could not be granted ad hoc observer status" (WTO 2010b: para. 347).

establishes general policy objectives and “is not prescriptive” on how to implement them, TRIPS

“provides legal minimum standards that must be enacted in national law, with an enforcement mechanism and sanctions available for non-compliance under WTO rules” (WTO 2001f: para. 9).

In other words, the WTO’s degree of legalization is far higher than that of the CBD. The addition that “[e]ach of the agreements can be implemented through specific implementing provisions” implicates in-between-the lines that the implementation of WTO obligations deserves more serious consideration (WTO 2001f: para. 9). Although the EU supported the CBD’s admission as observer, it emphasized that disclosure should be discussed at WIPO.³⁴⁹

By contrast, highly affected IP skeptics advocated the CBD’s admission. Among the most outspoken ones were the LLMC members, in particular Brazil³⁵⁰ and India³⁵¹ but also China³⁵², Peru³⁵³, and Ecuador^{354, 355}. They were supported by the African Group and as already mentioned by the EU.³⁵⁶ The Brazilian delegation reasoned that the General Council’s RoP establishes clear criteria for IOs to obtain observer status on a case-by-case

³⁴⁹ A similar stance was held by Switzerland (WTO 2001a: para. 164).

³⁵⁰ WTO 2010d: para. 148; WTO 2010c: para. 411; WTO 2010b: para. 346; WTO 2009a: para. 234; WTO 2009c: para. 101; WTO 2009b: para. 109; WTO 2008c: para. 208; WTO 2008b: para. 104-104; WTO 2008a: para. 121; WTO 2007b: para. 251; WTO 2007c: para. 155-156; WTO 2007a: para. 113; WTO 2004a: para. 145; WTO 2003d: para. 197; WTO 2002c: para. 230; WTO 2002b: para. 413; WTO 2002a: para. 506; WTO 2002d: para. 320, 334; WTO 2001g: para. 129, 178; WTO 2001a: para. 160; WTO 2000a: para. 3; WTO 2000c: para. 8.

³⁵¹ WTO 2010d: para. 149-150; WTO 2010c: para. 24, 62, 64, 410, 421; WTO 2010b: para. 344; WTO 2009a: para. 237; WTO 2009c: para. 103-105; WTO 2009b: para. 104-106; WTO 2008c: para. 206; WTO 2008a: para. 120; WTO 2007b: para. 252; WTO 2003d: para. 198; WTO 2001b: para. 124; WTO 2000a: para. 2; WTO 2000c: para. 8.

³⁵² WTO 2010d: para. 155; WTO 2010c: para. 65, 416; WTO 2009a: para. 242; WTO 2009c: para. 107; WTO 2009b: para. 112; WTO 2008a: para. 124; WTO 2007b: para. 252; WTO 2002a: para. 508.

³⁵³ WTO 2010c: para. 65, 415; WTO 2009a: para. 239; WTO 2007b: para. 252; WTO 2003d: para. 199; WTO 2002d: para. 210, 321; WTO 2001b: para. 128; WTO 2001g: para. 132; WTO 2000a: 4; WTO 2000c: para. 8.

³⁵⁴ WTO 2010c: para. 65, 413; WTO 2010d: para. 151; WTO 2010b: para. 345; WTO 2009a: para. 236; WTO 2009c: para. 106; WTO 2009b: para. 108; WTO 2008c: para. 207; WTO 2008a: para. 123; WTO 2007b: para. 252; WTO 2005d: para. 212.

³⁵⁵ Other LLMC members were not as active but also advocated the CBD’s admission. See for example: Bolivia (WTO 2009b: para. 110); Colombia (WTO 2010c: para. 414; WTO 2009a: para. 238; WTO 2009b: para. 111); Indonesia (WTO 2010c: para. 418; WTO 2009a: para. 241; WTO 2009b: para. 113); Kenya (WTO 2009a: para. 243; WTO 2002b: para. 415; WTO 2002d: para. 211; WTO 2000c: para. 8); Venezuela (WTO 2002d: para. 219; WTO 2001g: para. 136; WTO 2000c: para. 8); South Africa (WTO 2010c: para. 35-36, 65; WTO 2010b: para. 349).

³⁵⁶ African Group (WTO 2010d: para. 156; WTO 2010c: para. 412; WTO 2009a: para. 235; WTO 2009c: para. 99; WTO 2009b: para. 107); EU (WTO 2010c: para. 65; WTO 2010b: para. 348; WTO 2002a: para. 505, 518; WTO 2002d: para. 213; WTO 2001g: para. 179; WTO 2001a: para. 225; WTO 2001g: para. 179; WTO 2000a: para. 4; WTO 2000c: para. 8).

Other countries include the ACP Group (WTO 2010c: para. 420), Andean Community (WTO 2002b: para. 406), Angola (WTO 2010d: para. 154; WTO 2010b: para. 354), Cameroon (WTO 2009b: para. 114), Chile (WTO 2010b: para. 353; WTO 2007c: para. 159), Cuba (WTO 2010c: para. 65; WTO 2010b: para. 348; WTO 2009b: para. 114; WTO 2000c: para. 8), Egypt (WTO 2010d: para. 152; WTO 2010c: para. 417; WTO 2010b: para. 350 WTO 2002a: para. 515), Mauritius (WTO 2010b: para. 351), Nigeria (WTO 2010c: para. 39), Norway (WTO 2000a: para. 4), Sri Lanka (WTO 2002d: para. 509), Switzerland (WTO 2010c: para. 65), Turkey (WTO 2000c: para. 8, 132), and Uruguay (WTO 2010c: para. 34).

basis at the WTO. In his opinion, the majority of these requirements were met by the CBD. First, the CBD's nature of work was relevant to the WTO. Three permanent items on the TRIPS Council's agenda directly concerned the CBD's work: (1) the review of the provisions of Article 27(3b), (2) the protection of TK and folklore, and (3) in particular the relationship between TRIPS and the CBD. The CBD could provide first-hand information on these topics. Second, the CBD has universal membership, even one more member than the UN and far more members than UPOV and the OECD both of which are observers at the TRIPS Council. Third, all WTO members are parties to the CBD with the exceptions of the USA, Taiwan, and China's autonomous regions Hong Kong and Macao. Fourth, reciprocity concerning access to proceedings should be easily feasible in consultation with the CBD secretariat. Only the fifth criterion, which is of minor importance, was not fulfilled by the CBD as it was not associated with the work of the contracting parties to GATT in the past (WTO 2010d: para. 148).³⁵⁷ Besides the fulfillment of these criteria, the CBD was already invited on an ad hoc basis at a special session of the Committee on Trade and Environment and the Negotiating Group on Trade Facilitation that established a precedent that the TRIPS Council should follow (WTO 2007c: para. 155-156; WTO 2003d: para. 197). Also was the CBD already invited to WIPO (WTO 2010d: para. 150). Thus, also IP skeptics referred to the formalization of access to underpin their favored participation composition. Instead of pointing to loopholes as the USA, they emphasized the rules' unambiguousness.³⁵⁸

The demand of biodiversity- and TK-rich countries, especially those of mostly affected states like Brazil and India, to include the CBD in the TRIPS discussions is consistent with their cost-perspective.³⁵⁹ The CBD's participation in the TRIPS debate would have bolstered their requests to amend TRIPS with ABS and TK standards. Their integration into TRIPS would have increased their legal force and enforcement possibilities.³⁶⁰

The WTO's handling of IO observers is well mirrored in the Sutherland Report which was commissioned by the WTO Director-General. The board noted that decisions on IO observer status have been "the object of political and diplomatic manoeuvring rather than

³⁵⁷ For similar positions see also: WTO 2009a: para. 237; WTO 2003d: para. 198.

³⁵⁸ Only Egypt frequently criticized a lack of transparency in the admission criteria and supported a systematic solution instead of ad hoc observer status (WTO 2010d: para. 158; WTO 2002b: 373).

³⁵⁹ Brazil and India went further with their proposals of IO admission. Brazil suggested to extend observer status to IOs that were already granted observer status in another WTO body (WTO 2001g: para. 178). India called to admit every IO "that so desired" (WTO 2001a: para. 226). Both proposals were rejected by the USA.

³⁶⁰ With a similar rationale to further their interests, the African Group and African countries supported the admission of African organizations like the African Regional Intellectual Property Organization (ARIPO), African Intellectual Property Organisation (Organisation Africaine de la Propriété Intellectuelle; OAPI), and the Conférence des Ministres de l'Agriculture de l'Afrique de l'Ouest et du Centre (CMA/AOC).

The admission of ARIPO and OAPI was endorsed by the African Group (WTO 2010c: para. 397, 428; WTO 2010d: para. 156; WTO 2009a: para. 235; WTO 2009c: para. 99), ACP Group (WTO 2010c: para. 398), Kenya (WTO 2002b: para. 365), observer members of ARIPO such as Angola (WTO 2010d: para. 154, 157, 160; WTO 2010b: para. 354) and Egypt (WTO 2010c: para. 417; WTO 2010d: 158, 161). The CMA's inclusion was supported by the African Group (WTO 2009a: para. 235; WTO 2009c: para. 99).

judgments on practical merit” (Sutherland et al. 2004: 39). IOs have been treated as necessary evil. On the one hand, the WTO should be cautious with IO cooperation to “preserve both the creation and interpretation of WTO rules from undue external interference” (Sutherland et al. 2004: 38). On the other hand, the inclusion of IOs “helps legitimize the WTO since it complies with the general obligation of conduct, related to cooperation, that is part of public international law” (Sutherland et al. 2004: 39).

While IOs were at least selectively permitted as observers to the Councils, NGOs have been completely banned in these fora. Although the WTO responded to NGOs’ pressure for greater transparency, direct NGO participation remained limited to informal and ad hoc channels. This has been explicitly justified by cost calculations pertinent to hard law. The WTO rules are legally binding and the institution serves as a forum to negotiate further hard law (WTO 1996c). The guidelines for arrangements on relations with NGOs rightly state that there is a “broadly held view” not to grant NGOs formal access to the WTO (WTO 1996c). This general reluctance toward NGO participation has different causes. IP supporters have been concerned that NGOs disturb the already complicated trade negotiations (Åsa 2010: 123). They add to the intricate negotiation constellation of diametrical economic positions and non-economic demands of protecting the environment and human rights. By the same token, commercial interests require confidentiality in order to find a compromise (Sutherland et al. 2004: 45). Therefore, the highly legalized and technical WTO proceedings have to be shielded from these politicizing actors (Cho 2005: 396). Instead, NGOs have to communicate their interests at the national level where the formation of public interests should take place. Following this line of democratic logic, the former WTO Director-General Mike Moore declared in front of NGOs:

“The WTO is not a world government, a global policeman, or an agent for corporate interests. It has no authority to tell countries what trade policies - or any other policies - they should adopt. It does not overrule national laws. It does not force countries to kill turtles or lower wages or employ children in factories. Put simply, the WTO is not a supranational government - and no one has any intention of making it one. Our decisions must be made by our Member States” (WTO 1999c: 3).

The official WTO position suggests that transparency in the conduct of business should be favored over extensive NGO cooperation (Sutherland et al. 2004: 43). In the few possibilities to get involved, business NGOs were privileged. For instance, only business leaders could attend the WIPO-WTO workshop on implementation of Article 27(3) in Bangkok in March 1999 while affected farmers and local communities had to stay outside (Raghavan 1999).

Developing countries, which are mostly IP skeptics, have been suspicious of NGOs for two main reasons. First, environmental and human rights NGOs are considered to be very critical of developing countries’ policies and not very well versed with their immediate needs. Second, a WTO opening toward NGOs has been suspected to further

increase Northern dominance because the majority of NGOs present at international meetings originate from developed countries. By contrast, developing NGOs are typically underfunded and therefore face high hurdles to attend international negotiations (Loy 2001: 124).

Similar to the relationship with IOs, NGO access could not be completely prevented as the opening up toward civil society has become a necessary legitimizing move in IOs but it has been tried to keep it a minimum level (Åsa 2010: 125). One of the few instances of fruitful collaboration between NGOs and developing countries was during the negotiations leading to the Doha Declaration. In the case public health and IP, the circumstances were conducive. First, the MSF, TWN and Oxfam effectively joint forces in the debate on access to essential medicine in the late 1990s and early 2000s (Matthews 2006: 7-8). Second, developing countries – including key actors like Brazil, India, and the African Group – were more united in their interests and endorsed NGO participation to a greater extent than in any other policy area. NGOs assisted developing countries with technical expertise, training, formulation of draft submissions, and technical drafting work of the Doha Declaration (Matthews 2006: 7-8; Morin/Gold 2010: 571). But the relationship between developing countries and NGOs got more tensions-ridden when the discussion turned to technical details. Developing countries did no longer follow NGOs' advice during the post-Doha negotiations on the TRIPS amendment of which social NGOs were very critical (Matthews 2006: 8-9, 15).

Formalization was, like in the case of IOs, brought forward as a means to influence NGO participation. In the light of the WTO's closed doors toward NGOs, the latter have requested formalized and permanent participation mechanisms in the hope that this leads to greater NGO inclusion (Ratton Sanchez 2006: 107).

9.3.2.2 UPOV – Hard Law Forum Shielded from NSAs II

UPOV follows a club model for deepening IP protection on plant varieties. This endeavor has been shielded from critical NSA voices. UPOV is the second most exclusive institution concerning NGO access with the greatest Western bias in the sample. Between 1990 and 2010, only business NSA could attend the Council meetings. The rationale for exclusive NSA access has also been cost calculations. Neither should IP-skeptical NSAs water down the IP-friendly UPOV Convention. Nor should they prevent other states from becoming UPOV members since the highly legalized UPOV framework has served as a perfect means to subject states to the strict rules of the protection of plant varieties and breeders' rights.

If NSA participation has been allowed, it has almost exclusively included business actors. Similar to TRIPS, also UPOV's founding was considerably determined by business actors. A selected group of business associations participated in the Diplomatic Conference in 1961 leading to the UPOV Convention: the International Association of

Plant Breeders for the Protection of Plants Varieties (ASSINSEL), the International Association for the Protection of Industrial Property (AIPPI), the International Community of Breeders of Asexually Reproduced Ornamental Varieties (CIOFORA), and the International Federation of Seed Trade (FIS) (Jördens 2005: 233).

Likewise, business actors could participate in seminars on the protection of plant varieties organized by UPOV, WIPO and WTO while farmer organizations and civil society groups were excluded (GRAIN 1999a). The three institutions tried to persuade developing states to accede to UPOV in these events. Therefore, they did not want to face up to non-business NSAs' critical reflections of UPOV that might have raised further doubts among participants to join UPOV.

It was only in 2010 that the first two civil society organizations – the Association for Plant Breeding for the Benefit of Society (APBEBES) and the European Coordination of Via Campesina – were granted observer status to the Council following joint pressure by public action groups and public support by several states like Norway. The first applications of both organizations in 2009 were rejected due to their critical stance toward UPOV (APBEBES 2009).

9.3.2.3 WIPO – Blossoming NSA Inclusion with Withering Legal-Political Importance

WIPO's NSA access is moderate but has become more inclusive since the beginning of the new millennium. WIPO's decreasing legal-political importance has supported its openness toward NSAs. In this context, the role of indigenous and local groups as mostly affected actors in the realm of ABS and TK deserves special consideration in this subsection. Their interests sometimes conflict with those of 'their' national governments so that they cannot rely on the latter to represent them in international negotiations.

The IGC has served as platform for inclusive access of indigenous groups. This was possible because the IGC did not threaten the hard law framework of the IP regime as described above. The IGC accepted NGOs from diverse areas as observers (GRAIN 2004: 2). The first IGC session in 2001 was only attended by the two IP skeptics ICTSD and IUCN next to 13 IP supporters like BIO and IFPMA (WIPO 2001a: para. 4). But already in the same session, 34 more NGOs were granted ad hoc observer status to the IGC. Almost all of them were IP-skeptical organizations while the largest share was made up of indigenous groups. This included, for example, ATSIC, COICA, FAIRA, IPBN, RAIPON, Saami Council, Tebtebba Foundation, and WIMSA (WIPO 2001a: para. 18).³⁶¹ Even the U.S. delegation noted that "it supported the inclusion and appropriate participation as observers of non-governmental organizations" (WIPO 2001a: para. 16). Together with other IP supporters – such as the EU, Japan, and Switzerland – the USA

³⁶¹ ATSIC=Aboriginal and Torres Strait Islander Commission; COICA=Coordinator of Indigenous Organizations of the Amazon River Basin; FAIRA=Foundation for Aboriginal and Islander Research Action; IPBN=Indigenous Peoples' Biodiversity Network; RAIPON=Russian Association of Indigenous Peoples of the North; WIMSA=Working Group of Indigenous Minorities in Southern Africa.

welcomed the participation of indigenous groups in the IGC in order to obtain first-hand information on their situation and needs.

All requests by organizations for ad hoc observer status, most of them indigenous groups, were “unanimously approved” until the end of research period in 2010.³⁶² The improvement of local and indigenous communities’ participation was a constant item on the IGC’s agenda.³⁶³ In 2005, the voluntary fund for indigenous and local communities was established to further enhance indigenous participation at the IGC. Also New Zealand, which has often been concerned about strong indigenous rights, stood up for more effective indigenous participation. It proposed longer speaking times for indigenous representatives who should be able to make interventions also in-between state members’ statements. By the same token, panel presentations by indigenous and local groups should be incorporated in the IGC sessions. In order to acknowledge the value of indigenous groups’ attendance, seating should be changed and an indigenous co-chair should be elected (WIPO 2004b: para. 4). The Committee took up two of the proposals. It decided that indigenous and local groups should be allotted more speaking time for general statements at the beginning “wherever possible” and during sessions “at appropriate occasions”. Panel presentations should be organized before the commencement of the IGC sessions (WIPO 2004a: para. 63). Furthermore, the IGC encouraged NSA participation by releasing a practical guide on making statements in IGC sessions so that NSA speeches are heard and comprehensively and accurately covered in the IGC report.³⁶⁴ In fact, proposals by indigenous groups and other NGOs were included in draft documents at the IGC (Matthews 2006: 29-30).

Nevertheless, the endorsement of indigenous participation has not been unlimited by neither IP supporters nor IP skeptics. First, the U.S. support found its limit with the financial assistance of indigenous groups. Together with the other main IP supporters EU, Japan and Switzerland, it advocated that indigenous groups should be funded by donor states’ “voluntary extra-budgetary” contributions but not from the core budget.³⁶⁵ The USA was more than determinate to ensure that no single cent from the regular budget would be spent on indigenous participation (WIPO 2005a: para. 51). Likewise, the USA advocated that indigenous groups from both developed and developing countries should be equally financially supported by the voluntary fund. Alternatively, indigenous

³⁶² WIPO 2010e: para. 20; WIPO 2010f: para. 18; WIPO 2009c: para. 23; WIPO 2009d: para. 12; WIPO 2008a: para. 13; WIPO 2007c: para. 11; WIPO 2006c: para. 12; WIPO 2006b: para. 12-13; WIPO 2005a: para. 12; WIPO 2004c: para. 25; WIPO 2004a: para. 10; WIPO 2003b: para. 25-26; WIPO 2002b: para. 19; WIPO 2002a: para. 20; WIPO 2001b: para. 13. No information on the voting result for the thirteenth session are provided in the report (WIPO 2008b).

³⁶³ WIPO 2010d; WIPO 2010b; WIPO 2009a; WIPO 2008b; WIPO 2008c; WIPO 2007b; WIPO 2006d; WIPO 2006a; WIPO 2005b; WIPO 2004e; WIPO 2003c; WIPO 2003d.

³⁶⁴ Available at: <http://www.wipo.int/export/sites/www/tk/en/igc/pdf/intervention.pdf> (Accessed 3 September 2014).

³⁶⁵ See for example: EU (WIPO 2004a: para. 13; WIPO 2003b: para. 181); Japan (WIPO 2005a: para. 46; WIPO 2004a: para. 15; WIPO 2003b: 186); Switzerland (WIPO 2005a: para. 54; WIPO 2003b: para. 182); USA (WIPO 2004a: para. 14; WIPO 2003b: 188).

representatives could be directly included in member states' delegations.³⁶⁶ The U.S. proposals referred to critical issues for indigenous participation. The voluntary financing of indigenous representation, as a representative from Tupaj Amaru argued based on the experience from other UN bodies, would not work as the contribution only came on an ad hoc basis (WIPO 2004c: para. 51). Furthermore, indigenous representatives criticized that their governments have often not cooperated with them (WIPO 2004c: para. 50). Also the African Group and the Asian Group as well as Latin American countries like Colombia, Nicaragua, and Panama advocated voluntary funding as they worried about significant cuts in the funding of state delegations (WIPO 2003b: para. 178-179, 187, 191, 195). Only wealthier IP skeptics such as Brazil, India, and Venezuela preferred indirect funding out of the regular budget.³⁶⁷

Second, Brazil, Colombia, and the USA were eager to control the participation of indigenous groups and other NSAs. These countries unsuccessfully opposed NGO membership in the Advisory Board that decides on the beneficiaries of the Voluntary Fund (WIPO 2005a: para. 51, 58, 64). Their stance reflects the General RoP according to which national NGOs require the consent of their national governments. The joint position of IP-supportive and IP-skeptical countries is evident given the profits that are at stake in the ABS and TK debate. Indigenous-rich countries and indigenous groups share their interest in TK protection. But each of them would like to be the formal owner of these resources and, if applicable, get most out of the benefits that TK protection might yield.

Besides the relationship between states and NSAs, also the development of NSAs' composition is worth noticing. Not only the sheer number of NSA delegations that attended the WIPO Assemblies increased but also their composition changed. The proportion of business actors decreased in favor of indigenous and development organizations. This observation deserves some qualification in the light of the situation at the IGC. NSAs together with member states had the opportunity to make text-based statements on the draft provisions in three rounds of commenting processes.³⁶⁸ The development of NSA statements' number and composition is telling. Not only decreased the absolute number from 8 in the first round to 7 in the second round and eventually 4 in the third round. Also the share of indigenous contributions declined. There were 6 in the first round, 3 in the second, and none in the third round. At the same time, the number of business contributions raised from 1 in the first round to 3 in the second and third

³⁶⁶ See for example: WIPO 2005a: para. 51; WIPO 2003b: para. 188; WIPO 2002b: para. 27. This view was, for instance, shared by New Zealand (WIPO 2003b: para. 184.)

³⁶⁷ See: Brazil (WIPO 2003b: para. 192); India (WIPO 2005a: para. 63); Venezuela (WIPO 2003b: para. 180).

³⁶⁸ The first round took place between November 2004 and February 2005, the second between April and December 2006 and the third one between December 2009 and May 2010. Available at: http://www.wipo.int/tk/en/igc/draft_provisions.html (Accessed 20 October 2014).

round.³⁶⁹ It is certainly no accident that business participation increased with a growingly louder call for legally binding international instruments on ABS and TK at the IGC. This is just an illustration for the influence of legalization's costs on participation and no evidence for a general trend at WIPO as this commenting process had only a small number of participants and did not result in a hard law norm.

The role of formalization played a minor role at the WIPO but existed as one example illustrates. At the IGC's first session, the USA questioned if also national NGOs can be admitted (WIPO 2001a: para. 16). The secretariat instantly clarified that national NGOs can be accepted in accordance with the RoP and that this has been common practice in WIPO committees (WIPO 2001a: para. 17). The USA did not doubt the legitimacy of these formal provisions and accepted their usage. Similar to instances at other institutions, formal rules also worked toward more inclusive participation in this situation.

All in all, WIPO has been torn between legal relevance and inclusive NSA participation. Was WIPO previously described as "closed gentlemen's club" comparable to UPOV and the WTO, it has opened its doors to non-business actors (GRAIN 2004: 2). In the meantime, the moderately inclusive NSA participation has not led to legally binding outcomes. Although WIPO allowed for greater NSA participation, their access and involvement were limited. It should not be neglected that no indigenous groups, despite being strongly affected by ABS and TK policies, was accredited to the WIPO Assemblies between 1990 and 2010.

9.3.2.4 WHO – Formalization as Guardian of Controlled NSA Participation

WHO is no obvious candidate for democratic NSA participation since its highly formalized accreditation procedure is cumbersome. In practice, however, the strong formalization of NGO participation did not hamper NSA inclusion. The empirical results show that NSA participation became more exclusive with growing legal and political stakes and at the same time biased toward IP supporters. NSAs had important but few opportunities to exert influence on WHO policies.³⁷⁰ For instance, HAI helped Zimbabwe on request to develop a draft resolution for a WHO Revised Drug Strategy on short notice in 1998. The Executive Board only adopted this resolution, according to Susan Sell, because the USA was not on the Executive Board that year (Sell 2003: 148).

NSAs' participatory possibilities in working groups on public health and IP and later R&D shrank in the course of the debate with the growing threat of hard law on the horizon. The CIPIH's narrow mandate was accompanied by inclusive NSA participation. The CIPIH directly consulted with NSAs of different nature and from different regions

³⁶⁹ For individual comments see: http://www.wipo.int/tk/en/igc/draft_provisions.html (Accessed 20 October 2014).

³⁷⁰ Much attention has also received NGOs' influence in the negotiations of the Framework Convention of Tobacco Control (Lee 2010; Lencucha et al. 2011).

and held separate meetings with NGOs even if the host state was “not enthusiastic about the CIPIH meeting with NGOs” (Matthews 2006: 23, 30).

In the subsequent two WHO bodies – the IGWG and EWG – with more far-reaching mandates, NSA engagement in the discussion was only indirectly possible via the online submission of position papers. Web-based public hearings took place preceding and during the operation of the IGWG in December 2006 and November 2007.³⁷¹ Also the EWG held public hearings in March-April and August-September 2009.³⁷² This method has some potential to gather opinions from a wider scope of stakeholders. But the consideration of the submitted statements ultimately depends on state members’ will and therefore tends to be less effective than direct participation at the negotiation table. Given NGOs’ limited participatory possibilities in these time-limited bodies, NGOs can only take little comfort in the fact that NGO access to the WHA in terms of delegations had more or less continually increased from the end of the 1990s to 2010.

Furthermore, WHO has frequently been accused of having too close ties with private actors who exert undue influence on WHO policies (Lee 2009: 118-120). While no dominant business influence could be detected in NSA participation at the plenary sessions (see chapter 8), the pharmaceutical industry flexed its muscles whenever WHO threatened to spoil their business. During the IGWG’s negotiations, the pharmaceutical industry exerted great lobbying pressure on relevant decision-makers. It was constantly and in large numbers present outside the meetings “perhaps fearing the negotiations’ scope and sensing the risk of seeing its commercial interests impacted on the long-term” (Velasquez 2014: 70). The growing attempt of business actors to influence the negotiations is also mirrored in the second round of the IGWG’s online hearings in 2007. According to an analysis by the NGO Essential Action, the number of submissions from groups with links to the pharmaceutical industry where at least twice as high in comparison to other NGOs (Essential Action 2007: 2). Also the subsequent EWG was accused of being improperly influenced by the pharmaceutical industry (Agitha 2013b: 592). A dossier that surfaced on Wikileaks put the final nail in the coffin. It exposed that confidential EWG documents, including the final draft report, leaked to the IFPMA. An email to the IFPMA stated that the EWG findings were “in line with most of the industry positions” (Mullard 2010: 2133).³⁷³

Business influence cannot only be explained by the stakes at play for the pharmaceutical industry but also those of WHO. Being on good terms with the private industry is important in the light of WHO’s disastrous financial situation. Therefore, Director-General Gro Harlem Brundtland’s “corporate style” during her term of office

³⁷¹ Available at:

http://www.who.int/phi/news/igwg_public_hearings_proposals_recommendations_2011.pdf (Accessed 4 November 2014).

³⁷² For contributions see: http://www.who.int/phi/publichearing_rdf/en/ (Accessed 4 November 2014).

³⁷³ An internal investigation by WHO’s Office of Internal Oversight Services found that no WHO officer was responsible for the leakage (Mullard 2010: 2134).

between 1998 and 2003 also led to an intensified collaboration with the private industry (Clift 2013: 39; Lee/Pang 2014: 120). For example, it was established a rather informal WHO/Industry Drug Development Working Group in 1998. An IFPMA representative described the first meeting as “extremely private”.³⁷⁴

This section showed that WHO's openness toward NSAs leaves room for improvement. To this end, WHO launched the Civil Society Initiative (CSI) in 2001. This review of WHO's formal and informal relationships with civil society was mainly driven by Director-General Brundtland and made little progress under her successors (Lee 2009: 121). A new proposal to continue the Initiative was presented at the 57th WHA in 2004 but was rejected by China and other countries (van de Pas/van Schaik 2014: 197). In the course of WHO's reform endeavors, also its policies with NSAs are currently revisited.³⁷⁵

9.3.2.5 CBD – Lowly Legalized Doors Wide Open to NSA Inclusion

Among all institutions in the sample, the CBD is the most open one toward NSAs. The CBD ranks highest in terms of absolute numbers of NSA delegations, balance of NGOs' nature and geographical distribution, and share of NSA statements. One explanation can be found in the CBD's soft law character. Even the legally binding agreements, the CBD Convention and the Nagoya Protocol yielded no concrete legal obligations but only general principles (Aubertin/Filoché 2011: 61). As already described above, the 2000 mandate of the Ad Hoc Open-Ended Working Group on ABS was only to develop guidelines and provide preparatory work for future negotiations on ABS. At the same time, the COP decision clearly determines that the

“Working Group will be open to the participation of indigenous and local communities, non-governmental organizations, industry and scientific and academic institutions as well as intergovernmental organizations” (CBD 2000c: para. 11(a)).

Likewise, its successor, the Panel of Experts on Access and Benefit-Sharing with an equally low-profile mandate was “composed of representatives from the private and the public sectors as well as representatives of indigenous and local communities” (CBD 1998a: para. 3). Also the Working Group's 2004 mandate to table a proposal for an international ABS regime emphasized that inclusive participation should be ensured (CBD 2004b: para. D.1, D.7).³⁷⁶ The IOs FAO, the UN Environment Programme (UNEP), UPOV, WIPO, and the WTO were invited by name to cooperate with the Working Group (CBD 2004b: para. D.5). During the adoption of the Nagoya Protocol, COP appreciated that NSAs participated in the Working Group (CBD 2010g: preamble). And

³⁷⁴ Available at: <http://www.thepharmaletter.com/article/who-ifpma-to-set-up-working-group> (Accessed 3 July 2012).

³⁷⁵ For up-to-date information consult: http://www.who.int/about/who_reform/non-state-actors/en/ (Accessed 19 November 2014).

³⁷⁶ A similar trend could be observed with regard to TK. In preparation of establishing a working group on Article 8(j), many states supported the “full and effective participation of indigenous peoples in CBD processes” (ENB 2000c: 7). The support for indigenous participation was reflected in the decision (CBD 2000d).

in fact, a remarkable large number of NSAs attended the Working Group. The numbers ranged from 60 observers at the second session in 2003 to 145 at the fourth session in 2006 (CBD 2006e: para. 3-4; CBD 2003: para. 16).³⁷⁷ NSAs could also raise IP-skeptical opinions. So called environmental NGOs for

“[l]egally binding instruments [...] at least on a national level. [...] Parties should ensure that intellectual property rights should not be granted if they constrained further access to the genetic resources. [...] Parties to the Convention must ensure that its objectives and obligations were not subordinated to agreements of the WTO and regional trade agreements” (CBD 2001: para. 45).

Likewise, indigenous groups and the UNPFII had several opportunities to deliver statements from the first session onwards.³⁷⁸ The International Indigenous Forum on Biodiversity (IIFB) was allowed to suggest a draft decision on the participation of indigenous people (CBD 2006d: para. 154, 173). In order to discuss it, the Chair set up an open-ended informal consultative group (CBD 2006e: para. 17). An indigenous group was even granted the opportunity to introduce a draft proposal on screen during the sixth session (CBD 2008g: para. 52). But also IP-supportive NSAs like UPOV could raise its “concern about the introduction of unnecessary barriers to progress in breeding and the use of genetic resources” (CBD 2006d: para. 29). Also the WTO had the opportunity to speak despite the fact the CBD was not granted observer status at the TRIPS Council (CBD 2006d: para. 34). By the same token, business actors such as the American BioIndustry Alliance made statements (fCBD 2007: para. 37, 45, 64, 71).

Among all NSAs, indigenous and local groups had a special position at the CBD. This in particular caters the fulfillment of democratic congruence as indigenous groups are especially affected by ABS and TK provisions. COP established several points of access and involvement for these groups. At several occasions, COP invited indigenous and local communities to submit comments or provide information.³⁷⁹ This also applies to the

³⁷⁷ The report differentiates between UN agencies and observers. Observers include a few IOs and in one instance the state group G77 but are mostly composed of NGOs. The number of UN agencies and other observers for the other meetings were 88 at the first session (CBD 2001: para. 5), 92 at the third session (CBD 2006d: para. 44-45), 101 at the fifth session (CBD 2007: para. 3-4), 92 at the sixth session (CBD 2008g: para. 3-4), 106 at the seventh session (CBD 2009c: para. 3-4), 103 at the eighth session (CBD 2009a: para. 3-4), 95 at the first part of the ninth session (CBD 2010c: para. 3-4), 78 at the second part (CBD 2010i: para. 3-4), and 142 at the third part of the ninth session (CBD 2010f: para. 3-4). Also in other fora, indigenous organizations participated in large numbers. The 1997 Workshop on Traditional Knowledge and Biological Diversity, for instance, was attended by approximately 62 governments and 148 indigenous organizations (ENB 1998e: 2).

³⁷⁸ See for example: CBD 2010f: para. 14; CBD 2010i: para. 73; CBD 2010c: para. 35, 63, 141-143, 194-195; CBD 2009a: para. 44, 52, 60, 66, 75, 91, 142; CBD 2009a: para. 24; CBD 2009c: para. 72, 127; CBD 2008g: para. 27, 31, 35, 39, 42, 46; CBD 2007: para. 27, 33, 44, 50, 53, 63, 70, 77, 82, 88, 92; CBD 2006e: para. 24-27, 59, 63, 68, 73, 85, 96, 126; CBD 2006d: para. 30, 72-73, 79, 85, 120, 129, 148, 153, 163; CBD 2003: para. 53, 92; CBD 2001: para. 17, 46.

³⁷⁹ CBD 2011: para. 37-38, 141, 144, 194, 236, 301, 319, 328, 340, 357, 404; CBD 2008e: para. 27, 30, 91-92, 161, 191, 201-202, 237, 240, 245, 261, 264, 285, 331, 338, 366, 442; CBD 2006c: para. 66, 68, 104, 108, 129, 141, 147, 162, 182, 186, 192, 201, 238, 245, 248, 252, 254, 291, 304, 323, 345, 351, 380, 396, 402, 422, 471, 478, 491, 508; CBD 2004d: para. 61, 66, 85, 118, 141, 219, 257, 259, 271, 273, 278, 326, 409, 450, 482, 525, 528, 532, 566, 585, 593; CBD 2002g: para. 46, 61, 99, 133, 143-144, 147, 151, 199, 225, 266, 285, 291, 333, 369, 376, 392; CBD 2000b: para. 23-25, 228, 231, 235, 328; CBD 1998d: para. 87, 113, 128, 130-135; CBD 1997: para. 26-27, 73, 80, 98, 143; CBD 1995b: para. 103, 135.

Working Group on ABS.³⁸⁰ All members and stakeholders were encouraged to “facilitate effective participation of indigenous and local communities” (CBD 2006j: para. D.6).³⁸¹ Likewise, the CBD should take into consideration the “specific vulnerabilities of indigenous and local communities” in its work (CBD 2006j: B.6). The Executive Secretary was requested “to assist indigenous and local communities in capacity-building, education and training” (CBD 2006j: para. B.13). He should also support their participation, for instance, by “making available meeting rooms, access to documentation, and computer and photocopying facilities” (CBD 2006j: para. C.6(a)). Members were invited “to increase the participation of representatives of indigenous and local communities’ organizations in official delegations to meetings” of the Working Group on ABS and the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) (CBD 2006j: para. C.6(b)). Likewise, the working group’s chairperson should “facilitate the effective participation of representatives of indigenous and local communities and [...] consult them” (CBD 2006j: para. C.7). Documentation should be made available three months in advance to the respective meeting to “facilitate consultations with representatives of indigenous and local communities” (CBD 2006j: para. C.5). Last but not least, members were asked to financially support indigenous participation (CBD 2008f: para. 19; CBD 2006e: para. 33). In 2010, COP established a Voluntary Trust Fund to Facilitate the Participation of Indigenous and Local Communities (CBD 2010d). Due to the inclusive access and involvement of indigenous organizations, their participation was effective. Their proposals were endorsed by state members and their consent was often key for policies’ adoption (Jungcurt 2008: 211). The ENB described the deliberations within the Working Group on Article 8(j) that led to the Akwé Guidelines as “equal-footing negotiations between governments and indigenous representatives” (ENB 2003: 12).

There are only few instances in which indigenous groups were reportedly excluded. These are all connected to legality. First, a contact group discussed the terms and conditions of a working group on Article 8(j) during the fourth COP in 1998. Some parties requested that observers should be excluded from the meetings once “discussions” turned into “negotiations” (ENB 1998c). After the draft decision was distributed in the contact group on Article 8(j), observers had to leave the session at the request of one party and could only watch it on screen from outside the room. Afterwards, the Chair emphasized that this “participation process followed should not be taken as a precedent” (ENB 1998e: 7). The objector was presumably Brazil which justified its request by reference to the costs associated with a hard law framework in the COP’s plenary session:

“Brazil also firmly believes that, since this is an intergovernmental convention, and aware of the fact that ultimate responsibility for implementing our decisions relies on our Governments, [...] decision-making — which includes the negotiation process — should be reserved to Parties or potential Parties” (CBD 1998d: para. 139).

³⁸⁰ CBD 2008f: para. 9; CBD 2006j: para. C.2; CBD 2006i: para. 3, 8; CBD 2004b: para. A.3, B.1, C.1.

³⁸¹ Likewise: CBD 2008f: para. 18; CBD 2006i: para. A.3, A.8; CBD 2006j: para. B.5, B.7; CBD 2004b: D.6, F.4; CBD 2000c: para. 14.

Second, the IIFB lamented that “critical negotiations had mostly taken place in informal groups, in which indigenous and local communities did not participate” at the fourth session of the Working Group on ABS (CBD 2006e: para. 117). A recommendation by the EU to include indigenous groups also in informal meetings (CBD 2006e: para. 17: para. 112) was rejected by Argentina, Mexico, and Venezuela (CBD 2006e: para. 115). But eventually indigenous groups were also allowed to Friends-of-the-Co-Chairs meetings prior to the ninth session. There was even a balance among NSAs at the two sessions. Two representatives each from indigenous and local communities, the civil society, and the industry were invited (CBD 2009a: para. 116, 119). This procedure was also applied in subsequent contact groups (CBD 2010c: para. 88). The Chair, however, reminded that

“while the representatives of indigenous and local communities were welcome to provide guidance, the Parties retained the sole prerogative to propose text and determine the final draft of the Protocol” (CBD 2010i: para. 20).

All in all, NGOs had great influence in drafting several parts of the CBD Convention (Arts 2006: 7). Also at the CBD’s meetings, they had inclusive access and great participatory possibilities. Their leeway was facilitated by the fact that the CBD policies did neither harm IP skeptics nor IP supporters.

9.3.3 Legalization as Fuel for State Contestation – A Pyrrhic Victory

In this section, the analysis concentrates on the CBD, WHO, and the WTO since also the data on contestation was restricted to these three institutions. I also focus on state contestation as NSA involvement had little effect on the overall results. The analysis reveals that legalization’s costs spurred contestation in formal fora. But the distribution of opinions and the frequency with which they were uttered in plenary sessions did not automatically materialize in the policy outcome. Hence, legalization’s democracy-enhancing effect in terms of contestation was instantaneously diminished.³⁸² IP skeptics’ positions were dominant in all three institutions. However, not all of the institutions’ policies reflected IP skeptics’ points of view in the end. IP-skeptical demands were in general better represented in the final outcome at the CBD and WHO but often absent at the WTO where the highest degree of contestation could be observed.

Before I start with the discussion of the three institutions, another finding requires elaboration. IP skeptics’ positions prevailed in the discussions despite the fact that IP supporters mostly had a higher statement rate. Hence, the frequency of statements did not directly influence the rate of positions uttered in favor of a certain position. This indicates that actors strategically chose the intensity with which they expressed their view.

There are several explanations for IP supporters’ silence. First, IP supporters have pursued economic interests that run counter to moral principles that are often upheld in

³⁸² The analysis of contestation focused on plenary sessions. The measurement does not account for the shifting to informal negotiations. This is hardly feasible since information about informal sessions such as the exact number of meetings and participants’ positions are usually kept secret.

the public and supported by the media and civil society organizations. Therefore, IP supporters must act cautiously in conveying their arguments in order not to publicly delegitimize them. Second, it requires more 'noise' to change rules than to maintain them. The current IP regime completely works to IP supporters' advantage. This creates a situation in which, to put it bluntly, IP skeptics have almost nothing to lose while it can only get worse for IP supporters. The consensual working mode of most international institutions provides the supporters of the status quo with greater veto power than those actors who seek a policy change. Of course, IP supporters seek a further expansion of IP regulations and manifestation of their position, but the current status is already very beneficial to them.

9.3.3.1 WTO – Contested Negotiations in the Face of High Legal Stakes

Among all three analyzed institutions, the WTO displays the highest degree of contestation. The main causes for hard bargaining in this forum are the high costs resulting from the WTO's hard law and distinct adjudication. The cost rationale was dominant in the debate. The word 'costs' was mentioned over 450 times and 'obligation(s)' even almost 1,800 times. These terms could be found in the arguments of both IP supporters and IP skeptics.

IP supporters like Japan and the USA pointed to the costs involved in R&D that needed to be recovered.³⁸³ Likewise, the Doha Declaration's implementation should be cost-effective and not burden patent-holders.³⁸⁴ The inclusion of ABS requirements in patent applications would create onerous costs. For instance, the Australian delegate "questioned how this system could be implemented while avoiding substantial costs, particularly with regard to the effects of non-compliance" (WTO 2005f: para. 55).³⁸⁵

By contrast, IP skeptics such as TK-rich Malaysia emphasized the "high costs involved in enforcement and ensuring full implementation" of TRIPS (WTO 2000c: para. 153).³⁸⁶ Likewise, Brazil raised concerns that

"the TRIPS Agreement might not be a development friendly agreement. It had imposed a number of burdensome and complex obligations on developing countries since it had entered into force. In making strenuous efforts to comply with its terms, Brazil had had to cope with numerous economic, social and administrative costs" (WTO 2005e: 263).

Furthermore, biodiversity-rich countries like Peru highlighted the "additional costs [...] to take legal action" against biopiracy and illegitimate patents in the absence of legal ABS

³⁸³ Japan (WTO 2001i: para. 47); USA (WTO 2001b: para. 161).

³⁸⁴ Singapore (WTO 2002b: para. 27); Switzerland (WTO 2002b: para. 82).

³⁸⁵ Other examples include Australia (WTO 2008b: para. 49; WTO 2007c: para. 75), Canada (WTO 2006d: para. 95), and Israel (WTO 2010c: para. 17).

³⁸⁶ Likewise: Zambia (WTO 2005e: para. 247-249; WTO 2001g: 146).

standards (WTO 2004b: para. 44)³⁸⁷ and that “developing countries were burdened with all these costs” if they had to nationally enforce anti-biopiracy rules (WTO 2005f: 73).³⁸⁸

The different camps also challenged their cost calculations. IP skeptics disputed that the inclusion of ABS requirements would raise the costs for WTO members.³⁸⁹ Instead it would “reduce transaction costs” as Brazil put forward (WTO 2005e: para. 157). Similarly, India referred to the reduced costs for patent applicants if ABS requirements in patent applications would be introduced (WTO 2004d: para. 39). Japan as IP supporter illustrated with its own history that the IP establishment’s “costs had paid off” (WTO 2000b: 150).

Legality was a constant matter in the discussions. IP supporters did not get tired of emphasizing members’ legal obligations under TRIPS, for instance with regard to the scope of patentable subject matter and the IP protection of pharmaceuticals and plant varieties.³⁹⁰ It is striking that in particular the USA emphatically reminded all parties of their obligations. IP supporters also emphasized the limits of TRIPS obligations when these suited their interests such as the rejection of ABS standards as illegitimate patent criteria or further flexibility with regard to compulsory licensing.³⁹¹ If they had to make concessions to IP skeptics, they advocated voluntary commitments instead of legal obligations³⁹² or national measures instead of an international treaty as in the case of ABS³⁹³. In a similar vein, IP skeptics pointed to the limits of TRIPS obligations for example with regard to the protection of plant varieties or the obligations for developed countries under TRIPS.³⁹⁴

IP skeptics were not deterred from the hard bargaining that has been taken place at the WTO. They consciously chose the WTO as a forum to advance their interests. Only in this hard-law environment, policies would make a meaningful change in the existing IP regime (Aubertin/Filoché 2011: 57). Therefore, IP skeptics considered the WTO as the best forum to discuss ABS and TK.³⁹⁵ IP supporters such as Japan tried to shift such IP-

³⁸⁷ Similarly: Brazil (WTO 2009c: para. 122; WTO 2006d: para. 63); India (WTO 2009b: para. 42; WTO 2006c: para. 74); Peru (WTO 2005e: para. 70; WTO 2005a: para. 90; WTO 2004d: para. 51).

³⁸⁸ Likewise: Colombia (WTO 2002a: para. 115); Cuba (WTO 2001i: para. 50); Peru (WTO 2002d: para. 129; WTO 2000a: para. 148).

³⁸⁹ Peru (WTO 2004c: para. 30); India (WTO 2005f: para. 38; WTO 2002b: para. 78).

³⁹⁰ For instance: Japan (WTO 1999b: para. 92); Switzerland (WTO 2002a: para. 195; WTO 2001a: para. 166); USA (WTO 2003a: para. 109; WTO 2000b: para. 184; WTO 2000a: para. 130; WTO 1997b: para. 41; WTO 1997a: para. 25; WTO 1996a: para. 32; WTO 1996h: para. 23; WTO 1996g: para. 60).

³⁹¹ For example: Japan (WTO 2003b: para. 137; WTO 2001g: para. 142; WTO 2000b: para. 156; WTO 2000b: para. 155); USA (WTO 2010c: para. 54; WTO 2000b: para. 165).

³⁹² For example: South Korea (WTO 2005e: para. 189; WTO 2005a: para. 122).

³⁹³ For example: EU (WTO 2006d: para. 121); New Zealand (WTO 2006b: para. 121; WTO 2005e: para. 119; WTO 2005a: para. 79); Singapore (WTO 2005e: para. 147); South Korea (WTO 2009a: para. 85; WTO 2006c: para. 40; WTO 2001a: para. 171); Switzerland (WTO 2005e: para. 115); USA (WTO 2010c: para. 53; WTO 2010b: para. 84; WTO 2009c: para. 43; WTO 2009b: para. 49; WTO 2008c: para. 112; WTO 2007c: para. 44; WTO 2006b: para. 103; WTO 2005f: para. 43; WTO 2004a: para. 48; WTO 1999b: para. 71).

³⁹⁴ For example: India (WTO 2000a: para. 177); Kenya (WTO 2000a: para. 142, 144); Mexico (WTO 1999b: para. 90); Norway (WTO 1999b: para. 76); Peru (WTO 2001b: para. 167); Thailand (WTO 2000b: para. 172; WTO 1999b: para. 78).

³⁹⁵ Brazil (WTO 2006d: para. 42-67; WTO 2004d: para. 78); Cameroon (WTO 2010d: para. 49); China (WTO 2010d: para. 26-28; WTO 2010c: para. 16); Colombia (WTO 2007b: para. 119); Cuba (WTO 2010b:

critical policies to other fora like the WIPO's IGC (WTO 2005a: para. 75; WTO 2005f: para. 69).

IP supporters remained in general consciously reticent in the debate. But it is worth repeating from chapter 8 that IP supporters took the lead to ensure that all members are on the same page with regard to the deliberation's meta-level on IP matters. In this line, 78.4% of all statements advocated that IP has a positive effect on a country's technological development. The majority of these comments were made by the USA.

9.3.3.2 WHO – Ostensible Solidarity within an Moral and Lowly Legalized Environment

In comparison to the WTO, WHO's debate on public health and IP was less controversial and IP supporters' arguments were more moderate. Also the critique of TRIPS was more pragmatic and less radical in comparison to the position of UN human rights bodies (Helfer 2004: 43). The sugar-coated tone of IP supporters' arguments is well illustrated by the comments of a U.S. delegate at the WHA in 2001:

“Ours is a daunting task, routed in moral obligation, informed by history and animated by an awareness of our shared humanity. All nations have a stake as partners in a common battle. Yet too often our partnerships have been disconnected and incomplete. They must be so no longer. Working together is not a platitude, it is an imperative. Shared problems require shared solutions. I am here today to listen to better understand our common concerns.”

He concludes:

“Let me close by urging all of us in this room today to remember that beyond the numbers and the statistics, our true focus is the healing of bodies, the mending of hearts and the restoration of lives. There can be few more noble callings than that, nor many more urgent needs” (WHO 2001a: 44).

In this U.S. comment, like many others, the IP supporter emphasized cooperation instead of self-interest and social instead of economic values.³⁹⁶ Furthermore, parties seemed to consider the interests of weaker members. Switzerland, for instance, advocated that the “draft resolution should compromise a balanced text that would take into account [...] the special needs of developing and least developed countries” (WHO 2003f: 157). Overall, states' comments contributed to a constructive and friendly atmosphere at the WHA. Even great opponents, such as Brazil and the USA, got along. For instance, the Brazilian delegate praised the “energy put forward by my dear friend Mr Hohman”, the head of the U.S. delegation, and considered his proposal “an excellent way out” (WHO 2008a: 168).

para. 62); Nigeria (WTO 2010b: para. 65); Peru (WTO 2006b: para. 132); Uruguay (WTO 2010c: para. 34); Venezuela (WTO 2007a: para. 53).

³⁹⁶ Likewise, a U.S. representative announced that “we are committed to working with everyone in this room to expand access to [...] improve the health of all nations”(WHO 2010c: 26). She concludes with: “the United States is more committed than ever to following through on our shared commitments on global health” (WHO 2010c: 27). Another U.S. delegate stated: “And we know that working together, we can achieve the goals we all share” (WHO 2009e: 24). “President Obama will not shy away from the opportunity to lead and collaborate we work together to protect health and safety of communities across the globe” (WHO 2009e: 25). For further examples see: WHO 2005b: 43-44; WHO 2004b: 60; WHO 2003f: 29; WHO 2001a: 44; WHO 1999a: 37; WHO 1995: 31; WHO 1994: 31; WHO 1993: 45; WHO 1992: 26; WHO 1990: 30.

The USA noted that “there was a lot of good faith on the part of negotiating partners” despite the failure to reach a complete consensus on the IGWG’s Plan of Action (WHO 2008a: 161). Eventually, delegations even called each other “friends”.³⁹⁷ This happened in 253 instances at the WHA in contrast to only 11 times at the TRIPS Council.

The major IP supporter USA was more willing to compromise in the absence of legality and precise political commitments. So did the U.S. even relinquish an amendment to a contested provision so that resolution WHA61.21 on the IGWG’s report could be adopted by consensus (WHO 2008a: 170). Although the USA did not accept resolution WHA60.30 on the IGWA’s work, it stressed that it “will not block the consensus process” (WHO 2007b: 259).³⁹⁸ As these resolutions were neither legally binding nor demanded concrete action, the USA did not veto them and could show good will.

Ostensible harmony and solidarity could prevail since WHO avoided fundamental criticism of the IP system. WHA resolutions are mostly non-confrontational. They do not directly refer to the WTO and TRIPS but generally to ‘international trade agreements’ or even only ‘international agreements/law’.³⁹⁹ Critical points, such as a possible negative influence of patents on drug prices, are only mentioned in passing (WHO 2006b: Annex 2(3.2.4)). Most importantly, WHO policies do not bring IP in conflict with public health. Resolution WHA60.30, for example, repeats that IPRs “are an important incentive for the development of new health-care products” (WHO 2007e: preamble).⁴⁰⁰

Nevertheless, the USA frequently emphasized that the sphere of constructive cooperation is limited to WHO’s proper functions. In this framework, WHO oversteps its mandate if it assumes hard law and contentious subjects. For instance, an U.S. representative warned: “Our focus should be on things that bring us together. We should leave issues beyond our purview to other forums than WHO” (WHO 2008a: 36). Likewise, an U.S. delegate clarified that they “meet today, not as the Security Council, not as the General Assembly, or even as the Economic and Social Council, in which political opinions are properly dealt with” (WHO 1991: 25). In another situation, the USA regretted the “unnecessary politicization” of the Assembly (WHO 1991: 256).

WHO’s moderate and often balanced output was influenced by constant U.S. pressure that suppressed criticism of TRIPS in relation to health risks. This behavior roots not in WHO’s low legality but in TRIPS’s hard law nature. The danger was imminent as WHO policies directly and indirectly referred to TRIPS and encouraged developing countries – even if cautiously – to make full use of TRIPS flexibilities and join forces in their shared concerns (Helfer 2004: 43; ‘t Hoen/Arkininstall 2007). Therefore, the report “Globalization

³⁹⁷ To give one example, the U.S. delegate reminded his colleagues: “My friends, let us never forget that our common agenda for health cuts across all governments, all culture, all languages and all politics”(WHO 2003f: 29).

³⁹⁸ For similar situations see: WHO 2004b: 174; WHO 2003f: 179; WHO 2002a: 162; WHO 1993: 265; WHO 1990: 158, 289.

³⁹⁹ See for example: WHO 2006d: para. 2(4); WHO 2001e: para. 1(2).

⁴⁰⁰ Other examples: WHO 2010b: Annex 7(63); WHO 2008b: Annex para. 7, 25, 35; WHO 2007e: preamble; WHO 2006d: preamble.

and Access to Drugs” (WHO 1997a), also known as the ‘Red Book’, was immediately countered by the 1998 ‘Blue Book’ with the U.S. point of view. The Revised Drug Strategy that was proposed in 1998 had to undergo severe negotiations and revisions before it was adopted in 1999. Also the joint report “WTO Agreements and Public Health” between WHO and the WTO remained descriptive and uncritical at the WTO’s request (Helfer 2004: 43; Lee 2009: 65, 122-124; WHO/WTO 2002). Furthermore, the USA urged WHO to withdraw a joint report with the South Centre, a development IGO, on TRIPS flexibilities and developing countries. In a letter to the Director-General, a U.S. official criticized WHO’s inadequate review procedure. He further noted WHO’s “lack of competence in this area and its failure to consult with other relevant international organizations” like the WTO and WIPO. The USA also announced to request a full review of WHO’s publication policy (Gerhardsen 2006).⁴⁰¹ Eventually, a U.S. delegate criticized that a WHO representative took an adverse stance toward the USA at the TRIPS Council and informed the WHA that a complaint was lodged with WHO (WHO 2003b: 145).

Why is contestation higher at WHO than at the CBD despite both institutions being lowly legalized? The reason lies in WHO’s moral authority that attributes additional power to its policies in the absence of legal force.⁴⁰² WHO was founded with noble goals. Its main objective is the “attainment by all peoples of the highest possible level of health” (WHO 1947: Art. 1). This is “one of the fundamental rights of every human being” as stipulated in the Constitution’s preamble. “Health of all peoples is fundamental to the attainment of peace and security” so that the “achievement of any State in the promotion and protection of health is of value to all”. An IO whose function is to protect such a public good is endowed with moral authority.⁴⁰³ Moral reasoning could be frequently found in the WHA debates. By contrast, this is almost completely absent at the TRIPS Council at which the word ‘moral’ was only mentioned 35 times in 64 meetings in comparison to 235 times in 20 WHA meetings. For example, a delegate from Trinidad and Tobago called WHO the “moral conscience of the world” (WHO 1992: 176). Malawi warned that

⁴⁰¹ The original letter is available at: <http://www.ip-watch.org/files/28-09-2006%2016;21;26.PDF> (Accessed 20 October 2014).

⁴⁰² WHO was attributed with moral authority by scholars (Lee/Pang 2014: 121) but more importantly also by politicians and officials: WHO Director-General (WHO 1998b: 38); Egypt (WHO 1990: 184); France (WHO 1992: 25); Greece (WHO 1990: 175); Netherlands (WHO 1990: 54); Trinidad and Tobago (WHO 1992: 175).

⁴⁰³ Moral authority is an elusive concept but becomes more tangible if one considers its elements: (1) authority (*what*), (2) moral legitimacy (*on what basis*), (3) institutionalization (*how*), and (4) leadership (*what for*). Despite the absence of coercion, moral authority evokes an internal feeling that the conveyed norms are right and induces an obligation to adhere to them and, if necessary, enforce and defend them (Hurd 1999: 387-388; Johnstone 2007: 127). Therefore, moral authority can be a very powerful tool for manipulating actors’ interests by providing meaning to the adherence of certain norms while at the same time reducing the likelihood of resistance.

“WHO is in danger of losing its moral authority and institutional credibility if it readily marginalizes the small and weak under the political pressures from the big and strong Members” (WHO 2005b: 20).⁴⁰⁴

For the Holy See, it is was a “moral obligation” to protect public health (WHO 1990: 256). Also WHO itself evoked this special power resource. The Director-General elaborated on WHO’s “moral mission” (WHO 1993: 38). Furthermore, the CIPIH report refers to the “moral imperative” to improve access to essential medicine (WHO 2006a: 8). Remarkably, it is immediately linked to legality: “The moral obligation is backed by a *legal* imperative” (WHO 2006a: 9). This further emphasizes legality’s paramount importance.

This distinct kind of legitimacy is conferred to WHO on the grounds that it is expected and believed to further the common welfare on behalf of the international community. In addition to its remit, WHO has often been portrayed as technical-scientific organization that is insulated from political struggle. The 2012 WHO Stakeholder Perception Survey affirms that considerable independence is attributed to WHO. 89% of external and 85% of internal respondents believed that WHO’s information is reliable and accurate (Grayling 2013: 39, 75). Likewise, 79% of external and 77% of internal respondents believed “most of the times” or “always” that WHO ensures the independence of its public health expert advisers (Grayling 2013: 45, 78). Consequently, WHO is entitled to a leadership role in the area of public health that vests its policies with special credibility. 90% of the Survey’s respondents considered WHO the “most effective [organization] at influencing policy for improving people’s health” (Grayling 2013: 35). Last but not least, global health diplomacy has been utilized as a strategy of foreign affairs to harness policy goals. As the USA bluntly put it: “Health diplomacy makes good neighbours, and extends America’s spirit of compassion around the world” (WHO 2005b: 43).

All in all, WHO has been struggling to do the splits between being a technical-scientific and political organization (Hoffman/Röttingen 2014: 190). Contestation in the WHA debates was moderate. IP supporters were more prepared to compromise but paid great attention to protect TRIPS from IP-skeptical influence. The contestation at WHO has been additionally fuelled by the organization’s moral authority in the field of public health.

⁴⁰⁴ Moreover, a Greece delegate recalled that it “is our moral obligation to maintain the high level of reputation of our Organization among international organizations (WHO 1993: 71). Djibouti stated that international assistance in the area of public health must be strengthened for “moral reasons” (WHO 1991: 182). In order to gather support for draft resolutions, a Zimbabwean delegate “urged leaders to take a moral stand” (WHO 2003b: 156) or a Malawian representative spoke of a “serious moral challenge” (WHO 2006c: 27). A Mexican representative called it a “moral duty” to comply with WHO regulations (WHO 2009f: 18). For a Nepalese speaker it was industrialized countries’ “moral duty to ensure the health of the people of third-world countries” (WHO 1990: 154).

9.3.3.3 CBD – Putative Harmony within Legal Vagueness

Contestation was lowest at the CBD where most speakers argued in favor of a strong ABS regime. As the CBD policies had no substantial impact on IP supporters, they showed more willingness to make concessions

At least verbally, IP supporters advocated the consideration of IP-skeptical positions. The USA, which only acted as observer, stated that TK's usage requires the consent and involvement of indigenous groups (ENB 1998a: 1). The USA also advised that indigenous groups should be consulted in final decisions on impact assessments (ENB 2000d: 6). The EU emphasized the necessity to protect TK and also to obtain indigenous peoples' prior informed consent.⁴⁰⁵ It also later supported an international certificate of origin. The U.K. promoted the development of guidelines to respect, preserve, and maintain TK (ENB 2000d: 6). It was Switzerland supported by France that proposed the establishment of a working group to formulate minimum standards of access to genetic resources, even if only in the form of a code of conduct. Germany supported that also guidelines on benefit-sharing should be developed (ENB 1998a: 2). The EU and Japan underlined that benefit-sharing has to be based on mutually agreed terms (ENB 2009c: 1).

Contestation is presumably higher in working groups than in the plenary sessions, but there is evidence that a sense of harmony and cooperation existed as well in the sub-bodies. The final difficult stages of the negotiations on ABS were coined by a "collaborative spirit" (ENB 2009e: 2). The last-minute agreement on contentious ABS issues at a late-night session was considered as work in good faith to "finish what we started" as a delegate reported (ENB 2010d: 2). Also in the following meeting a "collaborative attitude" prevailed (ENB 2010a: 2). Similarly, the discussions at one session of the Working Group on Article 8(j) were described to have taken place in a "non-confrontational atmosphere", however, in a legal-political "low-key" context (ENB 2006a: 2). Shortly before the conclusion of the Tkarihwaí:ri Code of Ethical Conduct, delegates felt that negotiations "had been very constructive, avoiding necessary confrontations that are beyond the scope of Article 8(j) Working Group and thus paving the way to potential agreement" (ENB 2009b: 2). Despite "ideological complexities", there was a "spirit of cooperation" as an observer from the ENB noted (ENB 2000d: 1).

Agreements were often possible because politically contentious issues were left aside. Participants of the Expert Panel on ABS, for instance, did not consider their work to be "politically charged" (ENB 2001d: 2). From the onset, the Expert Panel on ABS resolved to "keep political issues at arm's length" in order to be able to agree on a final report (ENB 1999a: 2).

The low degree of contestation does not mean that IP supporters did not try to prevent IP-skeptical policies. IP supporters intended to keep the ABS discussion toned-down. Initially, the EU and Switzerland preferred to have ABS not as a "standing" but

⁴⁰⁵ ENB 2002a: 1; ENB 2002b: 1; ENB 2000b: 2.

only a “rotating” item on the COP agenda. By the same token, they favored an expert panel on ABS over an open-ended working group (ENB 1998d: 1).

Concerning the scope of ABS, international action, even if only in form of soft law, was regarded as a second choice after national means have been exhausted (ENB 2005c: 2; ENB 1998a: 2). ABS policies should be without prejudice to existing international agreements (ENB 2001c: 1) and consistent with the existing IP regime (ENB 2004: 2). Furthermore, the USA criticized that UNEP overstepped its mandate in the COP debates and “inappropriately set out to interpret the TRIPS agreement. It had no competence in that regard” (CBD 2006d: para. 180). It referred to comments by then Executive Director Klaus Töpfer who elaborated that there were essential conflicts between the CBD and TRIPS (CBD 2006d: para. 12-3). IP supporters – like the EU, Japan, and the USA – also frequently emphasized the need for “flexibility”.⁴⁰⁶

Besides that, the only costs that IP supporters seemed to be concerned with were the CBD’s own maintenance costs. The USA and Japan claimed that contributions to the CBD are voluntary (CBD 1995c: para. 109-110). Switzerland called an increase in the budget “audacious” (ENB 1998b: 1). Japan was skeptical as to the establishment of another working group because of the costs it would create (ENB 1998d: 1).

IP skeptics were aware that the abandonment of legality would forfeit implementation. When it became apparent in the debate leading to the Tkarihwaié:ri Code of Ethical Conduct that the outcome would be non-legally binding, delegates reminded of the Akwé: Kon Guidelines that were not transformed into any concrete political action (ENB 2009a: 2). In the end, IP skeptics chose a not legally binding policy above no outcome at all.

9.4 Influence beyond Legalization – Context Matters

The analysis showed trends of legalization’s effects across international institutions. At the same time, it also became evident that additional factors matter. Therefore, I briefly discuss variables that have to be recognized in the evaluation of the legalization-democracy relationship. This is not intended to be an exhaustive list.

First, state participation is affected by the distribution of power and interests. In the absence of a power asymmetry, some actors are always better prepared to use legalization to their advantage and circumvent it if necessary than others. At the same time, an irreconcilability of interests intensifies hard bargaining while constellations of less clashing interests facilitate compromises and inclusive participation.

Second, an institution’s culture affects democratic participation. For instance, Andrea Liese found in her study that FAO staff has been skeptical of NGOs and their lobbying endeavors (Liese 2010: 103). Thereby, also the institutional embeddedness has to be considered. In the case of WIPO, Barbara K. Woodward notes that WIPO as an UN

⁴⁰⁶ CBD 2001: para. 20; ENB 2007a: 1; ENB 2001b: 2.

agency has to respect UN values such as human rights and UN development goals whereas the WTO does not have such a moral baggage (Woodward 2012: 58).

A third variable is the skill to form effective coalitions. This holds true for both states and NSAs. One case in point is the coalition formed by IP skeptics during the IGWG's work. Several Latin American IP skeptics, including Argentina, Brazil, Mexico, and Venezuela, met in Rio de Janeiro in 2009 to agree on goals and principles. The resulting Rio document became influential in the subsequent IGWG sessions and served as frequent point of reference (Velasquez 2014: 71-72).

Similarly, NSAs successfully joint forces in the access campaign. HAI, CPT, Oxfam, and MSF were able to effectively coordinate their action which contributed to their success. In addition to that, the campaign profited from the MSF's award of the Nobel Peace Prize in 1999. The laureate could not only speak with a higher reputation but also donated its prize money of over \$1 million to the access campaign (Sell 2003: 149). In the past, public action NGOs working on IPRs have regularly met for coordination meetings in Geneva. These included NGOs like CIEL, ICTSD, CPT, TWN, but also IOs such as the South Centre and UNCTAD. These formal meetings have apparently died (Matthews 2006: 17). Likewise, the CBD's openness toward NSAs was supported by the fact that environmental NGOs have been well organized (Åsa 2010: 11).

Further factors influence NGOs' attendance and involvement. First, NGOs' work is improved if they establish stable and trustful relationships with delegates. This requires a daily presence at the institution's headquarters. The building of personal connections with delegates increases confidence in NGOs' work and the chance that a delegation takes up an NGO's argument or offers of technical input. Coherence can be hampered by the fact that sometimes, as in the case of biotechnological patents, different delegates deal with the same subject matter in different fora (Matthews 2006: 11-12). Eventually, NGOs often work rather project-oriented to the detriment of long-term commitments. In the debate on public health and IP, several international NGOs diverted their focus from TRIPS to other trade issues (Matthews 2006: 8).

Second, NGOs have to effectively communicate their requests. This requires good relationships with the media. In interviews with delegates, Duncan Matthews found that business actors sometimes communicate their positions more precisely and effectively (Matthews 2006: 15).

Third, an issue must attract NGOs' attention. Not all subject matters are equally workable for NGOs. In particular campaigns of public action NGOs are more likely to be successful if they generate some empathy with the public and donors. Studies show that this method was used in anti-whaling campaigns or climate change campaigns with polar bears (Bailey 2008). Also WIPO appealed to more public action NGOs after the organization had opened its formerly legal-technical IP discussion to human rights and environmental concerns. By contrast, the CBD as environmental organization attracted

more NGOs from the onset. Especially the last point shows that one has to be careful in the analysis of NGO participation because NGOs are not always intentionally barred from negotiations but sometimes do not wish to get involved.

Last but not least, also exogenous developments can have a tremendous influence on political developments (Sell/Prakash 2004). For instance, external shocks create public attention from which even powerful IP supporters cannot abscond themselves. For example, the debate on public health and IP received more public and media attention than the other issue areas. Access to essential medicine was perceived as a global problem whereas the other matters were rather considered to be Southern issues (Matthews 2006: 9). Also after the tremendous protests surrounding the WTO Ministerial Conference in Seattle in 1999, the WTO was forced to make changes in its public outreach.

9.5 Summary – Legalization’s Different Sides of the Democratic Coin

The cases illustrate five main results with regard to legalization’s influence on democratic participation.

First, dominant actors – IP supporters in this research – controlled participation in highly legalized institutions. IP supporters were better prepared to use legalization to their advantage. Legalization served as a means to exert pressure on IP skeptics in order to bring their national regulation in line with the international IP system. At the same time, IP supporters could better circumvent legalization if it worked against their interests. In general, legalization’s costs were far lower for IP supporters than IP skeptics since the international IP regime has worked in their favor.

Second, legality bolstered by high delegation impeded democratic access to international institutions due to its high costs and thereby great stakes involved. This did not only lead to the exclusion of mostly affected actors but also the undemocratic subjugation of IP-skeptical states under strict IP rules. By the same token, legal capacity’s costs created participatory impediments for IP skeptics as typically less affluent actors. In turn, democratic participation in lowlier legalized institutions took place at the expense of strong political commitments.

Third, legality strengthened by high delegation caused greater contestation in plenary sessions. IP skeptics insistently pushed for a policy change, but the dominance of their opinions in the plenary debate did not materialize in the policy outcome. A higher degree of contestation represented only a Pyrrhic victory as it was accompanied by IP supporters’ higher evasion of formal procedures.

Fourth, the lack of formalized membership rules was used by IP supporters to the detriment of democratic quality. But in comparison to legality and delegation, formalization represents the legalization dimensions with the lowest influence on democratic participation.

Fifth, IP supporter USA took a prominent role in employing and circumventing legalization to reach its policy goals and to this end also its favored participation constellation in the respective forum. At the hard law organizations UPOV and the WTO, it succeeded in subordinating other states to IL that has benefited the U.S. economic agenda. When the USA did not reach its optimal outcome in multilateral negotiations, it retreated to bilateral contracts as best demonstrated by the TRIPS-Plus agreements. The USA was also a major driving force in shifting IP-skeptical topics to soft law fora in order to protect the IP-friendly hard law regime. This finding is in line with previous work on the U.S. predominance in IL. The USA has not generally rejected IL but has used it selectively and instrumentally (Krisch 2004; Krisch 2003).

Beyond legalization's effect on democratic participation, the discussion also shows that law matters. Participants meticulously differentiated between non-legally binding and legally binding provisions in the negotiations. Being cognizant of legalization's force, actors bargained hard to avoid legally binding rules that run counter to their interests. At the same time, all actors sought matters that potentially positively affect them to be dealt with in highly legalized institutions and vice versa.⁴⁰⁷

⁴⁰⁷ This stands in contrast to previous research that assumes that IP supporters prefer per se the economically specialized institutions of UPOV, WIPO, and the WTO while IP skeptics are more inclined to participate in the CBD, FAO, and WHO as organizations with a more holistic IP approach (Choer Moraes/Brandelli 2009: 33-34).

Chapter 10

Conclusion – Laying Down the Law

Legalization is no silver bullet for international democratic deficiencies. But for categorically rejecting legalization, the picture is too complex as the main findings show.

10.1 Main Findings

The measurement of legalization and democratic participation as highly contested concepts was audacious but yielded crucial insights. Legalization has to be understood as a multidimensional concept in order to capture its various implications. Legality and delegation involve other structure-inherent effects than formalization. Legality and delegation create costs in terms of sovereignty costs, costs of non-compliance, and legal capacity while formalization reduces flexibility of legitimate behavior.

Concerning the evaluation of an institution's democratic quality, it is essential to differentiate between formal provisions and de facto practice. Both can considerably deviate from each other. In general, democratic participation's de facto dimensions turned out to be more exclusive than the de jure provisions. But there was also an instance in which the converse could be observed. Democratic participation is an elusive concept and therefore difficult to operationalize for empirical analysis. It is nevertheless worth the effort as it forms an important empirical basis to analyze trends in international relations. Prevailing assumptions like the dominance of economically strong states could be systematically confirmed. But other findings, such as the absence of a de facto increasing NGO access to IOs, refute commonly held views.

The results for the legalization-democracy relationship provide further evidence of IL's dual character oscillating between apology and utopia, however, with different weighting.

On the one hand, legalization proved to be an apology for existing power. Legalization was used as a means by powerful actors to consolidate their power position and to bind weaker actors to rules that are favorable to the former. Legalization's costs increased the stakes in negotiations which led to hard bargaining in highly legalized institutions. This created incentives for powerful IP supporters to restrict democratic access of IP-skeptical states and NSAs both with regard to congruence and contestation. There was one exception. State contestation in terms of opinions advanced in plenary sessions was most distinct in highly legalized institutions. The better performance in this dimension has to be critically reflected because it did not materialize in the policy outcome. In lowly legalized settings, by contrast, powerful actors were more willing to compromise on policies because soft law neither entails legal obligations nor can non-compliance brought before a court. Hence, powerful actors allowed for more inclusive state and NSA access and held back in bringing forward their opinions. Also the costs of legal capacity represented an

impediment for less affluent states to meaningfully participate in highly legalized procedures.

On the other hand, legalization showed some tendency to distance itself from dominant state behavior. The formalization of participatory rights had an overall positive effect on democratic access. By contrast, flexibility in the admission of new members was used by powerful actors to accept new members on undemocratic terms or to bar critical actors. This underlines legalization's structural utopian effect that is independent of states' will. Among all legalization dimensions, however, formalization had the lowest impact on democratic participation.

All in all, the results stress that legalization and politics are not separated modes of governance but reciprocally influence each other. Legalization seems currently to be more prone of becoming an apology of power politics rather than forming an independent normative order. This has important consequences for research and politics.

10.2 Implications for Research and Politics

First, legalization should not be misunderstood as depoliticization. Action within legal systems is of highly political nature or in other words, politics conducted within a legal framework. This changes in certain ways the rules of the game but not actors' pursuit of their interests. The high stakes involved increase strategic action and power games. In the costly environment of highly legalized institutions, actors are particularly interested in influencing negotiations while powerful actors are better equipped to use legalization to their advantage and bypass it if necessary. This information is key for political actors and activists in order to know what they get themselves into when they engage in highly or lowly legalized institutions as well as when they pursue hard or soft law. For IR scholars, this study proves that law and legal structures matter. Therefore, IO research profits from the inclusion of institutions' legal characteristics in the analysis. Even realists who discard IL as power politics should seek a deeper understanding of how legalization can operate to the advantage of powerful actors.

Second, the current dominance of legalization's apology facet threatens its normative foundation and thereby its entire legitimacy. With the crumbling of its legitimacy, legalization can no longer perform its vital functions such as regulating political interaction in a binding manner, conveying stability, and settling conflicts. Even if it is deceptive to equate law with justice, legalization has to provide a minimum of procedural fairness to demonstrate its independence from sheer power politics. From a policy perspective, a reform of international institutions is inevitable. One approach could be a stronger formalization of procedural rights. This measure can only be meaningful if states do not undermine multilateral fora with bilateral agreements as it has become en vogue. By the same token, it is a tightrope of constituting the right balance between formalized and informal procedures in negotiations. The latter might not be democratically desirable

but unavoidable in intricate and politically sensitive issue areas. For IO scholars, the study illustrates the importance to consider institutions' normative underpinning. Compliance and effectiveness cannot be analyzed in isolation from instrumental theories if one intends to obtain a comprehensive picture. Actors' willingness to subject themselves to binding rules and comply with them ultimately depends on legalization's normative structure. For normative research, the results show that legalization has a predominantly negative influence on democratic participation. This effect is partly structure-inherent but at the same time there exists toehold to mitigate institutions' democratic quality.

10.3 Outlook for Further Research – Whither From Here?

My project only meant to be a starting point for normative-empirical research on legalization. This project laid the foundation by providing an operationalization of two contested concepts as well as initial empirical evidence for their causal linkage. The research can be extended in various ways. First of all, the context factors of the legalization-democracy relationship require further in-depth research. Examples are indicated but not systematically explored in this project. Furthermore, the analysis of democratic participation was restrained to institutions' plenary sessions. Other international venues and issue areas can be added to the investigation. One can also include international legalization's effects on states' national democratic quality as the traditional home of democracy (for example: Aaronson/Abouharb 2011). The concept of democratic participation can be further advanced by, for example, having a closer look at the composition of delegations. In addition to that, the causal link between legalization and democratic participation needs further qualitative work to refine the mechanisms at work. To this end, it would be desirable to consider other important elements of democratic quality like transparency, accountability, and substantial fairness.

Despite the difficulties that come with legalization, it has proven to be an important mode of governance in a globalizing world. As there is no alternative in reach, we cannot dispense with legalization but have to strive toward enhancing its utopian dimension. The improvement of democratic participation in international institutions represents an important step toward this goal.

Appendix

Figure 11: Coding Scheme for Dimension 'Issue' and Frequency

Issue Area		Frequency	
Access and Benefit-Sharing			
ABS in general	+ ABS in general	23	
	- ABS in general	1	
	? ABS in general	143	
Access to genetic resources	Disclosure of origin	+ Disclosure of origin	289
		- Disclosure of origin	69
		? Disclosure of origin	56
	Prior informed consent	+ Prior inf. consent & mutual agreement	125
		- Prior inf. consent	13
		? Prior inf. consent	12
	State sovereignty	+ State sovereignty	39
	Identification of TK	+ TK identification	93
		- TK identification	5
		? TK identification	1
	Benefit-sharing	+ Benefit-sharing	136
		- Benefit-sharing	10
? Benefit-sharing		13	
Form	International legal protection	77	
	National legislation & bilateral contracts	40	
	Voluntary guidelines	1	
	Combination of national & international instruments	7	
	? Other/vague form	9	
Forum	CBD best forum	2	
	WIPO best forum	11	
	WTO best forum	9	
	not WTO	3	
	WIPO & WTO	10	
	No forum shopping	1	
	No single forum	11	
Biopiracy	Balanced solution	2	
	Existing means sufficient to fight biopiracy	12	
	Existing system not sufficient	94	
	? Other/vague biopiracy	114	

Traditional Knowledge

Benefit-sharing	Fund to distribute share of sales		1
IP protection of TK	+ non-IP or general indigenous rights		14
	+ Protection of TK	No patents on public TK	2
		Sui generis protection for TK	12
		Via int. (legal) agreement	36
		? TK protection	65
		- IP protection of TK	
	? IP protection of TK		20
TK database	+ Creation of database		58
	- No database/not sufficient		15
	? Creation of database		5
Forum	CBD & WTO best fora		1
	WIPO best forum		37
	WTO best forum		4
	Not WTO		6
	No single forum		12
Inclusion of indigenous peoples in policy process	+ Inclusion		16
	? Inclusion		1
? Other/vague TK			160

IP Protection of Plant Varieties

Form	UPOV as ONLY acceptable system		7
	UPOV as role model for protection of plant varieties		4
	UPOV as imp. reference point, but not obligatory		17
	UPOV not THE model for protection of plant varieties		37
	Sui generis protection		8
Breeders' rights	+ Protection of breeders' rights		5
	? Vague breeders' rights		26
Farmers' rights	+ Protection of farmers' rights	+ General support	8
		Exemptions for small & subsistence farmers	4
		Right to save seeds	10
		Right to sell seeds	6
		Already protected	6
		Remuneration if seeds saved	1
		- Restriction of farmers' rights	4

	? Other/vague farmers' rights		10
Scope of IP exemptions TRIPS under Art. 27(3b)	Greater IP exemptions		1
	IP exemptions according to Art. 27(3b) (status quo)		26
	No IP exemptions		1
	No lowering of IP protection on biotechnology		4
	? Vague IP exemptions		1
Review of Art. 27(3b) TRIPS	Scope of review	Limited; focus on implementation	32
		Substantive	56
	Forum	No shift to other fora	2
		Review could be discussed in other fora	4
		? Agnostic forum	2
	? Other/vague review		58
GURT	- GURT		6
Ex situ collections	No patents for material from gene-banks		1
	? Vague ex situ collections		1
Other plant protection	Patentability of life/living organisms	? Patents of living organism	25
		+ patents of life	12
		- patents of life	29
		Sui generis system for biotechnology	2
	Amendment of Art. 27(3b) TRIPS	+ Amendment	3
		- Amendment	4
		No weakening of Art. 27	2
	Other Art. 27(3b) TRIPS		29
General patentability (Art. 70)		6	

Public Health and IP

IP vs. public health	Public health more important than IP		15	
	Balance between IP and public health		5	
	IP NOT main cause of public health problems		2	
	IPRs must be respected		51	
Generics	Compulsory licensing under Art. 31 TRIPS	Use of Art. 31 TRIPS	+ Use of compulsory licenses to protect public health	92
			Limited use	22
			? Use of compulsory licensing	20
			Outside domestic market	+ Production under compulsory licensing

		abroad	
		Limited export/ production abroad	15
		- Import/ production abroad	5
		? Further analysis/ vague	6
	Art. 30 TRIPS (Bolar provision)	+ Use of Art. 30 to protect public policy	15
		Limited use	7
		- Use of Art. 30	1
		? Art. 30	4
	Art. 39(3) TRIPS	+ Allows for authorizing the production of generics	4
		- Does not allow for the production of generics	1
		? Art. 39(3)	3
	+ Support of generics		35
Parallel imports	+ Use of parallel imports		6
	Limited use		3
	- Use of parallel imports		1
	? Other/vague parallel imports		52
Doha Declaration	Beneficiaries of flexibilities	Any WTO member	15
		Only developing countries and LDCs/insuff. manufacturing capacities	15
		? Beneficiaries	3
	Suppliers	Developed countries only under certain circumstances	2
		No limitation	16
		? Suppliers	2
	Safeguards	Avoid trade diversion and abuse	12
		General importance of safeguards	16
		No burdensome additional requirements	11
		Right-holders	3
		Adequate remuneration	
		Patent-holder's rights should be taken into consideration	12
		No consent required	2
	+ Transparency		6
	Scope of IP exemptions relating to public health	List of diseases is not comprehensive	24

		Only public health crisis; specific diseases	9
Legal implementation	Amendment (general)	+ Amendment	11
		? Amendment	143
	Art. 31 TRIPS	+ Amendment	11
		- Amendment	1
		Deletion of Art. 31(f)	1
		+ Waiver	9
		- Waiver	11
		? Waiver	3
	Art. 30 TRIPS	+ Authoritative interpretation	11
		- Auth. interpretation	1
		- Amendment	1
		? Art. 30	1
Functioning	System functions/no violations of Doha Declaration	18	
	System does not function/violations of Doha Declaration	48	
	? Functioning	4	
Drug price	Differential prices	+ Differential prices	21
		- Differential prices	1
		? Differential prices	4
	IP effect on drug prices	IPRs increase drug prices	24
		IPRs can have effect on drug prices	1
		IPRs do not increase drug prices	6
Use of flexibilities	Further need of flexibilities	5	
	Use of flexibilities has to be facilitated	28	
	No reduction of flexibilities e.g. by TRIPS Plus	22	
	Use of flexibilities under TRIPS	60	
	Existing flexibilities are sufficient	14	
	Restricting flexibilities	1	
Art. 70(8-9) TRIPS	Extension of transition period	+ Extension	6
		Only in relation to exclusive marketing rights	2
		? Transition periods	2
	? Other/vague Art. 70(8-9)	90	
Art. 7 TRIPS	Art. 7 only applies to full-fledged IP systems	2	
	Art. 7 & interpretation	Does not cover public health	1

		Limited scope for interpretation	3
		Flexible interpret. in favor of developing countries	2
		Relevant for interpret. of all TRIPS provisions	18
	Importance of Art. 7		34
	TRIPS meets objectives of Art. 7		1
	? Other/vague Art. 7		65
Art. 8 TRIPS	Art. 8 & interpretation	Flexible interpret. to protect public health	9
		Limited scope for interpret./confined right to grant IP exemptions	10
		Relevant for interpret. of all TRIPS provisions	19
	Importance of Art. 8		30
	? Other/vague Art. 8		47
Forum	WHO best forum		5
	WTO main forum		1
Other means to protect public health	Change R&D incentives		15
	Voluntary licenses	+ Preference of volunt. licens.	6
		- Preference of volunt. licens.	2
	WHO measures	WHO monitoring of IP's consequences on public health	6
WHO database on patents		2	
? Other vague IP & public health		601	

Miscellaneous

Participation	Admission of state members	+ Admission	91	
		- Admission	97	
		? Admission	13	
	NSA inclusion	IO inclusion	+ IO inclusion	134
			- IO inclusion	20
			? IO inclusion	22
		NGO inclusion	+ NGO inclusion	6
			? NGO inclusion	6
	Constraints of preparation & participation	Own constraints	27	
		+ Support of country's	9	

		concern - Support of country's concern	1
	RoP	Competencies Language Participation Voting Sub-bodies RoP general	2 9 53 66 2 75
IP vs. public interests	Actors	Developed countries hold more compulsory licenses than developing countries	1
		Only small number of countries hold most patents	4
	IP & benefit-sharing	+ IP best system of benefit-sharing	1
		- IP no system for benefit-sharing	1
	IP & development (general)	IP did NOT promote development (incl. FDI)	11
		IP SHOULD promote development	11
		IP spurs development	10
	IP & environment	IP does not harm environment	1
		IP does not protect environment	2
		IP leads to loss of biodiversity	3
IP & food	Food security priority over IP	3	
IP & technological development	IP SHOULD promote tech. development	9	
	IP spurs tech. development	59	
	IP does NOT spur tech. development	6	
	? IP & tech. development	2	
Benefits/impact of IPRs	? Greater analysis needed	1	
Inter-institutional relationship	CBD-FAO relationship	CBD should follow FAO activities	1
		No conflict	1
	CBD-UPOV relationship	No conflict	1
CBD-WIPO relationship	CBD should follow WIPO activities	1	

CBD-WTO relationship	Form of cooperation	Informal information exchange	1
		Close cooperation	5
	CBD relevance for TRIPS (general)	Follow CBD activities	10
		+ Inclusion of CBD elements in TRIPS	133
		- Inclusion of CBD elements in TRIPS	51
	TK (Art. 8(j))	+ TRIPS's assistance to implement Art. 8(j)	1
		Art. 27(3b) TRIPS should be in harmony with Art. 8(j) CBD	4
		? Art. 27(3b) TRIPS should be in harmony with Art. 8(j) CBD	1
	Nature of relationship	CBD & WTO SHOULD be mutually supportive	111
		+ Conflict	26
- Conflict		97	
? Vague/further analysis nature		27	
FAO-WHO relationship	Better coordination	2	
FAO-WTO relationship	Close cooperation	FAO activities not relevant	1
		Follow FAO activities	9
	Nature of relationship	FAO and WTO SHOULD be mutually supportive	5
		+ Conflict	1
- Conflict	2		
WHO-WIPO relationship	Close cooperation	8	
WHO-WTO relationship	Close cooperation	12	
	WTO should take input from WHO	2	
	WHO no right to interpret TRIPS	2	
WIPO-WTO relationship	WIPO Development Agenda	WTO should consider Dev. Agenda	30
		WTO should NOT consider Dev. Agenda	11
		? Vague/undecided Dev. Agenda	2
	WIPO relevance for TRIPS	WTO should follow WIPO activities	33
	Form of cooperation	+ Close cooperation	33
Avoid duplication of	15		

			work of both		
			Skeptical as to joint work	3	
			? Cooperation	5	
	General avoid duplication			2	
IP-related	Patent criteria	Novelty	Isolated micro-org./gene also invention	1	
			Invention, not mere discovery	12	
		Scope	Patents not too broad in scope	5	
	Duration of protection (Art. 33 TRIPS)	+ At least 20 years - Not at least 20 years - Not at least 25 years for trees			1
					1
					1
	Transitional periods (IP-related)	Trans. period for LDCs	Longer transitional periods for LDCs	14	
			No open-ended extension of trans. periods for LDCs	4	
			? Vague/undecided trans. periods for LDCs	10	
		Trans. period for developing countries	Longer transitional periods for develop. Countries	11	
			No longer transitional periods for developing countries, only L	4	
			+ Use of Art. 65(2-3)	10	
			- Use Art. 65(2)	5	
		Notification requirement (Art. 65(5))	+ Notification obligation	7	
			- Notification obligation	6	
			? Notification requirement	2	
			? Other/vague trans. periods	49	
		Rights conferred (Art. 28 TRIPS)	Balance of rights	15	
Diff. btw. patent and control of prod./sale	5				
Protection of exclusive rights of patent holders	3				
Strengthening rights of patent users	1				

	Technical IP assistance	471
	Patent Cooperation Treaty	9
	Patent Law Treaty	8
Technology and Science	Access to/transfer of technology	243
	Technological and scientific cooperation	36
Implementation and monitoring (general or IP-related)		1235
Assistance (general)		251
CBD miscellaneous		670
WHO miscellaneous		2115
WTO miscellaneous		1310

Table 32: Categorization of Codes⁴⁰⁸

Issue area	Value	Codes (only in fact coded ones included)
Strong ABS	pro	ABS\... <ul style="list-style-type: none"> • ABS in general\+ ABS in general • Access to genetic resources\Disclosure of origin\+ Disclosure of origin • Access to genetic resources\Prior informed consent\+ Prior inform. consent & mutual agreement • Access to genetic resources\State sovereignty\+ State sovereignty • Access to genetic resources\Identification of TK\+ Identification of TK • Benefit-sharing\+ Benefit-sharing • Form\International legal protection • Form\Combination of national & international instruments
	contra	ABS\... <ul style="list-style-type: none"> • ABS in general\- ABS in general • Access to genetic resources\Disclosure of origin\- Disclosure of origin • Access to genetic resources\Prior informed consent\- Prior informed consent • Access to genetic resources\Identification of TK\- Identification of TK • Benefit-sharing\- Benefit-sharing • Form\National legislation & bilateral contracts • Form\ Voluntary guidelines
	indifferent/vague	ABS\... <ul style="list-style-type: none"> • ABS in general\? ABS in general • Access to genetic resources\Disclosure of origin\? Disclosure of origin • Access to genetic resources\Prior informed consent\? Prior informed consent • Access to genetic resources\Identification of TK\? Identification of TK • Benefit-sharing\? Benefit-sharing • Form\? Other/vague form • Forum\... • Biopiracy\...
Strong protection of TK	pro	Traditional knowledge\... <ul style="list-style-type: none"> • Benefit-sharing\Fund to distribute share of sales • IP protection of TK\+ non-IP or general indigenous rights • IP protection of TK\+ Protection of TK\... • Inclusion of indigenous peoples in policy process\+ Inclusion
	contra	Traditional knowledge\ - IP protection of TK
	indifferent/vague	Traditional knowledge\... <ul style="list-style-type: none"> • IP protection of TK \? IP protection of TK

⁴⁰⁸ The issue area 'IP protection of plant varieties' is excluded because only one of the three coded institutions addressed it so that no comparison would have been possible.

		<ul style="list-style-type: none"> • TK database\... • Forum\... • Inclusion of indigenous in policy process\? Inclusion • ? Other/vague TK
Public health prioritizes IP protection	pro	<p>IP & public health\...</p> <ul style="list-style-type: none"> • IP vs. public health\Public health more important than IP • Generics\Compulsory licensing under Art. 31 TRIPS\ Use of Art. 31 TRIPS\+ Use of compulsory licenses to protect public health • Generics\Compulsory licensing under Art. 31 TRIPS\Outside domestic market\Production under compulsory licensing abroad • Generics\Art. 30 TRIPS (Bolar provision)\Use of Art. 30 to protect public policy • Generics\Art. 39(3) TRIPS\Allows for authorizing the production of generics • Generics\+ Support of generics • Parallel importation\+ Use of parallel imports • Doha Declaration\Suppliers\No limitation • Doha Declaration\Safeguards\Right-holders\No consent required • Doha Declaration\Safeguards\No burdensome additional procedures requirements • Doha Declaration\Scope of IP exemptions relating to public health\List of diseases is not comprehensive • Drug price\Differential prices\+ Differential prices • Drug price\IP effect on drug prices\IP can have effect on drug prices • Drug price\IP effect on drug prices\IP increases drug prices • Use of flexibilities\Further need of flexibilities • Use of flexibilities\Use of flexibilities under TRIPS • Use of flexibilities\No reduction of flexibility e.g. by TRIPS Plus • Use of flexibilities\Use of flexibilities has to be facilitated • TRIPS Art. 70.8-9\Extension of transition period\+ Extension • Art. 7 TRIPS\Art. 7 & interpretation\Flexible interpretation in favor of developing countries • Art. 8 TRIPS\Art. 8 & interpretation\Flexible interpretation to protect public health • Other means to protect public health\Voluntary licenses\ - Preference of voluntary licenses
	contra	<p>IP & public health\...</p> <ul style="list-style-type: none"> • IP vs. public health\Balance btw IP and public health • IP vs. public health\IP NOT main cause of public health problems • IP vs. public health\IPRs must be respected • Generics\Compulsory licensing under Art. 31 TRIPS\Comp. Licensing/Use of Art. 31 TRIPS\Limited use of compulsory licensing • Generics\Compulsory licensing under Art. 31 TRIPS\Outside domestic market\Limited export/production abroad • Generics\Compulsory licensing under Art. 31 TRIPS\Outside domestic market\ - Import\production abroad • Generics\Art. 30 TRIPS (Bolar provision)\Limited use of Art. 30 • Generics\Art. 30 TRIPS (Bolar provision)\ - Use of Art. 30 • Generics\Art. 39(3) TRIPS\Does not allow for use of producing generics • Parallel importation\Limited use of parallel imports • Parallel importation\ - Use of parallel imports • Doha Declaration\Suppliers\Developed countries only under certain circumstances • Doha Declaration\Safeguards\Avoid trade diversion and abuse • Doha Declaration\Safeguards\General importance of safeguards • Doha Declaration\Safeguards\Right-holders\Adequate remuneration of right holders • Doha Declaration\Safeguards\Right-holders\Patent-holder's rights should be taken into consideration • Doha Declaration\Safeguards\+Transparency • Doha Declaration\Scope of IP exemptions relating to public health\Only public health crisis of specific diseases • Drug price\Differential prices\ - Differential prices • Drug price\IP effect on drug prices\IP does not increase drug prices • Use of flexibilities\Existing flexibilities are sufficient • Use of flexibilities\Restricting flexibilities • TRIPS Art. 70(8-9)\Extension of transition period\Only in relation to exclusive marketing rights • Art. 7 TRIPS\Art. 7 & interpretation\Does not cover public health • Art. 7 TRIPS\Art. 7 & interpretation\Limited scope for interpretation • Art. 8 TRIPS\Art. 8 & interpretation\Limited scope for interpretation/confined right to grant IP exemptions • Other means to protect public health\Voluntary licenses\+ Preference of voluntary licenses

indifferent/ vague	<p>IP & public health\...</p> <ul style="list-style-type: none"> • Generics\Compulsory licensing under Art. 31 TRIPS\Compulsory licensing/Use of Art. 31 TRIPS\? Use of compulsory licensing • Generics\ Compulsory licensing under Art. 31 TRIPS (Use without authorization of right holders)\Outside domestic market\? Further analysis/vague • Generics\Art. 30 TRIPS (Bolar provision)\? Art. 30 TRIPS • Generics\Art. 39(3) TRIPS\? Art. 39(3) TRIPS • Parallel importation\? Other/vague parallel imports • Doha Declaration\Beneficiaries of flexibilities\... • Doha Declaration\Suppliers\Undecided/? Suppliers • Doha Declaration\Legal implementation\... • Doha Declaration\Functioning\... • Drug price\Differential prices\? Differential prices • TRIPS Art. 70(8-9)\Extension of transition period\? Transition periods • TRIPS Art. 70(8-9)\? Other/vague Art. 70(8-9) • Art. 7 TRIPS\Art. 7 only applies to full-fledged IP systems • Art. 7 TRIPS\Art. 7 & interpretation\Relevant for interpretation of all TRIPS provisions • Art. 7 TRIPS\Importance of Art. 7 • Art. 7 TRIPS\TRIPS meets objectives of Art. 7 • Art. 7 TRIPS\? Other/vague Art. 7 TRIPS • Art. 7 TRIPS\Art. 7 only applies to full-fledged IP systems • Art. 8 TRIPS\Art. 8 & interpretation\Relevant for interpretation of all TRIPS provisions • Art. 8 TRIPS\Importance of Art. 8 TRIPS • Art. 8 TRIPS\? Other/vague Art. 8 TRIPS • Forum\... • Other means to protect public health\Change R&D incentives • Other means to protect public health\WHO measures\... • ? Other/vague IP & public health\...
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