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Global Health Governance and WTO/TRIPS: Conflicts Between 'Global Market-Creation' and 'Global Social Rights'

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Introduction: WTO/TRIPS: globalization and market creation

Transnational pharmaceutical corporations (TNPCs), and also producers of baby food like Nestlé, are important contributors to the production of global public goods for health. As private enterprises they do not, of course, directly produce public goods, but are primarily oriented towards maximizing profits. However, some of the goods they produce are supposed to be made available publicly for those in need of them, either through the state or through some form of publicly regulated collective scheme, mostly in the form of an insurance.

The ambiguity referred to has its basis in the different modes of governance that play a role in the interfacing between institutions politically responsible for public health (national health ministries as well as WHO) and private for-profit organizations. The former have to care for the availability and affordability of needed inputs or to prevent public damage from the marketing of harmful products or concepts. Conflicts can be observed on the introduction of the Essential Medicines concept in the 1970s or, quite prominently, with Nestlé on the marketing of baby food to substitute for breastfeeding – a conflict in which CSOs marked their first major worldwide success on a health issue.

Technical progress and international negotiations interacted to reduce barriers to a globalization of trade in goods and services. The creation of global markets implied a widening of the transnational space for TNCs and the development of international law, which is changing the legal interfaces

between institutions responsible for access to public goods and private producers of these goods. The effective international implementation of intellectual property rights (IPRs) constitutes the one area of international law where these two modes of governance – the state to guarantee the delivery of public goods and the market to use the incentive to maximize private benefits for optimizing the offer of goods – have clashed concerning essential health issues.

In short, this problem can be characterized as a problem of the global organization of private activities that produce 'global public goods for health'.[1] A medicine that yields improvements in health should be accessible to everyone, that is, there should be non-excludability in access to this good. Certainly, there is a rivalry in consumption, but if one refers to the pure production costs after research and development (R&D) has been financed, these are, in general, comparatively insignificant. So, if basic human rights are accepted,[2] *it should be rational for the global community to provide basic medicines as global public goods*.

This chapter will focus on the impact of the TRIPS agreement on access to drugs and on new forms of interfacing between public and private actors in global health. It provides an analysis of the interests and the strategies of the various groups of actors which are involved in these conflicts and examines their impact on the various intermediate outcomes from the 2001 Doha Declaration on the TRIPS Agreement and Public Health up to the TRIPS amendment in December 2005 and the beginning of negotiations on new ways to support essential health R&D in 2006. In doing so, it offers an overview of the conflicts about access to medicines and treatment of HIV/AIDS, which will be analysed from the perspective of specific actors and countries in the following chapters. The first section will look at the institutional structures of WTO and TRIPS and the legal and organizational interfaces created by them. Then, the role of intellectual property rights for pharmaceutical companies and the constitution of country positions in WTO negotiations is summarized, followed by an analysis of the effects of TRIPS concerning the human right to (the enjoyment of the highest attainable standard of) health[3] and the increasing strength of advocacy activities for the access to affordable medicines. The section ends with a presentation of the adjustment of TRIPS in response to these demands. The chapter concludes with an analysis of central interfaces in conflicts where market-creating rules might be challenged successfully by welfare-related actors and examines the contribution of these conflicts to the development of GHG.

International economic law: a system of global governance competing with global public health

WTO/TRIPS: characterizing the organization

The WTO constitutes the central institution for market-creation on the global scale and has thus far developed an extended corpus of international law regulating the development of world trade. Various parts of the 1994 Marrakesh Agreements establishing the WTO are closely related to the provision of health services in developing countries.[4] In recent years the Agreement on Trade-Related Intellectual Property Rights (TRIPS) has been at the centre of conflicts, but the General Agreement on Trade in Services (GATS) and the Agreement on Sanitary and Phytosanitary Measures (SPS) also have potentially important impacts on global health.

All the agreements are managed by WTO bodies in most of which all member states are represented. This holds for the Ministerial Conference as the governing body which meets at least every two years and decides on important current affairs and on the course of negotiations on new agreements. It is also the case for the General Council, which handles the day-to-day work of WTO between the Ministerial Conferences, the Dispute Settlement Body, the Trade Policy Review Body, the three councils for each broad area of trade (Goods, Services and TRIPS Council) and their subsidiary bodies ('Committees'). This broad representation of members can mislead the observer with regard to existing inequalities as many poor members are not in a position to send delegates to all meetings. Another critique refers to informal meetings of a smaller number of 'interested' delegations and the so-called Green-Room[5] meetings, called by a committee chairperson or the Director General. These should facilitate package deals which allow complex compromises. The WTO stresses (on its website) that these negotiations are nevertheless 'transparent', as every member is kept informed about what is going on and has an opportunity to provide inputs; an assumption that, however, needs to be questioned.

The existence of a strong dispute-settlement process (DSP) is a powerful instrument to implement WTO rules:[6] If *consultation and mediation* processes do not lead to a dispute settlement, the DSB establishes a *panel*[7] which is expected to produce a *final report* after half a year of examination of facts and arguments as well as meetings with the parties and other interested states. Each party has the right to appeal the panel findings; appeals are dealt with by the *Appellate Body* composed of seven persons broadly representative of WTO membership. Within 90 days a definite report is produced, which either rejects the complaint or allows the imposition of trade sanctions against the member that has violated

trade rules. The creation of an Advisory Centre on WTO Law (ACWL) in 2001 helped to compensate inequalities concerning legal expertise (see: www.acwl.ch/e/about/about_e.aspx). The uneven potentials and effects of trade sanctions, however, constitute a problem. In fact, a developing country suspending tariff concessions to an industrialized country might create more problems to its own economy, it being dependent on particular imports, than doing harm to big industrialized countries, which do not depend on markets in those countries (Hoekman and Kostecki 2001: 90).

The Secretariat (including the Director General) basically plays a facilitating role – for example by trying to propose compromise solutions in the case of deadlocks. Besides that, members of the Secretariat play an important role in the delivery of technical cooperation to developing countries (helping them to actively participate in WTO affairs) – which is part of their official mission – in addition to, and this is much more difficult to assess, participating in what I call the 'Geneva connection', a network of communications about issues important for the IGOs and CSOs present in Geneva (see section at the end of this chapter).

Implementing TRIPS: basic issues

The final goal of the TRIPS agreement[8] is to reach a global harmonization of IPR rules defining rather high minimum standards with which all member states have to comply. All member countries have to introduce a corresponding legislation on IPRs (for example twenty years' minimum protection of IPRs; rules on copyrights, trademarks, geographical indications and industrial design; rules on enforcement).

To understand the current situation on access to medicines, the provisions for transitory periods for implementation are important. While, in general, the TRIPS agreement only grants a one-year period to adjust national legislation to TRIPS provisions, developing countries were entitled to delay the date of application for a further period of four years (until 1 January 2000). In cases where a developing country already had a system of patent protection in place, but is obliged 'to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member' (TRIPS Art. 65.4), there would be an additional transitional period of five years until 2005. This was the case in India, which had introduced a Patents Act in 1972 protecting only production *processes* but not products as such. Least developed countries (LDCs) also have a transitional period of ten years (in 2002 this was extended until 2016 with respect to patents for pharmaceutical products). Besides monitoring implementation, the TRIPS Council is the first addressee for taking up new issues, such as those arising in the context of access to medicines.

Thus far, none of the conflicts which were finally settled by the DSP directly affected the issues around access to ARVs, though in the US versus Brazil case on local working requirements (patent protection DS 199/4) the issue of the production of ARVs was raised (but the case was withdrawn by the US). Another case with repercussions on the access question was the so-called India Mailbox case where the US complained that India had failed to provide an adequate mailbox facility[9] to receive and preserve applications during the transition period (WT/DS 50/AB/R, 19 December 1997; see: UNCTAD/ICTSD 2005: 776f.).

As the TRIPS agreement demands changes in national legislation, there is, however, another field of legal procedures. Pharmaceutical companies can use national judicial systems to complain against an infringement of political decisions against an allegedly TRIPS-consistent patent right. Such a court case, of course, implies an interpretation of TRIPS which will have an impact on the further development of TRIPS law. The two South African court cases in which TNPCs sued the government of South Africa are the most famous of such cases (see Chapter 8). These conflicts reflected the fact that many TRIPS provisions are rather vague, so that legal interpretations play an important role for defining the rights and obligations of member states (UNCTAD/ICTSD 2005: 703f.).

WTO/TRIPS and welfare

The objective of WTO is to regulate and facilitate world trade; it is not a welfare-oriented (or multi-purpose) organization. Nevertheless, free trade has always been promoted with the promise that it will create a win-win situation for all participants. Thus, in a number of ways, it is normatively related to global welfare: The WTO is based on the assumption that expanding trade has a generally positive impact on welfare. The preamble to the agreement establishing the World Trade Organization includes goals supporting 'development' and improving standards of living. Furthermore, safeguard mechanisms can be used in situations of social and economic crisis, and specific WTO committees deal with welfare-related problems. In the case of TRIPS, the following clauses can be seen as 'entry points' for social concerns:

(a) The preamble recognizes 'developmental and technological objectives' of national IPR systems and 'special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base'.

(b) Article 7 stresses that (IPRs) 'should contribute to the promotion of technological innovation . . . in a manner conducive to social and economic welfare'; Article 8.1 highlights that: 'Members may . . . 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.'
(c) Furthermore, there are safeguard mechanisms. Article 30 allows 'limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent'.[10] Article 31 deals with the authorization of compulsory licensing, which 'in the case of a national emergency or other circumstances of extreme urgency' can be used without authorization of the right holder. Parallel importing, that is imports of products supplied by the patent owner or a licensee at a lower price in another country, is also permitted, if not excluded by national patent law.[11]

In the case of an international agreement with 'teeth' like the WTO, however, making a broad use of these general clauses is not without risks: interpretations can be challenged by opposing positions, and in the case of a negative panel decision there is a threat of sanctions. The difficulties in effectively using the existing options in a complex legal framework constitutes one of the central weaknesses of most developing countries in this system; they played a role in the South African court cases (see Chapter 8) as well as in the Brazilian poker about licences (see Chapters 3 and 7).

Thus, issues of social development constitute normative points of reference to interpret and readjust provisions of the agreements – depending, of course, on relations of interests and power in global politics. In general, however, in the current world order, the problem of systematically relating trade order to social order is unresolved. The global governance system consists of a multiplicity of structures, as nation-states still constitute *barriers* to the development of a unified legal system to organize politics and resource transfers. Nevertheless, in the ongoing process of globalization, the need for coordination and conflict resolution is increasing. This can explain the rise of *new forms of interfaces which link organizations of global economic and global social governance*. Social forces which are not locked into the 'old' system of state-oriented institutions seem to be best situated to propel these links. As IGOs are by definition tied to nation-states, their existing organizational interfaces are much less flexible than civil society organizations to deal with global social problems

(see also Chapter 4). We will discuss these developments in detail after having looked at the triangular relationship between IPRs, TNPCs and nation-states.

Intellectual property rights: TNPCs, the prices of pharmaceuticals and the constitution of country positions in WTO negotiations

The World Trade Organization is based on *an intergovernmental agreement to reduce state intervention* concerning the global movement of goods and services basically organized by private actors. Thus, these private actors – in this context primarily pharmaceutical companies – are immediately affected by its regulations, but national governments are the formal actors in the WTO. In this section, we will look at the interface triangle between WTO, states, and the private for-profit sector, which is at the centre of the role of WTO as a global market-creating organization. As TNPCs will be analysed in more detail in Chapter 3, only the most basic features will be summarized here.

Pharmaceutical industry and R&D for required medicines: the rationale for intellectual property rights

TNPCs are prone to be in the midst of conflict, as they are clearly profit-oriented private firms, but are producing a good which, from a normative perspective, ought to be a global public good for health. The problem, obviously, is twofold. On the one hand, the global community (which in this context can be translated as 'global health governance') has to agree on guaranteeing production and access – which we will discuss later – and on the other hand, on how to stimulate and finance research and development.

If we take it for granted that the most cost-effective way to produce the medicines needed for the best possible care for global health is by having R&D for drugs carried out by large TNPCs – which is certainly not universally accepted – then the problem is how to attain the most adequate incentives for stimulating R&D for those medicines. This implies the question of how to allow TNPCs to amortize the R&D outlays for developing a specific drug, including costs of failure. The firm must be profitable as a whole, globally. Over a long period in capitalist societies, IPRs, and patent rights in particular, have developed as the central mechanism to give firms a temporary monopoly on the products they developed, in order to prevent competitors from copying the products and selling them for a price not reflecting development costs, thus enabling them to recover the

capital invested in R&D. One research project arrived at an estimate of US$802 million for the development costs for a new medicine.[12] Therefore, it is not surprising that the industry is strongly opposed to any form of weakening the patent system even if they might accept that this system has its flaws.

A discussion of the history of international standard setting in the field of intellectual property rights, dating back to the nineteenth century, goes beyond the scope of this study (see Drahos 2002). In 1967, the Stockholm Convention Establishing the World Intellectual Property Organization (WIPO) was signed. In WIPO, however, the industrialized countries faced the same situation as in UNCTAD or UNESCO: Developing country blocs could defeat Northern proposals and push their own concepts (Drahos 2002a: 8). Reacting to pressures from the industry (Drahos 2002a, 2002b; Sell and Prakash 2004), the US insisted on negotiating an agreement on trade-related intellectual property rights in the context of the WTO negotiations. Shifting the emphasis on international IPR rules from WIPO to TRIPS has been characterized as a strategy of forum or regime shifting (Helfer 2004, also in more detail Chapter 3).

The technologically leading industrialized countries were interested in strengthening international rules on IPRs due to new technological developments (in computer and information technology, biotechnology, and the patentability of life organisms) but also – and this is of particular importance in the field of medicines – due to the increasing capacity of the more advanced developing countries to copy patented drugs. Globalization and the reduction of trade barriers meant that the competition for exports by the producers of generics could have a growing impact on the market for patented drugs. This is the background for the considerable lobbying of R&D-oriented corporations to include IPRs into the Uruguay Round negotiations.

While the principal aim of a legal market-creating framework – in the course of globalization as well as in the historical constitution of national markets – has been to create the same formal conditions for all participating actors, this does not, of course, mean that everyone will benefit equally from these rules: though an opposition of developing countries to stronger IPRs also is related to the target of catching up technologically, the consumer perspective is of primary importance with respect to access to health care. Two aspects related to TNPCs have to be considered: (a) the availability of effective medicines to treat specific diseases and (b) the accessibility of these medicines (basically related to price levels).

In fact, the lack of access to ARVs for the majority of HIV-infected people in developing countries constituted the real scandal that mobilized a

broad political opposition. Millions of people were facing death because they (and their governments) could not afford patent-protected medicines at prices demanded by TNPCs. Parallel to this circumstance, the fact that the lack of profitable markets had also been a central factor preventing pharmaceutical corporations from undertaking any serious efforts to develop medicines for the treatment of tropical ('neglected') diseases became an important political issue.

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), established by WHO in 2004, published its final report in 2006 which discusses these problems at length. The report distinguishes between the status of the availability of treatment for three types of interventions (Type I: diseases with large numbers of vulnerable people in rich and poor countries; Type II: substantial proportion of cases in poor countries; Type III: overwhelming or exclusive incidence in poor countries). It refers to the lack of affordability in poor countries of existing interventions against Type I and II diseases, and the general non-existence of effective interventions for diseases occurring only in developing countries (CIPIH/WHO 2006: 27ff.).

Constitution of country positions: the aggregation of political interests at the country level

The Westphalian system of international relations is based on a primary aggregation of interests at the national level. Basically, two types of actors play a central role in influencing the position of national governments on the issue of access to medical treatment: the pharmaceutical industry (and, of course, other producers of medical implements which are not in the foreground of our research) and the 'development community', which in itself is quite heterogeneous. The following political forces and conflicts will have to be taken into account to analyse country positions:

- lobbying of interested actors in specific government institutions (pharmaceutical associations; actors of the 'development community');
- (perceived) impacts of WTO regulations on public health and public health-related issues as well as possible conflicts with other trade and/or investment interests (local pharmaceutical firms, health ministries, other economic actors);
- impacts of CSOs and other actors on country positions through public pressure;
- external pressures;
- political processes within administration and national political institutions.

As regards IGOs, the power of private actors depends on their ability to exert significant influence on the positions of powerful states. In this respect, the pharmaceutical industry basically uses the means of lobbying, which implies the use of resource-based power (if not for corruption, it will usually refer to the economic weight of the industry) to influence the decision-making power of government members and (where necessary) also of legislators.

The most important stronghold of pharmaceutical corporations has been the US government. Lobbying of pharmaceutical companies has played a decisive role in making the US push for the TRIPS agreement. Since then, the US government has always been a strong defender of IPRs – during both the Clinton and the Bush administrations. Throughout the negotiations on the Doha Declaration and afterwards, US positions only moved when intense public pressure, both from within and beyond the country's borders, rose against them. The EU position in the negotiations of the Agreement was basically similar (UNCTAD/ICTSD 2005: 4f.), but later on, the EU seemed to be more open to compromises. The EU Commission appears to be under more pressure to accommodate industrial interests to other actors' concerns, like those of civil society or the development community.

It was certainly not in the interest of developing countries to create a strong international system of IPRs which would hamper technological learning through processes of product copying and re-engineering. In the TRIPS Negotiating Group, India's demands that '[a]ny principle or standard relating to IPRs should be carefully tested against these needs of developing countries' (UNCTAD/ICTSD 2005: 6), did not achieve much more than a reference in the preamble of the agreement (see above). One should assume that developing countries try to defend and make use of the flexibilities TRIPS has left to them, as was the case concerning the Doha Declaration and the ensuing TRIPS amendment. In the process of interest aggregation at the national level, however, in many developing countries health considerations do not play a central role, and flexibilities in the field of IPRs are frequently sacrificed in favour of short-term economic interests like improving access to northern markets, as has been demonstrated in negotiations on bilateral and multilateral free trade agreements (FTAs).

In general, a situation of competing national systems striving for economic growth and economic development, where the most competitive economic actors and other elites have a better opportunity to influence the strategies of national governments than the poor, tends to relegate social issues to the second line of priorities (trickle-down argument). If economic growth is accompanied by increasing inequalities (as is the

case in many countries), the hopes for trickle-down effects seem to be rather empty promises. The actors that might throw in their weight to improve the situation of the poor appear to have more power in the context of global politics: these are (a) a technocratic elite contemplating the costs and benefits in the long run and organizing reactions to threats on a global scale and (b) a host of advocatory movements and organizations thinking in terms of a global society ('solidarity', 'global community').

TRIPS and social development: basic aspects

Human rights

During much of the 1990s, 'health as a human right' has not been very much at the forefront of the global discourse on poverty. Health was basically seen as one aspect of global inequalities. It was precisely the lack of access of HIV/AIDS patients in developing countries to available, life-saving medicines that became a global scandal and succeeded in mobilizing extended networks of CSOs and, quite rapidly, wider public opinion around the issue of the 'human right to health' (Fischer-Lescano and Liste 2005).

Article 25 of the Universal Declaration of Human Rights states: 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services'. This right was reinforced by Article 12 of the International Covenant on Economic, Social and Cultural Rights, a legally binding instrument concluded in 1966 and ratified by all OECD countries with the exception of the US: 'States Parties recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (Article 12.1), which includes 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness' (Article 12.2). These documents, however, are rather inconclusive with respect to the 'standard of health' that is supposed to be 'attainable'. In 2000, the Committee on Economic, Social and Cultural Rights (CESCR, a sub-committee of ECOSOC, the UN Economic and Social Council) adopted a twenty-page document entitled 'The Right to the Highest Attainable Standard of Health,'[13] stating that 'a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are non-derogable'(§47). Now, §43 obliges state parties 'to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs' (like ARVs since April 2002).

Most least developed countries (LDCs), which have per capita public annual health expenditures of less than US$10 (CMH 2001: 56), however,

are certainly not in a position to fulfill such an obligation. Therefore, states also have the obligation to assist other states in fully realizing the right to health and to 'ensure that the right to health is given due attention in international agreements' (§39); §64 explicitly calls for a number of IGOs to 'cooperate effectively with States parties, building on their respective expertise, in relation to the implementation of the right to health at the national level'.

The right to health is codified in a number of other international agreements,[14] but it is not enforceable by any institutionalized process. If people cannot afford available life-saving treatment, this is a matter of global responsibility. As the potential for powerful health interventions increased with economic and communicative globalization, the internationalization of IPRs through TRIPS obviously constitutes an ethical problem inasmuch as it interferes with the full use of these opportunities. In fact, it is an interesting point to see whether pressure by civil society can substitute for the lack of material sanctions available to support the implementation of human rights.

TRIPS regulations and health issues in developing countries

When in 1977 the WHO first produced a list of *essential medicines,* very few of the listed drugs were patent-protected. This means that there were no legal obstacles to copying them anywhere in the world, but it also points to the fact that there were rather few newly developed medicines on the market which were particularly geared to diseases prevailing in developing countries.

IPR rules ought to favour pharmaceutical R&D and prevent the copying of products and technology – this seems improbable in countries with a low technological basis and ignores the historical experience of industrialized countries (see Chapter 3). In general, there seem to be opportunities for those countries that already have a well-established local pharmaceutical industry, such as India, China and Brazil. In other middle-income countries the existing market and qualified labour force might attract investments from TNPCs, but the potential for developing local R&D capacities seems rather limited (MIHR 2005; Chaudhuri 2005).

It was the issue of ARVs which first led – at least for the wider public – to a discourse on the link between IPRs and the access to *affordable* medicines in the South. In fact, only after nearly another decade, is the question of the affordability of medicines for the treatment of chronic diseases increasingly becoming a political issue (see for example Gelders et al. 2006). ARVs have been on the market since the early 1990s and have been used to treat HIV/AIDS patients in developed countries. Prices of medicines to treat one

person for one year remained high until 2000: according to Médecins Sans Frontières (MSF), the lowest prices of the first-line antiretroviral (ARV) triple combination per patient per year was US$10 439 in October 2000.[15] At that time, IGOs active in the fight against HIV/AIDS in developing countries – basically the WHO and the World Bank – concentrated on strategies of prevention, as this was seen as the most 'cost-effective' strategy. This approach took the extremely high prices of ARVs for granted; 'treatment for all' was simply unaffordable for the international community. This situation changed since the late 1990s: the Brazilian government was determined to provide free access to ARVs to all infected people and successfully negotiated licensing agreements with pharmaceutical companies (see Chapters 3 and 8). Generic versions of ARVs entered the market in July 2000, initially at a price of US$2767 per person per annum (MSF testimony quoted above).

CSOs in global health governance: the campaign for improving access to ARVs

In the second half of the 1990s global civil society took the lead in organizing protests against the lack of access to treatment for people in developing countries and finally led the process of renegotiating WTO rules. From 1996 onwards, Health Action International (HAI) successfully developed a campaign against the effect of TRIPS on limiting the access of poor people to patented medicines. This campaign has been supported by MSF, which after receiving the Nobel Peace Prize in 1999, gained a strong position in global public opinion. In November 1999, the MSF Campaign for Access to Essential Medicines was launched, which since then has assumed the leading role in the coordination of civil society activities in this field.

CSOs organized pressure on Northern states basically by influencing public opinion. The rising media coverage of the access issue was an important development which has increased pressure on governments and the pharmaceutical industry. Political actors of interest groups frequently talk (or complain) about the pressure they feel from the media.[16] The strong presence of the access issue in specialized information networks can easily be demonstrated (for instance in ip-health mailings, or in the kaisernetwork); it is far more difficult, however, to find comprehensive information on the mass media coverage of a specific issue.[17] At least, US opinion polls demonstrate that (a) there is a rather considerable awareness of HIV/AIDS as a general threat to global health and (b) there is a certain skepticism about governments' activities in this field which are seen as ineffective (perhaps also due to costs to tax payers), but (c) there is support for government policies to improve 'access to affordable drugs'.[18]

Protests of CSOs against high drug prices and the impact of TRIPS can be seen in the tradition of contention of global social movements against GATT and the WTO and their schedules for international economic liberalization (see for example O'Brien et al. 2000). During the 1990s, however, CSOs became increasingly engaged as cooperating experts in policy-making processes and as actors in international negotiations. They also gained importance as advisers to developing country members of the WTO.[19] In this way, CSOs assumed an important role more or less as midwives for the development of formal global politics. There is also an increasing tendency for intergovernmental organizations and bilateral aid agencies to channel aid – in particular aid in the health sector – via CSOs, that were more and more accepted as partners of established organizations and as opinion-leaders (see Chapter 4).

Similar to the development of national civil society structures filling the public space which opened with the decay of feudal institutions, global civil society fills a space which arises with the increase of transnational social relations beyond the nation-states and the formal inter-state relations (Hein 2005). As within a nation-state, this refers to the construction of opinions, the formation of social norms, and the expression of political critique and demands as part of the process of agenda-setting in political institutions. We witness the development of a complex field of civil society activities and structures which to some degree substitute for non-existing state structures. Their hybrid character is also expressed in the fact that they are more or less recognized as legitimate representatives of underprivileged groups in a particular political field (for example Oxfam and MSF in health politics) and have a significant impact on negotiations between representatives of states in another political field that has attained a higher degree of formal organization on the international level (trade/WTO).

New types of political relations between CSOs, private corporations and IGOs are themselves embedded in a changing public understanding of specific issues. Linking global social movements to constructivist analysis, Sidney Tarrow (2005) discusses the origins of establishing a specific politic issue and of constructing the perceptive field in which it has to be interpreted. This social definition of a problem feeds back into politics – among others, through the changing perception of an issue through political actors themselves. Tarrow uses the concept of 'framing': 'Proposing frames that are new and challenging but still resonate with existing cultural understandings is a delicate balancing act, especially since society's "common sense" buttresses the position of elites and defends inherited inequalities' (Tarrow 2005: 61). He stresses the need for 'convergence': 'existing political streams that combine with long-standing bundles of

ideologies, practices, values, and targets' (ibid.: 62). Recently, Joshua Busby has shown the importance of AIDS advocates framing their arguments 'to tap into moral and religious attitudes' (Busby 2006: 2) and analyses the conditions for 'framing' created by culture (need for a 'cultural match') and politics (shaping the interest of 'policy entrepreneurs' to take up a specific issue, framed in a specific rhetoric).

The political conditions of 'framing' also relate to a situation in which the generally more powerful actors in a conflict feel threatened by the results of inequalities and inequities. Busby (2006) discusses the role of threats as part of the framing process of the HIV/AIDS issue. Feeling threatened by particular developments (the re-emergence of infectious diseases; political instability and so on, see Introduction) increases the readiness to reconsider the priority of one's own short-term interests in relation to an 'enlightened self-interest' in fighting the causes of these threats.

Corporate social responsibility

The global activities of CSOs, their reference to core human rights, and the successful framing of the issue in major industrialized societies – including the impact on public opinion and the reaction of politicians – have exerted a strong pressure on TNPCs. Pharmaceutical companies cannot deny that the industry as a whole is highly profitable. They had to show *corporate social responsibility* and to contribute to the fight for 'better health for all'. To offer effective cooperation to improve access, at least to ARVs, and to reach some results in the field of neglected diseases, were indispensable elements in a strategy to defend (or better re-establish) the image of the industry ('good practice in pharmaceutical industry', see DFID 2005). The Global Compact between industry, civil society and state actors, initiated by UN General Secretary Kofi Annan in 1999, was explicitly set up for this purpose. The participation in and support of global public–private partnerships (GPPPs) is obviously seen as an appropriate strategy: the voluntary character of these activities and the potential to keep control on GPPP activities are central aspects in this regard (see Chapter 3 for more details).

Another instrument which is accepted by the pharmaceutical industry is differential pricing. In 2002, the European Union proposed to add ARVs to a list of medicines with 'tiered prices' – implying either a price cut of 80 per cent or a price 10 per cent above production costs for 49 least developed and 23 other low-income countries – which would be identified by a logo in order to prevent reimportation to the EU.[20]

Whatever TNPCs were offering to cooperate in the field of access to drugs in poor countries, the basic objective has always been to prevent any

weakening of internationally accepted IPR rules as a basis for securing profitability. In comments on the CIPIH report, the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) rejects all critical comments on strong patents laws (Noehrenberg 2006).

TRIPS and health: adjustments of intellectual property rights regulations

The Doha Declaration on the TRIPS Agreement and Public Health

In the conflict around IPRs and health, CSOs insisted that the problem of access to medicines is not a problem to be solved by philanthropy alone, but that it is more deeply rooted in the emerging legal basis of the global economy. Based on fundamental doubts on the rationality of IPRs in the field of medicines and public health – and reinforced by the South African and Brazilian conflicts – there has been an increasing pressure from CSOs and governments from developing countries on the WTO to clarify the relation of TRIPS to public health concerns. After the failure to launch a so-called Millennium Round of trade negotiations at the Seattle Ministerial Conference in 1999, a declaration on IPRs and access to medicines which would take up developing countries' concerns seemed to be an important precondition for the success of the following ministerial meeting in November 2001 in Doha. In early 2001, the African Group requested that the TRIPS Council deal with this problem based on documents by the WHO and UNCTAD, which stressed the flexibility of TRIPS (Correa 2002).

During the Doha Ministerial Conference (9–14 November 2001), after some controversial debates in the TRIPS Council and the WTO's General Council due to the resistance among industrialized countries (USA, Japan, Switzerland, Australia and Canada), the so-called Doha Declaration on the TRIPS Agreement and Public Health was accepted. The declaration recognizes 'the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.' (§1). It explicitly acknowledges concerns about the effects of intellectual property protection on prices (§3). Section 4 constitutes the heart of the declaration stating (and implicitly refers to TRIPS Article 8.1):

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health

> and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Section 5 stresses the right of each country to make use of what I have called the 'entry points' for social concerns in TRIPS:

> In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (§5a)

Section 5 (b–d) refers to the flexibilities in TRIPS which could be used for securing access to required medicines (as summarized above) and to members' sovereignty to determine 'what constitutes a national emergency or other circumstances of extreme urgency'. Finally, §6 of the Declaration recognizes an omission in the TRIPS Agreement: compulsory licensing has been authorized 'predominantly for the supply of the domestic market' (Article 31(f) TRIPS), which makes it difficult for countries that have no generics industry to use this instrument. Further negotiations on compulsory licences for the supply from third countries are to be held. Finally, §7 extends the transition period for pharmaceutical patent protection in LDCs until 1 January 2016.

In general, developing countries and CSOs[21] recognized the Doha Declaration as a success for the access campaign and for strengthening the position of developing countries in conflicts with TNPCs and countries supporting strong IPRs on TRIPS matters.[22]

The WTO Medicines (§6) Decision and the TRIPS amendment

Basically, three points proved to be controversial between those countries which tried to limit the use of compulsory licences as narrowly as possible (the host countries of major TNPCs) and those that wanted to allow a broad use of them in support of 'public health':

(1) *The 'scope of diseases'*: The US used §1 of the Doha Declaration to argue that a §6 solution should be limited to the diseases specifically identified there, while developing country delegations insisted on the point that the Declaration always refers to the protection of 'public health' in general.[23]
(2) *The determination of eligible countries*: §6 refers to countries 'with insufficient or no manufacturing capacities in the pharmaceutical sector'. As capacities vary considerably according to the medicines

involved, developing countries insist that each country should be responsible for determining whether it has the capacity to produce the needed pharmaceuticals while the US and the EU wanted a more limited solution.

(3) *The question whether the agreement should be based on Article 30 or Article 31 TRIPS Agreement*: While Article 30 would have allowed a more flexible and non-bureaucratic use of the intended mechanism, it only refers to 'limited exceptions' to patent protection which would have required further specifications. Article 31 includes procedural requirements for a compulsory licence where only the reference 'basically for local consumption' had to be waived.

The final agreement allowed compulsory licensing for export to countries not capable of producing needed medicines irrespective of specific illnesses and did not include a narrow determination of eligible countries.[24] Only regarding the third point, the advocates of a more open agreement had to accept the reference to Article 31. In addition, the compromise included some requirements of notification and marking of medicines produced under this decision by 'special packaging and/or special colouring and/or shaping' and finally, the reading of a 'Chairperson's statement' which stresses the need to prevent a diversion of products from the markets for which they are intended and lists the countries which have opted out of using the system as importers.[25]

The Medicines Decision was implemented through a waiver of TRIPS Article 31 (f) and (h), which will terminate 'on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect' (§11).[26] Though somewhat cumbersome procedures related to the issuing of a compulsory licence and to preventing re-exportation into third countries had to be accepted, the §6 decision was basically seen as a success for developing countries, demonstrating, in particular, the strength of global civil society. In fact, for pharmaceutical corporations, a strategy to object strictly to any real adaptation of TRIPS proved difficult to pursue.

It was only with the Hong Kong ministerial conference that the General Council agreed on an amendment to the TRIPS agreement, finalizing the §6 decision (6 December 2005). In fact, it constitutes the first change of any of the WTO agreements. Developing countries and CSOs tried to achieve changes of the §6 decision based on the argument that the preconditions for using the mechanism have become too burdensome, as not a single country has made use of the mechanism since August 2003. The notification requirements and the Chairperson's statement should be eliminated. Most industrialized countries insisted in taking over the 2003 text (including the Chairperson's statement). Finally, the

latter position prevailed, as developing countries realized that, on the whole, the §6 solution was a success for them.

Improved access to medicines

Although until today we cannot observe an increased use of compulsory licences by developing countries, experts do agree that its legal and political strengthening has given developing countries a stronger position in conflicts with TNPCs on licences and price concessions. The presence of generic ARVs on the market, the activities of CSOs, the ensuing global public debate, and the reorientation of health IGOs have led to a different framing of the access problem in the global public debate. Relatively early on, TNPCs have realized that they need to demonstrate corporate social responsibility in order to uphold the political support of their home country in international negotiations. In the end, public pressure was so strong that TNPCs did not succeed in securing the continued support of their main political alliances for preventing modifications in TRIPS.[27] When the battle on the Doha Declaration and §6 was lost, TNPCs themselves were increasingly ready to compromise with respect to selling drugs cheaper, licensing developing countries (particularly Brazil) to produce drugs and to withdraw from legal action in doubtful cases.

All this has led the international prices of ARVs to plummet between June 2000 and July 2001 and then decrease gradually but constantly until 2005 (see Figure 3.4). This includes generic and originator products. According to recent information from MSF, which regularly produces 'a pricing guide for the purchase of ARVs for developing countries', originator corporations are now offering the package of drugs for the treatment of one person for one year (ARV triple-combination, lowest world prices) at US$562, while generic products are listed at around US$152.[28] When in 2004 the Clinton Foundation involved the World Bank, UNICEF and the Global Fund to negotiate with Indian generic producers on drug prices for more than 100 developing countries, a reduction to around US$140 (per person/year) was achieved.[29]

This means that, since 2001, ARV prices have been down to a level which – in combination with international aid – no longer prevents universal access, even without the explicit use of compulsory licences. Still, a number of problems prevent a very rapid extension of effective access to all people in need:

- There is still a lack of cheap drugs for the treatment of children: a treatment with the triple combination in a paediatric formulation for

a child weighing 10 kg can cost US$816, while treating an adult costs only US$182 (MSF 2005: 4f.).

- For patients who need second-line ARVs because of resistance and medical incompatibilities, the sole, rather low-priced drug (lopinavir/ritonavir from Abbott Laboratories) is only available in LDCs at the reduced price of US$550, while it is sold in low middle-income countries like El Salvador and Peru for between US$4468 and 4511 (Vasan et al. 2006: 395).
- Of course, an effective treatment also needs the establishment of diagnostic capacities, the accessibility of medical personnel and thus a functioning health system.

One can assume that the direct effects of the new 2005 Indian Patent Law regarding first-line ARVs will be negligible, as generics based on drugs patented before 1995 will not be affected. Furthermore, a generic manufacturer has the right to continue producing the drugs, even if an application filed to the mailbox (see note 9) has been granted a patent (then, the generic company has to pay a 'reasonable royalty' to the patent holder). However, whether India might use the compulsory licensing provisions included in the law to allow generic production of second-line ARVs is questionable and depends on whether India will define the need for these drugs as a national emergency and risk conflicts with TNPCs (Smart 2005; Abbott 2005b, 2006).

Chapters 5 and 6 will look at the changing policies of IGOs after the fall of ARV prices and at the activities of the Global Fund which, together with national endeavours, have allowed the number of infected people on ARV therapy in low- and middle-income countries to rise from 240 000 at the end of 2002 to approximately 1.3 million three years later (UNAIDS 2006: 151). Though this number remains well below the WHO 3 by 5 target, the increase can be seen as a positive result of increased international resources to finance the import of medicines as well as an improved health infrastructure to allow sustainable treatment.

New developments: TRIPS+ versus innovative proposals on IPRs

The amendment of TRIPS and the fall of ARV prices since 2000 are intermediate results of one specific conflict. The pharmaceutical industry successively adopted a rhetoric of supporting the global endeavour to improve access of the poor to medicines. Nevertheless, they pursued their agenda of trying to secure strong international IPRs, now shifting the forum of their activities towards bilateral and multilateral trade agreements. Taking into account the possibility of a limited impact of the newly

introduced patent right in India with the possible use of compulsory licences for producing second-line ARVs (and drugs for treating other diseases, for example Tamiflu), TNPCs did everything to secure TRIPS+ clauses in bilateral and multilateral trade agreements, particularly those of the US. In all the FTAs negotiated since the late 1990s they pushed the US government to include clauses which forced the trade partners to exclude the possibility of using flexibilities included in TRIPS. Most partners agreed to these demands, as their priorities were oriented towards gaining access to the US markets for their export industries.[30] Frederick Abbott talks of a TRIPS II agenda by 'strong mercantile interests[31] seeking to increase technology and expression rents'[32] as a reaction to the change of conditions since the late 1990s (Abbott 2006). These problems had been discussed at length in relation to different US trade agreements with Latin American countries and with Thailand.[33] The TRIPS II agenda is also used by the US in WTO accession negotiations, which include bilateral demands for concessions.

The Declaration of South American health ministers[34] at the 2006 World Health Assembly is an expression of conflicting interests within developing countries. Though some of these countries have accepted TRIPS+ rules in a free trade agreement with the US (Chile, Ecuador, Peru), they commit themselves to 'the successful implementation of the safeguards and flexibilities included both in the TRIPS agreement and in the Doha Declaration' (quoted from ip-health, 1 June 2006). However, they did not commit themselves to renegotiate FTAs that are in contradiction to their own declaration.

The new Indian Patent Law and the TRIPS+ agenda seem to shift the equilibrium of forces again towards IPR interests. This assumption, however, overlooks the importance of public pressures in this field. Pharmaceutical R&D and the pricing of drugs are not only at the heart of patent legislation, but are also matters of foremost public concern related to strong social and political threats, as well as strong feelings on social justice. Public sector initiatives in the context of development cooperation are now trying to take advantage of TRIPS transitory regulations for generic production in LDCs. There are some experiences in Ethiopia, Tanzania and Bangladesh as well as further plans to develop pharmaceutical production capacities in other LDCs.[35]

'Forum' or 'regime shifting' is a strategy which is not restricted to governments of the most powerful countries. New initiatives to develop alternative forms to fund research on medicines important to poor countries, like James Love's[36] proposal to negotiate a Medical R&D Treaty under the auspices of the WHO, indicate an attempt to shift the focus of setting

rules on IPRs in the field of essential medicines to the WHO. The Report of the Commission on Intellectual Property Rights and Innovation in Health (CIPIH/WHO 2006) played a central role in the deliberations of the World Health Assembly in May 2006. There is a rather broad consensus on a number of proposals in this report, in particular to eliminate taxes and tariffs on medicines in developing countries and on the promotion of so-called Advance Purchase Schemes, that is, public assurances (and pre-payments) to purchase medicines on which research is conducted, which would provide a level of security to inventors regarding the income they can expect. On the other hand, a number of points which called into question the function of IPRs to set research priorities have been heavily criticized by TNPCs (see for example Noehrenberg 2006). The WHA in 2006 passed a resolution based on the Kenyan and Brazilian proposal to establish a Global Framework on Essential Health R&D, closely related to the Medical R&D Treaty concept, which means that further conceptual work will be done on a system sharing the high costs of research and development of medicines and creating obligations and incentives to invest in projects which are considered a public priority. This has to be seen in terms of the fact that the concept of IPRs and the consequences of IPR regimes are quite heavily debated in the economic discipline.[37]

Taking into account the reluctance of industrialized countries concerning these proposals, however, one must consider what will happen at the organizational interfaces of an IGO like the WHO. Again, CSOs are taking the lead to spur innovation in GHG. In 2003, MSF founded a non-profit firm to develop new drugs, which cooperates with pharmaceutical enterprises in the context of an integrated enterprise oriented exclusively to discovering new drugs for neglected diseases ('Drugs for Neglected Diseases Initiative', DNDI), which, two years after its foundation, has already developed twenty projects.

The 'Geneva connection'

When considering the results of nearly ten years of conflicts in IPRs and access to medicines, it is important to realize that CSOs not only succeeded in mobilizing support for a stronger role of social rights in global governance, but that the whole framework of perceptions on this issue – and on the importance of global health in general – has changed. What we call the 'Geneva connection' can be seen as a microcosm of the whole complex of interfaces which moved the process of global health governance: it is a 'centre of communication' producing at least elements of a common understanding of affairs which are then reintroduced into

command centres of political action (WTO, WHO, powerful nation-states, but also important CSOs like MSF).

IGOs in the fields of social and economic development and human rights are concentrated in Geneva (WHO, ILO, UNCTAD, UNHCHR, UNAIDS, WIPO, WTO, to list only the most important); UNICEF has its regional office for Central and Eastern Europe in Geneva, there is a World Bank liaison office, and many countries have diplomatic missions in Geneva. Surprisingly enough, this did not guarantee a close communication and coordination between these various offices.[38]

Things seem to have changed with the strengthening of global civil society and the development of global governance structures which have created networks of cooperation and (at least) communication between various types of actors in specific policy fields and supposedly also function as catalysts for the cooperation between IGOs. Certainly, a network consisting of CSOs in the health sector (HAI, MSF, Oxfam, and the Consumer Project on Technology (CPT)), and human rights organizations like CIEL and 3D can be seen as a complex organizational interface between CSOs in the access to medicines campaign.[39]

The development of a CSO interface has not only led to a strengthening of CSO campaigns in this field. We find communication on strategies and on interpreting 'facts' between groups and organizations with opposing political positions, discussion on compromises, selective cooperation and so on, in a field of many different options for strategies, actions, and also institution-building. We find flexible relations between individuals working in different organizations (sometimes changing the workplace), constituting not a formal network, but linked into networks which facilitate access to media and to groups organizing campaigns as well as to national and international institutions in Geneva and elsewhere (with access to important information, but also people closely linked to CSOs working in IGOs as experts for specific topics).

A decisive basis for the concrete function of this 'Geneva connection'[40] is a certain common ground of norms – basically referring to human rights and certain forms of political and personal respect – beyond sizeable differences in concrete goals and strategies. We find all kinds of communication between CSOs in different fields, CSOs and delegates from industrialized and developing countries, CSOs and IGOs, market-creating IGOs and welfare-oriented IGOs, CSOs and the pharmaceutical industry, and so on.

At first glance, the resulting system of interactions looks like a 'network of networks'. But this term is not really accurate: some of them are formal IGOs, others are in fact networks (CSO networks), but in many

cases the interactions are informal and the participants are frequently not specifically legitimized representatives of their respective organization. On the other hand, not all of these interactions are even interfaces in the sense of recurrent interactions; some informal meetings might become ritualized but many are just one-time occurrences. There is no network in a narrower sense of implying a certain organizational effort for the exchange of information or joint activities.

A number of interviews with Geneva-based organizations focused on this communication system.[41] Most of the organizations are members of formal networks extending beyond Geneva (like the ESCR-net, the Access Campaign, Biomedical Adviser Group or WHO Scientific Working Groups, WHO Stakeholder Meetings), but all ascribed a great importance to regular and occasional informal meetings in Geneva. These include regular coordination meetings with other CSOs, briefings, workshops, and conferences organized by many Geneva-based organizations mostly with broad-based participation from all sorts of agencies, including national delegations in Geneva. In addition, there are many personal contacts at the margins of organized events (including receptions and parties, or 'national days' organized by the country missions) or just in the form of private meetings. Certainly, in general, people meet more frequently with colleagues from similar organizations, but all of them stressed the importance of meetings 'across the board' of all Geneva-based organizations. CSOs refer to meetings with delegates from Southern countries and the role of the South Centre in this context.

Job mobility among the Geneva-based organizations can be seen as one important element intensifying communication between different organizations, also by facilitating contacts between the old and the new colleagues. There seems to be job mobility between all kind of organizations present in Geneva, but, according to some of the interviewees, the most frequently observed paths are from CSOs to IGOs and from national delegations (in particular of the South) to CSOs; quite frequently people move from IGOs to CSOs after retirement. There are also no absolute ideological barriers to job mobility; thus, in one case, a person moved from IFPMA to MSF.

Thus, the 'Geneva connection' might be seen as a 'glocal' centre for approaching a common understanding of global health problems, which certainly does not imply a change of actors' interests and ultimate goals. It confirms the importance of discoursive interfaces which can be observed in the course of conflicts between global 'market creation' and the defenders of global social rights.

Approaching a conclusion: conflicts about intellectual property rights and the dynamics of interfaces in global health governance

During the last ten years we have observed a surprising process. The powerful pharmaceutical industry retreated on conflicts in Brazil and South Africa and finally had to accept a change in TRIPS, which strengthened the instrument of compulsory licences, as their political allies could not resist the human rights-based arguments on access to medicines (see Chapters 3, 7 and 8). This coincided with an awareness of the importance of health in the context of a broader understanding of human security. Global civil society organizations have successfully used discoursive interfaces in GHG to mobilize support for a stronger public responsibility as regards medical innovation and access to essential medicines and thus to strengthen an important aspect of welfare politics on the global level.

CSOs have been successful in framing the discourses on access to medicines and on alternatives to patent rights (or at least supplementary mechanisms to strengthen the role of medicines as global public goods). This discussion has successively integrated experts from national institutions of development cooperation and IGOs. International commissions on intellectual property rights took up these issues and played an important role in opening up a new field in inter-state health politics. The IFPMA had to acknowledge the need for better access to medicines and finally publicly welcomed the TRIPS amendment (IFPMA, News Releases, 12 December 2005). Now, TNPCs are engaged in GPPPs in the fields of access to medicines and neglected diseases and praise them as the most important strategy to contribute to these goals.

Certainly, communicative consensus-seeking among actors with very different material interests can be assumed to go, at best, only half way: TNPCs accept the need for affordable medicines for poor people and the need for action on neglected diseases, but this does not imply surrendering the use of their political and economic resources to fight for strong IPRs at the level of international law. Nevertheless, in spite of fundamental conflicts between critical CSOs and TNPCs, CSOs were flexible enough to cooperate with public actors at all levels and with TNPCs, for instance in the field of neglected diseases. In Chapter 4, the role of global civil society in the development of GHG will be analysed more broadly, in particular with reference to the diversity of CSOs.

In terms of the conflicts around the TRIPS agreement and the interfaces between actors oriented towards global market creation and those

oriented towards global public health, some implications on the development of GHG can be proposed:

- Through manifold processes of self-organization, the need to link different systems of governance (global health, human rights, the world trade order, the intellectual property system touching on issues such as biodiversity and genetic resources) has led to more intense communication and to the rise of new institutional forms to solve specific problems which are moving the core of global health politics from IGOs ('international health governance') to a complex system of global health governance.
- The system borders are constantly fluid; there are many 'overlappings' with other systems in global governance and the system is open to new actors at all times.
- By transcending various governance systems in the process of a successive intensification of global social relations, GHG actors have – at least in the field of access to medicines – successfully mobilized discoursive power.
- This has resulted in a reinforcement of actors fighting for global social rights in spite of the strong position the supporters of global market creation had won with the foundation of WTO and the development of hard legal interfaces.

Notes

1. See Introduction, note 4 for the definition.
2. One might also refer to the cost-benefit calculations on providing adequate health services (see for example the Report of the Commission on Macroeconomics and Health, CMH 2001), though this seems to be problematic from an ethical perspective.
3. When speaking of the 'right to health', it is always an abbreviation of this formulation used in the International Covenant on Economic, Social and Cultural Rights (Article 12.1) or the formulation used in Article 25 of the Universal Declaration of Human Rights, which refers in more detail to the circumstances affecting health.
4. See from different perspectives: Koivusalo 2003; Fink and Maskus 2005; Blouin et al. 2006; Bermann and Mavroidis 2006.
5. These types of meetings are named after the Director General's conference room even if they take place elsewhere.
6. For more details see Hoekman and Kostecki 2001, Chapter 3 (see also the explanation given on the WTO website at www.wto.org/english/thewto_e/ whatis_e/tif_e/disp1_e.htm.
7. Chosen from a list of potential panelists nominated by WTO members; parties can reject proposed panelists.

8. See the summaries on TRIPS in Hoekman and Kostecki 2001, WHO/WTO 2002, UNCTAD/ICTSD 2005.
9. A 'mailbox' is a facility stipulated by Article 70.8 TRIPS: 'Where a Member does not make available as of the date of entry into force of the WTO Agreement [i.e. Jan., 1 1995] patent protection for pharmaceutical and agricultural chemical products . . ., that member shall . . . provide . . . a means by which applications for patents for such inventions can be filed.'
10. Article 30 allows the so-called Bolar provision. Countries may allow manufacturers of generic drugs to use the patented invention to obtain marketing approval without the patent owner's permission and before the patent protection expires. Generic products can then be marketed as soon as the patent expires. (http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm, visited 19 June 2006).
11. This refers to the issue of the exhaustion of patent rights, which means that the IPR embodied in a product or service is exhausted 'when a good or service is first sold or marketed in a country'. If a national patent law recognizes a doctrine of 'international exhaustion', the IPR holder's right is extinguished whenever a good is sold or marketed anywhere in the world (UNCTAD/ICTSD 2005: 93f.). TRIPS Article 6 allows a country full freedom with respect to the doctrine of exhaustion it uses in its patent law.
12. See DiMasi et al. (2003) and some more details in Chapter 3. This number, however, does not refer explicitly to drugs for neglected diseases, and many critics argue that the R&D costs for typical diseases of the poor are much lower.
13. This document is part of a series of comments by the CESCR called 'Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights' adopted since 1989, here 'General Comment No. 14' (document E/C.12/2000/4), accessible under the following URL: http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument.
14. See the Convention on the Elimination of All Forms of Discrimination Against Women (Articles 10, 12 and 14), the Convention on the Elimination of All Forms of Racial Discrimination (Article 5) and the Convention on the Rights of the Child (Article 24). Also, Article 35 of the Charter of Fundamental Rights of the European Union demands that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'.
15. This refers to: stavudine (d4T) + lamivudine (3 TC) + neviparine (NVP); cf. MSF testimony submitted to DHHS (Department of Health and Human Services) for the Meeting of the International Subcommittee of PACHA (Presidential Advisory Council on HIV/AIDS) on 16 December 2003.
16. This was pointed out in several interviews carried out in Geneva.
17. The growth of the number of articles in major newspapers related to AIDS and Africa, from 500 in 1997 to 1000 in 2000 (Busby 2006: 28), can be seen as an indication of a growing media attention to HIV/AIDS issues in poor countries.
18. See three polls taken since 2002: Kaiser Family Foundation Survey of Americans on HIV/AIDS (www.kff.org/kaiserpolls/7513.cfm), accessed on 15 June 2006; Health News Index Poll, survey by Henry J. Kaiser Family Foundation, Harvard School of Public Health, conducted by Princeton

Survey Research Associates, 18–21 July 2002; and a Harris Poll conducted in July 2004 for the *Wall Street Journal*'s Health Industry Edition (www.harrisinteractive.com/news/printerfriend/index.asp?NewsID = 831), accessed 18 May 2006.

19. The South Centre has played an important role in organizing communication between health CSOs and Southern national delegates to the WTO (interviews of the authors with representatives in Geneva on §6 negotioations).
20. *The Pulse: Health and Pharma Quarterly Check-up*, November 2002: 5f. (www.hillandknowlton.be/HK/pressoffice/thepulse/ThePulse_Vol.1.pdf). It should be noted that, in 2001, the US government informed the European Union that it would oppose the EU move towards tiered pricing. A letter by US Trade Representative Robert Zoellick stated the 'specific opposition to any international regulation of drug prices as well as to the creation of a price database', which could increase market transparency and allowed poor countries to import medicines at lower prices (Harris and Siplon 2001).
21. See Drahos (2002a) and the websites of CSOs like MSF, Oxfam, HAI; also: personal interviews with people working for CSOs in Geneva (Oxfam, 3D, CIEL, MSF).
22. See for example Abbott (2002, 2005a); Correa (2002); ITC (2003); ip-health e-mail list.
23. As Frederick Abbott stressed: 'If developing countries were facing public health problems that required access to lower-priced medicines, it was not apparent why a distinction should be made between HIV/AIDS, on the one hand, and cancer, heart disease, diabetes or asthma, on the other' (Abbott 2005a: 328).
24. Least developed countries are eligible to use the mechanism without any restrictions; any other country must submit a notification to the TRIPS Council that it has insufficient or no manufacturing capacity for the 'product(s) in question'.
25. For the 'General Council Chairperson's statement' see: WTO General Council, WT/GC/M/82, 13 November 2003). The group of developing countries that declared using the mechanism only in 'circumstances of extreme urgency' comprises Macao, Hong Kong, Taiwan, Israel, Korea, Kuwait, Mexico, Qatar, Singapore, Turkey and the United Arab Emirates.
26. See: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), Doc. WT/L/540 (1 September 2003).
27. See for example Thomas (2004: 67) on public pressures on the US government in 2000 to push for stronger IPRs in developing countries.
28. See MSF (2005: 10). The comparison of prices between originator and generic producers is a field of unlimited manipulation. Thus, the Hudson Institute (a Washington-based think thank close to the industry) produced a White Paper (*Myths and Realities on Prices of Drugs*, Adelman et al. 2004) which used MSF data to prove that the average price of patented drugs is considerably lower than that of 'copy drugs'. This paper was obviously used extensively by organizations close to pharmaceutical corporations (IFPMA, News Release, 11 May 2004; Glassman 2004). The Hudson Institute Analysis (in its short study of six pages), however, can be criticized in various respects, among others: (1) it is not the average price of ARV drugs that is important, but the prices of

the needed triple-combinations; (2) fixed-dose combinations, which are more appropriate for use in developing countries, were not included in the Hudson study; (3) while the prices of generic products have no geographical limits, prices of originator drugs vary according to the system of differential pricing (the Hudson study uses only the lower prices for the 'poorest eligible countries' (Adelman et al. 2004: 2). MSF stresses that the latter system excludes the poor in countries which do not benefit from differential pricing.

29. See http://www.essentialdrugs.org/edrug/archive/200404/msg00014.php.
30. Agreements are in force or signed with Jordan, Singapore, Chile, the countries of the Central American Free Trade Area, Australia, Morocco, Bahrain, Oman, Peru and Colombia, and negotiations are underway with the Southern African Customs Union and Thailand (Abbott 2006: 8).
31. This concerns the copyright-dependent audio-visual industry and the pharmaceutical and agricultural chemical industry.
32. 'Expression rents': rents based on licences.
33. There are a large number of critical texts on Free Trade Agreements with TRIPS + provisions. The UNCTAD-ICTSD Project on IPRs and Sustainable Development has presented a number of interesting studies on these negotiations (see www.iprsonline.org/resources/FTAs-htm); Oxfam produced various briefing notes and briefing papers on this subject (Oxfam 2002a, 2002b, 2002c); see also Vivas-Eugui (2003) and Abbott 2006.
34. Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela.
35. A GTZ public–private partnership project supports the production of ARVs in Bukavu (DR Congo) in a pharmaceutical plant, erected by Boehringer Mannheim in 1972 and sold to a private investors in 1999 (Grill 2005; www.gtz.de/de/themen/soziale-entwicklung/hiv-aids/12394.htm).
36. James Love is the director of the Consumer Project on Technology (CPTech), the most important US consumer protection organization.
37. See Sturn (2006); Maskus (2000); various contributions in Fink and Maskus (2005); and, critical with respect to pharmaceuticals, Lanoszka (2003).
38. The joint study on 'WTO Agreements & Public Health' (WHO/WTO 2002) indicates that there are a few fields where there has been some long-term institutionalized cooperation, as in the field of the SPS Agreement and the role of the Codex Alimentarius. In many other areas, however, the authors identify 'potential for complementing each other's work' (ibid.: 143) and 'increasing opportunities for taking of synergies' (ibid.: 144), which implicitly recognizes that there has been little concrete cooperation in the past (seen from 2002).
39. For the development of the campaign since 1996 see Mayne (2002); Helfer (2004); and Sell and Prakash (2004).
40. Following Burris (2004) and Burris et al. (2005), one could try to define the 'Geneva connection' in terms of their concept of 'nodal governance'.
41. These interviews covered different types of CSOs (ICTSD, MSF, and 3D, the Quaker UN Office), IFPMA and WHO.