PRIF HSFK
Peace Research Institute Frankfurt
Leibniz-Institut Hessische Stiftung Friedens- und Konfliktforschung

PRIF Report No. 131

Transformation of an Order through Reversal of a Norm-Hierarchy

The Protection of Intellectual Property and the Right to Health

Saskia Scholz/Klaus Dieter Wolf

Member of the Leibniz Association

Translation: Margaret Clarke

Correspondence to:
PRIF · Baseler Str. 27–31 · 60329 Frankfurt am Main · Germany
Telephone: +49 69 959104-0 · Fax: +49 69 558481
E-Mail: scholz@hsfk.de · wolf@hsfk.de · Website: www.prif.org

ISBN: 978-3-942532-86-0

10,00 €

Summary

In this report we explore the conditions underlying the successful campaign waged by emerging nations and their civil-society allies against the rules governing the protection of intellectual property – rules that lie at the core of the liberal world-trade order. Used to regulate the trade in intangible goods, these provisions were incorporated into the world trade regime in 1994 as part of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). Opposition to them was aimed at getting a different normative order accepted – one in which the right to health takes precedence over patent rights on essential medicines and in which, as a consequence, public-health-based trade in state-licensed generics becomes a legitimate instrument of health-policy. Following a phase of confrontational interchange with the opponents of the patent regime – who were initially branded as "product pirates" – there was a reversal of the norm-hierarchy in their favour within the framework of the world trade order.

Even before the adoption of the TRIPS Agreement, the idea of incorporating rules on the comprehensive protection of intellectual property into the liberal world-trade regime had been a source of much contention. Patent monopolies were seen as being to blame for the fact that much of the world's population found its access to vital medicines blocked due to unaffordable prices. At the same time, producers of cheaper – generic – versions were initially treated as norm-flouting violators of the established international order. This was the fate of South Africa when, in 1997, it passed legislation that allowed for measures such as generics substitution and parallel imports of patented medicines. The country was placed on a "watch list" by the USA and an action was brought against it by a group of 40 pharma manufacturers who regarded the legislation as a breach of the TRIPS Agreement.

However, at the WTO's 2001 Ministerial Conference in Doha, a change in regime was agreed which meant that access to medicines was recognized as a norm that implemented the human right to health and must also be taken account of in the world trade order. Since then, world trade rules have accorded the right to health precedence over the right to intellectual property. Norm-based opposition has thus brought about a change in norm-hierarchy and nowadays it is the defence of patents and not the call to safeguard public health that stands in need of justification.

Against this background, the present report asks how it is that an initially successfully vilified alliance of states and civil-society organizations that was previously wont to circumvent patent restrictions via the market in government-licensed generics – citing the human right to health as its justification – now has right on its side. We try to establish how it was that the opposition of states such as India, Brazil, South Africa, Thailand, and the Philippines, and of their civil-society allies, ultimately resulted, after an initially highly confrontational period of exchange, in a compromise-led transformation of the prevailing order. One aspect in need of particular clarification is the sequence of events that led from the initial de-legitimization of divergent normative conceptions, and of practices deriving

from these, to the recognition of the primacy of these conceptions over patent protection. The following stages are identifiable in the conflict: establishment of a liberal normative order; norm-based contestation of this order; de-legitimization of divergent normative conceptions; and finally recognition of legitimacy and reshaping of the order.

In reconstructing this sequential paradigm, we take the TRIPS Agreement to be an instrument that both embodies and typifies the liberal world order. On this basis, a closer look at the conflict between international patent protection and the right to health can provide us with more general insights into the conditions under which transformation of an order takes place.

We begin by describing the nature of the TRIPS Agreement as a component of the prevailing liberal world trade order, at the same time outlining the latter's main players. We then turn to the de-legitimization of dissenting normative visions and practices and the process by which this ultimately gave way to acknowledgement of the latter's primacy. Next, we explore the conditions that made the resultant transformation of order possible. As enabling conditions that likely point beyond the case under scrutiny here we identify: norm-related factors; features and strategies of the actors in the conflict; and, finally, external factors such as exceptional crises and disasters that opened up windows of opportunity and enabled changes to occur in norm-hierarchies. In our conclusions, we consider possible ways in which a change in a contested normative order might be brought about without the phase of heightened and radicalized conflict that characterized the case under scrutiny here. In this connection, we pay particular attention to the qualities that an institutional architecture must have if it is to counteract a strategy of "institution hopping". As is clear from the case under investigation here, this kind of isolationism and lack of responsivity on the part of a negotiating forum that has been opted for on strategic grounds can result in the wrong choice of strategy and have costly consequences. In order to avoid these costs and at the same time create the preconditions in which transformation of an order can take place without a detour through regulatory breaches and strategies of de-legitimization, we need a governance architecture which is based much more systematically than is presently the case on linkage between different institutions and which enables us to identify conflicts between orders at an earlier stage. With such a set-up, we could ensure that competing normative claims not only get articulated but also have a chance to be recognized as valid.

Contents

1. Introduction

In 2001 Yale University in the United States received a request from the non-governmental organization *Doctors without Borders* (*Médecins sans frontiers* – MSF) asking it to grant South Africa permission to either import or produce a generic version of the drug d4T, for which Yale owned the patent. d4T is an antiretroviral used in the treatment of HIV/AIDS. At the time of the request, the price of antiretroviral therapies ranged from US-Dollar 10,000 to US-Dollar 15,000 per patient per year – a figure that made effective HIV/AIDS treatment unaffordable for the majority of the South African population (McNeil 2001; Mante/ Hanano 2008). The University initially rejected the request, citing a patent agreement it had with the pharmaceutical company Bristol-Myers Squibb (BMS) which granted the latter an exclusive licence to manufacture the drug. This prompted protests from students and also from academics, including the inventor of the drug, William Prusoff, who insisted d4T should be available "either cheap or free" in South Africa (Prusoff 2001; McNeil 2001). The resultant media-pressure on the University and the company bore fruit: BMS waived its exclusive rights and a South African company was granted permission to produce a generic version. Within a very short period of time, the price of the drug had fallen to around one hundredth of the original figure (UAEM n.d.).

That patents on pharmaceuticals make it harder for people in poor countries to obtain the treatments they need is beyond dispute. A third of the world's population lacks proper access to essential medicines (Ford 2004; MSF 2014a). Speaking at the World Health Summit in 2013, Rachel Kiddel-Monroe, a member of the Board of Directors of MSF, estimated that on average ten million people die each year as a result of this. This figure might well be far higher had the last fifteen years not seen a development for which the events surrounding d4T can be regarded as symbolic. The development in question is a move away from a rigid safeguarding of patents and towards improved health-provision, even where such improvement brings with it a curtailment of intellectual property rights. There has thus been a transformation of the prevailing normative order such that it is now the strict enforcers of patents rather than their critics who find themselves under pressure to justify their stance.

How is it that, having long been vilified as "product pirates," the states and civil-society organizations that opposed patent restrictions on life-saving medicines as contrary to the human right to health, and used the trade in government-licensed generics to circumvent them, now have right on their side?

This is the question that will guide us here as we explore a political process that leads eventually to a reversal in norm-hierarchy. In particular, we shall ask how it was that the opposition of states such as India, Brazil, South Africa, Thailand, and the Philippines, and of their civil-society allies, ultimately resulted, after an initially highly confrontational period of exchange, in a compromise-led transformation of the prevailing order. Specifically, we shall look at generic medicines as a focus of the debate on the rules governing the protection of intellectual property. These rules, which regulate the trade in intangible goods, were incorporated into the world trade regime in 1994 as part of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). This is a document that both embodies and typifies the liberal world order. As a result, the controversies to which it has given rise point

beyond the specific conflict between international patent-protection and the right to health, providing us with both politically and theoretically relevant indications as to how the struggle to secure recognition for divergent normative claims can result in the transformation of a normative order.

Patent protection of *Intellectual Property Rights* (IPR) is a highly contentious norm, but the entry into force of TRIPS saw it successfully pushed through and universalized as part of the WTO-sponsored world trade regime (Sell 1999). The end-result of the contention, as things currently stand, is an at least partial recognition of the validity of alternative normative conceptions. These alternatives call for right-to-health primacy in the patenting of so-called "essential medicines" – a primacy to which recognition was previously denied and whose advocates were forced into illegality. The sequence of the conflict – from "establishment of a liberal normative order", via "norm-based contestation of this order", to "de-legitimization of divergent normative conceptions," and finally to "recognition of legitimacy and reshaping of the order" – can be regarded as paradigmatic. Our aim here is to reconstruct this sequence and establish how it was possible, after an initially confrontational exchange and a period during which attempts were made to discredit alternative normative conceptions,[1] for the normative hierarchy to be reversed and the existing order transformed.

1.1 Object and course of the conflict

Even prior to the adoption of the TRIPS Agreement, the idea of incorporating rules on the comprehensive protection of intellectual property[2] into the liberal world trade regime was a source of contention. This was not least because patent monopolies were seen as being to blame for the fact that much of the world's population found its access to vital medicines blocked.[3] For a long time, the norm of the human right to health languished in the shadow of a free-market discourse dominated by the economic considerations attaching to

1 Our focus on the refusal to recognize the normative claims advanced by dissidents ties in directly with debates about international justice that are currently gaining momentum in International Relations and political theory and in which the "recognition" dimension of justice, together with the "right to justification," occupies a key position alongside the "distribution" and "representation" dimensions (HSFK 2010; Forst 2007; Fraser 2009).

2 "The term intellectual property right(s) is used as technical shorthand for a whole set of different rights such as patents, copyrights, trademarks, trade secrets, industrial designs and so on. Although most of these rights have been in the making for over five centuries, the term IPRs itself is no older than 30 years. This term is loaded and problematic in at least two accounts; for one, it naturalizes what have traditionally been, and continue to be, entitlements and privileges into rights and, second, it transforms knowledge into property, whose ownership must subsequently be regulated by law" (Muzaka 2011: 762).

3 In Cullet's view (2007: 413ff), there is a direct link between patents, drug-prices, and access to drugs. Schaaber too (2005: 257ff) describes how the TRIPS Agreement adversely affected drug prices and thus also public health. Bright and Muraguri (2011: 101) identify a number of points of tension between the right to intellectual property protection and the human right to health: the first makes itself felt at the level of implementation and is expressed in the distinct procedural norms underlying the latter ("patent protection" and "access"); the second relates to the costs of pharmaceutical research as against the costs of supplying poor people with medicines; and the third concerns the unequal potential for influence wielded on the one hand by the pharma industry and on the other by people who have no access, or only poor access, to medicines.

copyright protection (Ryan 1998; Maskus 2000). The dominant framing was one in which the topic was embedded in purely commercial rather than health-related debate and argumentation. Despite this, the massive recourse to repressive measures to prevent the issuing of compulsory licences[4] against the will of the patent-owners – most of whom were registered outside the countries in question – did not, in the long run, succeed in staving off the regime's transformation (Sell 1999; Ford et al. 2004). On the contrary, the dispute as to "whether it is not a violation of human rights legally to prevent generic manufacturers from supplying essential medicines cheaply to poor patients" (Pogge et al. 2010: xix) became even more intense.

In a remarkable volte-face, the 2001 WTO Ministerial Conference in Doha acknowledged the primacy of the (very strict) exceptions to patent protection which the TRIPS Agreement allowed on the grounds of safeguarding public health (WTO 2001a, b). In so doing, it transformed compulsory licences and parallel imports into legitimate instruments of health-policy (Sykes 2001; Smyth 2007). The change of regime initiated in Doha meant that the right to health now took precedence over the right to intellectual property. Norm-based opposition brought about a change in the hierarchy of norms and led to the introduction of market-correcting norms and rules into the liberally configured world trade order, which meant that it was no longer the champions of public health but the defenders of patent rights that were required to justify themselves.

In explaining this turn of events, we need, in particular, to trace the path that led from the initial de-legitimization of divergent normative conceptions, and of practices deriving from these, to the recognition of the primacy of these conceptions over patent protection. Our main focus, therefore, will be the background to the 2001 Doha Declaration and its re-legitimization of the issues raised by those challenging the free-market order.

1.2 Structure of the report

We begin by considering how the TRIPS Agreement came into being and how this order was then subject to norm-based challenge (Section 2). We then turn to the de-legitimization of the dissenting normative visions and practices, which ultimately gave way to an acknowledgement of the latter's primacy (Section 3). Section 4 looks at the conditions that made this reshaping of the order possible. In conclusion (Section 5), we set out a number of recommendations as to how a change in a contested normative order might be brought about without the phase of heightened conflict that characterized the case under scrutiny here. In this connection, we pay particular attention to the qualities that an institutional architecture must have if it is to counteract institutional isolationism and "institution hopping."

4 A compulsory license allows a company to make use of a patent without the consent/against the will of its owner.

2. From the establishment of a liberal order to its norm-based contestation

2.1 The agreement on trade-related aspects of intellectual property rights

The safeguarding of intellectual property rights, construed as a "trade issue" (Dreyfus 2010: 55), is a key component of the liberal economic and trade order. Patent protection acquired the status of an international norm as early as 1970, with the conclusion of the *Patent Cooperation Treaty*, negotiated under the aegis of the *World Intellectual Property Organization* (WIPO).[5] The Organization was able to promote intellectual property protection – for example, by providing support to national patent offices (Klug 2008: 211). It was not until 1986, however, that intellectual property protection was officially included in a world trade round – the eighth, "Uruguay Round" of 1986 to 1994 – as held within the framework of the *General Agreement on Tariffs and Trade* (GATT). When it came to patents for pharmaceutical products, this embedding of intellectual property into trade policy meant their status was transformed in a very specific and far from impartial way. As far back as 1977, the *World Health Organization* (WHO) had begun producing "model lists of essential medicines", updated approximately every two years, as a benchmark for governments in developing national health-care standards.[6] To obviate unnecessary expense, the list indicated the availability of low-cost generic alternatives to highly priced branded products. The move was successful: by as early as the first half of the 1980s increased demand and competition had brought the world price for medicines on the WHO list down by 40 per cent (Quick et al. 2002: 913). In a further development, the 1978 Alma Ata Declaration identified the provision of "essential medicines" as one of eight basic elements of primary care (ibid.).

The aim of the WHO programme was to ensure inexpensive worldwide access to these medicines, but for this very reason, the pharmaceutical industry viewed it as a threat to their core business. Big pharma companies, mostly based in industrialized countries, saw their opportunities to exploit patents and sell medicines as lucratively as possible coming under threat: a regulated drugs-market was not in their interest (McCoy/Hilson 2009: 219). They therefore used the Uruguay Round to campaign for stronger patent safeguards. This tactic worked: patents were presented not as hampering access to medication but as indispensable to innovation and economic progress. The choice of the WTO as a negotiating forum in itself demonstrates the power of the technologically superior Western industrialized countries to impose their will: it meant that it was not intellectual property protection but opposition to it that had to show just cause.

At the same time, it was clear from the actual practice of many states that pharmaceutical products were accorded a special status on grounds of health-policy:

> "Even where there were strong legal traditions protecting intellectual property rights, the recognition of rights in pharmaceuticals was often subject to special treatment. Many countries

5 On the history of the right to intellectual property, see Peukert (2013).

6 The most recent lists (18th WHO Essential Medicines List, 4th WHO Essential Medicines List for Children) were published in 2013, www.who.int/medicines/publications/essentialmedicines/en/ (12.9.2014).

> treated medicines as public goods and either did not grant patent protection to pharmaceuticals at all or limited intellectual property protection to the processes by which the particular products were produced. In fact, before the issue was put on the agenda at the Uruguay Round of trade talks in 1986, approximately forty states did not issue product patents for pharmaceuticals, leading in some countries to a proliferation of copies of patented drugs" (Klug 2008: 211).

The strategic dimension of IPR inclusion in the world trade regime becomes very clear when one takes a closer look at the prior history. The concern of technologically advanced industrialized countries to strengthen patent rights at the international level must be viewed against the background of their achievements in the areas of computing, information technology, and biotechnology (Wogart et al. 2009: 139). In the United States in particular, there was, at the start of the 1980s, a concern to maintain national competitiveness. On top of this came trade deficits and an overpriced dollar, which made US exports less competitive (Sell/Prakash 2004: 154). In response to these trends, large corporations lobbied the US government to support the introduction of a multilateral IPR treaty that would replace the 1861 Paris Convention and, in addition, would be located within the GATT framework. WIPO was increasingly seen as being dominated by the developing countries and as lacking the power to enforce decisions and therefore being shunned (ibid.; Sell 2003: 104ff).[7] Weak legal intellectual property protection abroad, concluded a study by the *US International Trade Commission*, had negative repercussions on the US economy, costing the USA an estimated US-Dollar 40 billion a year. Accordingly, an across-the-board adoption of strict IPRs by all the members of the international community was seen as indispensable by US corporations, who came together to found the *Intellectual Property Committee* (IPC) as a means of pushing through their aims (Carolan 2008: 299). Pharmaceutical industries in particular repeatedly complained about the losses occasioned by weak patent laws – notably in newly industrializing countries (Klug 2008: 211). Many of these losses were due to increasing competition from international generics-manufacturers, who circumvented the strict US patent laws.

The first – successful – response of the United States to these widespread practices was to resort to bilateral disciplinary measures via the *United States Trade Representative* (USTR). An illustration of this is provided by Klug (2008: 213), using the example of South Korea, which had built up one of the most highly developed national pharma industries outside the OECD sphere. The South Korean government

> "was persuaded in 1987 to adopt both patent and pipeline protection, i.e. providing protection for existing inventions before a patent is formally granted for pharmaceuticals. Continuing this strategy of bilateral pressure, the USTR began in 1991 to take up a series of cases aimed at countries that boasted burgeoning pharmaceutical manufacturing industries, most of which relied on reverse engineering to produce cheap forms of drugs initially developed in more industrialized countries."

The Uruguay Round now offered a platform from which patent rights could be pushed through at international level within the framework of the GATT and using the latter's

7 "Despite the adoption in 1970 of the Patent Cooperation Treaty by members of the World Intellectual Property Organization (WIPO), increasing that organization's capacity to promote the protection of intellectual property by providing technical support services to national patent offices, the pharmaceutical industry continued to complain about commercial losses they attributed to the weakness of patent protection, particularly in newly industrializing countries" (Klug 2008: 211).

dispute-settlement processes and mechanisms. At the close of the meeting, the TRIPS Agreement was appended to the GATT. After years of negotiation, and in line with proposals made by the United States and Japan, it was finally adopted, in 1994, as part of the Marrakesh Agreement Establishing the World Trade Organization (Watson 2009: 145; WTO 1994). A number of developing countries had initially rejected the idea of including intellectual property protection in the negotiations but had later dropped their objections under pressure from the USA – in the form, for example, of threats to impose bilateral trade sanctions. In any case, the developing countries lacked negotiating clout, as evidenced, for example, by the fact that the bulk of the negotiations were concerned with uniting American, European, and Japanese interests and not so much with addressing the matters that exercised less developed countries (Carolan 2008: 299). In addition, the direct involvement of representatives of "patent-intensive" industries in the TRIPS negotiations meant that the concentration of influence and expertise played very much in favour of the industrial countries (Klug 2008: 217).

In brief, the TRIPS regime was structured as follows. At the level of *basic principles*, it presumed, since it was driven by the demands of a successful knowledge- and information-based economy, that the protection of intellectual property was primarily a commercial matter and that intangible goods were only created where there were sufficient economic incentives for this to happen. The best way of ensuring this, it was claimed, was through patent protection – in other words, through a time-limited monopoly on innovation. The costs of this monopoly, in the form of higher prices for consumers, for example, were regarded as being outweighed by its benefits.[8] The *norms* of the regime, meanwhile, were embodied in the prohibition on the circumvention of TRIPS minimum standards on intellectual property protection – though there were to be exceptions allowing a balance to be struck between commercial objectives and social and health-related concerns. Two of the most important *rules* here were that competition from generics was to be allowed directly after expiry of the relevant patents and that the issuing of compulsory licences would be permissible in specific circumstances such as national emergencies.[9] Any disputes were to be resolved through the WTO dispute-settlement and arbitration procedures, the outcomes of which would be binding. Muzaka (2011: 755f) sums up the significance of the TRIPS Agreement in relation to patent protection as follows:

> "First, departing from earlier international arrangements whereby national governments had considerable policy space to design their own intellectual property laws provided certain principles were respected, TRIPS mandates high intellectual property protection standards and

8 "Society is thus ready to grant a time-limited monopoly on new inventions on the assumption that the costs in terms of higher prices to consumers, arising from the monopoly granted, are more than outweighed by the benefits of innovation" (WHO 2006: 19f). "While it is true that the high prices generated by patent protection may render access to the drugs selective, it is nevertheless better that a drug is available to some rather than nonexistent and available to no one" (Joseph 2003: 431).

9 "TRIPS attempts to create a global intellectual property consensus by requiring nations to establish minimum baseline intellectual property laws. The Agreement also provides exceptions for rare circumstances. A crucial flexibility contained in TRIPS is compulsory licensing, which is the process by which a government compels a patent-holder to license its rights to a generic manufacturer in exchange for compensation" (Watson 2009: 144); see TRIPS Art. 31 (WTO 1994).

> procedures in all member states. Second, this 'one-size-fits-all' approach to intellectual property protection is legally binding under the WTO dispute settlement mechanism."

The TRIPS Agreement not only establishes the first-ever binding multilateral intellectual property protection regime (Muzaka 2011: 755), it also tightens up earlier regulations on intellectual property protection in ways that significantly benefit the pharmaceutical industry (Klug 2008: 217). For one thing, it reinforces the framing of intellectual property protection as a world-trade issue and, in so doing, provides it with the back-up of the WTO's extremely robust dispute-settlement and enforcement mechanisms – including, for example, the *Dispute Settlement Board* (DSB). Secondly, and most notably, it opts for an approach designed to guarantee patent protection across all areas of technological development – a line of action that subsequently proved highly controversial. Lastly, it establishes patent protection as the sole incentivizing mechanism for fostering invention and technological innovation.

Having said all this, there is no doubt that, because there are public-health issues involved, TRIPS accords pharmaceuticals a special status as compared with other commodities. Articles 7 and 8 are designed to enable a balance of interests to be struck with socio-political and health-related concerns in cases where emergencies arise. The establishment of minimum standards creates a degree of leeway for national legislatures, formalized in a number of (limited) exceptions and other provisions. Article 31, for example, recognizes the right to issue compulsory licences (though generally only for the domestic market – Art. 31f). Again, flexibilities are included which aim, amongst other things, to prevent pharmaceutical companies from artificially extending their patents through "fictitious" discoveries (a practice known as "evergreening"). All in all, though, these conditions of exception are worded so vaguely that they have had little impact on judicial practice (Dreyfuss 2010: 42).

The minimum standards for patents set out in the TRIPS Agreement brought substantial gains for the pharma industry: the period of protection for patents was extended to 20 years; equal treatment of all areas of knowledge and technology was established as a principle; and limits were imposed on compulsory licensing (Klug 2008: 217). But for the pharma industry, this was not enough. It set out to secure new regulations providing for: a complete ban on compulsory licences and parallel imports; protection for inventions that were still at the development stage; and liberal provisions on patent extension ("TRIPS Plus"). The USA repeatedly exploited its dominant position in bilateral trade negotiations to try to get these TRIPS Plus standards – which excluded the TRIPS "wiggle room" for medicines (compulsory licences and parallel imports) – incorporated into free trade agreements (Klug 2008: 217f; Wogart et al. 2009: 140).

Overall, then, the TRIPS Agreement undoubtedly made an effort to address the tension between the two protective principles involved – both of which enjoyed the status of human

rights[10] – and it accepted that, in emergency situations, intellectual property rights could be curtailed in the interests of public health. But this was not enough to defuse the conflict. In fact, the issue of whether and how far the right to health should take precedence over the right to intellectual property protection became an even hotter topic following the conclusion of the Agreement.[11]

2.2 The norm-based challenge to the TRIPS-based order

Both camps in this conflict comprised governmental and non-governmental combatants alike. On the one side we find the champions and beneficiaries of the order which TRIPS had universalized, including, in particular, the corporations and associations of the highly knowledge-based and IT-based pharmaceutical, chemical, electronics, high-tech, and entertainment industries, and the governments of the economically advanced USA, EU, Switzerland, and Japan. Of these, it was the American corporations and the American government that applied the greatest pressure (Klug 2008: 215). Supported by Japan and Switzerland, they, more than any other of the parties, held out obstinately against making any kind of concession to public health in the form of easier access to medicines.

Ranged against these TRIPS champions were the developing countries. With poor levels of health-care, they were particularly reliant on affordable medicines and some amongst them had already gone or were contemplating the possibility of going into generics production. Completing this alliance of states – centred on Brazil, Argentina, India, Thailand, the Philippines, South Africa, and the "African Group" – was a contingent of NGOs active in the field of health-policy. The spectrum of motives within this band of opponents undoubtedly included some very tangible material interests (Sell/Prakash 2004),[12] but by challenging the basic principles of the liberal world order, they went radically

10 Art. 27 of the *Universal Declaration of Human Rights*, adopted by the United Nations in 1948, already accords the status of human right to "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." This is reaffirmed in Art. 15 of the 1966 *International Covenant on Economic, Social and Cultural Rights* (ICESR), which recognizes the right of every individual "[t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." But the right to health is also included both in the Universal Declaration of Human Rights (Art. 25) and in the ICESR (Art. 12). According to the latter document, the signatory states recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." They are called upon to take all necessary steps to ensure "[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness." Anand Grover, formerly UN Human Rights Council Special Rapporteur on the Right to Health, has identified the four core elements of availability, accessibility, acceptability, and quality as crucial in ensuring the realization of the right to health. Of these, he considers accessibility to be the most problematic (Grover/Lander 2012: 214f).

11 This view is shared by Muzaka (2011: 756): "[T]he TRIPs Agreement not only did not reconcile the many tensions inherent in IP protection, but it helped make them more problematic, obvious and acute. It is partly for this reason that the current IPRs regime is characterized by conflict and contestations."

12 "Almost all developing countries are IP net-importing countries and thus have a real material interest in looser IPRs standards, especially in those sectors where they do not have a competitive advantage. NGOs, too, have instrumental motives, if not in economic terms to themselves, then in securing benefits, economic or otherwise, to their members and constituents" (Muzaka 2011: 765).

beyond this. The patent regime that had taken shape was perceived as a universalization of US patent law and thus also as a manifestation of a dominant Western-capitalist notion of knowledge as property and commodity rather than as common good:

> "In mirroring those philosophical assumptions, patent law tends to see the world in a very Western way, such as by valuing abstract, disembodied (published) knowledge over oral and embodied forms. Recognizing this, countries (e.g. India, South Korea, Thailand, [Mongolia], Cambodia, South Africa, Nigeria, Pakistan, Nepal, Sri Lanka, and Bangladesh) are beginning to play a similar epistemic game by developing large digital libraries of their traditional knowledge, called Traditional Knowledge Data Libraries (TKDLs). The purpose of TKDLs is simple: to establish this long-held knowledge as prior art by transforming embodied/oral knowledge into a form that is visible to patent law" (Carolan 2008: 301).[13]

Amongst the NGOs that emerged as partners to these countries were MSF, Oxfam, and the W. J. Clinton Foundation, all of whom reproached the opposing side with disregard for public health. The charge was that the strong protection which the TRIPS Agreement afforded to pharmaceutical patents had negative repercussions on drug prices and thus also on access to vital medicines. These negative repercussions had been publicly decried since the end of the 1990s, notably by the *Access Campaign* – an MSF-initiated coalition of NGOs from the development, human rights, and health sectors which sought to improve access to essential medicines (Ford 2004: 138f) and which gained momentum with the spread of the HIV/AIDS epidemic and the resultant increase in the need for relevant medication.[14]

The tough IPR regime clearly hampered achievement of the WHO's "health for all" objective – and with it the attainment of worldwide cost-effective health-provision (WHO 1981): "Since the 1980s, the corporate agenda promoting a liberalized and minimally regulated pharmaceutical sector has held sway over the agenda promoting a rational and cost-effective PHC approach to the use of medicines" (McCoy/Hilson 2009: 219). Although access to essential medicines is only one aspect of the right to health, it is nonetheless seen as a touchstone of the international community's willingness to make social human rights a reality (Hein/Kohlmorgen 2008: 84). Accordingly, the newly created order was soon called into question by civil-society activists working in alliance with developing countries. This coalition's campaign against patent rights and in favour of improved access to medicines in the poor regions of the world reopened the debate not only about IPRs but ultimately also about a possible shift in the normative order in favour of a strengthened right to health.

The main criticism which developing countries and their civil-society allies subsequently directed against the IPR norms and rules that became part of the world trade regime as a

13 Watson (2009: 149f) talks in similar terms: "TRIPS has been a source of controversy since its inception. Some developing countries protest that patents are a Western concept and TRIPS forces Western values on their cultures. Indeed, some cultures in developing nations value shared knowledge and reject the competitiveness embodied in TRIPS. […] Developing countries object most forcefully to the implementation of Western values in an area of great concern to them: access to affordable pharmaceuticals. Justifiably, these nations fear that TRIPS will limit access to crucial medications by raising prices."

14 "Yet the existence of a medical regime that allows HIV-positive individuals to live extended and productive lives has transformed the very nature of this pandemic. This transformation has generated a transnational social movement and raised important questions about the relationship between domestic demands for social and economic justice and international claims of property rights and economic freedom" (Klug 2008: 209).

result of the TRIPS Agreement was that they were geared solely to the interests of the developed industrialized countries and that they drove a further wedge between countries in which inventions and technological developments took place and countries in which they did not. The right to intellectual property protection, they claimed, could not be an end in itself; it was inextricably bound up with the function of intellectual property as a generator of social benefit (Muzaka 2011: 763). Thus if, in poor countries, patents neither serve as an effective means of strengthening public health nor contribute to pharmaceutical innovation, they cannot be seen as justifiable curtailments of fundamental rights affecting life or health and therefore constitute a violation of human rights (Forman 2007: 350). The fact that IPRs were negotiated within the framework of the WTO, and the effects this had on access to medicines, were also viewed askance: in a commercially oriented forum such as the WTO, the right to health was hardly likely to triumph over commercial interests and patent rights (Cullet 2007: 418).

A striking illustration of this is provided by the HIV/AIDS crisis. From the second half of the 1990s, there were treatments available on the market which transformed HIV/AIDS from a fatal disease into a chronic one. At that stage, treatment per patient per year cost around US-Dollar 10,400. Most of these costs arose from the enforcement of patent rights by the pharmaceutical companies – as is clear from the fact that the very same drugs could be produced as generics for a fraction of this price (Hein/Kohlmorgen 2008: 88). Because of the lack of resources (such as a properly functioning national health-care/insurance system) and the high prices, the drugs in question were beyond the reach of most HIV/AIDS sufferers. And yet many countries – for example, India – were capable of producing generics at low cost.

The TRIPS regime has thus been challenged by patent opponents on a variety of levels. From a moral point of view, they argue that to hamper access to medicines is unethical and a violation of human rights.[15] Patent rights that do not facilitate access to intangible goods are, they say, morally unjustifiable (Muzaka 2011: 763). What is more, the regime creates social injustice[16] and it is the dominant, patent-based approach to regulation that is to blame for the "10/90 gap" – shorthand for the fact that only about 10 per cent of global medical research is devoted to the illnesses that make up 90 per cent of the global burden of disease. This approach, they claim, establishes the wrong kinds of incentives and ultimately results in too few resources being invested in research and development relevant to the diseases that affect particularly large numbers of people in the developing countries (Forman 2007: 350). This critical view is shared by the WHO, which notes that the burden of infectious

15 "Patents may promote some kinds of R&D but, at the same time, limit access to medicines they help to generate. The key point is that people in developing countries should not be deprived of medicines just because these are patented. This is unethical and against human rights" (Correa in WHO NEWS 2006: 350).

16 "TRIPS rewrites the history books. It does this by saying that the developing world needs strong international intellectual property protections if they hope to follow the trajectory of the developed West. Yet, as I have argued, this strategy effectively closes more doors toward economic and technological development than it opens. Rather than reduce global inequalities between nations, TRIPS helps solidify those divisions. In fact, if the past 10 years are of any indication, TRIPS will likely make those global divisions only worse" (Carolan 2008: 308).

disease is borne largely by developing countries. It views this disproportionate affliction as "an affront to our sense of shared humanity"[17] and calls for the world to "find ways to tackle more effectively the health needs of poor people" (WHO 2006: 171). But improving access to medicines is seen as a duty not only of private companies but also, and in particular, of governments: "Governments need to prioritize health care in their national agendas. […] Access to drugs cannot depend on the decisions of private companies but is also a government responsibility" (WHO 2006: 116). It seems clear from the allusion to worldwide entitlements to justice and to transborder equality of opportunity that the international community is here posited as having a moral duty, in its capacity as the party wielding responsibility. This implies that regimes must also take account of the rightful claims of poor people to health and to drug-provision. The prevailing normative order is felt to be unjust because a discrepancy is detected between what every person can claim to have a right to and the actual chances of their attaining it (Welch 1993: 19). In addition, at the level of power politics, it is claimed that the regime replicates asymmetric power-structures and has been forced on non-Western countries (Watson 2009: 143f, 149f). To the charge of a fundamental disregard for norm-based claims and of unequal access to a healthy life there can thus now also be added that of a lack of "procedural justice" (Fraser 2009).

3. From de-legitimization to the reversal of the norm-hierarchy

3.1 The refusal to recognize divergent normative conceptions and the de-legitimization of practices deriving from them

Conflict over the interpretation and possible modification of the TRIPS Agreement was particularly pronounced during the late 1990s and early 2000s. The case of South Africa attracted particular attention in this regard. In 1997, faced with a huge HIV/AIDS crisis and rising infection-rates, the country adopted the *Medicines and Related Substances Control Amendment*, which included provisions on generics substitution, transparent pricing, and parallel imports, and empowered the health minister to make use of measures such as unrestricted compulsory licensing at times of national emergency (Watson 2009: 152). The USA reacted by placing South Africa on a "watch list" and making moves to challenge the legislation in the WTO. In 1998, South Africa's own *Pharmaceutical Manufacturers Association*, together with a group of 40 – mainly multinational – pharma producers, brought an action against the South African government on the grounds that the legislation constituted a breach of the TRIPS Agreement. The action was backed by the USA and a number of European governments. By resorting to these kinds of measures, industrialized countries such as the USA, acting mainly under pressure from their pharma companies, sought to portray attempts to improve access to medicines – in the form of compulsory

17 "The burden of infectious diseases that disproportionately affect developing countries continues to increase. [...] The health needs of the poor and vulnerable, in particular women and children must receive the highest priority from the world community. Our task is how to alleviate this enormous burden which is an affront to our sense of shared humanity" (WHO 2006: 171).

licensing, for example – as violations of international patent law and thereby to de-legitimize them (see, inter alia, Hein/Kohlmorgen 2008; Klug 2008; Wogart et al. 2009; Watson 2009).

Mounting a legal challenge to compulsory licensing before a country's own courts (the South African case is cited as an example, but it was a method employed in other states as well) – in other words, *legal* de-legitimization – was only one of several devices used to criminalize attempts to make the right to affordable essential medicines a reality. The "softest" form of criminalization, comparatively speaking, was of a *moral* and verbal kind and was confined to stigmatizing the activities in question as "piracy," "theft," "unfair/unjust trade practices," or "inappropriate IP [Intellectual Property] standards" (Muzaka 2011: 765; Sell 2003: 45, 50). *Police-enacted* criminalization took a more serious form, involving, for example, the confiscation or destruction of goods (generics) in transit on the grounds that intellectual property rights deriving from patents issued in the transit country were being violated. One example of this was the seizure of Brazilian goods by the Dutch authorities, as raised by the Brazilian delegate to the TRIPS Council in 2009.[18] Attempts such as this to force states to implement stronger patent safeguards by getting the police in transit countries to confiscate pharmaceutical products not under patent either in the dispatching or in the recipient country reduce producers of generics to the status of norm-violators with no legitimate claim to have the normative basis for their behaviour acknowledged.

3.2 Recognition, transformation of the order, and reversal of the norm-hierarchy

In response to the action brought against South Africa, a large-scale campaign started up and the worldwide interest in this turned the proceedings into a public-relations disaster for the pharmaceutical companies (Ford 2004: 140f). The case enabled local NGOs such as the *Treatment Action Campaign* to make the link between the HIV/AIDS epidemic in South Africa, access to medicines, and the problem of patents in general (Klug 2008: 238). An Oxfam petition bearing 250,000 signatures called on the pharmaceutical company Glaxo to pull out of the action against South Africa and reduce its prices. Eventually, in 2001, negative headlines were generating so much pressure that the pharma companies decided to withdraw their suit in order to avoid further damage to their reputations (UNDP 2002: 105f; Ford 2004: 140f): "Suing Nelson Mandela to prevent his government from implementing a WHO inspired essential medicines program was symbolically the kiss of death for the pharmaceutical corporations" (Klug 2008: 238).

18 "First, the shipment did not follow its original course to Brazil due to an autonomous decision of the exporter to bring it back to India. Such action by the exporter was a result of negotiations with the holder of the patent in the Netherlands, who actually threatened to request the destruction of the apprehended goods. Second, we have evidence indicating that around half of last year's Dutch seizures resulted in the destruction of the goods in transit. […] A merely perfunctory examination of the WTO disciplines will lead us to the simple and straightforward conclusion that the Dutch authorities had no right to do what they did. They could not have detained the consignment, obstructed or delayed its transit, nor prevented its arrival in Brazil based on a claim of violation of patent rights" (Brazil 2009 TRIPS Council statement).

The WHO also began to encourage its members to take steps to safeguard access to essential medicines and to enshrine this access in international agreements (such as TRIPS) (Muzaka 2011: 767). At the 1999 WTO summit in Seattle, UNAIDS addressed member-countries in unambiguous terms:

> "International trade agreements and policies can affect access to goods and services which are crucial to HIV protection, care and impact mitigation. […] The vast majority of HIV-positive people in developing countries […] where 95% of HIV-positive people live, do not have access even to relatively simple medications for potentially fatal opportunistic infections, not to mention more sophisticated antiretroviral drugs that attack the virus itself. […] The availability of HIV/AIDS drugs, like others, depends upon at least three main factors: (i) sustainable financing for drug procurement at the national level; (ii) national and local health infrastructure for delivering drugs and monitoring patient compliance; and (iii) affordable drug prices. High HIV/AIDS drug prices are due, in part, to the fact that many HIV/AIDS drugs are protected by patents and their manufacture and sale can be exclusively controlled" (UNAIDS 1999).

Even the UN Security Council got involved: it passed a resolution on the potential impact of HIV/AIDS on *peacekeeping operations* in which it described the growing HIV epidemic as a potential threat to stability and international security and called for progress to be made both on access to treatment and on prevention (UNSC 2000). During the debate on the Resolution, Mali spoke for the Global South when it denounced a state of affairs in which, it said, the sick were to be found mainly in the South and treatments mainly in the North. It called for solid framework conditions that would ensure access to affordable medicines. These conditions, it said, "could be brought about […] through the development of resolute policies relying on generic products, bulk purchases, negotiations with pharmaceutical companies and appropriate financing" (UN 2000). A representative of Zimbabwe complained that the international community had taken far too long to begin fostering partnership between the different interest-groups – including governments and pharmaceutical industries – so that HIV medicines could be made more easily available to developing countries: "[I]t remained painfully clear that the profit motive continued to take precedence over humanity's medical well-being" (UN 2000). With the adoption of UNSC Resolution 1308, the need for access to medical care finally became a subject of *high politics*.

Once access to essential medicines had become part of the international agenda, demands for regulations to improve it were supported by an ever-growing number of states. At a special session of the TRIPS Council in Geneva in June 2001, India called for the WTO to show greater flexibility and clarity in its interpretation of the TRIPS Agreement, with a view to securing the affordable access to essential medicines that was required from the point of view of public health (India Department of Commerce 2001). Together with the group of African states and 15 other countries – including Brazil and Thailand – it submitted a document which demanded an assurance from the WTO that TRIPS would not be allowed "to undermine the right of WTO members to formulate their own public health policies and adopt measures for providing affordable access to medicines." The TRIPS Agreement, said the document, should be interpreted in a way that allowed member states to exploit its flexibilities to the advantage of public health. The forthcoming Doha conference, it said, should send out a strong message to the world that the WTO was not an organization that simply bent to the will of big business but one that cared about people (ibid.).

The 2001 UN General Assembly Special Session on HIV/AIDS was used by transnational civil-society actors as a platform for criticizing the economic policy which the USA pursued at the expense of AIDS sufferers. Brazil in particular – which at that time was embroiled in a dispute with the USA about the interpretation of TRIPS flexibilities – was able to exploit this underlying mood. At a session of the UN Commission on Human Rights, it succeeded in getting a resolution adopted – Resolution 2001/33 – which called on states to facilitate access to the medicines needed to treat illnesses such as AIDS, to increase cooperation in cases of emergency, and to have due regard for the right of every person to health (Fischer-Lescano/Teubner 2006: 79). The USA, which only a few months before, in January 2001, had requested that a WTO panel be set up to examine the patents situation in Brazil, was now forced to settle its quarrel with the latter over patents for HIV/AIDS medicines. The focus of this dispute had been Brazil's national AIDS programme, which the USA believed discriminated against US patent-holders. Brazilian patent law allowed for the possibility of generics production in cases where a patent holder had no local production-plants in operation in Brazil. Turning as it ultimately did on the question of whether the Brazilian patent law violated the TRIPS Agreement, this dispute highlighted the need for the contents and limits of international patent-protection within the WTO-system to be more clearly defined (Fischer-Lescano/Teubner 2006: 74ff).

In response to the growing opposition, the WTO Ministerial Conference held in Doha in 2001 finally agreed to build greater flexibility into the existing TRIPS regime. For the purposes of public health protection, the Doha Declaration accepted that the human right to essential medicines also formed a legitimate part of the world trade order. The promotion of public health was adopted as a guiding precept in the interpretation and implementation of TRIPS. Most notably, restriction of the production of compulsorily licensed medicines to the domestic market was relaxed:

> "We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration" (WTO 2001b).

This "separate declaration"[19] addresses the problem which patent protection poses for access to medicines by stipulating that the TRIPS Agreement must not prevent signatory states from taking measures to protect public health. In addition, it grants affected states the prerogative of determining what constitutes an emergency and it gives the least developed countries until 2016 to implement the TRIPS regulations.

The support which transnational NGOs such as MSF and *Health Action International* provided in the context of the debate on access to essential medicines was of crucial importance to the countries of the South both before and during the negotiations in Doha. One broad-based campaign, for example, called for an increase in the production of generic antiretroviral medicines for AIDS and exposed the way in which TRIPS contributed to the neglect of diseases that mostly affected poor countries (Novogrodsky 2010: 349f). Working with other transnational NGOs, MSF provided representatives of developing countries with

19 "Declaration on the TRIPS agreement and public health" (WTO 2001a).

information on the negative repercussions of US and European trade-policies and thus strengthened their hand in the Doha trade-talks (McCoy/Hilson 2009: 220).

As previously described, the dispute as to when clauses of exception could be invoked was initially characterized by a recourse to de-legitimization, in which practices involving the setting-aside or disregard of patent rights on the grounds of public health were condemned as breaches of law. With the regulations as they existed up to then, the patenting of medicines in a particular country prevented developing countries that did not have any production-plants of their own from making use of the option of compulsory licensing. According to Art. 31f of the TRIPS Agreement, compulsory licensing could be used to supply the domestic market but not to manufacture generics for export to countries that had no production-plants of their own (Fischer-Lescano/Teubner 2006: 82f). However, as the dispute progressed, de-legitimization of such practices was increasingly replaced by acceptance of them. The decision to review Art. 31 (recorded in § 6 of the Doha Declaration) was, once again, brought about with the help of transnational civil-society actors: during the negotiations on § 6, a number of NGOs, working in collaboration with journalists, managed, in their turn, to de-legitimize the US opposition to the extension of compulsory licensing. They were able to expose the hypocrisy of the USA, which (in the wake of the 2001 anthrax attacks) had itself sought, along with Canada, to issue a compulsory licence for Ciprofloxacin – a drug used to treat people exposed to the deadly pathogen – and thus circumvent Bayer's patent on the product (Novogrodsky 2010: 350; Klug 2008: 227f). The revelation of these double standards – a flagrant violation of the rules of fairness – lent other actors added negotiating power based on expectations of justice.

In order to make this recognition of their claims compatible with the world trade regime the Doha Declaration was proclaimed as an "interpretation aid" for TRIPS. With this, the normative clash between property rights and the right to health seemed to have been resolved. The safeguarding of public health had, in principle, gained admission to the intellectual property protection regime as a bona fide concern. However, the flexibilization of the regime proved fragile, a source of ongoing argument because of the margin for interpretation which it continued to allow when it came to translating the flexibilities into national law. This fragility was evident in the continuing conflicts over compulsory licensing and, in particular, over the export of medicines produced in this way to countries without domestic production-facilities. The WTO General Council Decision of 2003, which can be interpreted as providing exemption from the obligations set out in Art. 31f of the TRIPS Agreement, was designed to put an end to these conflicts. With this and the subsequent passage of the *TRIPS Amendment* in December 2005, in which WTO members officially adopted the changes to Art. 31 of TRIPS, the call expressed in § 6 of the Doha Declaration – for a solution to be found to the problem of the use of compulsory licences in countries without their own production capacity – was finally answered.

Nonetheless, the regulations on compulsory licences have come under fire from NGOs as being "unworkable," because, they say, the requirements imposed on states wishing to use such licences are still too stringent (Hein/Kohlmorgen 2008: 90f; Hein/Moon 2013: 80f, 183). In addition, the USA has now begun to try to get round the TRIPS Amendment through the use of bilateral trade agreements. Pharmaceutical companies themselves also continue to take legal action or apply other sanctions in order to thwart national patent laws

and their various provisions on compulsory licensing – as implemented by, for example, India, Thailand, Brazil, and Indonesia (Pogge et al. 2010: 13). Countries seeking to make use of the compulsory-licensing mechanisms constantly have obstacles put in their way. This was the case with Thailand, which in 2006/7 issued compulsory licences for AIDS and cancer medicines; it was also true of Brazil, whose 2007 compulsory licensing of the AIDS medication efavirenz was heavily criticized by the USA and the patent-owner, Merck. It is clear that any countries looking to make use of the TRIPS flexibilities continue to need both the legal clout and the financial wherewithal to stand up to external political pressure (So/Sachs 2012: 113f). That this is so is due to the fact that the new norm-hierarchy has still not been formalized in international law (Hein/Moon 2013).

The upshot of this is that there is still basic disagreement as to whether recourse to permitted exceptions to patent protection by individual countries falls within the legal bounds of TRIPS interpretation or whether it undercuts TRIPS standards. This argument was addressed in the 2006 WHO report on *Public Health Innovation and Intellectual Property Rights* produced by the *Commission on Intellectual Property Rights, Innovation and Public Health*.[20] The report discusses "[the] tragic failure by all governments to address poverty and sickness in developing countries" (WHO 2006: 173) and proposes a variety of measures for dealing with the situation. "Companies," it says "should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low income countries, they should avoid filing patents, or enforcing them in ways that might inhibit access" (WHO 2006: 181). The report also stresses that, where bilateral trade agreements are negotiated, steps should be taken to ensure that the relevant health-ministries are adequately represented and that the agreements themselves respect the principles of the Doha Declaration.[21]

The slow progress on ratification of the TRIPS Amendments – the deadline for which had to be put back several times – can also be viewed as an indication of the dissatisfaction with the outcome of the modification process (Hein/Moon 2013: 81). In order to ascertain how well the changes were working, the WTO General Council Decision of 2003 was once again debated in a series of TRIPS Council meetings convened at the request of developing countries. This opened up the possibility of a resumption of negotiations on Art. 31 of the TRIPS Agreement (Hein/Moon 2013: 82). The problem of making universal access to essential medicines a reality thus remains on the international agenda and has been addressed in various UN resolutions and reports. One such is a 2011 resolution of the UN Human Rights Council[22] in which the Council expresses concern at the fact that full

20 "The Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it. Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production" (WHO 2006: 180).

21 "Partners should consider carefully any trade-offs they may make in negotiation. Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries" (WHO 2006: 126).

22 "The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the context of development and access to medicines," HRC/RES/17/14, 14 July 2011.

realization of the right to health – specifically as regards ensuring access to affordable, reliable medicines for millions of people, particularly those living in poverty – remains a distant goal. The issue of the USA and Europe circumventing the Doha regulations through the use of free-trade agreements (see, for example, Nasu 2010; MSF 2011a) also continues to feature in the dialogue at international health forums – as, for example, at the 2013 World Health Summit in Berlin. Thus current practice seems still not quite to live up to the good intentions and rhetoric: at the same summit, José Manuel Barroso, the then President of the European Commission, was to be found describing health as a common good (WHS 2014: 4) and a fundamental right (European Commission 2014). Criticism has also come from MSF (MSF 2014b). Speaking only recently, at the 134th Executive Board Meeting of the WHO, it complained that:

> "The intersection between intellectual property, innovation and public health is recognized in a number of WHO resolutions and in the TRIPS Agreement. Yet it remains a challenge for WHO member states, especially developing countries, to use these flexibilities when drafting intellectual property policies that aim to promote access to affordable essential medicines. […] [M]ultinational pharmaceutical companies will go to great lengths to protect profit margins, even when it comes at the expense of people's lives, and involves the covert derailing of government policies aiming to balance intellectual property, public health and access to medicines. […] Also of grave concern are intellectual property clauses included in trade negotiations initiated by the United States and the European Union. The Trans-Pacific Partnership Agreement is especially worrying, and TRIPS-plus provisions, if accepted, would have a severe adverse impact on public health in developing countries."

4. Reasons for the reversal of the norm-hierarchy

The course of the conflict as described in the preceding section has a significance going beyond the policy-field involved. From this particular case, it is possible to draw systematic conclusions as to how, in the face of attempts to de-legitimize opposition, norms and orders can undergo transformation. In what follows, we consider three types of factors that may be at work here: norm-related factors, which are linked to particular features of the rival sets of norms, to the nature of the norm-conflict, and to the framing strategies that are in operation; actor-related factors, which have to do with modes of articulation, organizational capacity, material back-up, and power-resources; and exogenous factors such as exceptional crises that open up windows of opportunity and increase the likelihood of norm-change.

4.1 Norm-related factors

The reconfiguration in order that is under scrutiny here was aided by a fundamental *shift in the normative context* which meant there was increasing receptiveness to economic and social human rights in general.[23] Against this background, the human right to health found itself occupying an ever higher position in the international hierarchy of norms as compared with the right to intellectual property protection. As the conflict progressed, the

23 As set out in the International Covenant on Economic, Social and Cultural Rights (1966).

intellectual property right underwent a dramatic devaluation: from a situation in which, as a supposed end in itself, it had no need of further justification, it came increasingly to be judged in terms of its capacity to generate social benefit (Muzaka 2011: 763). At the same time, the right to health, and the concept of health itself, rose in estimation as cornerstones of political and economic stability.[24]

The *type of norm conflict* involved – namely, one comprising two explicitly competing norms – worked to the advantage of the regime-challengers. The TRIPS norms enshrined the idea that patent rights are always necessary for the development of new medicines and that they must therefore never, or only exceptionally, be encroached upon by compulsory licences or parallel imports. TRIPS questioners, meanwhile, united around the idea (embodied in the "access to essential medicines" norm) that universal access to medical drugs must be made a reality. They contested the claim that patents are necessary for the development of new medicines and rejected the idea that (excessive) profits should be made from the exploitation of patents on medicines on which the lives of millions of people depend (Joseph 2003). The fact that the opponents of what was, for the moment, still the prevailing order were able to agree on one specific rival idea, which they sought to promote via the access norm, made it easier for them, as norm entrepreneurs, to contest and undermine the norms of the TRIPS regime. This contrasts with cases where multiple rival orders emerge and it is a simple task for the representatives of the prevailing order to play these alternatives, and their spokespersons, off against each other.

Concerning the significance of *a norm's contents*, it is generally assumed, in norm-diffusion research, that norms relating to the protection of vulnerable groups from "bodily harm" or to equality of opportunity potentially have greater transnational resonance than other norms (Finnemore/Sikkink 1998: 907; see also Keck/Sikkink 1998: 27). In the conflict under consideration here, both these aspects were present: equality of opportunity, in the form of access to medicines for all; and the preservation of the physical integrity of at-risk populations. The fact that developing countries were the ones most affected by AIDS epidemics, and were therefore dependent on essential medicines, was transnationally more "campaignable," and easier to tie into widely held notions of what is appropriate, than the protection of intellectual property – particularly as the latter is regarded as a predominantly Western regulatory concept (Peukert 2013). The normative tension in the prevailing order was thus important on two counts. Firstly, it allowed the challengers to make a connection with concerns which, though recognized in principle, were not really taken seriously in the existing world trade regime (this is what Keck and Sikkink (1998: 19) dub an "appeal to shared principles"). Secondly, the norm that challengers were propagating was ultimately the one that could be "sold" as being of greater moral worth. As advocates of a common public good, namely "public health," right-to-health activists were able to assume the role of "spokespersons of the weak" against the interests of private profit and thus had relatively

24 By way of example: speaking at the 2013 WTO summit, the then President of the European Commission, Manuel Barroso, remarked that: "Investing in health systems is not just a social imperative. It is also, if you will, good economics, as it helps tackle the root causes of underdevelopment, poverty and instability. In many ways, personal health is a public good. […] These interconnections matter even more in the light of new and emerging health threats that arise from increasing global mobility, migration flows, demographic change, environmental pollution and climate change" (WHS 2013: 4f).

little difficulty in raising the conflict to a moral "right or wrong" level. This allowed them to make strategic use of moral pressure, rendering the topic "more negotiable" (Keck/Sikkink 1998: 23f, 26). Demands for justice – in relation to physical integrity or equality of opportunity – are clearly easier to tie into transnational sentiment than is the bald defence of economic interests by the industrialized countries – not least because such demands raise the dispute to an emotional level (Welch 1993).

Likewise, the underlying norm-conflict proved particularly amenable to what were some very *promising framing strategies* on the part of those opposing patent protection (Keck/Sikkink 1998: 19). A number of crucial conditions were present: the ability to point to a definite "culprit" (the pharmaceutical industry); a "man-made" wrong (violation of the right to health due to patent-based over-pricing of medicines); and a readily definable solution (partial removal of patent rights on medicines).

The wide range of civil-society "right to health" activists involved in the campaign highlights the fact that the latter's central cause was one that could be simultaneously tied into a number of different cross-policy normative discourses. Most notable here – in addition to the development discourse conducted in the context of the *Post-2015 Development Goals* – is the discourse on *Corporate Social responsibility* (CSR), which brings business and human rights together and to which most large corporations have publicly committed since the 1990s. Voluntary normative commitments are geared to CSR-inspired standards of behaviour, within which, in turn, the principle of "do no harm" marks a minimum requirement. Other notable features of the overall change in norms include the evolution of the concept of sovereignty into one of sovereignty as responsibility and an increasing acceptance of the idea of transborder responsibility, whereby states have a duty to support other states in their endeavour to make basic rights a reality.

4.2 Features and strategies of actors in the conflict

All this having been said, the "competitive advantage" enjoyed by the challenger-norm did not feed through automatically. Additional conditions had to be present which made reversal of the norm-hierarchy possible in the first place. Amongst these were, on the one hand, the *possibility of building strategic alliances* involving conflict-competent rising states such as Thailand, India, and Brazil and, on the other, the linking-together of transnational campaigns being waged in the health and development fields. With these elements in place, the normative dispute proved an ideal ground for *issue linkage* and for the formation of broad-based transnational networks of activists (Keck/Sikkink 1998) that were bound by common concerns, ideas, and values, enjoyed closely intermeshed information-sharing links, and were strategically skilled at pursuing normative goals (Sell/ Prakash 2004). In their quest to "challenge the existing logics of appropriateness," activists had necessarily to engage in "explicitly inappropriate behaviour" (Finnemore/Sikkink 1998: 897). Those advocating a change of norms to relax patent safeguards and strengthen the right to health thus resorted to dramatic measures in order to attract attention and call the existing order into question.

Despite the strengths of the NGOs – their access to institutions, their capacity to organize transnationally, and their ability to draw on the "power"-resources of moral

authority and "authoritative knowledge" (Risse 2000: 186; Keck/Sikkink 1998) – the *gain in power* which they secured in alliance with the rising states was not enough to wipe out the influence of the opposing camp. After all, the side fighting to preserve the prevailing order included in its ranks a well-networked multibillion-dollar pharma industry teamed with powerful, financially strong Western states such as the USA, the EU countries, Japan, and Switzerland. But this latter alliance inflicted considerable damage on itself through its inconsistency and the loss of credibility this occasioned – for example when the USA and Canada in their turn contemplated issuing compulsory licences to cope with relevant crises. This gave the lie to the norm hierarchy which this side was promoting and to the reasoning behind it – namely that intellectual property protection must be given priority because it alone was capable of providing the incentives needed for medical/scientific innovation and thus creating the basis for optimal medical provision. In addition, the patent opposers numbered amongst their ranks states such as Brazil, South Africa, and India, whose rising power as BRICS countries could no longer be dismissed on the international stage. These states are now represented not only in IP-relevant forums such as the WHO and the WTO, but also in gatherings – like the G20 (Kirton 2013) – that have acquired increasing importance in international politics and have already been called upon several times to assume a leadership-role in areas such as "health financing" (MSF 2011b; CSN BRICSAM n.d.).

The more easily assailable the reputation of those defending a prevailing order, the more successful de-legitimization through blaming and shaming is likely to be. And assailability was very much a feature of the present case, on both sides of the divide: all the states involved were democracies and as such necessarily offered discursive space which civil-society actors and the media could exploit to pose critical questions and mobilize the public; the pharmaceutical companies, meanwhile, being notorious butts of criticism, were particularly focused on effective reputation-management. A continued strategy of de-legitimization vis-à-vis the challengers and continued intransigence vis-à-vis their concerns would have cost dear in terms of legitimacy and good repute.

4.3 External influences

Finally, a major role was also played here by the dramatic failure of IP-based political programmes and by the experience of a number of crises that occurred at this time. The HIV/AIDS epidemic in South Africa and Thailand, and the resultant increase in the need for relevant medicines in developing countries, gave a boost to criticisms of patent rights at the international level and put the pharmaceutical industry increasingly in the position of having to justify itself. The epidemic opened up a crisis-induced window of opportunity (see, for example, Sandholtz/Stiles 2008; Florini 1996), which norm entrepreneurs were able to exploit to get a hearing for their normative visions. The tensions that were in any case present between the TRIPS norms and the right to health provided a fertile ground for challenges to the prevailing patent regime. The increased need for affordable medicines acted as a "triggering event" (Sandholtz/Stiles 2008: 325), causing the TRIPS patent rights – which offered only very narrow flexibilities on the production of generics – to be called into question. With the pharmaceutical companies proving far from immune to public pressure, the use of shaming strategies paid off (Keck/Sikkink 1998) – clearly this kind of pressure

works just as well against corporations as against countries (Wolf 2008; 2011). In addition, an agreement concluded between MSF and the Indian pharma company Cipla to supply HIV/AIDS generics to sufferers in Africa at a fraction of the patent-holder price put great pressure on politicians and big pharma companies to acknowledge the validity of calls for proper access to medicines as a means of enacting the right to health (UNDP 2002: 105f). Given their public image as staunch defenders of human rights, the states in question could not, in good conscience, continue to refuse to relax the existing patent regime. As early as 1999, at the chaotic WTO summit in Seattle, signs of movement began to be visible on the American side: US President Bill Clinton announced a change in US policy to the effect that "U.S. health care and trade policies would ensure access to needed medicines for people in developing countries" (UNDP 2002: 106).

Public-health crises thus clearly strengthened the position of the health norm vis-à-vis the intellectual property protection norm and altered the weightings of the various arguments in the discourse. Against this background, the case brought against the Mandela government in an attempt to prevent South Africa from implementing the WHO-sponsored Essential Medicines programme dealt a severe blow to the reputation of the pharmaceutical companies. Of less spectacular but longer-lasting advantage to the challengers as a practical motivating factor was the growing gap between supply and demand: IPR-initiated research was actually neglecting the most widespread diseases – the ones affecting developing countries in particular – because there was not sufficient profit to be made from tackling them.

5. Conclusions

At the start of the present paper, we indicated that a closer look at the conflict between international patent-protection and the right to health might provide some insights into the conditions under which an order undergoes transformation. The conflict we described involved a liberal normative order facing a norm-based challenge from an alliance of civil-society organizations and rising powers. Invoking the human right to health, this alliance opposed the imposition of patent restrictions on life-saving medicines and circumvented these via the trade in state-licensed generics, which at the time was portrayed as criminal. Following a phase of confrontational interchange with these challengers – who were branded as "product pirates" – the norms they were propagating became increasingly recognized as valid and were gradually incorporated into the existing regime.

The conclusions that will be drawn here in terms of political practice are not intended as guidelines for the further management of tensions between patent protection and the right to health: there are already numerous suggestions in this regard (see, for example, Pogge et al. 2010). What our follow-up observations will seek to do, rather, is address the over-arching question of how a normative order that comes under challenge can successfully undergo change without passing through the phase of radicalization of the conflict experienced in the case under scrutiny here. Particular attention will be paid to the sorts of

features an institutional architecture requires if it is to avoid losses of responsivity[25] due to institutional isolationism and "institution hopping."

One important observation, to begin with, is that where a normative order is perceived to be unjust, the chances of its being successfully defended diminish in inverse proportion to the breadth of the alliance challenging it. This principle can be seen at work in the case under review, where there is a coming-together of aspiring powers and transnational civil-society organizations, all seeking, for very different reasons, to challenge a pre-existing, dominant, Western-liberal norm-hierarchy. Denial of recognition based on de-legitimization actually proves a dysfunctional and ultimately self-damaging strategy: as the capacity of the challengers to articulate their case and successfully handle the conflict increases, the norm-hierarchy undergoes a change and de-legitimization bites back. The growing self-confidence of the rising powers, in combination with the mobilizing potential of NGOs with transnational reach, means that normative arguments for Western-conceived orders no longer automatically win the day in what is now a much more plural discourse. On the contrary: they very quickly emerge as interest-led and particularist once it becomes clear what costs they occasion in terms of the common good. Discursive predominance declines in proportion as it becomes more difficult for the party concerned to convey the superiority of its own normative conceptions and in proportion as rival norm-entrepreneurs are able to step up as champions of "the good" or "the weak" against the interests of private profit.

One of the reasons why the changes taking place in the normative context were misjudged was that although organizations such as the WTO, which tend to be the forums of choice for upholding a Western-liberal style of international order, do display an increasing degree of inclusivity in their memberships, this does not translate directly into responsivity. And yet, because of the increasing interdependence of different policy-areas, normative claims relating to health or development are almost invariably affected by rules laid down in the domain of world trade. In the case under review, the fact that, institutionally speaking, the WTO was sealed off from any negotiating forums concerned primarily with issues of health or development made it easier for US pharmaceutical companies to push through their interests. But it also triggered the subsequent confrontational process of challenge.

As is clear from the case under investigation here, this kind of isolationism and lack of responsivity on the part of a negotiating forum (opted for on strategic grounds) can result in the wrong choice of strategy and have costly consequences. In order to avoid these costs and at the same time create the preconditions in which transformation of an order can take place without a detour through regulatory breaches and strategies of de-legitimization, we need an institutional architecture which is based much more systematically than is presently the case on linkage between different institutions and enables us to identify conflicts between orders at an earlier stage. With such a set-up, we could ensure that competing normative claims not only get articulated but also have a chance to be recognized as valid.

25 We define an institution's responsivity as the degree of reliability it is able to demonstrate in recognizing, taking up, and dealing with the concerns and claims of actors who are subject to, or affected by, the norms and regulations it generates.

Existing institutions – in the present case, for example, these would be the WTO, the WIPO, and the WHO – would no longer regard themselves as operating alongside or in competition with one another. They would see themselves as forums interacting to ensure that what is likely, for the present, to be an increasing number of normative conflicts are identified in good time and dealt with according to set rules. Although such conflicts would continue to reflect situations of dominance and resistance, there would be other channels through which to manage them.

According to Fischer-Lescano and Teubner (2006), what the parties to the conflict under discussion here needed to do was find a "compatibility mode" which allowed the conflicting demands in the different regulatory areas to be correlated with one another and which thereby compelled the WTO decision-making system "to build a relation of responsiveness to the outside from within its own, economically determined perspective" (Fischer-Lescano/Teubner 2006: 87). The way this happened within the framework of Doha and its follow-up measures was confrontational. The point was then "to develop abstract, general incompatibility-norms relating to the interplay between the economic and health sectors and to treat WIPO, WTO, and UN regulations as part of a transnational scheme of patent law and prepare them for response to a series of destructive conflicts between incompatible rationales" (Fischer-Lescano/Teubner 2006: 97). That the compulsory licensing system agreed in the wake of the Doha Declaration was a viable approach to achieving the required compatibility is something which the authors doubt. Whatever the case, there seems no way round the fact that clarity must be established as to which set of norms – economic or health-related – has primacy.

Also helpful in identifying suitable strategies here are the approaches devised by Zimmermann et al. for dealing with overlap conflicts (2010; 2013). In particular, the idea of bringing about clarity through "harmonization" offers a useful option in the present case (Zimmermann et al. 2013: 36f). This involves working towards a lasting transformation of a normative order through negotiation, deliberation, and legal cross-fertilization that is aimed at resolving or tempering a conflict – for example, through fusion into a single order (Zimmermann et al. 2013: 52). This was precisely the course followed in the case of the Doha Declaration and the subsequent regulations on the TRIPS flexibilities: the TRIPS regime moved some way, content-wise, towards satisfying the norms that had evolved in the health context, and public-health concerns were recognized as a legitimate limitation on formal patent-protection (Zimmermann et al. 2013: 52f). However, given the ongoing conflicts over the application of the new regulations on compulsory licensing, we have to ask whether a clear, formal hierarchization, in which intellectual property protection is subordinated, across the board, to the overall aim of realizing the right to health, might not be a more effective solution than the harmonization strategy embodied in the Doha Declaration – which is ultimately not very practicable. Although scholars such as Hein and Moon (2013) think it unlikely that there could ever be a formalized right to medication, legal processes aimed at establishing clarity in the relationship between intellectual property protection and the right to health may offer the best solution in regard to the conflict under discussion here. At its most extreme, this could mean the complete removal of pharmaceutical innovations from patent protection. However, a "transparent, procedurally simplified and cost-effective system for granting the right to compulsory licensing" (Fischer-Lescano/Teubner 2006: 98) – based, for example, on a list of licensing fees

graduated according to economic strength (ibid.) – could, in certain circumstances, provide an interim solution likely to be acceptable to the broader constituency of the pharma industry, the industrialized countries, and civil society. This kind of graduated licensing or patent-exemption system could satisfy both the call for fairness and equality of opportunity and the economic interests underlying patent protection. In order to be accepted as appropriate and to produce stable outcomes, this system would need to be constructed in such a way that the global patent law it served ensured unimpeded access and effective flexibilities (practicability) (see Zimmermann et al. 2010: 32).

That said, given the transnational linkability of the principles involved, an across-the-board hierarchization in which norms relating to the protection of vulnerable groups from physical harm (Finnemore/Sikkink 1998: 907) are set above norms that only protect economic interests seems an obvious solution. Since the idea that patents act as incentives to research and development is already, at the very least, contested (Josef 2003: 432f; WHO 2006), and since it was customary, up until the Uruguay Round, for states to accord pharmaceutical products a special status on public-health grounds (Klug 2008: 211), to have an across-the-board reconfiguration of the relationship between patent rights and the right to health as an ultimate objective would be entirely reasonable. Once the precedence of health over intellectual property concerns was formalized, political exploitation of the loopholes left by non-formalization could be minimized. To establish clarity on the basis of legal processes whose outcomes are non-circumventable, practicable, and accepted by all relevant parties would seem to be critical to the achievement of effective conflict-management.

Bibliography

Bright, Keren/Muraguri, Lois 2011: Access to Medicines: Intellectual Property Rights, Human Rights and Justice, in: Voiculescu, Aurora/Yanacopulos, Helen (eds.): The Business of Human Rights: An Evolving Agenda for Corporate Responsibility, London: Zed Books, 101–121.

Carolan, Michael S. 2008: Making Patents and Intellectual Property Work. The Asymmetrical 'Harmonization' of TRIPS, in: Organization & Environment, 21: 3, 295–310.

Cullet, Philippe 2007: Human Rights and Intellectual Property Protection in the TRIPS Era, in: Human Rights Quarterly 29: 2, 403–430.

Dreyfuss, Rochelle C. 2010: TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis, in: Pogge, Thomas/Rimmer, Matthew/Rubenstein, Kim (eds.): Incentives for Global Public Health. Patent Law and Access to Essential Medicines, Cambridge: Cambridge University Press, 35–55.

Drezner, Daniel W. 2007: All Politics Is Global: Explaining International Regulatory Regimes, Princeton, NJ: Princeton University Press.

Finnemore, Martha/Sikkink, Kathryn 1998: International Norm Dynamics and Political Change, in: International Organization 52: 4, 887–917.

Fischer-Lescano, Andreas/Teubner, Gunther 2006: Regime-Kollisionen. Zur Fragmentierung des globalen Rechts, Frankfurt am Main: Suhrkamp.

Florini, Ann M. 1996: The Evolution of International Norms, in: International Studies Quarterly 40: 3, 363–389.

Ford, Nathan 2004: Patents, Access to Medicines and the Role of Non-governmental Organisations, in: Journal of Generic Medicines 1: 2, 137–145.

Ford, Nathan/Wilson, David/Bunjumnong, Onanong/von Schoen Angerer, Tido 2004: The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand, in: The Lancet 363, 560–563.

Forman, Lisa 2007: Trade Rules, Intellectual Property, and the Right to Health, in: Ethics & International Affairs 21: 3, 337–357.

Forst, Rainer 2007: Das Recht auf Rechtfertigung, Frankfurt am Main: Suhrkamp.

Fraser, Nancy 2009: Scales of Justice, New York, NY: Columbia University Press.

Friedman, Michael A./den Besten, Henk/Attaran, Amir 2003: Out-licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries, in: The Lancet 361, 341–344.

Grover, Anand/Lander, Fiona 2012: Das Recht auf Gesundheit in Theorie und Praxis. Ein Rahmenübereinkommen wäre sinnvoll, in: Vereinte Nationen, 60: 5, 214–218.

Hein, Wolfgang/Kohlmorgen, Lars 2008: Global Health Governance: Conflicts on Global Social Rights, in: Global Social Policy 8: 1, 80–108.

Hein, Wolfgang/Moon, Suerie 2013: Informal Norms in Global Governance. Human Rights, Intellectual Property Rules and Access to Medicines, Farnham: Ashgate.

Joseph, Sarah 2003: Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny, in: Human Rights Quarterly 25: 2, 425–452.

Keck, Margaret E./Sikkink, Kathryn 1998: Activists Beyond Borders, Ithaca, NY: Cornell University Press.

Kirton, John J. 2013: G20 Governance for a Globalized World, Farnham: Ashgate.

Klug, Heinz 2008: Law, Politics, and Access to Essential Medicines in Developing Countries, in: Politics & Society 36: 2, 207–246.

Mante, Gabriele/Hanano, Rima 2008: Generika – von Patenten und Lizenzen, http://bit.ly/1silDaM (23.7.2015).

Maskus, Keith E. 2000: Intellectual Property Rights in the Global Economy, Washington, DC: Institute for International Economics.

McCoy, David/Hilson, Margaret 2009: Civil Society, Its Organizations, and Global Health Governance, in: Buse, Kent/Hein, Wolfgang/Drager, Nick (eds.): Making Sense of Global Health Governance. A Policy Perspective, Houndmills: Palgrave Macmillan, 209–231.

McNeil, Donald G. 2001: Yale Pressed to Help Cut Drug Costs in Africa, in: The New York Times, 12.3.2001, http://nyti.ms/1vOj4Cp (23.7.2015).

Muzaka, Valbona 2011: Linkages, Contests and Overlaps in the Global Intellectual Property Rights Regime, in: European Journal of International Relations 17: 4, 755–776.

Nasu, Hitoshi 2010: Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreements, in: Pogge, Thomas/Rimmer, Matthew/Rubenstein, Kim (eds.): Incentives for Global Public Health. Patent Law and Access to Essential Medicines, Cambridge: Cambridge University Press, 77–100.

Novogrodsky, Noah Benjamin 2010: Beyond TRIPS: The Role of Non-state Actors and Access to Essential Medicines, in: Pogge, Thomas/Rimmer, Matthew/Rubenstein, Kim (eds.): Incentives for Global Public Health. Patent Law and Access to Essential Medicines, Cambridge: Cambridge University Press, 343–356.

Peukert, Alexander 2013: Intellectual Property: The Global Spread of a Legal Concept. Faculty of Law Research Paper No. 2/2013, Goethe University, Frankfurt am Main.

Pogge, Thomas/Rimmer, Matthew/Rubenstein, Kim (eds.) 2010: Incentives for Global Public Health. Patent Law and Access to Essential Medicines, Cambridge: Cambridge University Press.

PRIF (Peace Research Institute Frankfurt) 2010: Just Peace Governance (PRIF-Working Paper 1), Frankfurt am Main.

Prusoff, William 2001: The Scientist's Story, in: The New York Times, 19.3.2001, http://nyti.ms/1MK7pdu (12.11.2014).

Quick, Jonathan/Hogerzeil, Hans V./Velásquez, Germán/Rägo, Lembit 2002: Twenty-five Years of Essential Medicines, in: Bulletin of the World Health Organization 80: 11, 913–914.

Risse, Thomas 2000: The Power of Norms versus the Norms of Power. Transnational Civil Society and Human Rights, in: Florini, Ann M. (ed.): The Third Force. The Rise of Transnational Civil Society, Tokyo: Japan Center for International Exchange, 177–209.

Ryan, Michael P. 1998: Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property, Washington, DC: Brookings.

Sandholtz, Wayne /Stiles, Kendall 2008: International Norms and Cycles of Change, Oxford/New York, NY: Oxford University Press.

Schaaber, Jörg 2005: Keine Medikamente für die Armen? Hindernisse auf dem Weg zu einer gerechten Arzneimittelversorgung am Beispiel AIDS, Frankfurt am Main: Mabuse.

Sell, Susan K. 1999: Multinational Corporations as Agents of Change: The Globalization of Intellectual Property Rights, in: Cutler, A. Claire/Haufler, Virginia/Porter, Tony (eds.): Private Authority and International Affairs, Albany, NY: Sunypress, 169–197.

Sell, Susan K. 2003: Private Power, Public Law: The Globalization of Intellectual Property Rights, Cambridge: Cambridge University Press.

Sell, Susan K./Prakash, Aseem 2004: Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights, in: International Studies Quarterly 48: 1, 143–175.

Smyth, Alyna C. 2007: Intellectual Property Rights and the Right to Health: Considering the Case of Access to Medicines, in: Lenk, Christian/Hoppe, Nils/Andorno, Roberto (eds.): Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology, Surrey: Ashgate, 47–72.

So, Anthony D./Sachs, Rachel 2012: Making Intellectual Property Work for Global Health, in: Harvard International Law Journal 53, 106–143.

Sykes, Alan O. 2001: TRIPS, Pharmaceuticals, Developing Countries and the Doha "Solution", Chicago John M. Olin Law and Economics Working Paper Series No. 140, Chicago, IL.

Watson, Alexandra G. 2009*:* International Intellectual Property Rights: Do TRIPS' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?, in: Boston College International and Comparative Law Review, 32: 1, 143–159.

Welch, David 1993: Justice and the Genesis of War, Cambridge: Cambridge University Press.

Wolf, Klaus Dieter 2008: Emerging Patterns of Global Governance: The New Interplay between the State, Business and Civil Society, in: Scherer, Andreas Georg/Palazzo, Guido (eds.): Handbook of Research on Global Corporate Citizenship, Cheltenham: Edward Elgar, 225–248.

Wolf, Klaus Dieter 2011: Unternehmen als Normunternehmer: Global Governance und das Gemeinwohl, in: Baumgart-Ochse, Claudia/Schörnig, Niklas/Wisotzki, Simone/ Wolff, Jonas (eds.): Auf dem Weg zu Just Peace Governance. Beiträge zum Auftakt des neuen Forschungsprogramms der HSFK, 255–274.

Wogart, Jan Peter/Calcagnotto, Gilberto/Hein, Wolfgang/von Soest, Christian 2009: AIDS and Access to Medicines: Brazil, South Africa and Global Health Governance, in: Buse, Kent/Hein, Wolfgang/Drager, Nick (eds.): Making Sense of Global Health Governance. A Policy Perspective, Houndmills: Palgrave Macmillan, 137–163.

Zimmermann, Lisbeth/von Staden, Andreas/Marciniak, Angela/Arndt, Friedrich 2010: Pluralisierung normativer Ordnungen und resultierende Normkonflikte: Lösungsstrategien und ihr Erfolg, Normative Orders Working Paper 06/2010.

Zimmermann, Lisbeth/von Staden, Andreas/Marciniak, Angela/Wallbott, Linda/Arndt, Friedrich 2013*:* Muss Ordnung sein? Zum Umgang mit Konflikten zwischen normativen Ordnungen, in: Zeitschrift für Internationale Beziehungen 20: 1, 35–60.

Source Materials

Brazil 2009: Statement by Brazil at TRIPS Council: Public Health Dimension of TRIPS Agreement, http://bit.ly/1vE0aZX (23.7.2015).

CSN BRICSAM n.d.: Tackling Inequalities in Access to Healthcare: Will the G20 Take up Global Leadership?, http://bit.ly/1qMwFXN (23.7.2015).

European Commission 2014: President Barroso Attends 5th World Health Summit in Berlin, http://bit.ly/1yPugQj (23.7.2015).

HRC 2011*:* Resolution Adopted by the Human Rights Council: The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health in the Context of Development and Access to Medicines, http://bit.ly/12Mqdas (23.7.2015).

India Department of Commerce 2001: India Seeks Flexibility in Interpretation of TRIPS Agreement to Ensure Affordable Access to Medicines and Life Saving Drugs, http://bit.ly/1Oznrbx (23.7.2015).

MSF 2011a: Trips, Trips Plus and Doha, http://bit.ly/1B7XJEg (23.7.2015).

MSF 2011b: G20 Leaders Should Bail out Global Health with a Financial Transaction Tax, www.msfaccess.org/our-work/malnutrition/article/1658 (23.7.2015).

MSF 2014a: Issue Details. Access to Medicines, http://bit.ly/1yywiW1 (23.7.2015).

MSF 2014b*:* MSF Intervention on Access to Medicines at WHO 134th Executive Board Meeting, http://bit.ly/1sitnte (23.7.2015).

UAEM n.d.: Sozial gerechte Lizenzierungsmodelle – was ist das eigentlich?, http://bit.ly/1zOMXSe (23.7.2015).

UN 2000: Press Release SC/6890 Security Council, Adopting 'Historic' Resolution 1308 on HIV AIDS, Calls for Pre-Deployment Testing, Counselling for Peacekeeping Personnel, www.un.org/News/Press/docs/2000/20000717.sc6890.doc.html (23.7.2015).

UNAIDS 1999: Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference Seattle, 30.11.–3.12.1999.

UNDP 2002: Human Development Report 2002. Deepening Democracy in a Fragmented World, http://bit.ly/1vGMTQt (23.7.2015).

UNSC 2000: UN Security Council Resolution 1308 (2000) on the Responsibility of the Security Council in the Maintenance of International Peace and Security: HIV/AIDS and International Peace-keeping Operations, http://bit.ly/1x53J1Q (23.7.2015).

WHO 1981**:** Global Strategy for Health for All by the Year 2000, http://bit.ly/1vGN6D9 (23.7.2015).

WHO 2006: Public Health Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health, http://bit.ly/1uqcIoo (23.7.2015).

WHO News 2006: Bulletin interview: Do Patents Work for Public Health? – Interview with Carlos Correa, in: Bulletin of the World Health Organization 84: 5, 249–351, www.who.int/bulletin/volumes/84/5/who_news.pdf?ua=1 (23.7.2015).

WHS 2013: World Health Summit 2013 – Report, http://bit.ly/1Aju21W (23.7.2015).

WTO 1994: Uruguay Round Agreement: TRIPS. Trade-Related Aspects of Intellectual Property Rights, http://bit.ly/1vTBzWf (23.7.2015).

WTO 2001a: Doha WTO Ministerial 2001: Declaration on the TRIPS Agreement and Public Health, http://bit.ly/IXJa04 (23.7.2015).

WTO 2001b: Doha WTO Ministerial 2001: Ministerial Declaration, http://bit.ly/1Ggl89l (23.7.2015).

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
BMS	Bristol-Myers Squibb (Pharmaceutical Company)
BRICS	Association of Emerging Economies: Brazil, Russia, India, China, South Africa
CSN BRICSAM	Civil Society Networks: Brazil, Russia, India, Indonesia, China, South Africa and Mexico
CSR	Corporate Social Responsibility
DSB	Dispute Settlement Board
EU	European Union
G20	Group of 20 Major Industrialized and Newly Industrializing Countries
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
HRC	Human Rights Council
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPC	Intellectual Property Committee
IPR	Intellectual Property Rights
MSF	Médecins Sans Frontières (Doctors without Borders)
NGO	Non-Governmental Organization
OECD	Organisation for Economic Co-operation and Development
PHC	Primary Health Care
R&D	Research and Development
TKDL	Traditional Knowledge Data Library
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UAEM	Universities Allied for Essential Medicines
UN	United Nations
UNDP	United Nations Development Programme
UNSC	United Nations Security Council
USTR	United States Trade Representative
WIPO	World Intellectual Property Organization
WTO	World Trade Organization