Access to essential medicines: rationality and consensus in the conflict over intellectual property rights

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DISCUSSION PAPER

WISSENSCHAFTSZENTRUM BERLIN
FÜR SOZIALFORSCHUNG

SOCIAL SCIENCE RESEARCH
CENTER BERLIN

SP IV 2003-108

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Rationality and Consensus in the Conflict Over Intellectual Property Rights

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ZITIERWEISE ● CITATION

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Discussion Paper SP IV 2003-108, Wissenschaftszentrum Berlin für Sozialforschung 2003.

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SUMMARY STATEMENT

This report summarizes deliberations over the *Access to Essential Medicines* held during a stakeholder dialogue process launched by the World Business Council for Sustainable Development (WBCSD) in 2001/2002. The dialogue process was designed to explore options of companies to address contested issues of intellectual property in their business strategies. To that end, companies were exposed to the concerns of stakeholders and urged to define responses to these concerns. The project involved major companies and transnational non-governmental organizations as well as renowned experts in the field of intellectual property rights.

This paper briefly sketches the sociological dimensions of the project that relate to issues of rationality and governance. It then describes in detail the setup and the course of the dialogue process. Major steps in the process were provided through comprehensive surveys of argumentation which integrated all points raised in the deliberations and fed them back to the participants. On the basis of such recursive communication the participants constructed "conclusions" that exhibit a considerable amount of argumentative flexibility and represent gains in rationality. However, the consensus reached in the dialogue process remained partial. It stopped short of "governance" in the sense of a binding decision on the contested subject matter.

ZUSAMMENFASSUNG

Dieser Bericht stellt Verlauf und Ergebnisses eines Diskurses zum Thema *Zugang zu wesentlichen Medikamenten* dar, der in den Jahren 2001/2002 im Rahmen eines vom World Business Council for Sustainable Development (WBCSD) initiierten Stakeholder Dialoges durchgeführt wurde. Der Dialog sollte prüfen, welche Optionen Unternehmen haben, den in der Öffentlichkeit geäußerten Kritiken am geltenden Regime des geistigen Eigentums durch Anpassung ihrer Geschäftsstrategien Rechnung zu tragen. Beteiligt waren Vertreter von großen pharmazeutischen Firmen, von transnational operierenden Nichtegierungsorganisationen, sowie Experten des Rechts des geistigen Eigentums.

Der Bericht skizziert in Kürze die soziologischen Dimensionen des Projekts; diese betreffen Aspekte von Rationalität und Governance. Er beschreibt sodann im Detail Anlage und Verlauf des Dialogprozesses. Eine wesentliche Rolle spielten in dem Prozess umfassende Argumentationsbilanzen, in denen die Argumente aller Beteiligten zusammengefasst und an diese zurückgeleitet wurden. Auf der Grundlage solcher rekursiven Kommunikation konstruierten die Beteiligten dann Schlussfolgerungen, die ein erhebliches Maß an argumentativer Flexibilität offenbarten und erkennbar Rationalitätsgewinne verkörperten. Allerdings blieb der im Dialog erreichte Konsens unvollkommen; er lag unterhalb von Governance, wenn man damit eine verbindliche Entscheidung über die umstrittenen Sachfragen meint.

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APPENDICES

1. The Project and the Issue: Globalization of Intellectual Property Rights

In 2001 the World Business Council for Sustainable Development (WBCSD) launched a stakeholder dialogue project to engage transnational pharmaceutical companies and non-governmental organizations in deliberations over the proper role and limits of intellectual property rights (IPRs) in the development of medical biotechnology. The project involved some 50 participants: representatives from companies and NGOs, experts in IPR and a number of observers from international organizations and governmental bodies.[1]

The WBCSD is a coalition of some 150 international companies sharing a commitment to sustainable development.[2] The WBCSD members considered their participation in the dialogue project as part of their broader efforts to find options for business strategies that meet the requirements of social, political, and ethical "sustainability". Accordingly the focus of the project was what the companies themselves might contribute to resolve contested IPR issues, given the economic criteria under which they operate.

Conflicts over IPRs have intensified in global economic and political relations, and particularly in the North-South context, since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into force in 1995. The Trips Agreement requires all member states of the World Trade Organization (WTO) to introduce minimum standards for the protection of intellectual property rights. The perspective that IPRs would have to be extended to and enforced in all countries raised great concerns that the developing part of the world might be further put at a disadvantage. IPR standards approximate to the relatively high level of IPR protection prevailing in industrialized countries might jeopardize the prospects of developing countries to benefit from the transition of modern societies to "knowledge societies" in which information becomes a crucial source of productivity and prosperity. Kofi Annan, in his 2000 Millennium Report to the United Nations, emphasized the prospects of the information economy for the developing countries:

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1 A complete list of the participants is included in the final report of the project, see World Business Council for Sustainable Development (ed.), Intellectual Property Rights in Biotechnology and Healthcare — Results of a Stakeholder Dialogue, Conches-Geneva, Switzerland: WBCSD, 2003, pp. 31-32. In electronic form, available from <http://www.wbcsd.org>.

2 See <http://www.wbcsd.org>.

> "… the capital that matters most in the digital revolution increasingly is intellectual capital. … The shift from hardware to software as the cutting edge of industry helps to overcome what has been a major impediment to development — the shortage of finance. … Clearly the requisite intellectual capital is not universally available, but it is far more widespread in the developing world and in the transition economies than is finance capital. … We in the policy-making world need to understand better how the economics of information differs from the economics of inherently scarce physical goods — and use it to advance our policy goals." (2000, pp. 33-34).

Comprehensive and stringent regimes of IPR protection appear to be at odds with high hopes that the transition to an information economy will propel the development of poor countries. Such protection makes information that is "intellectually" available, which could, in principle, be shared without being consumed and multiplied at negligible costs, "economically" unavailable to a certain extent. Patents, in particular, withdraw information from the public domain to the extent that they reserve the right to exploit it commercially for the patent holder.

On the other hand, IPRs are essentially compromise constructions. They are designed not only to reward individual inventors and provide returns on private investment in research and development, they are also intended to promote the creation of knowledge and technological innovation as social goals. Hence, IPR regimes imply safeguards, such as compulsory licensing schemes or public use exemptions, to guarantee the social utility of IP-protected knowledge. The TRIPS Agreement, too, refers conspicuously to the public interest and gives the contracting states some flexibility to design IPR regimes in such a way that national requirements of economic development, health policy, and public morality can be taken into account. Nevertheless, the obligation to impose "comparable" standards of IP protection restricts the flexibility of developing countries. And in the short run, at least, the developed countries of the North (and highly developed industries in newly industrialized countries), which hold the vast majority of patents issued worldwide, will benefit most from the globalization of IPRs.

It is therefore hardly surprising that the enforcement of the TRIPS Agreement has exacerbated the North-South conflict. Existing inequities have tended to intensify, and this runs counter to the declared political will in both South *and* North. The perception of injustice is further fueled by the fact that the now developed countries, in their own economic histories, have dealt with IPRs in a very opportunistic way, by recognizing, interpreting, or applying such rights according to the impera-

tives of their national interests. For example, many countries refused either to grant or recognize patents on drugs in order to build a national pharmaceuticals industry by enabling it to develop manufacturing capacities and acquire know-how by copying medicines. With the globalization of IPRs under the TRIPS Agreement, developing countries no longer have similar options.

The perceived injustice of the TRIPS Agreement and the "widening of the North-South gap" play a major role in the public debates over IPRs. They also constituted the background for the deliberations in the stakeholder dialogue project. The topic that crystallized the issues most conspicuously was "*Access to Essential Medicines*". To ensure that patients have access to affordable drugs is no doubt a paramount goal of public policy. In view of the Declaration of Universal Human Rights, which includes a right to medical care, one may even say that governments have a duty to provide such access. To deny patent protection on drugs may be seen as means to discharge that duty. In fact, practically no developing country has until recently granted patents on drugs. It is precisely this situation that the TRIPS Agreement is intended to change.

This report describes and summarizes the deliberations held in the in the stakeholder dialogue on *Access to Essential Medicines*.[3] We will briefly introduce some theoretical sociological assumptions underlying the staging and design of the dialogue process (section 2). These assumptions pertain to dialogue or discourse with encompassing participation as a reliable device to contribute to "governance" in the sense of binding decision making, on the one hand, and on argumentation as a means to promote "rationality" or as an effective medium of communication, on the other hand. We cannot give a full-fledged sociological account of the dialogue process in this report. But we want the reader to understand what motivated the WZB team of social scientists to become involved in the organization and analysis of the project. The setup and the procedural rules of the dialogue process are presented section 3. The main purpose of the report is to describe in detail the communication process through which the participants proceeded during the course of the project (section 4). Major steps in this process were provided through comprehensive surveys of argumentation which integrated all points raised in the deliberations and fed them back to the participants. On the

3 The results of the working groups on *Protection of Traditional Knowledge* and *Access to Human Genetic Resources* were published earlier in this series of discussion papers; see van den Daele/Döbert/Seiler (2003), WZB Discussion Papers SP IV 2003-102 and SP IV 2003-107.

basis of such recursive communication the participants constructed the "conclusions" that were integrated in the final report of the project (section 5). These conclusions exhibit a considerable amount of argumentative flexibility and represent gains in rationality. However, the consensus reached in the dialogue process remained partial and stopped short of "governance" in the sense of a binding decision on the contested subject matter (section 6).

2. Theoretical Assumptions

2.1 Global Governance and Civil Society Participation

Capacity for governance in the sense of providing collectively binding decisions that regulate social conflict is a scarce resource. Even at the domestic level, trust in the regulatory competence of the nation state and the legitimacy of its regulatory efforts have been called into question in recent decades. Buzzwords like deregulation and self-regulation, more participation, democratization, and the involvement of civil-society players are indicative in this respect.[4] Government authorities have privileged rights of intervention and can act as arbiters (third parties) vis-à-vis conflicting societal forces. If this authority is not sufficient to ensure efficient and legitimate forms of societal control and if, for that reason, alternative mechanisms of governance have to be set up within the nation state, how much more urgently might such arrangements be needed in developing international institutions and regimes? For in this arena of conflict and negotiation the third party is conspicuously absent. As a rule, intergovernmental, equal partners with veto power (individual governments) have to reach comprehensive agreement. Normally, this requires extraordinarily protracted negotiation. At this global level it therefore seems especially plausible to try corporatist strategies, under which non-governmental players from industry and the informal civil society area (NGOs) assume a kind of political mandate to give new impetus and shape to an emerging global order. This is the context for the discourse project we are discussing.

"New impetus and shape" can be imparted only if the players/organizations involved have scope to act and are manifestly willing to use it. One of the reasons why the WBCSD was founded was to sort out such scope for action. The concept of an embedded economy is behind this endeavor. Although firms have to bow to

4 For a recent discussion of types of governance, see Kooiman (2003).

the imperatives of a competitive market economy, markets are not merely economic arrangements linking profit-maximizing players. They are also communities where citizens meet who are guided by social, political, and cultural values over and above purely economic objectives. The extent to which these interests can be taken into account under the pressure of competition in a global economy may vary from case to case, and may also be a controversial issue. But there is wide agreement that the differentiation of the economy from politics, religion, and culture ought not and need not go so far as to leave no room for the ethical dimension of economic activities.

In the case of intellectual property rights, companies must seek

> "to devise business strategies and use legal rights in such a way that they strike a fair balance between the need to protect intellectual property and maximize return on investment, on the one hand, and the need to provide access to new knowledge and distribute the benefits of innovation to the society — especially the developing countries — on the other".[5]

As indicated, intellectual property rights are supposed to bring private interests (incentives, rewards for inventors) into balance with public interests (research and innovation, economic growth and prosperity). If the economy is to be "embedded," the balance will have to be "right", and this amounts to saying that the competing functional imperatives implied in IPRs have to relativize one another.

If industry has to relativize the "profit" goal, the other side, the NGO sector, specializing on the public interest side of IPRs, must at least attempt to suspend one of its functional imperatives, namely orientation to *mobilization* and the concomitant reduction of complex situations to one-dimensional slogans, scandalization, and blanket moral condemnation. For this reason the project proposal stated:

> "This implies … that non-governmental organizations are able and willing to engage in limited taskforce-like cooperation in addition to and beyond strategies of protest designed to raise public awareness or encourage public resistance." (p. 3)

5 Quote from the project proposal: "Issues of Intellectual Property Rights in Biotechnology and Information Technology — Framework for a Stakeholder Dialogue Proposed by the World Business Council for Sustainable Development," March 2001, p. 4 (downloadable — see <http://www.wz-berlin.de/ipr-dialogue/framework.pdf>).

Not only were participants in the planned dialogue process aware of this demand for considerateness and flexibility, they had postulated it and expected to be able to cope with it — at the latest when deciding to take part. However, these expectations define no more than minimum conditions for a successful process of understanding or negotiation, because what concessions to the other side are finally to be made under the pressure of argument cannot be known at the beginning of the dialogue process. Discourses, as Piaget once put it, are "methods that lead 'God knows where'" (Piaget, 1928, p. 237). And this openness implies a *discourse risk*: In entering into a discourse, one runs the risk of reaching a point where one's own position is thoroughly undermined (cf. van den Daele/Döbert, 1995). This risk is often underestimated and it is almost necessarily underestimated. After all, a person who decides to participate in a discourse *must* consider his or her own position well-founded and legitimate, and is therefore likely to underestimate the strength of opposing positions.

But what happens if the discourse turns against interlocutors and threatens to dismantle crucial positions? "Normal" regulatory agencies (governments) often fail to reach a solution in such cases. Can one expect that alternative conflict resolution procedures such as a stakeholder dialogue will fare any better in this respect — not only occasionally but, due to their mode of operation, systematically, predictably, and replicably? We do not believe that this is the case. It is not by chance that attempts to ease the burden of courts through arbitration proceedings have largely failed. The reason is that win-win solutions tend to be the exception in conflicts. Genuine compromise, on the other hand, produces *action costs*: the parties have to renounce something. In a representative setting *participation costs* must be added: participants who are willing to impose action costs on themselves are bound to confront criticism from their clientele/organization.[6] Therefore, consensus will be not the likely, but the unlikely result of a dialogue process.

The argumentative outcome of the process may nevertheless be evident to observers. Action and participation costs that could deter participants from further cooperation may only become clear at the end of the discourse when the final balance of the argumentation begins to emerge. Until then the process continues unaffected by the fear of costs that might be implied in the results of argumenta-

6 See van den Daele/Döbert (1995) and Döbert (1996b) for an analysis of the various "costs" implied in discourse participation.

tion. In the end, the participants may have to declare dissent or discontinue participation, defying the argumentative pressure they have helped to build up, and which proves them wrong.

The debate over the TRIPS Agreement may, on the other hand, not be a case where solutions reached through argumentation put excessive costs on one side. Since international agreements, as we have indicated, are brought about only in unanimity (or in the absence of a veto from even a single signatory country), they can scarcely be other than compromise constructions. This being the case, it would be astonishing if there were no interpretations of the agreement that distribute the costs of conflict resolution more evenly and permit the conflict parties to come together.

Given these ambivalent perspectives and expectations, the goals of the pending dialogue process were cautiously formulated and kept somewhat ambiguous in the project proposal:

> "In practical terms, the objectives of the project must be modest. Basically, it will be up to the participants to decide what they want to achieve and what they consider as success or failure of their efforts. One clear aim is to produce an input into the RIO + 10 conference in July 2002, to be presented in a common session by companies and stakeholders at that conference. The input could be both substantive and procedural. The participants should perhaps try to clarify problems and policy options for selected issues of IPR, and assess cases in which new solutions have been tried. If they find common ground, they might recommend revisions of or amendments to existing IP regimes. This would include examples of what companies could do, what governments should do, and what the possible role of civil society actors (NGOs) might be. Where the participants disagree, they might at least try to define an agenda for future discussions and indicate whether they think that new forums are needed to deal with the open questions." (pp. 4-5)

Only the actual course taken by the stakeholder dialogue process can show how much governance civil society can generate through such arrangements. The formulations used in the project proposals allowed participants to define dissent, too, as a success of their efforts, to produce only procedural proposals, and to postulate further forums. This would clearly have been no more than a modest contribution to finding new forms of governance, because the process would stop short of implementable arrangements. "Input into the Rio + 10 conference" would have to be somewhat more ambitious, possibly including "revisions of or amendments to existing IP regimes." If such proposals could be agreed on, there

would be greater justification in describing the dialogue process as a contribution to global governance.

2.2 The Power of Argumentation: Rationality and Selection

The stakeholder dialogue process involved the participants in a discourse, that proceeded through extended exchanges of arguments over the conflicted issues. Those who invest time and effort in such a discourse, obviously, share the assumption that *arguments matter*. They presuppose that reasons must be given for claims and positions, that such reasons can be valid or invalid, and, hence, an assessment is possible whether the claims and positions are well-founded or unfounded.

While these presuppositions may have been uncontested among the participants of our stakeholder dialogue they are fundamentally called into doubt by some variants of constructivist philosophy and sociology. We cannot discuss these variants here in depth. But we will elaborate on them to the extent necessary to understand why we, nevertheless, feel justified to defend the position that *arguments matter* — both with respect to descriptive and to normative judgments.

At the center of the debate is the role of "truth" in social processes. Max Weber once remarked that the truth of interpretations can be a factor of the highest causal relevance, because the success or failure of a course of action often depends on the truth of the definition of a situation. It is difficult to imagine how societies in general, let alone modern societies dependent on permanent technical dynamism, could survive if they were unable to distinguish between truth and falsehood, sense and nonsense, illusion and reality. Implicitly or explicitly, policy decisions in the technology field make numerous assumptions about how technologies work, about their physical, biological, economic, and social impacts. One reason why technology assessment has been institutionalized is to permit this complexity to be at least partly mastered. Social scientists cannot analyze technology policy controversies without assessing the knowledge claims made in such controversies. More generally, they cannot make statements about the future of a society without assessing the knowledge held in the society. Such assessment implies more than just registering from an observer's perspective which claims various social actors put forward. The analyst must grapple with the validity of these claims. For that matter he/she must explore the ocean of arguments dis-

played in the field of observation and try to reach what John Rawls called a well-considered personal judgment in reflective equilibrium and sort out which claims make sense and which not.[7]

Naturally, such efforts only make sense if a distinction can indeed be drawn between sense and nonsense. However, this possibility is fundamentally denied by constructivist epistemologies that denounce ideas of objectivity or truth as "naïve", since all knowledge must be considered as "constructed" or "socially constructed", depending on the state of individual or social consciousness as modified by incompatible conceptions of the world/cosmologies. Such notions have been inspired, for instance, by the writings of von Foerster (1981), Maturana (1982), von Glasersfeld (1987), Luhmann (1984) and Douglas et al. (Douglas/Wildavsky, 1982) They inflate the undeniable empirical fact that social actors differ in their views and frames of interpretation into the epistemological and cosmological premise that such differences are irreducible and that the actors live in separated worlds. Another (by no means new) premise of the constructivist credo is that the mind can only have to do with its own states. The distinction between internal and external, consciousness or reality must be inferential, and thus an "internal" conclusion. The premise may go unchallenged, but it needs to be explained how the mind can "escape" from its reflexive loops and circularities when people function in shifting environments.[8] In their present state these epistemologies tend to end up with relativism; they preclude any understanding of the objectivity and intersubjectivity of cognition, and they do not stand the test of applicability to themselves.

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7 The public media typically operate without such a sorting mechanism. As a rule, journalists have neither the time nor the forum for an adequate assessment of the arguments raised in political controversies. So they are either forced to rally behind the slogans of one party or (if they seek a balanced presentation) to juxtapose the arguments of all sides without any selection in terms of well-founded/unfounded. In such unselective argumentation games, sense and nonsense have an equal "chance of surviving", and this gives rise to endless circulation of "pro" and "con" in different forums.

8 If reality can only be accessed through inferences the question, is how cogent such inferences are. One touchstone of the notion of the brain as a closed system is probably perception. We construct "perception machines" and call them perception machines only if they satisfy certain requirements, the most important of which perhaps is the capacity of the machine to adapt its moment-to-moment shifting behavior to its environment. As the brain of the machine is held constant, the behavioral shifts *must* be attributed to its environment. Von Foerster's statement — "The environment contains no information. The environment is as it is." (1981, p. 270) — is misleading. When we talk of perception, we imply information from the environment; otherwise, there is no perception.

The solution is already implied in Plato's cave parable which suggests that we are inescapably imprisoned within the cave of our cognitive apparatus, but we do see the shadows of objects "out there". The subjectivity of consciousness is thus anchored in an objective world.

We cannot not go into the details of constructivist epistemologies. We wish only to point out that the premises for these epistemologies, the diversity of ideational content and its dependence on consciousness, have long been known and taken as a challenge for notions of objectivity and truth — not as a reason to do away with them. Interpretations that amount to arbitrariness and solipsism, and do not stand the test of self-reflexivity are, as a rule, relegated from this philosophical debate.

In particular, the cognitivist psychologist Jean Piaget, to whom we owe the tenet "all knowledge is *constructed*" and who is therefore often cited, cannot be claimed by any of variant of relativist-solipsistic constructivism (cf. Sutter, 1999). Although Piaget rejected Kant's answer to the question of how our knowledge can "fit" reality (Kant's answer being: through the a priori categories of human understanding), the question was fundamental to all of his thought. And so he provided a new answer to the problem of rationality of action and objectivity of knowledge: our ideas and actions "fit" reality because in the course of development they are *made to fit*. This is in principle the answer given by evolutionary epistemology, too. Hence the typical developmental changes identified by Piaget can and do serve as a model for explicating rationality and objectivity in such a way that not all constructions have to be accepted as "equally valid".

Let us take a look at a classical Piaget experiment and at the changes in "constructions" that can be observed. The task is to predict the behavior of a balance beam (tilting to which side?) on which a varying number of weight units have been placed at discrete positions (see Miller, 1986). The formula "units of distance times units of weight" permits a precise prediction of the beam tilt. The youngest children pay attention either only to the weights or only to the distance, and naturally often predict wrongly. Somewhat older children know that weight and distance are important and try to combine the two parameters: sometimes weight is the crucial factor, sometimes distance (differentiation). Finally the exact formula (units of weight times units of distance) is construed and the tilt of the beam becomes perfectly predictable. In radical/social constructivist terms, the findings would have to be described as follows: Some construe in a "weight frame", others in a "distance frame," and still others use a "sometimes-sometimes" construction, while a last group uses a multiplication schema. All these constructions occur empirically and have to be respected as equally valid constructions of reality or world views. The children who actually do the construction see it quite differently: For once they have acquired the multiplication formula they reject other constructions as deficient.

We would like to be able to join them and insist that one can check whether arguments are founded or unfounded, and, hence, distinguish (rationality from rationalization) in societal discourses. Now it must, of course, be immediately admitted that the problems that arise in major societal and technology-policy controversies cannot, without further ado, be compared with the determinist behavior of a balance beam. But "without further ado" does not mean "not at all." To give an example from a comparable discourse project that dealt with the risks of genetically engineered herbicide resistant crops. One risk assumption is that excessive herbicide dosages will be applied because crop plants are resistant. This risk perception refers to just one dimension, to the technology side of herbicide-resistant crops. It reflects, if you wish, a *technological* construction or cosmology. The view that denies the risk applies an *economic* construction or cosmology: since herbicides cost money they will be used sparingly and there is therefore no risk of over-dosage. In the discourse, both views were integrated: Agriculture is technology under economic constraints. The argumentation therefore developed towards a conclusion along the lines: if herbicides are not extremely cheap the technical possibilities of over-dosage are not exploited for economic reasons. Thus, economics times technology equals actual herbicide application. This is the fully comprehended balance beam with distance times weight, and this construction is similarly superior to one-dimensional constructions.[9]

Such transition from one-dimensional to multi-dimensional analysis is often provoked in discourse because the dimension ignored by one group is introduced into the debate by other groups focusing on complementary dimensions As one would expect, comparable effects were apparent in the discussion on access to essential medicines. To take just one example: patent protection is essentially price protection. If only the legal possibilities are considered, globalizing patent protection for medicines is therefore tantamount to increasing prices, making drugs inaccessible to poor countries. This naturally provokes normative and moral criticism of the TRIPS Agreement. This moral criticism presupposes the empirical fact of material price increases. But an empirical increase in prices cannot be evaluated without looking at another legal dimension of the problem — the rights of governments as opposed to patent holders under patent law (special conditions) — and at the economic dimension of de facto price fixing by producers (differen-

9 See van den Daele/Pühler/Sukopp, 1996, pp. 123-140.

tial pricing, i.e., discounts for countries with low purchasing power). Statements about access to essential medicines that take account of only one of these dimensions do not correspond to the fully comprehended balance beam and, in this sense, cannot be regarded as "well-founded". They ignore part of the system's actual mode of operation, and, given this state of affairs, whoever insists that the views of all parties are equally rational world views or constructions in this context claims that the correct perception of a problem is just as rational as its simplification or suppression.

Gains in rationality in Piaget's sense may be possible with respect to descriptive constructions of reality. However, what is true of description need not necessarily be true of normative aspects. In view of the plurality of values and norms, it seems easy to be convinced that argumentation in this area must remain ineffective— not least of all because the methods of demonstration and persuasion that the descriptive sciences apply do not operate in the normative field. Social constructivists from the so-called "cultural theory"[10] assume that people become committed to "cosmologies" and values in accordance with their position in the social structure. Such cosmologies are incompatible and collide in irreconcilable conflict., These assumptions do have a degree of plausibility in the field of value conflicts. Actually, two of the types described by the theory — egalitarians and hierarchists — seem to be identifiable in the discussions on access to essential medicines. "Egalitarians", exemplified by activists of social movements, invoke the universal, equal, and indivisible human right of access to medical care, which is to be applied without regard to international regimes like the TRIPS Agreement. "Hierarchists", exemplified by administrators and regulators, insist, in contrast, on the prevailing property system, admitting only adaptive modifications to be implemented by experts.

There can be no doubt that argumentation on normative issues operates in a gray area, so to speak, because people and groups can to a certain extent choose their life plans and values. But arguing with absolutely no prospect of success is highly unlikely. If we assume that societal values and norms are at least partly linked with basic societal functions, the non-performance of which would in the long run prevent society from reproducing, then each value must stand the test whether the manner in which it is realized is compatible with the realization of the other fundamental values. One is thus automatically operating in a multi-dimensional

10 See Thompson, Ellis, Wildavsky 1990.

value space, and every "construction" or "cosmology" that relies *exclusively* on one value finds itself under argumentative pressure. "Health," the value that egalitarians dramatize in the case above, must, as the debates on intellectual property rights have shown, be brought together with, for example, property and legal reliability, with justice, with gains in scientific knowledge, with technical innovation, economic development, and with the public interest commitments of government authorities. A "well-founded" bundle of legal and non-legal strategies most apt to achieve this "bringing together" must therefore be the aim of the discourse. This would provide at least minimum criteria for rationality or, as the case may be, rationality deficiencies. What is at issue can, however, be ascertained only by getting to the bottom of a societal argumentative constellation, by compiling all relevant arguments and leading them towards conclusions.

Arguments over normative issues may not reach a result and it may prove impossible to draw conclusions because of insufficient knowledge about legal consequences, economic conditions, or technical background, or because the interpretation of the legal situation itself is contentious. Gray areas and uncertainty allow for a variety of possible "constructions". It is, however, unlikely that normative controversies end up as totally undecidable. If we assume that from the multitude of arguments that relate to a controversy finally, say, ten arguments can be extracted that are not disputed by any party, then each of these ten arguments will act as a filter through which every possible interpretation of the given issue has to pass to be considered acceptable. If ten such "filters" exist, it is unlikely that several equal, similarly rational constructions will "survive" the selection process.

Argumentation in a discourse includes phases of variation and selection. The participants will begin with adding and compiling points and views to contested matter, but they will then proceed to check evidence, work on inconsistencies, and integrate arguments. Radical constructivists who claim that all "constructions" of people and groups are equally valid because they are socially relative and irreconcilable tend to draw their evidence entirely from the variation phase of controversies. In this phase, there can by definition be no well-considered judgment because argument and counterargument, sense and nonsense are still competing without distinction and assessment by the participants. The true meaning of contests over perception and of values will only be understandable, if sociology pays equal attention to the process of selection. Such analysis is bound to rehabilitate notions and criteria of rationality that are valid beyond groups and individuals. The materi-

als presented in this report allow the reader to check what the discourse of the stakeholder dialogue achieved in this respect.[11]

3. Procedural Setting and Course of the Dialogue Process

It is clear that a discourse can only produce an accepted outcome if it complies with accepted rules of procedural fairness. Unfair processes produce unfair outcomes, which will be rejected and not included in effective regulatory arrangements. If the discourse risk runs against a particular party and argumentative defeat is imminent, the party will evade conclusions on substantive matter with formal grounds if the procedures are flawed — for instance, if the participation is unbalanced, if the proceedings lack transparency, or the steering of the process is biased. This section describes in detail how the stakeholder dialogue took shape and proceeded. The WZB team was mandated with the task to organize the process. The obvious task was to observe the norms of discourse and all standards of procedural justice. Parties are supposed to cope under such conditions with outcomes of the process that may not meet their expectations (Lind/Tylor 1988). On the other hand, no amount of procedural care constitutes a guarantee that parties will accept a loss of crucial arguments and not then decry the procedure as unfair. In this case, observers will be able to judge whether such criticism is a rational argument or a rationalization.[12]

Under real conditions no discourse can ever be ideal. Time, for instance, is always too short to scrutinize all the arguments raised to the very end. Therefore, it is hard to see how a dialogue process like the one organized here by the WBCSD and the WZB can be immune to procedural criticism. This potential trap can be avoided only if as much *process and outcome control* as possible is shifted to the participants themselves. Ultimately it should be the participants who decide on contents (What is to be discussed?) and the social aspects (Who is to take part?) of the discourse. The participants should define the limits of the process and agree on procedure (process control). Similarly, at the end of discussions, they should seek to formulate conclusions that reflect possible consensus, remaining dissent, and future discussion needs (outcome control). Complete transparency must be en-

11 For an analysis of the stakeholder dialogue process along these lines, see van den Daele/Döbert (2004).

12 In the discourse project (participatory technology assessment) on herbicide-resistant crops mentioned earlier rationalization processes (allegations of procedural flaws) set in to cover up and "explain away" argumentative defeats (cf. Döbert, 1996, p. 2).

sured throughout, as well as the right to demand modifications to proceedings and decisions at all times. Under such conditions, all the pragmatically necessary strictures on discourse idealization are the responsibility of the participants themselves, so that almost all criticism of the process turns, in effect, into self-criticism.

These terms of discourse were offered to participants with the invitation to take part in the dialogue. To ensure that the wishes and demands of those invited could be met to the fullest possible extent from the very start, an initial survey was conducted on what expectations there were with respect to a successful or acceptable discourse.

Three main points emerged from the survey:

(1) The process should be socially and objectively representative (all important groups should be represented and all relevant arguments should be taken into account).

(2) On this basis, it should provide more than a reiteration of known positions; argumentative mobility and a readiness to accept compromises were demanded.

(3) And, finally, it should be ensured that the final report take due account of and give adequate space to dissenting minority opinions.

Points 1 and 2 can be combined in the postulate that the discourse should ultimately produce a well-considered judgment in reflective equilibrium in the sense of Rawls (1971) and as envisaged in the theory underlying the project (see section 2.2 above). The philosophical construct of comprehensive rationality thus finds colloquial expression and constitutes the intuitive aspiration of the lay philosopher, too.

The participants entered the discourse on the premise that a distinction can be drawn between reasonable and unreasonable judgments. Despite the plurality of opinions and value judgments and the semi-institutional relativism that prevail in modern society they committed themselves to rely on the force of the *good* argument that persuades *everyone*. Such commitment implies that argumentative flexibility is considered a realistic option; it is ascribed to oneself and to the others in the discourse. The test for the force of good arguments and for argumentative flexibility comes, however, only when arguments and counterarguments are synthesized

into *conclusions*. Thus, by implication, the participants were aware, that they *must* try to reach conclusions.[13]

In real discourses approximations to the ideal rules of discourse must suffice. In addition, there are pragmatic restrictions with which the participants must agree. The most important restrictions in the stakeholder dialogue project were the setting up of an executive body — the Steering Committee — the forms of participation, and the role of the WZB team.

With some 50 participants, it is neither always possible nor necessary to ponder every procedural detail in the full circle. There are good but never optimum dates for conferences. Non-scheduled opportunities for face-to-face meetings present themselves and should be taken.[14] Care must be taken that discussions proceed in a more or less orderly fashion and that sights are held steady on a possible conference outcome. As decisions must constantly be made, a Steering Committee — with a balanced membership — was proposed and confirmed by participants at the opening conference of the dialogue without notable conflict. One of its main tasks was to prepare a tentative final report. This was to be done in a fiduciary role and in constant consultation with participants. The invitation to the dialogue had this to say about the role of the Steering Committee: "… it should not be its role to define the results of the project and draw conclusions in its name" (project proposal, p. 11). Whatever rules are followed, the setting up of an executive body always means differential opportunities to exert influence and a certain extent of delegation — unavoidable, and therefore legitimated and agreed limitations to idealized discourse.[15]

The next restriction concerned the form of participation. Discussion among physically present participants cannot be fully replaced by any form of indirect

13 In the project technology assessment of herbicide-resistant crops, a proposal was put forward to avoid conclusions and leave the opposing positions as they stand. Not only does this proposal contradict the very idea of a discourse, it also suggests that the authors have little in the force of their own substantive arguments. In the stakeholder dialogue, it was common understanding among the participants that conclusions should be aimed at.

14 Thus the WZB team used the 2001 meeting of a CBD ad hoc group in Bonn to organize a special session of some members the working on Protection of Traditional Knowledge, although such meeting had not been agreed upon by all participants.

15 Members of the Steering Committee were: Carlos Correa, University of Buenos Aires; Thomas Cueni, Roche Pharmaceuticals; Wolfgang van den Daele, Social Science Research Center Berlin; Johnson A. Ekpere, University of Ibadan, Nigeria; Maurice Iwu, Bioresources Development and Conservation Programme, Burkina Faso; Achim Seiler, Social Science Research Center Berlin; Patricia Solaro, Aventis; Ross Stevens, World Business Council for Sustainable Development.

communication. Divergent reactions to theses, leaving uncomfortable arguments out of account, and rationalization of all sorts can always be directly attacked by the opposing side before an audience of observers — uninvolved participants — whose presence exerts additional "pressure." But discussion rounds would need an enormous amount of time to compile, sort, and conclusively process all relevant arguments of the IPR issues under examination. For most participants, processes like the present one come on top of their professional commitments — as a rule they cannot simply abandon their other duties. Time not money is the really scarce resource of "participation." There is therefore absolutely no hope — especially for a body with international membership — of "extorting" the conference time participants need for the careful consideration of so complex a matter as intellectual property rights. Three forms of participation were therefore proposed:

(1) participation in an introductory conference in Montreux (May 2001) and a final conference in London (February 2002),

(2) the specification of relevant literature paradigmatically incorporating the position taken, and

(3) participation in a permanent "electronic discourse" in the form of reactions (E-mail) to circulars in which the WZB team summarized the status of discussion at a given point in time.

The combination of these forms of participation proved extraordinarily helpful. For without the combination it would have proved impossible to prepare argumentation balances on the controversies at issue that could do justice to participants' demand to gather all arguments without exception.[16]

Furthermore, the outcome of the conference — the conclusions — would have had to be greatly simplified without the electronic discourse. For in the course of exchanging E-mails, partial areas of consensus emerged which — for reasons of time and owing to the absence of important participants — could not be dealt with at the final conference in London. In the final report, all areas of consensus were summarized and, with permanent feedback from participants, put into as acceptable a form as possible.

16 For example, the important contributions by the NGO, Oxfam, to the overall results are based throughout on the literature they supplied and on E-mails.

Finally, the role of the WZB team can be interpreted as a restriction on idealized discourse, since it contained an element of delegation: preparatory information management for the project had to be delegated to the WZB because controversies of this sort generate masses of arguments in a very brief space of time (up to 100 pro and contra arguments) which without professional support would overtax the data processing capacity of the human mind (H. A. Simon 1969). On this point the project proposal states:

> "The WZB will document and analyze ongoing discussions in and contributions to the project. Documentation and analysis will serve to explicate and relate arguments put forward by the group, to determine subsequent working steps, identify open questions and tasks, and stimulate and organize feedback among participants." (project proposal, p. 12)

The resulting material on "access to essential medicines" is to be presented below.

As far as the form of this documentation is concerned, the WZB team proposed that the points raised by the participants and the documents consulted be condensed into "argumentation trees" which dissect contested issues into sub-issues, to each of which blocks of pro and contra arguments are assigned. These blocks can be worked through in sequence and only their outputs (sub-conclusions) have to be kept in mind at the next level of inference. Argumentation trees appear to reflect the way the human mind operates; great complexity has to be dealt with sequentially. The argumentation trees were supposed to produce the concentration and clarity the participants needed to reach a verifiable judgment in reflective equilibrium.

An argumentation tree containing up to 100 arguments still makes great demands on the reader, and can even have a deterrent effect. There were regular complaints about information overload. The participants — each of them a specialist for only a sub-block of arguments — were probably unaware of the amount of information they would get when they demanded a compilation of *all* relevant arguments on *all* sub-issues. To counter these complaints, "condensed versions" of all argumentation surveys were prepared, so that the material to be worked through at the final conference was reduced to about 30 pages — still a great deal, perhaps too much to permit orderly conclusions to be drawn at a conference without additional structuring. Therefore, "rapporteurs" were appointed for the three Working Groups from among the participants, whose task it was to prepare the transition to

conclusions by extracting possible consensus lines from the documents on the argumentation in the dialogue process.

The following scheme summarizes the steps taken in the course of the dialogue process. The documents relating to these steps and the evolution towards the final conclusions are presented in subsequent sections. The long versions of the argumentation trees can be found in the appendix.

STEPS IN THE IPR STAKEHOLDER DIALOGUE PROCESS

March 2001	Framework for a Stakeholder Dialogue Proposed by the WBCSD
May 2001	First Conference (in Montreux, Switzerland)
Up to February 2002	Circulars to the participants (surveys of arguments from the First Conference and related documents)
	Responses to the circulars
	Synthesis of responses to the circulars and points to consider for conclusions
	Steps towards conclusions (proposals to be considered for the final report at the Second Conference)
February 2002	Second Conference (in London, United Kingdom)
Up to July 2002	Proposals for the Final Report based on the proceedings of the London conference
	Responses to the proposals, revisions, additions, dissenting opinions
July 2002	Final Report of the Dialogue Process to the WBCSD

4. Access to Essential Medicines: Circulars to the Participants

4.1 Introduction

Among the tasks of the initial conference of the project (Montreux) was to settle the final circle of participants. It was agreed to include about 50 representatives of public authorities, companies, and non-governmental organizations from Europe,

North and South America, India, and Africa who were known to be acquainted with (aspects of) the subject matter at issue. This prior knowledge of participants made it possible to keep the circulars updating the status of argumentation relatively brief. The relevant international agreements, definitions, and safeguards, the "functioning" of intellectual property rights, could be taken as known in outline. Had the circle of readers been broader, this would not have been necessarily the case. But, of course, the actual proceedings of the project are based on this more or less implicit knowledge of participants and cannot be understood without it. It will therefore be useful to start by sketching the overall architecture of the TRIPS Agreement and briefly explaining less obvious technical terms. The focus is on the implications of the TRIPS provision that national legislation must provide patent protection for medicines.

In essence, patents for medicines, like all patents, confer on the holder the right to prevent third parties from making, using, offering for sale, selling or importing a product and/or using a process. This time-limited monopoly allows for higher prices and increased profits which can be used in return to recoup R & D and investment costs, thus accommodating the interests of innovators/inventors. Higher prices imply, of course, a higher hurdle for access to drugs, a hurdle that can prove too high, especially for patients in developing countries without a functioning public health system. But patent law generally tries to establish a compromise between private and public interests, and the TRIPS Agreement was also designed as a compromise construction in which the protection of private interests is expected to be compatible with and, in fact, supportive of public interests (including moral values and health policy objectives). To a certain extent it is assumed that public interests would be served more or less automatically. Thus, patents reward innovation and encourage innovative activities; and this should expedite economic growth and scientific progress (in societies that take part in the patent system). Other public interests can be taken into account through mechanisms explicitly built into patent law to constrain and mitigate the monopolistic effects of IPRs and prevent their abuse.

These mechanisms have been dealt with in the deliberations of the stakeholder dialogue under the heading of "safeguards". The most important (and most controversial) of these safeguards is the option of the state to grant compulsory licenses for the use of patents. In the context of health policies this may mean that generics can be manufactured without the consent of the patent holder. The TRIPS agreement defines several conditions under which compulsory licenses can

be granted; among them: when there is a health emergency (e.g., an epidemic) and when drugs are to be distributed freely (on a non-commercial basis) in the national health system. In these cases the use of a patented subject matter under a compulsory license requires adequate remuneration of the patent holder.

As to the scope of protection, there is also considerable latitude both under patent law and under TRIPS. Especially the question of national or international exhaustion has been left open in TRIPS (see Art. 6). "Exhaustion" means that the right of the patent holder to restrict the use of the patented products ends once these products have been brought to the market with the consent of the patent holder. This means, for instance, that the products can be sold to and legitimately used by third parties. The open question is whether such exhaustion operates on a national or international scale. In the latter case products that are legally available in one country can be sold to and used in any country. Accordingly, developing countries in need of medicines, which they could not manufacture without consent of the patent holder, could source all markets to which such medicines have been lawfully introduced and import them from there at the lowest available price without consent of the patent holder (parallel imports).

The relevance of these *safeguards* for access to essential medicines should be assessed in the context of *supplemental strategies* on cost reduction that can be adopted by governmental or private players. Two of these supplemental strategies address the use of patent law. The one is that patent holders grant *voluntary licenses* to manufacture patented drugs for specific markets. The other one is that drug companies file patents only for specific markets (*differential filing).* For example, patents could be filed only for rich countries of the North, in which high drug prices can be achieved that cover the costs of drug development, leaving the patented subject matter freely available in other countries. Other supplemental strategies address drug prices directly or indirectly. The most important one is *differential pricing.* Patent holders can lower drug prices for poorer countries with less purchasing power. This strategy bears the risk that governments in the rich countries take note of the lower prices elsewhere (*referential pricing*) and exert pressure for comparable discounts to relieve their health budgets. Differential pricing therefore depends on intransparency of markets or on a declared political will to establish a *global system of differential pricing* and to abstain from referential pricing. Since companies are aware of the risk of referential pricing they prefer strategies which improve access to medicines in poorer countries but leave official drug prices unaffected: they combine drug purchases with gifts (e.g., one pack is

sold, three are added as a gift) or they operate with rebates on the purchase price (*purchase-donation combinations and reimbursements*).

There is far-reaching agreement that the protection of intellectual property has to be aligned with broader issues, which include access to medicines and affordability of drugs for poorer countries, on the one side, and the need to recoup high investment costs for drug development, on the other. There is consensus that, so far, R & D costs have largely been borne by the countries of the North — and met through correspondingly high prices. Hence, all supplemental strategies in favor of developing countries, as well as the safeguards mentioned, are subject to one core constraint: the markets of the North have to be protected against low-priced medicines from the South by *market segmentation*. This requires northern countries to implement a system of national exhaustion in order to prevent re-imports of patented drugs from low-price countries. And it requires northern governments to abstain from *referential pricing*, i.e., taking prices in developing countries as their reference — whether through governmental *cost controls* in the health system or price negotiations as major buyers (*bulk purchases*). Without market segmentation in this sense, R & D could not be protected.

The aforementioned safeguards and strategies may still not suffice to grant access to essential medicines in poor countries in every case. In some regions not even pure gifts of drugs would be of any use, since the public health system cannot cope with distribution. Developing capacities with the aid of *international funds* must in these cases be given priority. An integral part of this context of poverty, underdevelopment, and lacking health care is the problem referred to as "*neglected diseases*". With the exception of international funds, all the measures listed presuppose that some sort of markets exist in which R & D costs can be recaptured. In the case of worldwide diseases, these are doubtless the markets of the North. However, there are specific diseases that occur only in developing countries where the purchasing power is negligible. These are "neglected diseases" — "neglected" because hardly any money is spent on research into them. Since the economy can solve societal problems only when markets exist, public funding is imperative in these cases. To ensure the optimum use of funding, "*purchase precommitments*" have been proposed (e.g., a commitment on the part of the WHO to purchase a large quantity of the drug to be developed to combat a neglected disease).

This concludes the introduction and explanation of technical terminology. The aim has been to show the dimensions that have to be taken into account in assessing

the impact of patent protection required under the TRIPS Agreement on access to medicines. The effects of patents must be evaluated by taking into account existing legal safeguards and "supplemental strategies" companies may apply. Furthermore it must be considered that patent protection is granted for a limited time and that many essential medicines are already off-patent. Equipped with this background information, the reader unacquainted with the subject matter should now be in a position to follow the course of argumentation in the dialogue project.

4.2 Survey of Arguments

The dispute on access to essential medicines has a descriptive and a normative aspect. On the one hand, it is concerned with whether and to what extent the TRIPS Agreement and the resulting globalized obligation to introduce patents for drugs is a significant causal factor for (inadequate) access to essential medicines and the global crisis of health care systems. On the other hand, there is controversy on whether the TRIPS Agreement violates key values, rights, and standards of equity both in how it came about (procedure) and in its legal substance. A circular on the state of argumentation was prepared for each of these sub-complexes. The argument surveys printed below are the final, corrected, and supplemented versions. They include all corrections and improvements deriving from the E-mail dialogue, correspondence, and conference discussions. In this supplemented form they underpin the conclusions.

As far as the form of the argument surveys is concerned, it should also be pointed out that the issues that dominate the trees were chosen to produce as little branching as possible. It was feared that complex branching would be difficult to manage by E-mail. For the same reason many sub-references — i.e., sub-controversies within an argumentation field — were not marked, in confidence that participants would be able to grasp how they related. It should be noted that the contra side of argumentation fields — unlike the pro side — logically contains very heterogeneous information and assertions: thus the heading "Contra/Rel" for "contra/relativizations." This is because assertions can be attacked for a wide range of reasons: because they are false, irrelevant, or valid only in special circumstances. For example, the assertion that compulsory licenses are the safest path to affordable drugs can be attacked by pointing out that this possibility has been hardly ever used in actual fact, that differential pricing is better, or that there are hardly any medicines for which a generic substitute is not available. The goal assertion ("compulsory licenses …") is undermined by counterarguments in very different

ways, and for this reason they are subsumed under the heading "Contra/Rel". Such a structure would not be suitable for every scientific purpose. Here, too, it was decided to condense multiplicity for reasons of workability.

Now to the argument surveys. Each consists of a brief exposition of the issue followed by a "condensed" and a "long" version of the state of argumentation. The "long" version was to be relegated to the appendix for the same reason the condensed versions were prepared in the first place: the complexity would put the reader off. At the end of the circulars (or sections of them), a number of questions were formulated in order to stimulate participants to prepare the possible conclusions.

The first circular on essential medicines (5th Circular) ran as follows.

IPR Dialogue Working Group III (Access to Essential Medicines)

5th Circular:
IP Regimes and Access to Health Care, Part One
(Rainer Döbert)

Arguments: IP and Drug Prices

(condensed version)

A. Introduction

Lack of access to essential medicines is an element in the health crisis that threatens many countries in the poorer parts of the world. Access to medicines is affected by many factors, IPRs (especially patents) being just one such factor. In this respect a broad consensus exists among representatives of the most different organizations. Controversial issues are the exact relevance of patents, i.e. the extent to which they actually affect access to medicines and whether such impact warrants (or requires) the revision of current regimes of intellectual property, especially of the TRIPS agreement.

The assessment of the relevance of IPRs has a factual dimension and a normative one. In the factual dimension crucial questions seems to be whether patents because they lead to higher prices will make essential medicines unaffordable for poor people. In the normative dimension, the question is whether, because of such impact, patents on medicines violate the basic human right of access to healthcare or other legal obligations or moral duties.

We will postpone the survey of normative arguments to a later Circular. There we will deal with questions raised with respect to the meaning and the status of a *human right to healthcare.* To whom does one appeal in demanding that such a right be upheld? Government, private companies, fellow citizens? What happens if this right clashes with other rights such as property? We may also have to discuss whether other normative principles must be invoked to underpin access to healthcare, for instance, obligations of *responsibility*. And we will include the questions whether the TRIPS agreement should be revised because it is *unjust* from the very beginning.

The present 5th Circular surveys the discussions over the relation between patents, drug prices and access to medicines. It also covers the discussion over measures to mitigate or avoid negative impacts of patents on the access to medicines. In this respect the participants (and the documents consulted) addressed a number of *safeguards* normally built into IP regimes, such as compulsory license or parallel imports. The participants discussed how these safeguards can be used (and redesigned) under the TRIPS agreement. In principle, conceptions could range from denying patents for medicines altogether to making even stronger provisions for IP-protection (TRIPS plus). The participants also referred to *supplemental strategies*, that might function as equivalents to those safeguards: differential pricing, donations etc. Some of these strategies (international funds, new health policies) require interventions from the public sector, governments or WHO.

The existence and interpretation of safeguards offered within the IP regime and the availability of supplemental strategies which may substitute those safeguards are conditions clearly to be taken into account for the question whether current legal regimes, especially TRIPS, must be revised if one is to cope with negative impacts of patents on access to medicines.

The participants expressed divergent views and preferences with regard to the options implied in various safeguards and supplemental strategies. This divergence reflects (among other factors) different notions of how the conflicting objectives can be balanced that must be met in pricing medicines produced by private companies: Prices should be low enough to make medicines affordable for the poor, and they should be high enough to provide incentives for investment in R & D to create these medicines in the first place. Thus, the impacts of patents on access to medicines may be looked at from a short-term or a long-term perspective. In the short term patents may reduce access by impinging on the prices of medicines so as to make them unaffordable for those in need. In the long term, they may increase access by inducing research that will lead to new effective drugs. There seems to be broad consensus among participants that both sides of the coin—the long-term and the short-term effects—must be somehow taken into account in designing and assessing the regime of IP. We include arguments that have been raised in this respect in our survey. … The arguments surveyed in this CIRCULAR relate only to the "factual dimension" of access to essential medicines.*

B. Arguments: IP and Drug Prices

In the following we summarize main arguments on whether IPRs (especially patents) will have a negative impact on access to healthcare because they lead to higher prices for essential medicines. The arguments address three topics:

1. The relevance of patents for the prices of medicines and the relative weight of patents (and patented drugs) among the other factors that determine access to healthcare?
2. The options to avoid or compensate negative impacts of patents on drug prices by applying the "safeguards" offered within the IP-regime or by using appropriate "supplemental strategies".
3. The need to balance drug prices with the protection of private investment in R & D that creates new medicines

* For reasons of redundancy, a table has been omitted here.

Question (1) Do patents preclude access to healthcare because they lead to high (unaffordable) prices for medicines in poor countries?

[Numbers in brackets refer to the list of full text arguments in the long version file; R-numbers refer to responses to the circulars]

NO/not necessarily	YES
a. Drug Prices and Other Factors	
1. Access to healthcare is determined by a many factors. IPRs and drug prices are not the most relevant factor—compared to factors connected with government responsibilities, e.g., widespread poverty and healthcare policies [1, 4, 8, 9, R5:1, R5:6, R5:7].	2. Other factors are relevant. But patent abuse leads to unaffordable prices of medicines, and these prices are or become the bottleneck if the other relevant factors are complied with [2, 3, 5, 7].
b. Price Effects of Patents	
3. Retail prices for medicines are not the prices set by the pharmaceutical industry. On the whole medicines are not cheaper medicines in countries without IP protection [5, 6, 7, R5:4]. And recent price diminution were agreed upon without modifying the patent status of medicines. [R5:4]	4. Higher prices belong to the essence of patents; the "patent multiplier" (generic price × patent factor = brand price) seems to range somewhere between 2 and 4 [14, 15, 16]. Other cost factors (distribution) can be equally high.
c. Off-patent Drugs and Competition	
5. Most essential medicines are off-patent, and patented drugs face competition which will drive prices down. [R5:4] The current discussion on IP and access to healthcare is ill-directed because it refers to HIV which is a special case (new disease) [17, 20, 21].	6. Price comparisons demonstrate "monopolistic pricing practices". HIV is not so special. New drug resistances are spreading, and will generate dependency on new, patented drugs. Competition by substitutes is restricted by drug properties (e.g., different immune responses by patients) [18, 19, 22]. 7. Patents on drugs may have a limited impact, but when peoples lives are at stake that impact is too much [18, 19].
d. Overriding influence of poverty	
8. To make drugs affordable for the poorest is beyond the market, special means (public funds) are needed [23, 24].	

Further Questions:

1.1 Which arguments have to be added to gain a well-considered judgment on the controversial issues?

1.2 In view of the fact that patenting and higher prices are essentially interrelated, what remains as the real focus of the controversy? What follows from this?

1.3 If industry lowers the drug prices to increase access to essential medicines governments may take this as an excuse for not fulfilling their own duties to contribute to the solution of the problems (and vice versa). How can this be prevented?

Question (2) In view of the various safeguards and supplemental strategies that are available to lower drug prices and make medicines affordable are compulsory licensing and parallel imports the best instruments?

YES	NO, not necessarily

Compulsory Licensing (CP) and Parallel Imports (PI)

9. If the safeguards of CL and PI are interpreted in a broad manner, which means: not bound to narrow "exceptional circumstances", they will guarantee affordable drug prices and access to medicines in the long run [26, 28, 32]; especially when the private sector is included [36].

11. It contradicts the TRIPS Agreement when governments and industry exert pressure not to use CL and PI, and when they try to implement stricter rules than envisaged by TRIPS (TRIPS-plus) through bilateral agreements [29].

13. Lower drug prices came only after threat with CL [47a]. And only by CL will be possible to determine the lowest price [R5:5]

10. CL and PI are not routine solutions; there are factual (advanced industry) and procedural restrictions. In addition, Article 31 of TRIPS circumscribes at least the types of grounds to be applied—e.g., extreme urgency, public use [27, 33, 34].

10a. In developed countries CL was in no case necessary to overcome health crisis; in developing countries the issue of drug distribution would still be unresolved [R5:4].

12. Industry and governments in industrial countries are changing their positions; they accept the safeguards. Use of the safeguards is not, however the preferred policy. Negotiated solutions are better [30, 31], as recent reductions of prices for medicines demonstrate [47]. Prices will be even lower when more public money comes in [35].

YES	NO, not necessarily
15. [Product quality] is a problem of control and reinforcement of law [41, 46], generated partly by the high prices of patented drugs [42].	14. In addition, CL and PI are connected with counterfeiting and substandard products [40]. They will yield little benefit for patients [43] and result in illegal exports to the developed world [45], because they are a strategy of industrial development not of access to medicines for the poor [R5;4].
15a. Illegal exports are manageable [Oxfam 2001].	
17. CL and PI should also be practiced in the developed countries [37]. They could be combined with a 1% R & D tax on generics and 5% royalty for companies that have provided the R & D [39]).	16. Unrestricted CL and PI will drive prices down to marginal costs with no margin left for R & D [38]. A frequent use of CL will destroy the IPR system [R5:7].
	16a. CL an IP should be combined with other measures and applied according to stage of economic development [R5:12].
	16b. Industry prefers CL as compared to PI because it requires a health emergency, local manufacturer and fair royalties to patent holders. [R5:6].
Voluntary Licenses and Public Funding	
19. Even voluntary licensing may not work in all cases. The commercial production presupposes markets which do not exist for medicines in many poor countries. Without markets we need systems of public funding [50, 51] and public-private partnership.	18. In view of the overriding health disaster of HIV one should not discuss narrow IP interests but instead grant voluntary licenses to the WHO or to anyone who wants to use them. [48].
	18a. Poor countries would get essential medicine credits in exchange for biodiversity conversation [R5:1].
	18b. Public private partnership is not a sustainable solution [Oxfam 2001].
20. If we link commercial standards of drug production with the human right of access to medicines the question of funding inevitably comes up and of compensation for the company that is supposed to grant a voluntary license. Is the global community prepared to pay? [52, 54].	21. Once it is acknowledged that licenses should be granted one can discuss how the needs of public health and fairness to industry can be balanced in CL [53].

YES	NO, not necessarily
Differential Pricing	
23. CL is better than differential pricing because it is sustainable, steady and not open to manipulation in difficult negotiations [57, 59].	22. A global system of differential pricing based upon a worldwide classification of markets and guidelines for pricing which also applies to generics and is backed by formal agreements would be more efficient in terms of transaction costs (bargaining) and prices (90% or below) than any results of CL [56, 58, 60, 61, 62].
25. Market segmentation is difficult to defend, it will break down. [64, 65].	24. Differential pricing presupposes effective segmentation of markets [63, 66].
25a. A general policy would not be workable, *inter alia* for antitrust reasons [R5:4]	
Differential Filing (Proposal of Lanjouw*)	
27. "Differential filing" contradicts TRIPS and the US law. And it overestimates the role of patents for access to medicines [69, 72].	26. For specific diseases prevalent mainly in developing countries stronger patent protection may be needed. However, there is no need to have strong patent protection in developing countries for medicines to treat global diseases which affect all people. Here profits realized in rich countries suffice to protect investment in R & D. Companies could file in rich countries only and let unrestricted generic competition evolve in poor countries. This could easily be done by formulating the "foreign filing license" appropriately [68].
28. "Differential filing" undermines the incentive system of patents because it restricts the markets for the pharmaceutical industry. The advantages for the generic producers are not justified, they don not contribute to the development of new drugs [67, 71].	
28a. Differential filing is workable only in combination with market segmentation which is up to now not ensured [R5:4].	

Further Questions:

2.1 Which arguments have to be added to gain a well-considered judgment on the controversial issues?

2.2 Safeguards and supplemental strategies can be combined. Are all combinations possible? E.g. differential pricing and parallel imports, or more flexible compulsory licensing and parallel imports? Which mix seems to be best?

2.3 How can "tiered pricing" be turned into a sustainable strategy?

*The Lanjouw proposal was published after "Montreux"; the WBCSD introduced it together with some comments of the industry. We take this as a valuable contribution.

2.4 Countries can be classified as developed, developing and least developed. What safeguard/supplemental strategy serves the interests of which type of country best?

Question (3) Is strong patent protection a necessary condition for having a pharmaceutical industry with high investment in R & D?

YES	NO/not necessarily
29. Patents are imperative for the pharmaceutical industry because the financial risks of developing new products are enormous and copying products is easy [R5:4]. The contribution of the public sectors is small [R5:9]. In fact, countries without product patents do not invest in R & D [73, 75]; accordingly, TRIPS will lead to a globalization of research efforts on neglected diseases [79].	30. Higher than normal profits of the pharmaceutical sector show that the financial risks can't be too high. These profits have largely been realized at a time when many developing countries did not recognize product patents [74, 84, 86]. In addition, poor countries will not be able to contribute to higher revenues [Oxfam 2001]
32. Patents are a necessary but not sufficient condition. Where markets do not exist, one must rely on funds [81] and, among other things, biodiversity credits [R5:1]. States' failure is the main cause of lack of access [R5:6]	31. South Africa and Chile [R5:8] had strong patent protection but did not attract investments and did not invest into neglected diseases, because there was no market [80].
33. Developing countries will attract investments into the pharmaceutical industry if patent protection becomes stronger [77] and profitability rises [90, R5:4]	34. There is little evidence of an increase in investment. Different forms of intellectual property may be required in different stages of industrial development. That is one lesson to be learnt from the history of developed countries: They introduced patent protection when their companies were ready to innovate [R5:8]. India built up a strong generic pharmaceutical industry without product patents. The development of such industry may be a by-product of compulsory licenses. [76, 78].
35. Unrestricted use of compulsory licensing would drive prices to marginal costs without compensation for R & D [83]. Research activities would diminish under pressure of generic competition without patent protection [R5:7].	36. Investment could be protected by a right to compensation, e.g. a 5% royalty and a 1% tax on generics [R5:5], not by a right to exclude others from the use intellectual property [82].

Further Questions:

3.1 Which arguments have to be added to gain a well-considered judgment on the controversial issues?

3.2 If there is no controversy about the need to protect investments, how do we get closer to a delimitation of legitimate margins?

3.3 Under which conditions could strong product patent protection contribute to the development of new drugs for neglected diseases?

The circular on the normative dimension (8th circular) ran as follows (the overviews from the earlier 5th circular which were reproduced at this point have been omitted).

IPR Dialogue Working Group III (Access to Essential Medicines)
8th Circular:
Part Two: Access to Health Care and IPRs — The Normative Issues
(Rainer Döbert 02-01-02)

Arguments*:* Access to Healthcare and IPRs — The Normative Issues

(condensed version)

Introduction

This Circular addresses the normative dimension of the conflict about access to essential medicines. There is bitterness in the debates about the TRIPS Agreement and this has to do with the fact that not only interests, but also values and norms, are at stake. The respective normative arguments pertaining to the TRIPS Agreement can be subsumed under three headings: human rights, "care" or "responsibility", and injustice.

The Declaration of Human Rights grants to everyone, among other things, the right to medical care, including the right to essential medicines. As plausible and as convincing the respective right may look at first glance, as many uncertainties arise at the second. Its *exact* meaning is far from clear in view of the fact that—as a positive, "social" human right—the right to healthcare and essential medicines presupposes the consumption and spending of resources that may be owned by others like the medicines that are owned by the pharmaceutical companies. Does one have a human right to a company's property—at least to that part of its property that is partly in the public domain? The Declaration of Human Rights does not imply this, because it specifies unequivocally States or governments as addressees of human rights claims. But, again, the question arises as to how far States' duties reach, in view of budgetary bottlenecks.

In view of these contingencies, some participants proposed to distinguish between strict human rights claims and mere policy goals. Others denied the applicability of the human rights terminology in the context of access to medicines altogether, but even these did not deny any moral duties of companies. Instead, they proposed to construct them not as human rights, but as implications of our general moral duty to help, namely, as "care" and "responsibility".

The whole picture is complicated by the interplay of public and private goods in the field of healthcare. If governments have the duty to further the public good, "access to healthcare", could this not imply among other things, a duty to tailor the regulatory framework of companies in such a way that companies could not but contribute to the public good by offering affordable prices for their private goods (medicines)? Here is where compulsory licensing and parallel imports come in. This line of reasoning is all the more convincing, if one keeps it in mind that TRIPS will oblige some governments for the first time to grant product patents on medicines. And, among them, in

the short run, will be some which will not benefit from the system of IPRs at all, namely, the least developed countries. One way to take care of the special needs of the least developed countries could be a global system of differential prices, a system that would also be compatible with an imperative, under which the whole system of healthcare also operates: funding, especially of R & D.

The introduction of norms is always connected with a distribution of burdens and benefits of cooperation (gains and losses), and this distribution of gains and losses is hardly ever in the equal interest of all concerned. "Property" divides people into "haves" and "have-nots", and the introduction of this institution divides societies into those who did not (developed countries) and those who will have to respect the rules (developing countries) while still in the process of development. Will the less privileged accept all this without any form of pressure or any form of compensation? Therefore, it does not come as a surprise that many of the arguments raised against the TRIPS Agreement pertain to inequalities and injustice in procedure (participation and pressure), in outcome (colonialism by the North, for example), and in application (litigation costs, for instance). Their relative weight will, in the final analysis, probably depend not least upon the value one attributes to the IPR system on the whole.

In the following, the arguments of participants will be presented under the three questions:

1. Do patents on essential medicines violate the human right of access to healthcare?
2. Do companies have moral obligations to contribute to the solution of the health crisis in developing countries?
3. Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

Normative issues in the debate over IP protection (and TRIPS)

1. Do patents on essential medicines violate the human right to access to healthcare?

PRO	CONTRA/REL
1. Access to medicines is a basic human right defining a strict duty of States to reduce the price of essential drugs, even if this means breaching international trade agreements (1, 4, 5) that do not generate "an environment of responsibility"(R8:6, R8:12).	2. Not companies but States are addressees of human rights and there can be no fundamental right to medicines, because these are complex, invented private goods. They are objects not of basic, but of aspirational rights or policy goals, which can be and are overruled by the budgetary constraints of States (2, 3).

PRO	CONTRA/REL
3. In this respect, compulsory licensing and parallel imports are of vital importance, but they are denied and undermined by bilateral agreements (6). And Doha has still to be implemented (R5:6).	4. The safeguards in TRIPS are now accepted and reaffirmed in Doha (7, R8:6).
5. The patent system has to further the public good of equal access to medicines for all; otherwise its legitimacy is questionable.	6. As long as incomes are distributed unequally, medicines cannot be affordable to everyone. If they are to become a public good, a purchaser has to buy them as private goods and can then offer them, for instance, in health promotion programs as part of a public good (8, 10; cf. Circular 5, safeguards and supplemental strategies).
	7. The public goods corresponding to the patent system are information and R & D.
9. Rights are just social constructions, which, especially in the case of IPRs, make little sense: Advancing knowledge does not create property, and TRIPS confuses the inclusive human right with the exclusivity of property rights (15, 16, 18).	8. The protection of property, including intellectual property, is a human right, too, and not at all a completely new one. In the past, societies have tried to evolve mechanisms of exclusion, too, in order to allocate benefits to "traditional inventors" (14, 17, R8:6).
10. The International Undertaking for Genetic Resources demonstrates that one can successfully allocate benefits „to the whole society" (19).	11. Even if companies accept "design[ing] the issues as a human rights issue", implying obligations for themselves, two question remain unresolved: Where are the limits of companies' responsibilities, implying, among other things, a dividing line between essential and less essential medicines? And, how should especially R & D be funded, if not by additional public money? (20, 21, 22, 23)

2. Do companies have obligations to contribute to the solution of the health crisis in developing countries?

PRO	CONTRA/REL
12. Even if there is no strict human right to medicines, pharmaceutical companies have duties to contribute to a solution of the health crisis: They are part of the healthcare system and accept the corporate responsibility connected with this fact—all the more so, as they are confronted with the moral convictions of their shareholders and employees. If one adds to this responsibility the principle of "ability to pay", one ends up with a global system of differential prices, which offers medicines to the least developed countries at cost prices (24, 25, 27). In addition, contributions to international funds and drug donations are part of this corporate responsibility (R8:6)	

3. Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

a. Participation and Pressure

PRO	CONTRA/REL
13. The whole negotiation process of the TRIPS Agreement was „flawed" because there was too much influence from powerful industries, no representation of the least developed—especially African—countries, too little time to acquire the relevant expertise, and, in addition, a lot of coercion (28, 29, 31, 33). Thus the TRIPS Agreement will have to be re-negotiated (R8:12)	14. WTO decision-making is generally based on unanimous consent and therefore not as one-sided as people believe. The flexibility (safeguards) of the TRIPS Agreement, owing to a "tough battle", are proof of the relative fairness of the procedure. Admittedly, there are some shortcomings having to do with lacking expertise of delegations or with time constraints leading to an undue extension of "Western concepts" (30, 32).
15. The flawed process can only result in a flawed product: TRIPS is one "simple system of neo-colonialism" that neglects cultural differences and imposes Western ideas to which the West will not even stick when "it is no longer in their interest" (34, 35).	15a. The mere exploitation of inventors by society can also not be "morally right" (R8:6).
15b. Even if IPR is not a western concept, its implementation is biased (no adequate balance between social needs and private profits, no benefit sharing for TK)(R8:6)	

b. Inequalities and Development

PRO	CONTRA/REL
16. TRIPS—unlike other agreements within the WTO—is based on a one-size-fits-all approach, which denies the right to development; this is because the early phases of industrialization depend on copying technologies of more advanced countries. Therefore different IP systems adapted to different stages of industrialization are needed and available (e.g., copyright; 36, 37). But they are not used, and the safeguards are being undermined (bilaterialism; 39, R8:8, R8:12).	17. Cf. Circular 5: *Research and Development*: Benefits for inventiveness are needed. The only resource which poor people have is their knowledge (R8:6).
	18. The provisions/safeguards of the TRIPS Agreement, just reaffirmed in Doha, guarantee the necessary flexibility (38, 40).
16a. In developing countries , the introduction of patents does not foster the domestic industry, but international companies and endangers at the same time public health. This has been different in advanced countries (36a, R5:8)	
16b. TRIPS violates the principle of reciprocity of international trade, because it leads to high rent transfers to industrialized countries without reciprocal benefits for developing countries (R8:8). To come to an acceptable balance rent transfers should be used for R6D in neglected diseases (R8:8)	
19. The uniqueness of genetic information precludes "inventing around", and it is used to block genuine competition from generic products—and all this based on minor inventions (41).	20. Compare: Gene Patenting, Circular 9.
	21. Generic competition is often unfair competition (cf. Circular 5, compulsory licensing; 43).

c. Other Normative Infringements

PRO	CONTRA/REL
22. One element of unfairness relates to appropriations of benefits from nothing (minor inventions), the public domain (discoveries), or from other people's work (farmers who selected and conserved germ plasm; traditional knowledge; 44, 46, 49). There should be severe penalties for these kinds of abuses of patent law (R8:6). Cf. Section on TK	23. "Inventiveness" and "discovery" can be defined by each country on its own standards; and patents based on public domain knowledge can be revoked (45, 47).
24. To revoke a patent is extremely costly, as the whole system is too costly for poor countries (46, 52) and small inventors (R8:6).	

25. There are many unkept promises with respect to technology transfer, and instead of investments, one observes de-investment (50).

25a. To balance the TRIPS agreement concessions with respect to textiles and agricultural products have been promised. These promises were also not kept.

26. It's too early to make an assessment (51).

Further Questions:

1. What arguments are missing or inadequately stressed?

2. How far can the moral duties of companies reach in view of the fact that companies have to be profit oriented?

3. What division of labor should obtain between States and companies with respect to the moral duty to improve access to healthcare?

4. Is there a need to confine proposed solutions to essential medicines and how are these to be defined?

5. Are (inclusive) human rights and (exclusive) property rights to be treated on the same level?

6. Would there still be normative criticisms of the IPR system if safeguards plus differential pricing were implemented?

7. If TRIPS implies an "undue extension of Western concepts" and a neglect of the "cultural dimension", which aspects would have to be changed and how?

8. The assignment of property rights is, by definition, connected with inequalities and exclusion. What are the reasons for classifying these implications as injustice?

9. Is the "right to development" compatible/incompatible with IPRs?

10. What mechanism should be used to improve access to the whole IPR system (in terms of costs, for instance, of filing, revoking) for the poor (countries)?

11. Which other questions should be posed?

4.3 Steps Towards Conclusions

The circulars contained questions addressed to participants. The answers received by E-mail were summed up and passed on to participants in "Steps Toward Conclusions" to give them an idea of the direction taken by the discussion. Since a completely new "supplemental strategy" had meanwhile begun to influence the international discussion, namely differential filing, and since the totality of safeguards and supplemental strategies with their differing strengths, weaknesses, and functions offered a highly complicated picture, participants were again sent a systematizing overview. The aim was to permit appropriate fine tuning of international IPRs in the context of other measures. The material distributed is printed below.

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File name = AEM-2 Steps towards conclusions.doc/pdf

Rainer Döbert

31 January 2002

IPR Dialogue Process

Steps Towards Conclusions

Part II.1: Access to Healthcare

With this communication, we try to come a bit closer to conclusions that might be drawn from the dialogue process, pertaining to the issues of Working Group III: Access to Essential Medicines (AEM). This is Part II.1 on IP and Drug Prices; Part II.2 on Normative Issues will follow.

Arguments referring to IP and Drug Prices were surveyed in the 5th Circular. Twelve participants responded to this Circular. Their responses, which also consist of first, tentative conclusions, will be inserted into the respective "argumentation tree". (These responses are also documented in the members corner of the project website.) The first part of this communication (A) gives you a rough summary of points raised in the participants' responses. The second part (B) comprises a survey of safeguards and supplemental strategies designed to improve the balance between public and private interests in the IPR system. In the third part (C) we ask you to propose conclusions. For that matter we suggest that you follow the leading questions in Circular 5.

Please read the statements presented in the following as participants assessments, not those of the WZB.

(A) RESPONSES FROM THE PARTICIPANT

General Remark

We have set up a condensed and a long version of the state of argumentation and have also tried to group arguments into "chapters". But condensing and grouping arguments have a price: condensing entails abstraction and possibly a certain selectiv-

ity of emphasis; grouping may insinuate an independence of blocks of arguments that goes too far. To give just two examples: "Factors connected with government responsibilities, e.g., economic and healthcare polices" in the condensed version may be too abstract a formulation to transport the full meaning of arguments 1 and 2 in the long version, touching upon poverty, inequality and States' failures. And, of course, in the final analysis, price effects of patents (1b) cannot be discussed adequately without reference to R & D (3). A part of the participants' responses result from the dangers of abstracting, condensing and isolating sections, which can be overcome just by stressing these dangers and emphasizing the fact that the condensed version was designed to serve as an aid for the memory, and that it is not the "full meal". Now to the details!

Leading Question 1:
Do patents preclude access to healthcare because they lead to high (unaffordable) prices for medicines in poor countries?

1.1 Which arguments have to be added to gain a well-considered judgment on the controversial issues?

In this connection, it is reaffirmed that there can be no R & D without price protection. But despite this, IPRs—not even being implemented in many countries—cannot be identified as the main obstacle to access to healthcare, because (a) few drugs are without generic substitutes; (b) the patent status of drugs does not tell anything about access to healthcare—generics are as inaccessible as patented drugs; (c) lowest prices have been achieved without patent modification. The main causes of the global health crisis are poverty and States' political-economic failures, which make *all* items of healthcare—and not just medicines—inaccessible. Against this background, one participant reaffirms the necessity for compulsory licensing as a device to determine lowest prices (through generic competition).

Argument 19 of the long version (high prices result in incomplete treatments) needs at least to be supplemented: people stop taking medicines when they start to feel better. Other missing arguments pertain to supplemental strategies (a global private/public fund should be set up and combined with biodiversity credits, in the sense that biodiversity conservation is exchanged for resources from the fund) and to the adaptation of the patent system to claims of justice. Historically, patent protection has varied from country to country and, as a rule, has been connected with gains for the domestic industry and not with threats to public health. This is different for developing countries today. Therefore, one should think about modifications to the patent system (e.g., lower testing standards for drugs, lower prices, shorter duration of patents).

1.2 In view of the fact that patenting and higher prices are essentially interrelated, what remains as the real focus of the controversy? What follows from this?

Responses to this question can be grouped under the two headings of "justice" and "relevance". On the one hand, inequality and injustice are seen as the focus of the controversy, either the inequitable distribution of resources as such, or the inequality built into the IPR system. Critics argue that IPRs are a system of rules appropriate for developed countries, which has been imposed on developing countries without differentiating monopoly rights of patents according to purchasing power—a differentiation that would at least be accomplished partially by implementing pro-

competitive measures like compulsory licensing (CL) or parallel imports (PI). On the other hand, the focus of the controversy is seen in an undue emphasis on patents and prices as compared to the failure of the public sector (infrastructure, funding).

1.3 If industry lowers the drug prices to increase access to essential medicines governments may take this as an excuse for not fulfilling their own duties to contribute to the solution of the problems (and vice versa). How can this be prevented?

Probably it would have been better had we framed this question directly: How can one exert pressure on States and companies? In any case, to set up a framework of incentives for governments is seen as "difficult". Suggestions range from international philanthropic coalitions, other governments, international organizations, or civil society exerting pressure on governments to not get in the way of appropriate measures and to invest in health systems and infrastructure. On this basis, industry could negotiate lower prices (e.g., bulk purchases), and urgencies could be dealt with on the basis of safeguards. In addition, a new international framework for differential pricing should be combined with regulations for retail prices.

Leading Question 2:
In view of the various safeguards and supplemental strategies that are available to lower drug prices and make medicines affordable are compulsory licensing and parallel imports the best instruments?

2.1 Which arguments have to be added to gain a well-considered judgment on the controversial issues?

The circular seems to have "reflected quite well the debates held in Montreux", as one respondent put it. Thus, we find in the responses of participants more stress on aspects of given arguments then fundamentally new arguments. The indispensability of patents for R & D is highlighted again, and connected "logically" with the exceptional, but nonetheless effective, nature of CL. It is argued that some of those who advocate a liberal use of compulsory licenses combined with parallel imports have the industrial development of countries in mind that produce generics, rather than the access to medicines for the local poor, who cannot even pay for generics and have to struggle with unresolved distribution problems. Also, the problem of counterfeiting is mentioned.

In addition, market segmentation is a crucial condition to make sure that CL, differential filing, and differential pricing are compatible with sustained investments in drug development. The condition has to be backed legally in the future. Doha has, however, shown that modifications to the interpretation the TRIPS Agreement to facilitate recourse to these mechanisms, can even now be accepted by the developed countries—which is taken as proof that previous more rigid interpretations reflect "serious errors and tensions". Finally, investments in R & D have to be compared with promotion and marketing costs—a comparison that may also change the picture.

2.2 Safeguards and supplemental strategies can be combined. Are all combinations possible? E.g. differential pricing and parallel imports, or more flexible compulsory licensing and parallel imports? Which mix seems to be best?

and

2.4 Countries can be classified as developed, developing and least developed. What safeguard/supplemental strategy serves the interests of which type of country best?

Responses to these questions can be combined. By and large, the following picture emerges: Where developed countries are mentioned at all, participants plead for strong patent protection—CL would destroy the industry, because a 5% royalty (for instance) would be too low—combined with a system of public healthcare and protected by market segmentation against, for instance, differentially priced products. Others reaffirm the validity of TRIPS as interpreted according to the Doha Declaration, and argue for a free combination of CL, PI, exceptions (Bolar), differential pricing (DP), and longer transitional periods for developing countries. Some stress more than others the exceptional nature of the safeguards: only in cases of crises should they be applied by the poorest countries—a clause that may astonish those who witnessed the behavior of the U.S. and Canadian governments under the threat of anthrax. There is also dissent over the usefulness of classifying countries as least developed, developing, and developed, because development is unpredictable and, therefore, local industries' needs for protection (against PI products, for instance) may have to be taken into account.

Nevertheless, with respect to LDCs, a certain consensus emerges. For them, public funding, perhaps as biodiversity credits combined with DP (and possibly PI), seems to be indispensable, among other things, because product patents do not exist in many LCDs, manufacturing capacities are lacking, and CL may make industry reluctant to participate in DP.

2.3 How can "differential (tiered) pricing" be turned into a sustainable strategy?

Maybe this question was not elaborated enough to spur participants' fantasies. Responses mention national measures to protect market segmentation, a case-by-case procedure in order to avoid anti-trust concerns, possible rules for fair negotiations between companies and countries, and a return to the situation before TRIPS (possibly with the help of Lanjouw). One participant suggests a combination of items: namely, a radical change of mentality within industry, long-term commitments by the entirety of industry, a clear definition of initiatives deserving the label, "DP", and a coordinating agency.

Leading Question 3:
Is strong patent protection a necessary condition for having a pharmaceutical industry with high investment in R & D?

3.1 Which arguments have to be added to gain a well-considered judgment on the controversial issues?

Against the argument that the established markets in developed countries have been large enough to generate higher than normal profits, it is held that (a) statements on profits are exaggerated, and (b) 95% of research is financed by private investment, which—if not protected—would be allocated elsewhere. The protection is needed in

view of the growing competition by generic companies and the increasing market presence of counterfeit drugs; moreover, protection cannot be compensated with 5% royalties (see above) or 1% research tax on generics.

Chile is another counterexample to the assertion that patent protection will increase R & D and foreign investment. However, patent protection is just a necessary but not a sufficient condition for R & D. There are other relevant factors (educational, economic), and there is massive global over-capacity in manufacturing. In terms of economic efficiency, India and China are first choice for generic production.

3.2 If there is no controversy about the need to protect investments, how do we get closer to a delimitation of legitimate margins?

It is argued that the term "legitimate margin" does not make sense economically or cannot be delimited theoretically, because each case is specific. Instead, one may choose a pro-competitive approach, recovering investment and protecting public interest, as CL involving compensation does. One principle could be ability to pay (zero for LDCs), but where should the line be drawn? One soon ends up with little of the world paying for innovation.

3.3 Under which conditions could strong product patent protection contribute to the development of new drugs for neglected diseases?

Patents cannot contribute anything, because markets or technical-scientific infrastructure are missing. Maybe the creation of a market of whatsoever sort could help (purchase pre-commitments? See below: "Survey of Strategies) or stronger protection against substitutes in cases where the market is just large enough for one product. But, on the whole, only the international community and global funding can help.

(B) ACCESS TO ESSENTIAL MEDICINES: A SURVEY OF STRATEGIES

1. Access to medicines

It may be useful to summarize the measures touched upon in our dialogue or in the relevant literature. This holds all the more so, since one new proposal has been introduced just recently. Such a survey—if supplemented by some remarks with respect to advantages or disadvantages and basic interconnections—can help to come to final conclusions. In their responses to the 5th Circular, some participants already indicated how they would like to tune the IPR system. We have to thank them and know that we cannot expect them to repeat this effort. Nevertheless, maybe this "Summary of Strategies" and other participants' initial responses will motivate them to refine their positions or add a remark on "purchase pre-commitments". In any case, we urge *all* other participants—also those from other working groups—to ponder carefully over this part of our dialogue, because this is one of the central points at which the balance of the IPR system is at stake.

Measures may lie completely beyond the legal-economic framework, within which pharmaceutical companies (or States) routinely operate: *donations* and contributions to *national or international funds*. These are commonly seen as welcome supplements of the healthcare system—destined for the poorest populations. But, for reasons of sustainability, they cannot carry the main burden of healthcare. Other

strategies aim at the prices of medicines, either directly or indirectly, by stimulating generic competition.

Generic production/competition is stimulated by using or granting flexibilities of the patent law, namely, first, by recourse to *compulsory licensing* (CL) and *parallel imports* (PI) as implied in the TRIPS Agreement. Bottlenecks or difficulties may be lacking production capacities—least developed countries will often have no sufficiently developed pharmaceutical industries—and legal restrictions (e.g., production for the home market only). *Voluntary licensing* would be preferable to compulsory licensing, among other things, for reasons of a better chance for technology transfer. But companies, possibly struggling with overcapacities, may hesitate—CL may be needed as a threat. Flexibilities of the patent law, secondly, may be used in the form of voluntarily *waivering patent rights* for specific countries: *differential filing*, e.g., in the form of Lanjouw's proposal or otherwise.

Among States' first measures to cut costs are, of course, *price controls*. But significant price reductions have also been gained by *negotiated price discounts* and *bulk purchases*. Probably, the larger the bulk purchased, the higher the price reduction will be. Thus the idea of *international purchasing funds* emerges. But which target prices are to be aimed at, when cost/price information is not completely transparent? One possible solution could be a *global system of differential pricing* that would grant least developed countries (and what segments of developing countries?) essential medicines at cost prices.

2. Research and Development

Many of these strategies can be compatible with investment in R & D only under one central presupposition: *market segmentation* between rich and poor countries must be upheld—a presupposition that requires support by States, and this not only in the form of *import-export controls*. In order to be better able to fulfill their obligation of guaranteeing the human right to healthcare, States among the developed countries will be tempted to administer *cost controls* and, in so doing, use prices in the developing countries as *reference prices*. If this becomes common practice, the strategy of differential pricing breaks down. Thus, a political decision *not* to go into this sort of referential pricing is needed. This decision may be all the more acceptable to the respective populations, the less transparent the whole pricing system is. In this respect, *sale-donation combinations* and *reimbursements* of expenditures may be advisable; otherwise, the system is to be run by an international agency. In addition, access to international funds could be coupled to a criterion putting least developed countries under pressure, e.g., *a minimum per capita public expenditure on health*.

Even if the best mix of strategies listed so far were realized, research on the neglected diseases would still fall through the sieve, because there are no markets for the respective drugs. One could set up *research funds for neglected diseases*, but these are notoriously inefficient. More efficient could be *purchase pre-commitments* that guarantee the purchase of a certain quantity of medicines with specified properties. Firms would then compete in developing this product. The winning product could be given at low price to developing countries. The following table summarizes:

Table: Survey of Strategies

STRATEGY	ADVANTAGES	BOTTLENECKS
Donations, funds	• An extra	• Sustainability?
Compulsory licenses (plus Bolar exemption)	• Generic competition and respective prices	• Industrial capacities? • Technology transfer? • Market segmentation?
Parallel imports	• Lowest price on the market	• Legal barriers? • Repercussions on exporter's market? • Market segmentation?
Voluntary licenses	• Lower prices • Technology transfer	• Sustainability (willingness of companies)? • Market segmentation?
Differential filing	• Prices of generic products	• R & D for neglected diseases?
Cost controls	• Low prices	• R & D? • Margin for price reduction on other markets?
Negotiated bulk prices	• Lower prices	• Target price? • Differences according to size of countries?
Global system of differential pricing, backed by international agreement	• Cost prices for least developed countries • Compatible with R & D	• Referential pricing and market segmentation? • Sustainability and transparency? • Developing countries?
Purchase-donation combinations and reimbursements	• Price reduction • Intransparency	
Research funds for neglected diseases	• R & D	• Markets? • Efficiency?
Purchase pre-commitments	• R & D for neglected diseases • Market substitution • Lowest prices for least-developed countries • Efficiency	• ?

(C) POINTS FOR CONCLUSIONS

Participants are invited to consider all the aspects mentioned and propose conclusions. It may be useful first to come back to the leading questions of this section:

1. The first leading question was: *"Do patents preclude access to healthcare because they lead to high (unaffordable) prices for medicines in poor countries?"*

The transactions in the dialogue process suggest that in answering this question one has to take into account the weight of other factors determining healthcare (poverty, infrastructure), the role of competition and generic products, the availability of safeguards as confirmed by the Doha Declaration, and supplemental strategies like bulk purchases etc., and also the need to sustain R & D in drug development. So, which answer to this question (conclusion) gives an gives an adequate account of these factors?

2. The second leading question was: *"In view of the various safeguards and supplemental strategies that are available to lower drug prices and make medicines affordable are compulsory licensing and parallel imports the best instruments?"*

Since Doha has definitely reaffirmed the safeguards in the TRIPS Agreement (CL, PI, exceptions, and delays) the questions might be reframed as follows: In view of the survey of strategies (in the table above), what should be added to the Doha Declaration in order to improve access to medicines for the poor?

3. The third leading question was: *"Is strong patent protection a necessary condition for having a pharmaceutical industry with high investment in R & D?"*

This question can also be reframed a little bit. Participants are invited to take the possibilities of safeguards, generic competition, price controls, etc. into account and conclude: Can the balance between access to medicines and protection of investment in patent law now be considered acceptable; or what improvements or modifications are still indispensable?

Further conclusions should be proposed regarding the following questions:

4. *Where do we see common ground?*

5. *What issues/points are still highly controversial?*

The next circular contains a summary of participants' answers to the questions on normative arguments. It runs as follows.

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File name = AEM-2 Steps towards conclusions.doc/pdf

Rainer Döbert

12 February 2002

IPR Dialogue Process

Steps Towards Conclusions

Part II.2: Summary of Participants' Responses to Circular 8, Access to Essential Medicines—The Normative Arguments

The normative issues and arguments of access to healthcare were dealt with in the 8th Circular. Nine participants responded to this Circular. Their responses are documented in the members corner of the IPR website, and they will be summarized below. There will be no new questions! Up to now, industry has been a bit more industrious than other participants. It would be very helpful, however, if we could base the final round in London on a more balanced distribution of responses. This is why we once again urge participants to send us some additional reactions to Circular 8 and to "Steps towards Conclusions, Part II.1" (especially answers to the questions at the end).

1. What arguments are missing or inadequately stressed?

Most missing arguments pertain to patents on essential medicines and the human right to healthcare. On a meta-level, some emphasize that the relevance of the controversy might easily be misperceived, if one failed to recognize the context: Access to medicines is deficient in many countries, irrespective of the patent status of medicines (i.e., also for generics), because of the "enormous inequity between nations", and false priorities and political strategies of countries that have resulted in totally deficient healthcare systems.

Taking this for granted, possible conflicts between IPRs and the human right to healthcare are addressed differentially. On the one hand, it is stressed that a correct interpretation of the Universal Declaration of Human Rights precludes placing IPRs and a right of access to healthcare "in opposition to each other". This is because (a) property (Art. 17), including intellectual property (Art. 27) is protected by the Declaration; (b) the right to essential medicines has to be read as a right to a standard

of living adequate (to buy medicines); and (c) undermining of others' rights is forbidden. In addition, the social human rights cannot claim precedence over other norms, but have to be compatible, among other things, with international agreements (paper sent to the WZB).

This general thrust of argumentation could also be backed by arguments pertaining to the moral inadequacy of exploiting inventors, to the necessity of stimulating and protecting R & D, and to the comparatively small contribution of public sector research to the development of medicines. Furthermore, if "need" (for healthcare) were a sufficient reason to deny patents on medicines, "any socially applicable technology must be in the public domain". But all societies had also used instruments of exclusions—these are not new constructions. On the whole, the patent system is not the instrument to ensure equal access to medicines for all. "It can only ensure equal access [to patents] to all inventors."

On the other hand, it is argued that IPRs in themselves represent a "delicate balance" between inventors' property rights and rights of society as a whole (here qua purchasers of medicines). Certainly, the balance cannot be struck in such a way that "10-25% of the population" cannot be kept alive. Instead, the balance should be struck by each country, according to the level of development. This differentiation does not imply that the poorest countries need no IP. But especially with respect to patents on medicines, companies have to show responsibility: "Right to life is first." Furthermore, the way IP has been created may generate obligations (drawing resources from society using traditional knowledge, tax breaks and withholding of legitimate dues by big players). These obligations can be met only by instituting adequate safeguards, offering reasonable prices (in a system of DP) and possibly contributions to international funds. But, one may object, differential pricing is difficult to implement (free riders) and safeguards are not used to improve access to medicines, but rather to "boost local industrial development".

Under the topic, "injustice of the IPR system", one main point was added: there is no equality of access to IP protection for the big, rich players, and the small inventors. For the latter, a whole new system of low-cost IP protection (including databases, registration, penalties for wrongful disclosure, etc.), possibly funded by a "new tax on super-selling drugs", should be set up. On the other hand, there were also some arguments refuting/modifying assertions about the injustice of the system: Doha has shown that developing countries do have a say; the system is not simply Western neo-colonialism, because it has been successfully used in developing countries; there is no one-size-fits-all approach, because of safeguards and still valid delays for implementation, and, in any case, it is highly questionable whether the development of an indigenous pharmaceutical industry is the right way to achieve industrialization for many countries (consider, e.g., overcapacity, competition with India, China).

2. How far can the moral duties of companies reach in view of the fact that companies have to be profit oriented?

Companies' right to make profit is undisputed and held to be compatible with moral duties and responsibilities. But this can mean more or less. One sees main responsibilities in long-term perspectives for employees, shareholders, and in the development of new medicines combined with punctual actions like drug donations for the poor populations. To this are added differential pricing, more commitment in combating grave diseases, redirecting parts of astronomical salaries into healthcare for the poorest, refraining from lobbying for TRIPS-*Plus* legislation, and treating

developing countries on an equal footing (no forbidden pesticides, dialogue on small patents).

3. What division of labor should obtain between States and companies with respect to the moral duty to improve access to healthcare?

With one exception—States have to provide tax incentives and companies have to contribute to healthcare infrastructure—participants stress States' responsibilities first. States should set new budgetary priorities, build up an infrastructure, create a framework for international action, give tax incentives for participation in differential pricing, and provide funds for the poorest segments of the population. Pharmaceutical companies' role is restricted (only 10 to 20% of total healthcare costs are drug costs) but important: participate in differential pricing, refrain from undue interference (TRIPS-*Plus*), and support R & D.

4. Is there a need to confine proposed solutions to essential medicines and how are these to be defined?

The definition of "essential medicines" is too vague. Irrespective of this, responses of participants can be somehow classified as ranging from more narrow to broader approaches. There is the position that CL should remain "exceptional" and be restricted to public purchases of medicines, that parallel trade has to be confined, and that there can be no systematic differential pricing beyond what companies practice anyway (very low prices for States)—mainly for reasons of antitrust law. Others think that essential medicines would be a good "place to start", or plead, only for pragmatic reasons, for a "narrower" first stage (the major diseases, HIV, malaria, TB, etc.). And there are some who vote for more far-reaching solutions, among other things, because most essential medicines are off-patent and there is also a lack of access in developed countries. The battle will not be to confine solutions, but to expand the self-perceived limits of companies.

5. Are (inclusive) human rights and (exclusive) property rights to be treated on the same level?

On the one hand, there is the position that these concepts cannot be placed in opposition, or that the question is based on "naïve confusion". Others differentiate between the property rights domain and the political/moral domain; they grant that property rights are not absolute rights, but also see that the human rights concept is becoming overburdened. Finally, human rights are held to prevail over private property rights, especially in life-and-death conflicts. This holds especially for IPRs, which are a "public policy instrument", not full-fledged ownership.

6. Would there still be normative criticisms of the IPR system if safeguards plus differential pricing were implemented?

Except for professional critics, generics manufacturers, and irresponsible governments hiding behind the IPR scapegoat, criticism would lessen because the system, as interpreted by Doha, now allows (L)DCs "to tailor their IP regime to their development needs". The situation would be even better if public health infrastructures could be strengthened at the same time. On the other hand, CL and PI have to be held compatible with R & D.

7. If TRIPS implies an "undue extension of Western concepts" and a neglect of the "cultural dimension", which aspects would have to be changed and how?

Some see no "undue extension of Western concepts" and no need for change. Others concede that Western concepts are used, but inevitably in a global economy. A need for change is seen in "a more balanced form of representation", "staged implementation according to development need", "protection of TK and small inventors", and "interface with the CBD". Possibly an agreement against counterfeiting, and just that, would be better than TRIPS.

8. The assignment of property rights is, by definition, connected with inequalities and exclusion. What are the reasons for classifying these implications as injustice?

There are no credible reasons, because IPRs reward risk taking and R & D, and it would be unjust not to do so. Others see an injustice in the ever-growing gap between rich and poor, and in lack of access to property. With respect to IPRs, there can be unjust manners of exercising them (monopoly prices, overcharging) and, because it is selective, an unjust way of granting them (small inventors, TK).

9. Is the "right to development" compatible/incompatible with IPRs?

IPRs serve "best the right to development", because they further investment, stop brain drain, and open up access to developed country markets. The fact that developed countries themselves did not have to respect IPRs in former times, does not prove anything, because, at that time, international trade was irrelevant, contrary to today's world. To this position, it is objected that development does not follow from IPRs, but IPRs from development. Nevertheless, IPRs can be compatible with development, if the property system were more equitable, and IPRs would be adapted to development needs. On a meta-level, one may ask "what the right to development really means".

10. What mechanism should be used to improve access to the whole IPR system (in terms of costs, for instance, of filing, revoking) for the poor (countries)?

Lower the costs! This is to be done through a no-cost network of IPR lawyers, an IPR foundation for indigenous groups, incentives for inventors to apply for protection, regional acceptance of patents, piggy-backing on richer countries, and civil action against infringers.

11. What other questions should be posed?

4.4 Rapporteur's Report to the Final Conference

Steps Toward Conclusions, Part II.1 once again put questions to participants with the specific aim of attaining summary conclusions. Only six replies were received. Given this meagre response, they were not evaluated. The resulting picture would have been too aleatory or one-sided. This highly unsatisfactory response rate had to do with timing problems. Since the reactions of participants tended to trickle in at a slow pace, there were delays and greater pressure shortly before the start of the final conference in London. Not all the "homework" could be finished and the argument surveys were not condensed. However, this omission was fully compensated by the contribution of the rapporteur at the final conference, a stroke of luck in every regard. The rapporteur in question, representing an African NGO, presented a balanced "report" — at any rate balanced enough to elicit the following spontaneous statement from a representative of industry: "I was able to go along with it to a great extent." The presentation on "access to health care" — announced as being from "an NGO perspective" — was oriented on questions put in the circulars, and ran as follows (continuous numbering added).

Access to healthcare—an NGO perspective

Dr Christopher Ouma, ActionAid

Patents and access—-what is the real focus of the controversy?

1. The actualisation of basic rights for the poor, their ability to recognise and claim their rights, and the states right to pursue policies to that effect.
2. No agreement should prevent a state from preserving the basic rights of her citizens

Do patents on essential medicines violate the right to access healthcare?

3. Human rights and property rights are part of the same spectrum—we have to draw a line that will have the best outcome.
4. A right to remuneration rather than a right to exclusion.
5. Access should be based on need rather than on the ability to pay.
6. Patents have represented a significant hurdle in the drive towards access for the poor.

Are CL and PI the best instruments to increase access?

7. Solutions for access are varied, in the same way that incomes are different. Every state must have the right to use the options that it feels serve the interests of its people best.
8. CL and PI represent some of the most effective options so far. Some sanity has returned in terms of pricing of AIDS drugs.

Is strong patent protection necessary for investment in R & D?

9. It is an important incentive [in developed countries].
10. Sometimes forgotten are political will (despots, tyrants, dictators and villains), human rights and security.
11. To exert pressure on States—we use participatory planning and reviews, and budget tracking.

How can strong patent protection contribute to neglected diseases?

12. Can stimulate research if there is increased patent period, purchase precommitments and tax exemptions.
13. Will need input through political stability, increased political will and state investment.

Other options

14. Tier pricing,
    Bulk purchasing,
    Purchase precommitments,
    Voluntary licensing,
    Negotiated price discounts,
    Increasing per capita expenditure on health e.g. African countries commitment to spend 15$ per person per year.

In conclusion

15. The current IPR regime has led to deinvestment and limited technology transfer, and no commitments in the agreement have been forthcoming.

16. In the new round of trade talks we hope to see support for resource poor nations (Financial and personnel), greater involvement of CSOs and greater involvement of stakeholders.

Many of the statements are easy to assign to a NGO perspective. "No agreement should prevent a state from preserving the basic rights of its citizens" (2); Patents should not grant a monopoly: "a right to remuneration rather than a right to exclusion" (4); "access should be based on need rather than on ability to pay" (5); "CL and PI represent some of the most effective options so far" (8); and "every state must have the right to use the options that it feels serve the interests of its people best" (7) are fully pertinent in this regard and, taken together, describe a quite unambiguous position — or so it appears. However, the exact meaning of these statements must be seen in the context of other statements, which provide a balanced picture. "Human rights and property rights are part of the same spectrum — we have to draw a line that will have the best outcome" (3) contrasts markedly with the usual counterargumentative slogans demanding clear prioritizing of the "human right to essential medicines." In this case a reconciliation of interests on a continuum is sought. The IPR system is not called into question in principle. In developed countries, patents are "an important incentive" (9), and patent protection should even be strengthened in the case of neglected diseases (increased patent period (12)). "More flexibility for poor countries" is thus the core message of the presentation, an issue on which the opposing side is open to negotiation. It is also striking that the role of the failure of governmental agencies is more strongly underlined than usual in NGO publications. Not that this point is entirely neglected. But it is hardly every given more than cursory treatment. In the presentation under discussion it is addressed four times (10, 11, 13, 14 last point) — and using very strong language like "despots, tyrants, dictators and villains" (16). Thus the buck is not simply passed to industry, a manoeuvre that otherwise always produces a degree of indignation in business circles.

In all, it is therefore understandable that representatives of industry found this presentation of an NGO perspective moderate. An attempt, initially in separate talks, was accordingly made to develop the declaration into a common platform. It failed. Nevertheless, the presentation gave major impetus to the search for common ground, and the author was requested to structure further discussions by presenting a concrete case history from his practical experience. The case history made the relevance of the conflict on the patenting of medicines drastically clear. An NGO had taken on the task of supplying a district in an African country with AIDS medicines, and entered into negotiations with drugs companies. The patented brand preparation cost about $10,000 per year, a corresponding generic

product would cost only about $260 a year. For Africa this difference is naturally the difference between hopelessness and hope.

The presentation of the case did not determine the further progress of the discourse, but did supply the emotional backdrop. In order to achieve results under increasing time pressure, the moderator especially engaged for the final conference suggested carrying out a brainstorming session with subsequent selection. Members of the working group identified statements which, in their view, ought to be included in the common conclusions of the process. Statements were checked to see if they met with opposition and were then presented to the plenum at the final session. The documents and plenary discussions were to provide the basis for the final report to be prepared by the Steering Committee with the assistance of the WZB team.

4.5 Note from the WZB Team for the Final Report: Attractors of Argumentation

The draft for final report was drawn up on a broader basis than the discussions in London. This was because the group of people who took part in the sessions of the working group on access to essential medicines in London overlapped only partly with the group that had expressed their views in the Internet discourse. And the results of the London conference were as a whole "thinner" and less substantial than what had emerged in the course of E-mail correspondence as possibly capable of finding a consensus. "*Possibly* capable of finding a consensus" because a weaker consensus criterion was chosen than "full agreement." Since some organizations in effect prevented their representatives from showing enough argumentative flexibility — a sort of imperative mandate — full agreement would almost inevitably have implied reduction to a substantive zero. To avoid this it was proposed to include statements from the Internet exchanges in the final report that could find the support of representatives of *both* conflict parties. Such statements can be regarded as *attractors of argumentation*, which incorporate a real balance of interests. Dissenting participants — keyword "minorities" — were to have the option of declaring themselves "observers." This procedure was explained to the Steering Committee and participants in the first draft of the final report as follows.

(Tentative) Attractors of Argumentation in the Discussions on AEM

Rainer Döbert

Remarks for the SC

In the following you will find six pages on AEM. They do not reproduce the entire complexity of argumentation on that topic—why reproduce the argumentation tree in toto? Instead, they concentrate in a specific way on a sort of common ground, which is a little bit less than unanimity. For this purpose, I add to the statements agreed upon in London further statements that emerged from the electronic dialogue (and sometimes directly from the argumentation trees) as *widely*—not completely—acceptable. Some of these additional statements help to clarify and delimit the meaning of those statements accepted in London; others supplement the range of considerations. Maybe at one point or another, one would like to add some further, semi-consensual statements; maybe at one point or another, one would like to take one more glance at divergences. We shall see!

In any case, it would be extremely helpful to find out at that point in the process, whether the Steering Committee, wants to set up this *type* of final report for the topic of AEM. If you have the impression that it is the right type of report, then please respond with details in the form of constructive criticism. For those worried about being put away with the wrong party to a non-existent common ground let me stress: Everyone can remain observer! And let me add that the whole thing was put together with an eye on one goal, namely, to demarcate what industry can contribute. If one wants to make industry move in the right direction, one may be well advised to ease tension and anger. That is why emphasis has been laid on the fact that not principles as such or the very existence of a research-based pharmaceuticals industry are at stake, but the *point* of a compromise. Hopefully, stress has been adequately placed without generating unwanted imbalances!

Rainer Döbert

A. How Much Consensus Is Required for Coming Up with a Significant Result?

In a conflict like that about an adequate relationship between AEM and IPRs, one finds, as a rule, a distribution of opinions in the beginning of a dialogue process and also at its end. If the dialogue process has done what it was supposed to do, namely, to generate some argumentative reasons to change position, then the distribution of opinions may have become narrower, and more „points“ in the distribution are supported by representatives of the most divergent views—for instance, *both* by industry and NGOs. Let us call these points „attractors of argumentation“, points that

attract many, but do not succeed in attracting all participants. This is less than perfect consensus or unanimity.

An additional restriction will be useful with respect to the meaning of „support" of an argument by participants. Full, explicit support of an argument („I agree …", „In my view …") would of course be the best indicator of support. But there may be more indirect forms of agreement like „not opposing a statement by someone else" or logical implication of one statement by another (even if silence cannot in general be taken as approval). To give an example, if one agrees that a margin for R & D has to be guaranteed in prices of pharmaceuticals, then it becomes difficult to stick to the position that the use of compulsory licenses can be left *completely* unconditional, because such an unrestricted use would drive prices to marginal costs with no protection of R & D investment.

What would one gain by scrutinizing the transactions of the WBCSD dialogue project with these qualifications in mind? First, since representatives of the most divergent views join in backing/not opposing the statements identified, one may conclude that the ensemble of respective statements circumscribes something like a workable compromise of conflicting claims. Second, this can be stated in an observer's perspective without having to enter the resulting field of convergences. Since neither unanimity nor enthusiastic support (non-opposition suffices) is required, whoever refers to the result can signal as much distance to it as he or she wants. What is said is simply that we can observe an attractor, a region of convergence in the dialogue process with the specifications as indicated. Third, by proceeding in this manner, one gains something of the advantages of „voting" without having to „swallow" its disadvantages. The advantage consists of „numbers" as one indicator of acceptability, however weak or strong. The disadvantage being avoided consists of splitting participants into a rigid disjunction of pro and contra. One concentrates on middle ground. Fourth, because the requirements for this sort of limited consensus are weaker than those for outspoken, unanimous support, we may find more substance and thus be able to come up with more than truisms like „health is a precious good". By having more content, it may be possible to demonstrate a peculiarity of the conflict over IPRs and AEM: Contrary to initial impressions, this conflict is not about basically diverging values in the sense that fundamental values, norms or goals of opponents are rejected or disqualified as irrelevant; instead, the controversy is one about tuning a system in such a way that the legitimate claims of all involved are respected as much as possible. It is not „principles" that are at stake, but rather adequate compromise.

5. The Final Report: Conclusions on Access to Essential Medicines

The proposal to proceed in the way outlined in the "attractors of argumentation" was accepted, and the final report was drawn up on this basis with the statements approved in London being indicated by footnotes. Suggestions from participants for improvements were worked in, dissenting opinions and the corresponding formulations were taken into account in footnotes. The final report ran as follows.

Access to Essential Medicines

Introduction

Lack of access to essential medicines is an element in the health crisis that threatens many countries in the poorer parts of the world. Access to medicines is affected by many factors, IPRs (especially patents) being one of those factors. In this respect, a broad consensus exists among representatives of the most different organizations. Controversial issues are the extent to which patents affect access to medicines and whether such impact warrants (or requires) the revision of current regimes of intellectual property, especially of the TRIPS Agreement.

The assessment of the relevance of patents has a factual dimension and a normative one. In the factual dimension the crucial question is whether patents, because they lead to higher prices, will make essential medicines unaffordable for poor people. It was understood that any discussion of this question must also touch upon the *safeguards* — such as compulsory license or parallel imports — built into IPR regimes to mitigate possible negative impacts of patents on access to medicines. The participants discussed how these safeguards could be used (and redesigned) under the TRIPS Agreement. In principle, conceptions could range from denying patents for medicines altogether to making even stronger provisions for IPR protection (TRIPS-*plus*). Some participants also referred to *supplemental strategies* that might function as equivalents to those safeguards: differential pricing, donations, etc. Some of these strategies (international funds, new health policies) require interventions from the public sector (governments or WHO).

In the normative dimension the discussions focused on three main questions: (1) Do patents on essential medicines violate the human right of access to health-care? (2) Do companies have moral obligations to contribute to the solution of the health crisis in developing countries? (3) Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

Controversy over both the factual and the normative issues prevailed in the *Dialogue Process*. The participants had divergent views and preferences with regard to the options implied in various safeguards and supplemental strategies. This divergence reflects (among other factors) different notions of how conflicting objectives of IPR regimes should be balanced: Prices should be low enough to make medicines affordable for the poor, and they should be high enough to provide incentives for investment in R & D to create these medicines in the first place. There seemed to be broad consensus among participants that both objectives must somehow be taken into account in designing and assessing the regime of IPRs — but how exactly? In this respect many divergences remained.

Controversy over normative issues can hardly come as a surprise. Value conflicts are notoriously difficult to settle. Nevertheless, in this dimension, too, one could observe some argumentative flexibility: Participants managed to come up with conclusions which represent at least more consensus than existed at the beginning of the dialogue.

The conclusions listed below for the Working Group on Access to Essential Medicines hardly represent perfect consensus. The London conference succeeded in passing a series of statements that came very close to unanimity (footnoted as "London"). However, often the best result achieved consisted in statements that attracted many, but not all, participants. Such statements, especially because they are supported by representatives from both the industry and the NGOs, indicate "attrac-

tors of argumentation". They should be included in the conclusions to give a more complete picture of the whole field of argumentation.[35]

A. The Need to Integrate Conflicting Objectives and Values

The following three statements taken together suggest that a workable compromise is at stake in the whole debate. The statements acknowledge in principle the goals and values of the conflicting parties, establish the primacy of public health in the case of conflict, and restrict the possible interpretation of "primacy" in such a way that industry does not have to pay the whole bill. Not all participants, but many with otherwise opposing views, supported the balance represented by the following three statements in combination. The "in combination" has to be emphasized especially in this section because each of the three statements taken in isolation would be misleading as a representation of the discussion.

115. Any sustainable solution to the conflict between IPRs and access to medicines should combine respect for human rights, the acknowledgement of property rights, and it should be compatible with R & D.[36]

116. If there is a conflict, public health has primacy over IPRs.[37]

117. Companies are economic agents and as such have a right to be profit oriented, but have a responsibility to act ethically and respect human rights. A right to compensation for innovation must be acknowledged. In particular, the human right to health does not apply to private products (medicines), but to the information required for manufacturing medicines as implied in the States´ right to grant compulsory licenses".[38]

B. The Role of Patents, Prices, and R & D

The participants joined in the assessment that high prices for IPR-protected medicines can be one barrier for access to healthcare in poor countries — but among other factors. They acknowledged that special conditions should obtain for those in need, and that the *safeguards* of the TRIPS Agreement and *supplemental strategies* like differential pricing must be considered in this respect. The participants did not agree on the interpretation of the "exceptional nature" of compulsory licensing and on the adequacy and reach of parallel imports; but there was a rather broad consensus that these instrument should be used under the conditions/restrictions spelled out by international treaties.

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35 One participant found section A, "The Need to Integrate Conflicting Objectives and Values", unbalanced and preferred to remain "observer", saying neither "yes" nor "no".

36 One participant (expert) preferred the following wording of paragraph 115: "Any sustainable solution … should combine respect for human rights with a recognition that there is a need to provide public support and private incentives to fund R&D of new medicines"

37 Statement 116 was opposed by some participants, because "one human right cannot prevail over the other". One participant (industry) emphasized that the statement does not imply "that any public health issue is enough to override IPRs …, [rather:] if serious problems arise and no sustainable solutions have been found through public spending, donations, etc., then, of course, public health has primacy over IPRs and waivers could be implemented to safeguard that poor people still have access to essential medicines. But this should be the ultimate solution." Statement 115 was opposed by another participant *if not* combined with statement 116. One may say that 115 was adopted in London with one qualification; there was no unanimity, but the *combination* of 115 and 116 was acceptable to many representatives of opposing views.

38 One participant (expert) disagreed with the last sentence "In particular, the human right …" since this statement is misleading in view of the fact that States do have the right to expropriate private products as necessary.

118. Patents can represent a barrier, but they are not the only barrier to (healthcare) access in poor countries.[39]

119. The main causes of the global health crises are widespread poverty, inadequate political priorities and the inability/failure of States and of the international community to provide public funding, especially for those segments of the populations that cannot even afford to buy generics.

120. The outcome of the Doha Declaration is endorsed "as it stands".[40]

121. A combination of safeguards, essentially in the form of compulsory licensing, with a system of differential pricing[41] would be a significant improvement in the status quo. In a differential pricing system, least developed countries would have access to essential medicines at cost prices or below (drug donations).[42]

122. Differential pricing schemes presuppose the establishment of market segmentation, preventing re-imports to developed countries. They also presuppose a renunciation of referential pricing by governments of developed countries. Otherwise they would be incompatible with R & D.[43]

123. The costs of R & D are covered to such an extent by the markets of developed countries that least developed countries can be relieved from contributing to the profits and costs of R & D. This is a variant of the moral principle of distribution according to need, as adapted to the business system. Otherwise a principle of contribution (to R & D) according to ability to pay should prevail.[44]

124. Governments should initiate multi-stakeholder processes to address a (health) crisis. Patent owners should "exercise their rights in a manner supportive of access to healthcare by all, and patent owners and other suppliers should respond promptly and in good faith, in procedures for the granting of compulsory licenses in consistency with TRIPS".[45]

125. R & D for neglected diseases should be increased, including public research and the use of public-private partnerships.[46]

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39 Agreed upon at the London conference.

40 Agreed upon at the London conference.

41 A system of differential pricing, if based on collusion or other anti-competitive practices may be incompatible with some national anti-trust laws.

42 One participant (expert) preferred the formulation "or below" to be deleted since drug donations are unrelated to pricing issues. Another participant disagreed with the whole paragraph, because "there is no consensus that compulsory licenses are linked with the use of differential pricing." In addition, the same participant stated that differential pricing schemes will not improve access to essential medicines, because other factors are much more relevant in this regard." Another participant (industry) pointed out that a scheme of differential pricing should not prevent the search for individual, possibly better, solutions.

43 One participant preferred the following formulation: "Parallel imports and differential pricing may require stronger controls in developed countries to avoid diversion of products from low-priced developing countries´ markets and a renunciation of referential pricing by developed countries´ governments.

44 Some preferred the following formulation: "If the costs of R & D are covered by the markets of developed countries, then public health care systems in least developed countries (LDCs) can be relieved from contributing to the profits and costs of R & D", because "in developing countries (DCs) [not least developed] there is a private market that can bear R & D costs".

45 Agreed upon at the London conference.

46 Agreed upon at the London conference.

C. Human Rights and Justice

(1) Human Rights and IPRs

There was a broad consensus that companies have a moral duty to help those in need, and to promote better access to medicines for the poor. Participants did not agree, however, that such a duty could be framed in terms of human rights. As a legal document, the Declaration of Human Rights obliges States, not private companies. There was consensus that the right to healthcare obliges governments, for example, to set policy priorities that support access to medicines, including appropriate funding of healthcare systems, or to use the safeguards and flexibilities of patent law accordingly. These obligations do not necessarily imply a mandate to disregard the protection of private property, since the latter is a human right as well[47]. Companies, in turn, have a duty not to undermine legitimate government policies for better access to medicines.

126. Public healthcare is primarily the responsibility of the government.[48]

127. Governments have the right to define "emergency" and a duty to act upon it, e.g., by allocating appropriate funding, giving primacy to public health, setting the right priorities.[49]

128. In view of the Declaration of Human Rights and in view of the very nature of IPRs, both as public policy and legal instruments, States have the duty to couch intellectual property law in such a way that the common good, especially public health, is respected. TRIPS, as interpreted by the Doha Declaration, can be read as an application of this duty.

129. Within the limits of reasonable economic calculation, companies have to show responsibility; that is, they must try to help further the common good through donations or contributions to funds and differential pricing practices.

130. As States have to integrate respect for the common good into their IPR legislation, companies have to accept the safeguards of TRIPS and abstain from any lobbying for TRIPS-*plus* legislation, which undermines the use of the safeguards.

(2) Debate over the Justice of TRIPS

The justice of the TRIPS agreement, both in the sense of the fairness of the procedure of negotiation and the equity of the contents of the treaty, are a matter of ongoing debate. This debate is, in the final instance, propelled by concerns that the enforcement of IPRs could contribute to widening the gap between North and South. The participants could not discuss the issue at great length. However, at some points there was convergence that may serve as the basis for further discussion.

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47 One participant (expert) requested that the half-sentence "since the latter is a human right" be deleted, since "the idea that corporations hold property as part of their 'human rights' is awkward and legally flawed". On the other hand, one participant (industry) argued that the notion that rights to knowledge are protected as human rights is also implied in the demand that rights regarding traditional knowledge should be protected as rights held by the respective community.

48 Agreed upon at the London conference.

49 Agreed upon at the London conference.

131. Even if the procedure of arriving at TRIPS was not as "flawed" as some assert, it was flawed enough to justify that the TRIPS agreement will either be amended or interpreted by the TRIPS Council in line with the Doha Declaration.[50]

132. The imposition of a global order of IPRs favors developed countries. To undo resulting imbalances and lacking reciprocities, compensation in the trade sector for textiles and agricultural products, as well technology transfer has been promised. Up to now many of these promises have not been kept.[51]

133. The whole IPR system discriminates against poor countries[52] and small inventors because it is too costly.

50 Representatives of industry emphasized that this point should be deleted, because *"the dialogue was not made to discuss this issue"*.

51 Some representatives of industry said that this point should be deleted for the following reason: "It is the other way round … GATT … if implemented correctly … would result in advantages for both developed and developing countries. Only because the USA and the EU have not yet done this in the agricultural and textile sector, developing countries are still behind."

52 Some representatives of industry said that the phrase *"against poor countries"* ought to be deleted.

6. Tentative Evaluation of Process and Outcome: Rationality, Consensus, Governance

Finally, a number of explanatory remarks on the status of the above final report are needed. This report is, by and large, meant to give an account of the visible course of the stakeholder dialogue on access to essential medicines and IPRs. Orientations and assumptions of the organizing agencies (WZB and WBCSD) and participants were touched upon just to such an extent that the whole process can be understood step by step. A detailed analysis of the implications for sociological theory has been postponed for the time being. This will be dealt with in subsequent publications. Quite a bit of microanalysis will be required, for instance, to clarify how the discourse process transforms given inputs (single arguments) by putting them into the context of competing arguments. But, after all, an outcome — the final report — is present now, and some of its implications for the theoretical considerations spelled out at the beginning of this paper (governance, consensus, rationality) can be read from the result without going into details of its genesis. How comprehensive was the participation on which it was based? To what extent can it be considered a rational judgment in reflective equilibrium? How broad is the consensus it incorporates? Broad enough to generate governance?

To begin with the positive aspects, it should be noted that the Steering Committee, backing the conclusions, included representatives of all conflict parties. Although dissenting opinions were registered in the footnotes, we do not consider them weighty enough to refute the assessment that the discourse process produced a relevant and agreed result. This would have been impossible without the argumentative flexibility of participants. The process has been overtaken by the Doha Declaration, but at the time when the latter was published the dialogue was in the throes of deriving something along Doha lines from the arguments it had mobilized. And the argumentative basis for the Doha Declaration is to be found not in the Declaration itself but in the argumentation surveys of the discourse process under discussion. Furthermore, the debates stressed (extralegal) supplemental strategies like differential pricing — now becoming official EU policy — in order to lighten the burden of poor countries. In effect, the report aimed to improve a multifunctional balance, thus blocking the way for monofunctionally inspired bias. And in its diagnosis of the causes of the global crisis in the health care system it cleared a logjam by emphasizing the role of governmental failure. These are rationality gains in the sense of this process presentation that show convincingly

why the content of the final report was indeed able to find limited consensus. Up to a certain point, argumentation works a a genuine medium of communication informing *and* motivating agents.

However, a number of undoubted shortcomings are to be noted. First, representatives of three NGOs withdrew to observer status, despite the possibility to include dissenting formulations in the final report. A majority of NGOs, it appears, believe themselves unable to run the risk of deviating from the official stance of their organizations, and say neither "yes" nor "no." This is not dissent, but it is a great deal less than consent.

There were also deficiencies in participation, largely as far as NGOs were concerned. Important NGO representatives were absent from the final conference. Their participation in the E-mail dialogue was somewhat poor in comparison with industry. In our view, this implies that many of them did not explicitly process the arguments of the other side and, where necessary, reject them point by point. It is no exaggeration to assert that the NGOs — often the most vehement critics of representative democracy — are themselves the most diligent practitioners of the principle in their internal operations. A very small number of "IPR experts" in the world bear the brunt of criticism. Finally, there is reason to believe that only a few of all the participants made the effort to study the detailed argumentation surveys (two of twelve E-mails inserted corrections). If the condensed versions were well done, this shortcoming need not necessarily have implied serious omissions in preparing a well-considered judgment in reflective equilibrium. Nevertheless, we feel that some sub-controversies could be solved only by devoting a great deal of thought to the overall bulk of information. But the time needed obviously exceeded the time budgets of many participants. The same bottleneck was apparent at the final conference. The time available for discussion was not sufficient to go through the entire field of argumentation in detail. Finally it was necessary to rely on a more "holistic" procedure and to stage a brainstorming session with selection (see above).

All this certainly involved losses in rationality — but not necessarily so serious that the outcome of the discourse could not be qualified as "more rational" than the starting positions of the conflict parties. In general, it can be asked how much detailed knowledge is needed in situations requiring action to provide adequate "bounded rationality" (Simon) in deciding what action to take. There may very well be situations in which the full load of information may be more a hindrance than a

help for rational decision making. The discussion of this problem must be reserved for later thoughts. Overall, it can tentatively be said that processes of this type generate enough argumentative pressure to discover consensual domains — with corresponding effects in the social dimension: neither were the conclusions explicitly rejected, nor were there demands for comprehensive minority votes, or a refusal to engage in discourse. But they certainly do not generate the extent of consensus needed for binding decisions: when in doubt, action and participation costs (having to waive tried-and-tested arguments/slogans and justifying this course vis-à-vis the organization of origin) and, not least of all, transaction costs (time) proved to be too high. This assessment naturally has implications for the role that processes of this sort can have in the constitution of governance. They prepare governance but are not yet themselves governance.

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APPENDIX I
Circular 5: The Argumentation (long version)

IPR Dialogue Working Group III (Access to Essential Medicines)

5th Circular:
IP Regimes and Access to Health Care, Part One
(Rainer Döbert)

Arguments: IP and Drug Prices
(long version)

This file contains full length arguments pertaining to the question whether IPRs (especially patents) will have a negative impact on access to healthcare because they lead to higher prices for essential medicines. We present the arguments under three lead questions which broadly differentiate the topics discussed by the participants and in the documents that have been consulted by the WZB team. The lead questions are:

Question (1) **Do patents preclude access to healthcare because they lead to high (unaffordable) prices for medicines in poor countries?**

Discussions of the relevance of patents for the prices of medicines and the relative weight of patents (and patented drugs) among the other factors that determine access to healthcare.

Question (2) **In view of the various safeguards and supplemental strategies that are available to lower drug prices and make medicines affordable are compulsory licensing and parallel imports the best instruments?**

Discussion of the options to avoid or compensate negative impacts of patents on drug prices by applying the "safeguards" offered within the IP-regime or by using appropriate "supplemental strategies".

Question (3) **Is strong patent protection a necessary condition for having a pharmaceutical industry with high investment in R & D?**

Discussion of the need to balance drug prices with the protection of private investment in R & D that creates new medicines

The reasons for distinguishing these lead questions are further explained in the Introduction of the condensed version file.

The documents consulted by the WZB team are listed in the appendix at the end of this file.

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1. Do patents preclude access to healthcare because they lead to high (unaffordable) prices for medicines in poor countries?

NO/not necessarily	YES
a. Drug Prices and Other Factors	
1. Access to health care depends on so many factors (poverty, conflict, inequality, infrastructure, economic policies, informational gaps and cost/price issues) that focusing on patent protection and pricing would be "simplistic" (Bale, 12 ff.; WTO, 7; M 13/14-1a, 2; Oxfam, June, 1, R5:1).	2. Patent abuse is a central obstacle to successful treatment (M 13/14-1a, 2).
	3. Medicines will comprise half of the resources of the UNAIDS global trust fund; the cheapest prices will "allow more people to be treated" (M 13/14-1a, 14; Oxfam, 2001, Montreux 13/14, 227).
4. States' economic failures are the main cause of lack of access (M, 15, 103 R5:6).	5. High price of drugs is one of the main factors causing poor households to avoid seeking treatment (Oxfam, 2001, 13).
4a. Successful treatment depends on new products supported by patents (R5:9)	6. Prices and infrastructure interact: only after "drastic dropping prices" did it make sense to build up the "the infrastructure which is necessary" (M, 13/14, 361); in South Africa government hasn't had an intelligent response to treatment . . . because until now there haven't been new options (best prices) to that; now, ". . . we eventually force the government to bring treatment into the public sector . . ." (M, 13/14, 154 ff.).
4b. Industry has offered products at substantially discounted prices (R5:9)	
4c. High prices or costs are an obstacle for all healthcare interventions, not only medicines (R5:9)	
4d. Medicines are private, not public goods (R5:9)	
8. Even when generic versions of drugs are available, access may be poor in some countries regardless of status of patents (India, Africa) (Bale 15; WHO-WTO, 8, R5:4, R5:9). So the price differentials between India and Pakistan as reported by Oxfam (2001) (up to factor 14) existed although both countries "excluded pharmaceuticals from patent protection in the relevant period" (WTO, 7).	7. One cannot lump all poor countries together: South Africa and Russia "struggle to treat multi-drug resistant TB", but the necessary medicines are patented and unaffordable (M 13/14-1a, 14).
8a. Patients not suffering from drug resistant TB are also not treated (R5:9).	
9. South Africa is not such a poor country that it can't afford medicines . . . the defense expenses of South Africa are much higher than its health expenses (M, 13/14, 96 ff.). The problem is, that the poorest continent has "the greatest member of armed conflicts" (M, 15, 1374)—and all this holds for many developing countries with priorities on "military budgets" (Oxfam II, 2).	10. South Africa is one of the most unequal societies with much poverty and unemployment (M, 13/14, 146).

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NO/not necessarily	YES
b. Price Effects of Patents	
11. In South Africa, the public sector prices were lower than the quoted retail pharmacy prices (M, 13/14, 182 f), according to ability to pay.	14. There is "overwhelming evidence that with generic competition drug prices fall substantially . . . This will result in more people gaining access to essential HIV/AIDS medicines . . ." (M 13/14-1a, 10/11;): South Africa with strong patent protection treats 10 000 HIV patients; Brazil, via the production of generic antiretrovirals, over 100,000 (M 13/14-1a, 12; cf. Bale 11/6; WTO 6; Oxfam 2001, 12, 26 ff.).
11a. Selected use of statistics attempting to link unrelated facts (patents – access) (R5:9).	
12. The final retail prices include taxes and distribution costs which may make up to 80% of the consumer price (WTO 5; Montreux, 15, 1359).	15. Estimates of price reductions induced by generic competition range between 40% and more than 80% in the USA; simulations for Argentina and India yield a highest possible increase of 200-300% by the introduction of product patents (WTO, 7; cf. Oxfam II, 19, factor 3 or 4).
13. On the whole "countries with intellectual property protection did not have higher prices than countries without such protection" (Bale, 15).	16. The possibility of charging higher prices "is essential to the patent rights" (Montreux, C., 385).
13a. Generics companies don't spend billions on R & D (R5:9)	
c. Off-patent Drugs and Competition	
17. Most essential drugs for developing countries are off-patent (Bale, 15; WTO 6/7). The same holds for developed countries. The IP discussion "is irrelevant on that" (Montreux, 15, 1354).	18. With the spread of drug resistance and with new drugs appearing the number of essential, patented products will grow . . . When people's lives are at stake five percent (patented drugs) is five percent too many (Oxfam, 2001, 25).
20. "Patented drugs face competition from off-patent products"—sometimes after one year (Bale, 16) and "few patented drugs have no effective substitutes (me-too drugs, WTO 6, R5:6)	19. There is a natural tendency of people to stop treatment, when they feel better (R5:9). Higher prices propel failure to complete treatment, which, in turn, "contributes to the spread of drug resistance" (Oxfam, II, 3). This holds all the more so, since most medicines are paid "out of pockets" in developing countries (Oxfam, II, 2).
21. HIV is a special case (new disease, new drugs; Montreux, 13/4, 322 ff.; 15, 1421; that afflicts not all poor countries (WTO 6, 96); therefore, it should not lead to a change of the whole TRIPS	22. Price comparisons "demonstrate monopolistic pricing practices". Competition by substitutes is limited since "medicines" in the same antiretroviral class have different properties (different allergic reactions, different resistance patterns, M 13/14-1a, 14).

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NO/not necessarily	YES
23. A drug, even a generic one cannot be "affordable" to everyone as long as incomes are unequally distributed! Special means (funds) must be developed to improve access for the poorest population (Bale, 12, 15/16; Montreux, 13/4, 419 ff.; 15, 1755).	
24. "If we go on opposing civil society interests and the patients and the industry . . . front to front . . . we will go nowhere; we will not find a solution . . . We have to introduce a third party . . . public money . . . like the Kofi Annan Funds. If there is . . . a new possibility to involve the industry . . . and to make a deal on prices and . . . the more public money will come to buy medicines the cheaper the medicines will be" (M, 14, 1367 ff.).	
25. [See below arguments nos. 26-72 ("safeguards", especially differential pricing)]	

2. In view of the various safeguards and supplemental strategies that are available to lower drug prices and make medicines affordable are compulsory licensing and parallel imports the best instruments?

YES	NO/not necessarily
a. Compulsory Licensing and Parallel Imports	
26. There is overwhelming evidence that only CL and PI guarantee affordable prices in the long run (cf. M 13/14-1a, 10). In South Africa, prices dropped only after the government talked about CL and under pressure of offers from Indian companies (cf. M 13/14-1a, 17). This shows that "a lot can be done" by "just applying the safeguards (M, 2A, 276).	27. But CL is an exception (M, 13/14, 525) bound to "national emergency", a difficult last resort (Oxfam, II, 27) from which "developing countries cannot derive advantage"; this is because they do not have an "advanced pharmaceutical industry" and there are difficult procedural preconditions (Oxfam, II, 27). 27a. CL was not necessary in developed countries to overcome health crises; in developing countries one main obstacle, lack of distribution, would still exist (R5:4)
28. "When the TRIPS agreement is interpreted . . . exceptions conferred under the TRIPS agreement should be interpreted in a broad manner" (M, B, 19 ff.)—and this is a realistic option (Correa, 2000).	

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YES	NO/not necessarily
29. In this respect, it is unacceptable that there has been a lot of pressure from industry and governments to prevent CL and PI (TRIPS plus) (M 13/14-1a 9, 17; M, 2B, 40, 207 ff.)—culminating in a new bilateralism with highest IPR standards (M, 2A, 379 ff.; Grain, July 2001).	30. The European Commission is not "preventing anybody from using compulsory licenses . . . The TRIPS agreement . . . says that you can issue compulsory licenses for any reason . . . (in this respect the Commission has moved in the last 18 months)" (M, 15, 683 ff.). 31. Industry does not say "don't use CL. Let's be honest, which country has already used CL . . . although they had the right to do so?" (M, 15, 613 ff.) CL "has not been very much used. It's not a good instrument. Normally you should find a solution by negotiation . . . maybe it's a question of how to practice it" (M, 3A, 217 ff.).
32. "The grounds on which this [CL] can be done are not limited by the agreement (WTO, 26) and there is no reference to "exceptional circumstances" or "emergencies" in the agreement (M, 2B, 207 ff.; cf. Correa, 2000, 20).	33. Article 31 of TRIPS (reprinted in Oxfam, II, 48) states on CL, among other things, that one may circumvent getting a voluntary license "in case of a national emergency or other circumstances of extreme urgency" or "in cases of public non-commercial use", "predominantly for the supply of the domestic market". These reasons are mentioned "to illustrate the type of grounds that may be applied" (Correa, 2000, 20). 34. CL "is presented within TRIPS (not as a routine situation . . . there are quite a lot of conditions" (M, 15, 819 ff.). It's no problem when a government gives a CL to a manufacturer who then sells to the public health facilities to distribute his products "for free". "I have more difficulties with . . . the government saying, I do not want to put a coin of money in this particular drug . . . I will give a license to a producer . . . I see a government which would have created a competitor for me and then I wonder is it a fair competitor" (no "upper costs"; M, 15, 911 ff.).
36. "Governments will be unable to raise enough money; that is why the private sector is essential to this as well"; by CL "prices will go low enough . . . so that thousands . . . will be able to afford those medicines" (M, 15, 973 ff.). Low prices should "[also cover] not-for-profit providers and employers of large numbers of low-income workers" (WHO/WTO, April 2001, 9).	35. When a third party (public money) is introduced "the cheaper the medicines will be" (M, 15, 1386 f.).

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YES	NO/not necessarily
37. CL should be used in the USA too (M, 13/14, 670).	38. Unrestricted CL will drive "prices down to marginal costs or close to marginal costs (M, 13/14, 687 ff. "So the question is, in the existing system where you have a private sector . . . doing R & D, if you were to drive prices down to cost in all markets would you expect them to do R & D? . . . It's not realistic" (M, 13/14, 721 ff.).
39. "We have never asked a company to reduce its price to cost price" (M, 13/14, 1110 ff.); they should have a "5% royalty" (M 13/14-1a, 2) and there should be a 1% R & D tax on all generics.	38a. 5% royalties would not sustain R & D of 50 billion a year (R5:9) 38b. CL and PI must be continued with other measures and there must be a spectrum of application of IPRs—from strict to lenient in accordance with economic development (R5:12)
41. [Product quality] is a problem of enforcement and control that should not affect patent legislation (M, 13/14, 1146). 42. Patent protection may even "act as an incentive to counterfeiting" (high prices: Oxfam, 2001, 24)	40. CL and PI are "no magic policy potion" (Bale, 7 ff.): licensees may "lack skills in manufacturing an equally safe and effective product"; PI "increases opportunities for counterfeit and substandard products" (Bale, 18). 40a. Counterfeit generics are probably more common than of branded products (R5:9)
44. [CL has influence on prices; see above arguments no. 26]	43. Governments use CL and PI "as industrial policy, not "as a pro-consumer tool": benefits accrue mainly to copiers and traders, not to patients (Bale, 8, 18, R5:4).
46. Illegal exports are manageable (Oxfam 2001).	45. In the developing countries there is "a lot of criminal energy and we see a lot… of pharmaceutical products… being shipped elsewhere. They are not kept in the country where the need is, but they are shipped to the [developed] world to make some people rich in these countries. And this is a point which all these pharmaceutical organizations drives crazy . . . (M, 3A, 226 ff.).
47a. Without CL government would not have had enough bargaining power (M, 15, 844) and it would not be possible to determine the lowest prices (R5:5).	47. It's a false assumption that CL will result in much cheaper medicines; there are new much lower prices without CL (M, 15, 1108; cf. differential prices) or modifying the patent status of products (R5:4)

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YES	NO/not necessarily
b Voluntary Licensing and Funding	
49 Should these voluntary licenses also be "for use in the industrialized world"? (M, 13/14, 459)	48. "I don't know what goes through your head that you are sitting here having a discussion about [this] narrow intellectual property interest, this commercial interest, while there is just an overriding public health disaster . . . It's insane!" (M, 13/14, 501) "It will be much more useful for the industry to say . . . there are indeed questions . . . where the compulsory licensing is the proper [instrument]" (M, 13/14, 531 ff.). "Why doesn't the industry just license the drugs to WHO—voluntarily licenses them to anyone who wants to use them; end this discussion on HIV/AIDS and then have a more serious discussion of what proper policies are"? (M 13/14, 453 ff.) "That is a completely separate issue to what we are dealing with here" (587).
50. Giving patents to the WHO . . . could be a solution not always working. In the case of Eflornithin against sleeping sickness "even by giving the patent rights to WHO, it was not possible to find a generic producer in any kind of country" (M, 13/14, 478 ff.). Production was resumed only after another application (cream) had been found. (letter from Industry) and it had been included into a humanitarian program (R5:4)	
51. The IP system and commercial system actually requires the existence of a market. And, in many countries there simply is no market . . . There should be probably some kind of equivalent to the Food Aid Program . . . If you want to have long-term research in tropical diseases without markets, we need to have a public funding system (M, 13/14, 565 ff. 628 ff.; cf. Oxfam, 2001, 44) or a public private partnership (R5:9)	51a. Public private partnership bear little relation to the scale of the problem (Oxfam 2001)
52. "We are starting to make the links between commercial law standards with the Human Rights . . . And inevitably the question comes up, if the global community is prepared to pay for it, and how you will organize it (M, 13/14, 639 ff.).	
54. "The big legal issue . . . has [become] what is compensation—how much will that cost" (M, 15, 844 ff.).	53. On this basis [CL clearly admissible], one could have "a more serious and focused discussion of how can compulsory licensing be done, or should be done, because it can be done whenever. When should it be done and what are the terms . . . to make it fair toward the brand name industry as well as toward public health?" (M, 13/14, 538 ff.)
55. "It will be coming close to voluntary licensing then" (M, 13/14, 551).	

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YES	NO/not necessarily
c. Differential Pricing	
57. "What argument I am hearing from the pharmaceutical companies is, 'don't exercise your rights on compulsory licenses; do it our way; do it [the] differential pricing way.' . . . That is not as sustainable as doing it the way we want to do it" (CL) (M, 15, 613 ff.).	56. A global system of differential pricing would be a better solution than compulsory licensing "because we can have all actors—private actors, public actors—together to set up such a system (M, 15, 539 ff., 701).
	58. Differential pricing would also apply to generics (M, 15, 1290).
59. "We don't know what the supply is [that is] going to be sustained over time" (M, 15, 1256); and differential pricing "leaves us open to being manipulated by the companies" (M, 15, 1280)—"It's an attractive offer, but it's a short-term offer."	60. A global system of differential prices would be "more efficient than individual negotiations on products with companies" (M, 15, 1245 ff.); and "if you sign an agreement it's . . . an obligation" (M, 15, 1260).
	61. There could be a "WHO sponsored worldwide classification of markets . . . with guidelines for pricing" (Oxfam, 2001, 37).
	62. "Experiences . . . show that reductions of 90% or more below developed country prices can be possible through bulk purchasing, competitive tenders and skillful negotiation"
64. But, in parts of the world market "separability is breaking down. Price regulation of pharmaceuticals is increasingly based . . . on international price comparisons—including developing country prices" (WHO, WTO, April 2001, 23).	63. Differential pricing and CL and PI—to the extent that they depend on price differences—presuppose conditions that must be guaranteed also politically; to be compatible with R & D, "market segmentation" is required; "resale from low-priced markets to high-priced markets must be constrained" (WTO, 11, cf. Oxfam, 2001, 24, R5:9).
65. Until the early 80s, companies had tiered prices—until they "got beaten up in Congress for this supposed discrimination against American children" (letter from Industry II).	
65a. A general policy would not be workable, among other things, for anti trust reasons (R5:4).	66 Differential pricing could theoretically imply a win-win situation for sellers and for consumers in poor countries if previously the price of pharmaceuticals was "set with only the conditions in the wealthier markets taken into account" (cf. WTO12.13). This implicitly assumes that diversion to other markets and "international reference pricing" (i.e. where prices in poorer countries are used as reference in wealthier countries) can be prevented.

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YES	NO/not necessarily
d. Differential Filing (Lanjouw Proposal∗)	
67. This suggestion, implying "drastic changes to the legal basis for patenting" (letter from IND), is not "sustainable" because it "risks destroying the incentive system" of patents by making it "harder to forecast investment risk, at a time when . . . an unfettered global market is critical to the industry's long-term capacity to spend on research" (dependency on few blockbusters).	.68 Even more efficient and sustainable than CL or differential pricing may be a suggestion by Lanjouw: differential filing. For drugs against *global diseases* prevalent in all countries (e.g., HIV, cancer, heart disease), profits realized in rich countries suffice as incentives for R & D; therefore companies can file only "in rich countries coupled with unrestricted competition by generic drug makers in poor ones" (letter from Industry II). This can be done by couching the "foreign filing license" appropriately. For drugs against *specific diseases*, prevalent in poor countries only, stronger patent protection may be necessary to spur invention.
67a. Differential filing presupposes market segmentation (R5:4)	
69 "Patent changes alone [do not] hold a solution to the access problem"—as can be learned from India, where, without patent protection, access "is as bad as anywhere in the world" (letter from IND).	
70 The pro-patent industry also leads to "developing drugs relevant to third world diseases". More needs to be done. "But the focus here is on building [together with the WHO] an approach around a combination of tax credits, regulatory changes and market-based incentives, [rather] than on drastic changes to the legal basis for patenting (2, letter from IND).	
71. "Those who would benefit most from the Lanjouw proposal, the generic producers, are not actively engaged in supplying drugs for poor consumers" (letter from IND), 2).	
72. The "proposal contradicts basic elements of US law" and with Article 27 of the TRIPS Agreement (letter from IND, 3).	

3. Is strong patent protection a necessary condition for having a pharmaceutical industry with high investment in R & D?

To deny explicitly the necessity of pharmaceutical research and the requisite funding would be a position of apparent thoughtlessness, and that is why *nobody* holds it. There is controversy about the fine tuning of the system of research funding and IPR protection in connection with imperatives of industrial development. Questions arising pertain to the *form of IPR protection* (a) in the context of different stages of

∗The Lanjouw proposal was published after "Montreux"; the WBCSD introduced it together with some comments of the industry. We take this as a valuable contribution.

industrial development, (b) in view of considerations of public health and a considerable share of public funding, and (c) taking account of neglected diseases prevalent in poor countries. Further, the pharmaceutical industry's profits were such that the need for strengthening and globalizing IPR protection is not self-evident. These topics "generated" the following set of pro and contra arguments.

YES	NO/not necessarily
73. Patents are more important for the pharmaceutical industry than for any other industry because of the enormous and risky investments going into the development of new products (Bale, 5; M 13/14-1b, M, R5:6) and because copying final products is "always relatively easy" (R5:6).	74. The risks cannot be as high as depicted: the pharma industry is the most profitable industrial sector (Oxfam, 2001, 31); "claims about research costs of new drugs are frequently exaggerated"; "a great deal of research into drugs is funded by governments, charities and tax breaks (Oxfam, 2001, 31, cf. M 13/14-1a, 15). In view of all this, patent protection is "excessive" (M 13/14-1a, 15).
73a. Very little of total costs for R & D comes from the public sector (R5:9).	
75. Countries without product patents cannot and do not develop new drugs. Since Canada, for example, repealed its CL policy, "increases in investments in R & D . . . have been dramatic" (Bale, 9). A comparable shift may be observed in India (M, 2 B, 91 ff.), that begins to take advantage of product patents, because "opportunities are emerging . . . as the competitive situation . . . ability of a country is changing" (M, 2 B, 123).	76. But India had comparatively weak patent protection (only processes) and built up "a tremendous capacity" to "reverse-synthesize any drug (M, 2 B, 112 ff.). "There's a need for looking at contingent conditions under which different kinds of IP systems would be appropriate for providing different kinds of incentives" (M, 2 B, 126 f.). Thus, as a "by-product of compulsory licenses . . . some developing countries will develop stronger generic pharmaceutical industries" (M 13/14-1a, 11). In general the balance between patent protection, safety regulations and access to medicines may be different for developed and developing countries (R5:8).
77. Developing countries with strong patent protection will also benefit "especially in terms of attracting investment" (Bale, 5)—at least once the provisions are in force long enough. Now "it's probably too early to make that assessment . . . the provisions are not yet operational" (M, 2 A, 260 ff.).	78. There is little evidence of an increase in investments; instead there are de-investments and closing of plants (M, 2B, 27 ff.) as can be learned from Chile (R5:9).
77a. Only a few countries will be able to compete with countries like India and China (R5:9).	

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YES	NO/not necessarily
79. There will be a "globalization of the effort to find cures for disease, spreading the effort to countries that have core scientific skills but previously lacked the incentives." This is important especially "for diseases such as malaria and TB that have been 'neglected' in drug development" (Bale, 6/7). Without patent protection, money will be allocated elsewhere "to the detriment of those suffering from unmet medical conditions" (R5:4).	80. South Africa "offers an excellent counterexample". It has had a strong patent system, suffers from a TB and malaria problem, but "no new medicines . . . have been developed in the last thirty years" (M 13/14-1a, 12). This is because "developing countries do not have wealthy enough markets . . ." (M 13/14-1a, 12) and this will not be changed by patent protection (Oxfam 2001).
81. "The patent system, while a necessary condition for much R & D, . . . [is] not a sufficient one to secure adequate R & D into the neglected diseases of the poor" (WHO/WTO, 5). The IP system as part of the commercial system can work only on the basis of markets (M, 13/14, 565 ff.). Where these do not exist, "additional measures of support for such R & D are necessary" (WHO/WTO, 5). And could be granted a.o. in the form of biodiversity credits (R5:1)	82. Intellectual property rights do not have to rely on "exclusion of rights" but may be framed as a "right to compensation" that protects "investment" (e.g., copyright) (M, 3 A, 135, 170 ff.), for example, by a 5% royalty and a 1% tax on generics (R5:5).
83. Cf. argument no. 38: An unrestricted use of the safeguards would drive prices to marginal costs without compensation for R & D and generic competition could have the same effect (R5:9)	84. "During the 80s and 90s the pharmaceutical industry . . . was one of the most profitable industries . . . [although] patents were not recognized for pharmaceutical products in many developing countries . . . What is it now that is so important for the companies to get every little company to grant patents and base income on the system of those patents?" (M, 13/14, 847 ff.) There is "[no need] to get this additional income in order to sustain the sector 'development' and to sustain profitability" (M, 13/14, 1017 f.). Developed countries can absorb high prices, but not developing countries. A uniform system will not increase revenues, but limit access to healthcare for the poor (Oxfam 2001)
85. "There is no need [to take additional income] from the least developed countries" (Ramsey pricing!) (M, 13/14, 1021). But countries "that are intermediately rich may contribute to R & D" (M, 13/14, 1087); they have "effective local producers . . . which will potentially represent a significant competition and . . . competition should be directed at R & D in new areas . . ." (M, 13/14, 980 ff.).	86. It can't be true that "the whole budget for . . . is broken down and the future of the industry is at risk" if one developing country grants a compulsory license; there must be other reasons for expanding the IP system (M, 13/14, 1038 ff.), for instance, "to acquire a higher share of the market" in view of "a higher demand for medicines in developing countries" (M, 13/14, 889), or just to have "more income", which is "reason enough for business" (M, 13/14, 1029).

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YES	NO/not necessarily
87. An increasing number of competitors are—in these countries—producing not only for the local market but also for other markets, and it's much easier to stop illegal actions . . . [by filing] in the origin (M, 13/14, 950 ff.). And "there was factual evidence that there was a lot of reproduction . . . of drugs which were of low quality and actually harmed."	88. Counterfeiting is a problem of control, not IPR (M, 13/14, 1162 ff.).
89. There is a "competitive situation for Western producers on these markets"; you have to "discipline—to extend the disciplines in the competitive environment among the industrialized country producers" (M, 13/14, 1058 ff.).	
90. It has been shown empirically that "when profits rise, R & D rises; when profits fall, R & D falls . . . increased profits . . . will go into R & D to the extent . . . that profits will go" (M, 13/14, 1188 ff.). But you don't know for what diseases, whether they are relevant diseases—all those questions still remain (1207).	91. There is no guarantee that this additional income will be devoted to R & D (M, 13/14, 11=1).

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Addendum: Selected Documents Reviewed by the WZB Team

Bale, Harvey, TRIPS, Pharmaceuticals and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development, 2000, http://www.ifpma.org/pdfifpma/TRIPS.pdf

CEFIC, The Chemical Industry Comments on a Possible New Round & TRIPs, April 2001, http://europa.eu.int/comm/trade/pdf/trips_c12.pdf

Correa, Carlos M. Intellectual Property Rights, the WTO and the Developing Countries. The TRIPS Agreement and Policy Options, London and New York, 2000

GRAIN, SANFEC, 'TRIPS-plus' through the back door. How bilateral treaties impose much stronger rules for IPRs on life than the WTO, July 2001 http://www.grain.org/publications/trips-plus-en.cfm

Lanjouw, Jean O., A Patent Policy Proposal for Global Diseases, June 2001, http://www.brook.edu/views/papers/lanjouw/20010611.pdf

OXFAM, Fatal Side Effects: Medicine Patents under the Microscope, Cut the Cost, n.d., http://www.oxfam.org.uk/cutthecost/policy3.rtf

OXFAM, Patent Injustice: How World Trade Rules Threaten the Health of Poor People, Cut the Cost, n.d., http://www.oxfam.org.uk/cutthecost/patent.pdf

OXFAM, Global HIV/AIDS and Health Fund: Foundation for action or fig leaf? Cut the Cost, June 2001, http://www.oxfam.org.uk/policy/papers/globalhiv.html

Transatlantic Consumer Dialogue, TACD Recommendations on Health Care and Intellectual Property and European Commission Services Responses, February 2001

WTO, Workshop on Differential Pricing and Financing of Essential Drugs, Background Paper, 2001, http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/wto_background_e.doc

WHO-WTO, More Equitable Pricing for Essential Drugs: What do we mean and what are the Issues? Background Paper 2001, http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/equitable_pricing.doc

WHO-WTO, Workshop on Differential Pricing and Financing of Essential Drugs, Executive Summary of Report, April 2001, http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/hosbjorexe-eng.pdf

APPENDIX II
Circular 8: The Argumentation (long version)

IPR Dialogue Working Group III (Access to Essential Medicines)
8th Circular:
Part Two: Access to Health Care and IPRs — The Normative Issues
(Rainer Döbert, 02-01-02)

Arguments*:* Access to Healthcare and IPRs — The Normative Issues

(long version)

This file contains full length arguments pertaining to normative issues that raised with respect to the legitimacy and justification of IPR regimes (especially patents) and the TRIPS Agreement. The leading question is whether existing IPR regimes (and TRIPS) must be revised or supplemented in order to provide respect for human rights, moral values and norms of justice and fairness. We survey the arguments of the participants and the documents consulted under three more specific questions:

1. Do patents on essential medicines violate the human right of access to healthcare?
2. Do companies have moral obligations to contribute to the solution of the health crisis in developing countries?
3. Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

The reasons for distinguishing these questions are further explained in the *Introduction* of the condensed version file.

The documents consulted by the WZB team are listed in the *addenum* at the end of this file.

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Must Existing IPR Regimes (and TRIPS) be modified/rejected for Normative Reasons?

1. Do patents on essential medicines violate the human right of access to healthcare?

Issues	*Pro*	*Contra*
Strict (enforceable) vs. conditional human rights	**1.** Access to healthcare (including medicines) is a basic human right that "should have higher status than international trade agreements" [which require IPR protection]. (M 13/14-1a 4)	**2.** The addressee of the human right of access to healthcare are States (governments), not private companies (M 13/14-1a 4; M15/276, 1400). And the obligations of States are conditional on "resource constraints applying within the country". (M 13/14-1a 7, 11, 15, 156)
		2a. There is no "right of access to health care" but a "right to a standard of living adequate …" (Art 25.1 Univ. Declaration of Human Rights) (R8:2)
	4. The right of access to healthcare implies a duty of States to create "conditions which would assure to all medical service and medical attention in the event of sickness" (M 13/14-1a 4). This duty is strict with respect to a "minimum core obligation". (M 13/14-1a 7)	**3.** Access to medicines is an "aspirational right, not a fundamental right" (M 13/14-1b). One must distinguish human rights which can be enforced vis-à-vis governments from other human rights (social rights), which are (less binding) policy goals. "All over the world … governments have not … treated the rights to food and health as true [strict] human rights. Overstressing [social rights] claims runs the risk of strangling the systems". (M15/236)
Obligations under TRIPS and human rights	**5.** "There is a pressing constitutional obligation on the State to take all measures at its disposal to reduce the price of [essential] drugs"— "even if this means breaking the TRIPS Agreement" (M 13/14-1a 6/7).	
	6. The legitimacy of IPRs is questionable also because the most important measures States may possibly take to reduce drug prices, namely compulsory licensing (CL) and parallel imports (PI), are being denied and undermined by many forms of pressure and TRIPS-*Plus* legislation (M 13/14-1a 9, 10; cf. also 5th Circular).	**7.** CL and PI, properly applied, are legitimate options under TRIPS and are beginning to be fully accepted. (see below no. 45). Little TRIPS-*Plus* legislation is being advocated and TRIPS-*Minus* is designed to foster industrial development, not access to healthcare (R8:5)

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Issues	*Pro*	*Contra*
Medicines as private goods		**8.** If companies have obligations it is „not because there are rights to medicines and not because medicines are a public good“ (M15/354). “Goods and services which may be used to produce a public good are thereby not themselves public goods. … The suppliers [of medicines] … to a health program are providing private goods to a purchaser who may then supply a public good …” (M 13/14-1b). Hence, if the private goods (medicines) are to become part of a public good like equal access to essential medicines the respective policy objective has to be defined and health promotion programs have to be set up (M 13/14-1b).
IPRs and the public interest *affordable medicines*	**9.** The patent system has to further the public interest while at the same time “fairly rewarding innovators”. “The public interest is served by ensuring access to essential drugs for all, not just for the wealthy or those with drug insurance. If people do not have access to life-saving drugs it does not make sense to provide incentives for their innovation” (M 13/14-1a 10). In this respect one may plausibly “question the economic, social and political foundations of the TRIPS Agreement“, i.e., its legitimacy. (M 13/14-1a 9)	**10.** A drug or any other health intervention cannot be “affordable to everyone as long as incomes are unequally distributed” (Bale 12). Governments can not always deliver. Special measures/programs are needed to provide access to medicines for the poorest populations (cf. below nos. 23,26, R8:4, R8:5)
	9a. IPRs are a question of a delicate balance between public and private interests that must be adapted to each country. The current system seems to favour too much private interests (R8:4).	**11.** The public goods provided through the patent system are information and research and development (derived from M 13/14-1b), not private, physical goods (R8:5).
	12. “Nobody will discuss [deny] that medicines as such, the physical product, are a private good. The problem is that the information that allows you to produce these medicines is a public good”. (M15/368, 374)	**13.** “We all know that intellectual property is a restriction on the public good quality” [of information] (M15/447)
		13a. Public sector research rarely results in a medicine (R8:5)

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Issues	*Pro*	*Contra*
Human rights and property rights	**15.** "[Human] rights suggests generally some kind of higher standard. … [To put them on the same level as property rights] is a wrong conception. … These [latter] rights are really [a] social creation". (M2A/342)	**14.** The protection of property, including intellectual property, is a human right, too (Art. 17.2 and 27.2 of the Univ. Declaration of Human Rights, R8:2), and "property rights are an enormously important element of the rule of law". (M2A/251)
	15a. Citizens of developed countries would not allow governments to respect patent rights if that meant death of 10 to 25 percent of the population (R8:3)	**14a.** Respecting and enforcing human rights cannot be done by undermining other similarly basic human rights (R8:2).
	16. "Property rights and human rights are two totally different systems that should not be subsumed under one umbrella. … Belonging to the human kind you have some inalienable rights. That … is not addressed by the TRIPS regime. This is [only] a regime of exclusivity". (M2A/342, 356)	**17.** "Let us not argue over the fact that societies have evolved mechanisms of exclusion from privately produced knowledge … even from public domain knowledge … [Also in the case when] you want benefits to be given to communities and individuals who have produced traditional knowledge then you must accept that there must be [exclusion] certain rights. … Rights can only exist by exclusion". (M2B/150, 176)
	18. "What property is being created by somebody advancing knowledge, for instance in drug manufacturing? There is no property being created, so there are no property rights". (M2A/342)	
The analogy of the international undertaking	**19.** The International Undertaking for genetic resources demonstrates that public benefits result from having less IP protection, namely: "free access to new varieties as a benefit for the whole society". (M 2B/186)	**19a.** This is a static argument around currently existing technology (R8:5). State-run approaches to innovation do nor work (R8:5)
The scope of a human right to essential medicines ***The need to sustain the funding of R & D of new medicines***		**20.** "If we agree that there is the basic human right of access to essential medicines…where do we draw the line? Would you also argue that there is a basic human right to have access to the latest technology on cancer drugs …? So the question is where to draw the line and how can we find the proper tools … [such] that there is research and development done on these drugs" (M15/574).

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Issues	*Pro*	*Contra*
		21. "You can't address the [relation of] human rights standards and commercial law properly without looking into the funding structures" [for R & D that provides new medicines]. (M 13(14)/609)
Indirect contributions of the private sector to social human rights: The crucial role of governmental action		**22.** "If we design [access to medicines] as a human rights issue and actually engage the private sector, we have to redo the whole debate. …To what extent are companies actually bound by the human rights standards other than through their own governments? … It's a question of how do we fund the whole thing. … You can actually justify human rights obligations with governments' funding efforts and the rights then being realized by private actions as well". (M 15/504)

2. Do companies have moral obligations to contribute to the solution of the health crisis in developing countries?

Issues	*Pro*	*Contra*
The case for a direct contribution of the private sector to social human rights: The moral duty to help	**23.** Even if one agrees that it is governments who are responsible for realizing human rights, one may raise the question, "whether the companies should … contribute to health needs which would under any definition of human rights be the minimum standard". (M15/518).	
Obligations to "care"	**24.** Companies see themselves as part of social and economic solutions; they are being observed by a public with moral convictions and run by employees who "are actual humans who do care. [Such persons go] into the pharmaceuticals industry because they are motivated by high ideals". (M13/1245; M 13/14-1b)	

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Issues	*Pro*	*Contra*
Commitment to Social Responsibility	**25.** There are obligations of "corporate social responsibility" (Oxfam 7); these imply "a moral duty for companies to provide medicines … in the least developed countries at cost prices". (M 13/831) That is why companies are prepared to back a global system of differential pricing. (see 5th Circular)	**26**. [There cannot be a duty to provide essential medicines at cost prices] for the developing countries, because the latter can be expected to contribute to R & D "according to ability to pay". (M13/1090).
		26a. The ideal scheme is hard to implement (R8:5)
	27. There will be no solution for the health crisis in the South without additional public money. But this is "not to remove every responsibility from the industries. … Industry has a responsibility in the game, but others [do] too". (M15/1380)	

3. Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

a. Pressure and Lack of Participation

Issues	*Pro*	*Contra*
Flaws in the TRIPS negotiations? *Because of pressure from developed countries*	**28.** The negotiation process has been unduly influenced by "quite powerful industries in the United States and other developed countries". (M1/348)	**28a.** Doha showed that developing countries do have a say. (R8:5)

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Issues	*Pro*	*Contra*
Because of lack of equal participation	**29.** The system has to be reformed fundamentally—"fundamental in the sense that to have a global treaty that does not represent three-quarters of the world in the decision making is patently unjust" (M3A/300). "The negotiation was then … very non-transparent …" between developed and developing countries; "the rest of the countries in fact almost never participated at all"—in particular, "there was no African input at all in this negotiation". (M3A/188, 235, 262).	**30.** "Decision making in the WTO is generally made by consensus. … If somebody were to disagree, there is no way that that decision would go through. …The fact that developing countries were not widely represented …is because of the way it is done" [i.e., small groups drafting texts for larger groups]. "The fact that some countries don't have enough expertise to get represented in these drafting groups etc. is another problem, but it's not as if the rules of the WTO are somehow loaded against the countries" (M3A/71). Proof is *inter alia* "the flexibility in the TRIPS agreement" which "didn't come about by sheer accident", but by a "tough battle". The same holds for the "ambiguities in the agreement" which leave room for interpretations in accordance with countries' needs and interests. "And, therefore, it isn't exactly as one-sided as people think it is". (M3A/84)
	31. "It's not due to incompetence. … As a matter of fact, … the CBD was headed by an African, and they did not allow us to participate. … Imagine a small country like Burkina Faso opposing the United States openly: … Burkina Faso's loan [would] not be negotiated … Burkina Faso [would] be sanctioned … made a pariah State" (M3A/291). "There was a lot of coercion also during the negotiation [of TRIPS]" (M1B/358).	**32**. African delegations "never developed an interest in this question. … But with respect to Latin American and Asian countries, … there has been a very long process in the beginning", characterized by "ideological debates" and "blockages". And, in the end, "a lot of Western concepts were extended without having time to adjust them to a global situation" (M, 3A, 235 ff.)
Because of uneven distribution of expertise	**33**. The "issue [of IPRs] was very new for developing countries … There were no resources for a country like ours—and perhaps the same applies to African countries and many Asian countries—to have expertise really, to have a real expert to discuss all these very difficult problems at that time" (M3A/195)	

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Issues	*Pro*	*Contra*
Because cultural differences have been disregarded	**34**. "If the process is flawed, the product cannot be any better" (M3A/264). "The process is flawed in the sense that the whole cultural dimension has not been inputted. … As far back as 1992, … we did mention that there is a very strong problem between WTO, GATT, the CBD and our way of life. … People then assumed that we [were] not right. … Silence to us … means you don't agree, and this was the kind of position we took" (M3A/264)	
Because the interests of the West predominate	**35.** "The patent system is just one idea that came essentially from the West. … Now that it is in the interest of the West, patents have been encouraged. Very soon they will realize that it is no longer in their interest … and [they] will appropriate the value from other parts of the world: … The rest of the world considers this whole apparatus as one simple system of neo-colonialism". (M3A/322)	**35a.** It is no coincidence, that the highest level of innovation is in countries that reward creativity. (R8:5)

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b. Inequalities and Development

Issues	*Pro*	*Contra*
Violation of the right to development? *Uniform IPRs foreclose the standard route of copying advanced technology*	**36.** TRIPS implies "the imposition of standards prevailing in developed countries on developing countries" (M1B/346), despite the fact that, in the area of science and technology, we probably face the most dramatic asymmetry in the North-South relationship (M1B/368). "Unlike other agreements within the WTO, the TRIPS Agreement does not contain any special or differential treatment for developing countries except the transitional periods which for developing countries have already expired and are still valid only for the least developed countries" (M1B/361). But this "one-size-fits-all approach" (Oxfam) denies the "right to development" (M1B/391): "Industrialization usually relies on reproducing the technologies of the more advanced economies. … By depriving developing countries of a policy instrument for promoting national development that they themselves used, the rich countries are effectively 'pulling up the ladder'" (Oxfam 6, M2A/138)	**36a.** The argument is false in general thrust, among other things because the development of an indigenous pharmaceutical industry will be the wrong way for industrialization in many cases (overcapacity competitive advantages of few countries, high-tech-low-employment as characteristic of pharmaceutical industry) (R8:5).
	36b. In industrial countries the introduction of patents was always fostered by clear gains to the domestic economy while in developing countries this policy was forced for the benefit of international companies. "And in advanced countries public health goals were never under threat" (by patents) This is different for developing countries today (R5:8).	
Options for differential treatment of developing countries	**37**. "There is a need for looking at contingent conditions under which different kinds of IP systems would be appropriate" (M2B/125). "We have areas such as trade secrets and many cases under copyright in which the right is a right to a remuneration and not a right to exclusion". (M3A/134, M2A/230)	**38.** There are a number of provisions (safeguards) in the TRIPS Agreement that provide flexibility for developing countries (e.g., delays until 2016, compulsory licenses). (M1B/401, *see 5th Circular*)

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Issues	*Pro*	*Contra*
	39. Recourse to the flexibilities offered by the IP system is often blocked through pressure from industrialized countries and bilateralism. (M2A/3, 384, *see 5th Circular*)	**40.** The WTO assembly at Doha reaffirmed the "right of WTO members to use to the full the provisions in the TRIPS Agreement". (WTO 2001)
Special aspects of gene patents: Blocking competition with generics	**41.** Problems are aggravated because "the information which is protected is unique. … There is no possibility at all to invent around, and to find something which is similar. So the ethical and economic and social consequences of patenting genes are serious (M2A/25). Among other things, patents can be abused "to block genuine competition" (generic products)—"evergreening" on the basis of "very poor contributions to the state of the art". (M2A/58, M2B/6)	**42.** *See 9th Circular on Gene Patenting* **43.** Patents by definition exclude competition through copies of protected inventions. Compulsory licensing, while possible in principle, can as well be abused. To that extent competition through generics constitutes unfair competition. *(See 5th Circular)*

c. Other Normative Infringements

Issues	*Pro*	*Contra*
Unfair benefits through patenting? *Discoveries*	**44.** "One element of unfairness relates to the appropriation of nature" in the form of protecting mere "discoveries which should belong to humanity as a whole". (M2A/15)	**45.** "There are no uniform standards" for inventiveness; "the line [distinguishing discovery and invention] can be drawn by the courts, and every country can draw its own lines". (M2A/265, Correa 2000, 19) (*see 9th Circular Gen Patenting*)
		45a. Gene discoveries are not medicine innovations (R8:5)
Lack of inventive steps	**46.** In addition, there is the appropriation of knowledge that should remain in the public domain because of too little inventiveness (M, 2A, 58 ff.)	**47.** How can TRIPS allow public domain "knowledge to be privatized? … Once it is demonstrated that public domain knowledge existed, … one can certainly revoke the patent". (M3A/326)
	48. To revoke a patent is extremely costly and time consuming. (M4/11)	

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Issues	*Pro*	*Contra*
Unequal acknowledgement of inventions? *Seed companies vs. farmers* *"Biopiracy"*	**49.** It's also unfair that "the seed companies can get benefits through the intellectual property system, [but that] this does not apply to the farmers [who,] in the first place, conserved, improved, and provided germ plasm [to the gene banks]" (M2A/47). To this come cases of biopiracy where "traditional and indigenous knowledge" is being appropriated. (M2A/47)	
Unkept promises? *Technology transfer*	**50.** There are unkept promises: Instead of investments and technology transfers, "the introduction of patents has led, in many countries, to de-investment", and TRIPS will not in any way increase the flow of technology transfer as such. (M2B/27)	**51. "**Many of the provisions [of TRIPS] are not even in force, … so it's probably too early to make [a negative] assessment". (M2A/261)
	50a. There are unkept promises with respect to textiles and agricultural products, too, with the effect of lacking reciprocity of benefits and uncompensated transfers of rent to the North (R8:5)	
Unequal access to the IPR system	**52.** "The current system is not accessible for many poor people" because "the transaction costs" (filing, disputing, enforcing) are too high (M3A/313, R8:6). There is "a huge administrative and financial burden of instituting complex IP systems" (Oxfam 2000, 6)	**52a.** Most patents are not taken by "poor people" but by companies (R8:5)

APPENDIX II

Addendum: Additional documents consulted for the survey of arguments in the 8th Circular

Correa, Carlos (2000): Integrating Public Health Concerns into Patent Legislation in Developing Countries

Oxfam (ed.) (2000): Fatal Side Effects. Medicine Patents under the Microscope